

**MINUTES OF 351ST MEETING OF REGISTRATION BOARD
HELD ON 23RD – 24TH SEPTEMBER, 2025**

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

351st meeting of Registration Board was held on 23rd – 24th September, 2025 in the Committee Room, Drug Regulatory Authority of Pakistan, Prime Minister’s National Health Complex Park Road, Chak Shehzad, Islamabad.

The meeting was chaired by Mr. Sayyad Hussain Khan, Director, Pharmaceutical Evaluation & Registration Division, DRAP / Chairman, Registration Board, DRAP. The meeting started with recitation of the Holy Verses.

The meeting was attended by the following:

1.	Dr. Syed Asad Ali Shah, Principal Animal Husbandry In-Service Training Institute, Peshawar.	Member
2.	Dr. Tehseen Fatima, Dow College of Biotechnology, Dow University of Health Sciences, Karachi.	Member (Virtual)
3.	Mr. Syed Adnan Rizvi, Director, Drugs Testing Laboratory, Govt. of Sindh, Karachi.	Member (Virtual)
4.	Dr. Ali Jan, Director, Drugs Testing Laboratory, Govt. of Baluchistan Quetta.	Member
5.	Mr. Hafeez ur Rehman, Representative of Director DTL, Govt. of Punjab, Rawalpindi.	Member (Virtual)
6.	Mr. Imranullah Khan, Director Drugs Testing Laboratory, Govt. of Khyber Pakhtunkhuwa, Peshawar.	Member (Virtual)
7.	Mr. Muhammad Aslam, Additional Draftsman, Law & Justice Division, Islamabad.	Member
8.	Mr. Ghulam Mujtaba, Deputy Director, Representative of IPO, Islamabad.	Member
9.	Ch. Zeeshan Nazir Bajar, Director, Quality Assurance & Lab Testing Division, DRAP.	Member
10.	Mr. Muneeb Ahmed Cheema, Representative of Biological Evaluation & Research Division, DRAP.	Member
11.	Hafiz M. Ali Tayyab, Additional Director, Pharmaceutical Evaluation & Registration Division, DRAP.	Member/ Secretary
12.	Dr. Junaid Akhtar, Director, Drugs Testing Laboratory, Govt. of Gilgit Baltistan.	Co-Opted Member

Mr. Nadeem Alamgir (Pharma Bureau), Dr. Zafar Mustafa Jajja and Dr. Laila Mughal (PPMA), Dr. Saif ur Rehman and Dr. Shahnawaz (PCDA) attended the meeting as observers.

Item No. I Confirmation of Minutes of 349th & 350th meeting of Registration Board.

349th and 350th meetings of Registration Board were held on 14th July, 2025 and 29th – 30th July, 2025 respectively. Accordingly, draft minutes of the 349th and 350th meeting of Registration Board were prepared and circulated among the members through email for their perusal / approval / comments (if any). Following members has submitted their comments / suggestions.

- i. Mr. Muzzamil Waheed, Director, DTL, Faisalabad through email dated 15-08-2025 has submitted as under:

“Plz note following suggestions for future

1. The agenda must be circulated 7 days before the meeting.
2. In the remarks section the remarks by various evaluators vary. There is a dire need to adopt a standard uniform practice enabling the board members to discuss the cases without any labour. The conclusive statement from the evaluators must be there whether the case is considerable for approval or any direction by the board otherwise.
3. It has been observed in Some cases that the information incorporated is either incorrect or partially correct. Decision regarding such cases becomes difficult. Make it sure to incorporate correct information.
4. The data submitted by the manufacturers in response to various queries of the registration board must be deeply analysed to avoid the forgery and manipulation. submitted for further action and information please.”

- ii. Dr. Ali Jan, Director, DTL, Quetta thorough email dated 15-08-2025 has submitted as under:

“I agree with the observations of the Director, DTL Faisalabad. All agenda items should be circulated at least one week prior to the meeting. It has been observed that items under the heading “Additional Agenda” are regularly added during the meeting, which makes it very difficult for members to provide proper feedback. Any additional agenda items should either be circulated in advance or included in the agenda of the next meeting.

In another email dated 15-08-2025, he has also submitted as under:

It has been observed that without final approval some firms have launched semaglutide products in market which i came to know last night from one of pharmacy set ups in Balochistan.



I want clarification that whether M/S Macter Pharma has completed all pre-requisites which we have decided in 350th Meeting i.e. 350th Decision of Registration Board:

The evaluation and approval of Peptide Drug Products either biotechnologically or chemically derived, with the following additional requirements: vi. vii. viii. ix. X. Registration holders of Semaglutide and Tirzepatide shall conduct pharmacokinetic/ pharmacodynamic (PK/PD) equivalence studies using the reference product within six months of obtaining registration. Initially, the registration holder shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: c. Peptide mapping, d. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA&LT. Registration holders shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP. The above requirements shall be incorporated as condition of registration and any violation shall be dealt in accordance with law including the cancellation of registration. The above criteria shall be applicable on cases where registrations had been granted or under processing of issuance or will be processed in future.”

In email dated 18-08-2025, he has submitted as under:

“Dear Sir,

I agree with the remarks and observations of my fellow member. All points raised must be addressed, and it is imperative that every member’s input is given due weightage to ensure that decisions of the Drug Registration Board are uniform, transparent, and across the board.

It has also been observed that in cases relating to Sildenafil and Tadalafil, despite clear violations and fraudulent practices, none of the concerned firms were blacklisted. Instead, they were allowed to reapply. Such decisions risk undermining the sanctity, credibility, and deterrent authority of the Board.

I respectfully urge that consistent and strict action be taken in all cases of non-compliance, including blacklisting where warranted, so that regulatory integrity and patient safety remain uncompromised.”

- iii. Syed Adnan Rizvi Director, DTL Karachi, through email dated 18-08-2025 has submitted as under;

“Dear Sir,

I hope this email finds you well. I would like to formally record my observations and reservations regarding the deliberations of the 349th (14 July 2025) and 350th Registration Board (DRB) meetings concerning Semaglutide and Tirzepatide.

My detailed remarks submitted in the 349th DRB meeting were unfortunately not incorporated in the 350th DRB minutes. I had highlighted that Semaglutide is a critical biological product warranting stringent regulatory oversight due to its complex tertiary structure, long-acting profile, narrow therapeutic index in metabolic disorders, immunogenicity concerns, and integration with a drug–device delivery system. I had also emphasized that complete CTD submissions covering analytical, non-clinical, clinical, device, and immunogenicity data must be mandatory. Additionally, validated impurity profiling as per ICH Q3A/B and Q2R2, retrospective bridging and stability studies, phenol-specific toxicological justification, and robust PK/PD biosimilarity studies with immunogenicity monitoring should be considered non-waivable requirements.

In the 350th DRB meeting, however, Semaglutide and Tirzepatide were approved (Case # 04, Sr No. 01 to 11) (Case # 06 Sr. No. 01 to 05) (Case # 08 Sr. No. 01 to 11) subject to certain conditions, including PK/PD equivalence studies within six months, LC-MS peptide mapping and impurity profiling of the first two commercial batches, installation or arrangement of LC-MS facilities, post-authorization safety and efficacy studies, ADR collection and reporting under PV Rules 2022, and submission of PBRERs. While these conditions are scientifically valid, in my considered opinion such requirements should be treated as pre-registration prerequisites rather than post-registration obligations. Approving such complex peptide products prior to the completion of PK/PD, impurity profiling, and safety data compromises patient safety and regulatory consistency.

I would also like to summarize the approvals granted during these meetings. For Semaglutide (biosimilar to Ozempic®), Macter International Limited (Case # 08 Sr. No. 01 to 11) received approval for 11 presentations, including pre-filled pens (PFP) and pre-filled syringes (PFS) ranging from 0.25 mg/0.5ml to 9.6 mg/3ml. Deferred cases from the 349th DRB were also approved in the 350th meeting (Case # 05), covering CCL Pharmaceuticals (Semavic Injection), Weather Folds Pharmaceuticals (multiple Semma Injection strengths: 0.25 mg to 4 mg/3ml), and Nextar Pharma (Pvt) Ltd (SEMAVI-PFS in 0.25 mg, 0.5 mg, and 1 mg presentations). For Tirzepatide, Getz Pharma (Pvt) Ltd was granted approval, covering four strengths of Tirzi Injection (2.5 mg, 5 mg, 7.5 mg, and 10 mg, all in 0.5 ml presentations). In summary, multiple local companies were cleared.

It is also important to note the significant safety, quality, and regulatory compliance gaps observed in several submissions. For both API and finished formulations, safety studies are not established in the relevant countries of origin, and in many cases valid GMP certification, Free Sale Certificates, and CoPPs are not established. Furthermore, critical data have been omitted in some dossiers, with deficiencies noted in GLP toxicology, receptor binding, clinical PK/PD comparability, immunogenicity risk assessments, and device usability testing. Impurity profiling has also been inconsistent between applicants, with a lack of validated studies and absence of dedicated phenol toxicological evaluations. Trial batches should only be manufactured after area/section approval under final conditions to ensure compliance and reliability of data.

Therapeutically, Semaglutide and Tirzepatide are neither life-saving nor emergency medicines. Their primary use is in weight reduction and metabolic control, which is often

lifestyle or cosmetic in nature. Misuse or inappropriate use poses significant risks of irreversible and long-term harm. Given this risk–benefit context, registrations should not be granted until all safety, efficacy, and quality parameters are fully satisfied in advance.

I would also like to second the remarks of a fellow evaluator that certain firms have reportedly marketed Semaglutide without final DRB approval, with one such case observed at a pharmacy in Balochistan. Such practices undermine regulatory authority and patient safety. Strict regulatory action should be taken against any firm marketing these products without fulfilling DRB prerequisites.

In light of the above, I strongly recommend that the six conditions listed in the 350th DRB be treated as mandatory pre-registration requirements. No registration should be granted until complete analytical, non-clinical, clinical, device, and immunogenicity data are submitted and verified. Uniform enforcement of ICH, EMA, WHO, and DRAP guidelines must be ensured for all applicants, and firms found marketing prematurely should face strict action, including cancellation of registration where applicable.

For future DRB meetings, I would also suggest circulation of the agenda at least seven days in advance, the use of standardized evaluator remarks with clear recommendations, and ensuring accurate reflection of evaluators' observations in the official minutes.

In conclusion, for the sake of regulatory uniformity and patient safety, I respectfully request that my consolidated remarks be formally annexed to the 350th DRB record and duly considered in all future deliberations concerning peptide drug products.”

Accordingly, fair minutes of 349th and 350th meeting were processed to Chairman, Registration Board for perusal/approval. After approval from Chairman Registration Board, fair minutes of 349th and 350th meeting of Registration Board were circulated among concerned divisions/sections for implementation.

Decision: Registration Board deliberated above mentioned comments / observations in detail and decided as under:

- **All registration holders / manufactures of Semaglutide and Tirzapetide shall be directed to submit data including LC/MS peptide mapping of previously marketed batches as per condition of registration as decided by Registration Board.**
- **In future, all registration holders / manufacturers of Semaglutide and Tirzapetide be directed to conduct LC/MS peptide mapping of their registered products from any government approved Drug Testing Laboratory or any other DRAP licensed laboratory till procurement of LCMS by themselves and to submit testing data before marketing/sale of every batch to the relevant field office.**
- **Division of BE&R to issue letter to all registration holders to take updated status regarding initiation of Bio-equivalence/PK/PD Studies and inform the Board accordingly.**

Furthermore, Registration Board noted the information and confirmed the minutes of 349th and 350th meetings. Mr. Adnan Rizvi, Director, DTL, Sindh gave his note of dissent of all registrations of simaglutide and tirzapetide containing products to local manufacturer.



Drug Regulatory Authority of Pakistan
(Pharmaceutical Evaluation & Registration Division)



Item No. II **Division of Pharmaceutical Evaluation & Registration**
Pharmaceutical Evaluation Cell (PEC)

Sr. No	Title	Description
1	Case Category	Priority As Per 257-M of RB (Abdul Mughees)
	Name, address of Applicant.	AstraZeneca Pharmaceuticals Pakistan Private Limited C-50, Block-2, Clifton, Karachi Pakistan (290)
	Application Form Dy. No / Tracking ID & date of submission	(34U-5YZ-NAE6, 2024-03-13)
	Detail of Fee Submitted	, 225000.0 , 2024-01-18
	The proposed proprietary name / brand name	LYNPARZA (Olaparib) 150mg film-coated tablets
	Label Claim	Indicated for 1. Ovarian cancer: for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in a complete or partial respo
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	56 Film-Coated Table-Controlled
	Shelf Life (Unit)	24 Month(s)Do not store above 30°C. Store in the original package in order to protect from moisture.
	For generic drugs (me-too Status)	Lynparza is an Originator Brand (Research Brand)
	Pharmacotherapeutic Group of (API)	It falls under the L01XK category, which includes Poly (ADP-ribose) polymerase (PARP) inhibitors, and indicates that olaparib is an antineoplastic agent that functions as a PARP inhibitor.
	Name, address of Manufacturing site:	AbbVie Limited -Carretera 2 KM 58.0 Cruce Davilia Barceloneta, PR 00617 Puerto Rico USA-United
	Pharmaceutical Equivalence and Comparative Dissolution Profile	.
	Name, address of Marketing Authorization Holder:	AstraZeneca AB, Sweden, AstraZeneca AB, SE-151 85 Sodertalje, Sweden, Sweden
	Details of Certificates (CoPP/FSC/cGMP):	Scanned copy of attested EMA issued CoPP bearing number 01/23/008919 dated 23 August 2023 has been attached. US FDA Approved site with FDA establishment identifier 3000210838
	Details of Authorization Letter :	.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability was set down under the long-term storage condition of 30°C/75% RH and accelerated condition of 40°C/75% RH. The tablets were manufactured using olaparib extrudate intermediate material from AbbVie Puerto Rico and packed in Al/Al blisters.
	The status in reference regulatory authorities	Approved in US, UK, EMA, Canada, Australia, New Zealand & Japan
Evaluation Remarks		

LYNPARZA (Olaparib) 150 mg film coated tablet is manufactured at AbbVie Limited KM 58 Carretera 2 Cruce Davila Barceloneta Puerto Rico 00617 United States whereas primary and secondary packaging and batch release is performed at AstraZeneca UK Limited Silk Road Business Park Macclesfield Cheshire SK10 2NA United Kingdom as per information provided in Module 3. It is presented as Green to green/grey film-coated, oval, bi-convex tablet, debossed with “OP 150” on one side and plain on the reverse. Olaparib is classified as BCS Class IV, but formulation strategies adopted by the manufacturer mitigate biopharmaceutical risks. All excipients are either pharmacopoeial or approved food-grade colorants. 95–105% of label claim at release and end of shelf-life is appropriate for a small molecule oral IR tablet and meets compendial/ICH expectations. Method performance is supported with system suitability (tailing ≤ 1.5 , RSD $\leq 2\%$), and typical RT --- min on a USP L1 column. Content uniformity per Ph. Eur. is specified (acceptance value compliant), with supporting validation batch data (AV values around 1.8–3.4). DP has an immediate release profile with complete dissolution in <60 minutes. Specifications include identity, assay, dissolution, uniformity, and degradation limits and are claimed to be innovator’s specs. Analytical methods validated and aligned with pharmacopoeial standards. Microbiological testing confirms absence of contamination. Degradants are not tested at release, limits are NMT 0.2% for largest individual unspecified and NMT 0.5% total impurities. The 0.2% aligns with the ICH Q3B(R2) qualification threshold cited in the development section, and the total limit is conservative. Validation batches show total impurities ~0.05–0.06% at release, supporting the “not tested at release” position for routine control. A stability-indicating LC-UV method (same chromatographic conditions as assay) with SST including resolution to olaparib acid, LOQ solution, and gradient robustness ranges is described. System suitability includes interference checks and resolution criteria vs. olaparib acid, supporting specificity per Q6A. The strength-dependent time is justified by the erosion mechanism and surface area-to-volume differences. Full profiles show rapid erosion with complete release by 60–90 min and low RSD. The data submitted supports robustness and discrimination claims.

Decision

Not Applicable

Since the product is already registered bearing Registration Number 125524, the Registration Board disposed of the application.

2	Case Category	Priority As Per 257-M of RB (Abdul Mughees)
	Name, address of Applicant.	AstraZeneca Pharmaceuticals Pakistan Private Limited C-50, Block-2, Clifton, Karachi Pakistan (290)
	Application Form Dy. No / Tracking ID & date of submission	(SPV-8ZB-6X5U, 2024-03-13)
	Detail of Fee Submitted	75000.0, 225000.0 2023-12-05, 2024-01-18
	The proposed proprietary name / brand name	LYNPARZA (Olaparib) 100mg film-coated tablets
	Label Claim	1. Ovarian cancer: for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in a complete or partial response to platinum
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	56 Film-Coated Table-Controlled
	Shelf Life (Unit)	24 Month(s) Do not store above 30°C. Store in the original package in order to protect from moisture.
	For generic drugs (me-too Status)	Lynparza is an Originator Brand (Research Brand)
	Pharmacotherapeutic Group of (API)	.
	Name, address of Manufacturing site:	AbbVie Limited -Carretera 2 KM 58.0 Cruce Davilia Barceloneta, PR 00617 Puerto Rico USA-United
	Pharmaceutical Equivalence and Comparative Dissolution Profile	.
	Name, address of Marketing Authorization Holder:	AstraZeneca AB, Sweden, AstraZeneca AB, SE-151 85 Sodertalje, Sweden, Sweden

Details of Certificates (CoPP/FSC/cGMP):	Scanned copy of attested EMA issued CoPP bearing number 01/23/008919 dated 23 August 2023 has been attached. US FDA Approved site with FDA establishment identifier 3000210838
Details of Authorization Letter :	.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability was set down under the long-term storage condition of 30°C/75% RH and accelerated condition of 40°C/75% RH. The tablets were manufactured using olaparib extrudate intermediate material from AbbVie Puerto Rico and packed in Al/Al blisters.
The status in reference regulatory authorities	Approved in US, UK, EMA, Canada, Australia, New Zealand & Japan

Evaluation Remarks

LYNPARZA (Olaparib) 100mg film coated tablet is manufactured at AbbVie Limited KM 58 Carretera 2 Cruce Davila Barceloneta Puerto Rico 00617 United States whereas primary and secondary packaging and batch release is performed at AstraZeneca UK Limited Silk Road Business Park Macclesfield Cheshire SK10 2NA United Kingdom as per information provided in Module 3. It is presented as Yellow to dark yellow film-coated, oval, bi-convex tablet, debossed with “OP 100” on one side and plain on the reverse. Olaparib is classified as BCS Class IV, but formulation strategies adopted by the manufacturer mitigate biopharmaceutical risks. All excipients are either pharmacopoeial or approved food-grade colorants. 95–105% of label claim at release and end of shelf-life is appropriate for a small molecule oral IR tablet and meets compendial/ICH expectations. Method performance is supported with system suitability (tailing ≤ 1.5 , RSD $\leq 2\%$), and typical RT --- min on a USP L1 column. Content uniformity per Ph. Eur. is specified (acceptance value compliant), with supporting validation batch data. DP has an immediate release profile with complete dissolution in <60 minutes. Specifications include identity, assay, dissolution, uniformity, and degradation limits and are claimed to be innovator’s specs. Analytical methods validated and aligned with pharmacopoeial standards. Microbiological testing confirms absence of contamination. Degradants are not tested at release, limits are NMT 0.2% for largest individual unspecified and NMT 0.5% total impurities. The 0.2% aligns with the ICH Q3B(R2) qualification threshold cited in the development section, and the total limit is conservative. Validation batches show total impurities ~0.05–0.06% at release, supporting the “not tested at release” position for routine control. A stability-indicating LC-UV method (same chromatographic conditions as assay) with SST including resolution to olaparib acid, LOQ solution, and gradient robustness ranges is described. System suitability includes interference checks and resolution criteria vs. olaparib acid, supporting specificity per Q6A. The strength-dependent time is justified by the erosion mechanism and surface area-to-volume differences. Full profiles show rapid erosion with complete release by 60–90 min and low RSD. The data submitted supports robustness and discrimination claims.

Decision

Not Applicable

Since the product is already registered bearing Registration Number 125524, the Registration Board disposed of the application.

3

Case Category	Priority As Per 257-M of RB (Abdul Mughees)
Name, address of Applicant.	AJ Mirza Pharma Pvt Ltd 1st Floor, Shafi Court, Merewether Road, Civil Lines. Karachi–Pakistan. (235)
Application Form Dy. No / Tracking ID & date of submission	(8H1-PJD-8P69, 2024-05-24)
Detail of Fee Submitted	150000.0, 150000.0 2023-10-14, 2024-05-03
The proposed proprietary name / brand name	NILOTINIB CAPSULES 150 mg
Label Claim	Each hard gelatin capsule contains: Nilotinib (As D Tartrate) 150 mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	4's-As per SRO

Shelf Life (Unit)	24 Month(s) "Store below 30°C "
For generic drugs (me-too Status)	Tasigna 150 mg (Novartis)
Pharmacotherapeutic Group of (API)	L01E PROTEIN KINASE INHIBITORS
Name, address of Manufacturing site:	Cipla Ltd.-Cipla Limited, (Unit-X) Plot No. S-103 to S-105, S-107 to S-112 & L-147, L-147/1 to L-147/3, L-147/A & L-138 Verna Industrial Estate, Verna, Salcette, Goa 403722, India-India
Pharmaceutical Equivalence and Comparative Dissolution Profile	
Name, address of Marketing Authorization Holder:	AJ Mirza Pharma (Pvt.) Ltd., 1st Floor, Shafi Court, Merewether Road, Civil Lines. Karachi–Pakistan., Pakistan
Details of Certificates (CoPP/FSC/cGMP):	CoPP from India valid upto 13.06.2025 bearing number 789/MFG/WHO-GMP/DFDA/2024/80 attested by Pakistan Embassy 30.04.2024
Details of Authorization Letter :	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted along with forced degradation studies
The status in reference regulatory authorities	Tasigna® 150 mg (Novartis Europharm Limited, Ireland)
Evaluation Remarks	
The instant application was considered in the 336th meeting of the Registration Board and was deferred for following reasons: "Decision: Deferred for following:a) Reference Drug Product utilizes Nilotinib Hydrochloride Monohydrate however, Cipla test product is developed with Nilotinib D-Tartrate. Justification shall be submitted in this regard.b) Long term stability studies data shall be submitted till claimed shelf life."It was again considered by the Board in its 340th meeting held from 1st October to 2nd October, 2024 and the Board decided as followed:"Decision: Deferred for the provision reference of applied formulation from Reference Regulatory Authority or any international guidelines for the acceptance of interchangeability of a generic drug with different salt form from that of an innovator product." Now the applicant has submitted that their principal's product "Nilotinib D-Tartrate" eq. to 50 mg base, 150 mg base and 200 mg base has been approved by US FDA, which is available at Drugs@ FDA under New Drugs Approval (NDA) 218922 as a Type 3 - New Dosage Form submission. The approval letter from US FDA bears date 02/19/2025. Furthermore, the firm has also submitted long-term stability data for 24 months. US FDA has mentioned in its approval letter that "Based on the stability data submitted to date, the expiry dating period for Nilotinib Capsules shall be 24 months from the date of manufacture when stored at USP controlled room temperature conditions i.e., 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30°C (59°F to 86°F)."	
Decision	
Approved	
4	
Case Category	Priority As Per 257-M of RB (Abdul Mughees)
Name, address of Applicant.	AJ Mirza Pharma Pvt Ltd 1st Floor, Shafi Court, Merewether Road, Civil Lines. Karachi–Pakistan. (235)
Application Form Dy. No / Tracking ID & date of submission	(GVB-MTT-J9RM, 2024-05-24)
Detail of Fee Submitted	150000.0, 150000.0 2023-10-14, 2024-05-03
The proposed proprietary name / brand name	NILOTINIB CAPSULES 200 mg
Label Claim	Each hard gelatin capsule contains: Nilotinib (As D Tartrate) 200 mg
Reference to Finished product specifications	Manufacturer Specification
Proposed Pack Size	4's-As per SRO
Shelf Life (Unit)	24 Month(s) "Store below 30°C "

For generic drugs (me-too Status)	Tasigna 200 mg (Novartis)
Pharmacotherapeutic Group of (API)	L01E PROTEIN KINASE INHIBITORS
Name, address of Manufacturing site:	Cipla Ltd.-Cipla Limited, (Unit-X) Plot No. S-103 to S-105, S-107 to S-112 & L-147, L-147/1 to L-147/3, L-147/A & L-138 Verna Industrial Estate, Verna, Salcette, Goa 403722, India-India
Pharmaceutical Equivalence and Comparative Dissolution Profile	
Name, address of Marketing Authorization Holder:	AJ Mirza Pharma (Pvt.) Ltd., 1st Floor, Shafi Court, Merewether Road, Civil Lines. Karachi–Pakistan., India
Details of Certificates (CoPP/FSC/cGMP):	CoPP from India valid upto 13.06.2025 bearing number 789/MFG/WHO-GMP/DFDA/2024/80 attested by Pakistan Embassy 30.04.2024
Details of Authorization Letter :	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted along with forced degradation studies
The status in reference regulatory authorities	Tasigna® 200 mg (Novartis Europharm Limited, Ireland)

Evaluation Remarks

The instant application was considered in the 336th meeting of the Registration Board and was deferred for following reasons: “Decision: Deferred for following:a) Reference Drug Product utilizes Nilotinib Hydrochloride Monohydrate however, Cipla test product is developed with Nilotinib D-Tartrate. Justification shall be submitted in this regard.b) Long term stability studies data shall be submitted till claimed shelf life.”It was again considered by the Board in its 340th meeting held from 1st October to 2nd October, 2024 and the Board decided as followed:“Decision: Deferred for the provision reference of applied formulation from Reference Regulatory Authority or any international guidelines for the acceptance of interchangeability of a generic drug with different salt form from that of an innovator product.” Now the applicant has submitted that their principal’s product “Nilotinib D-Tartrate” eq. to 50 mg base, 150 mg base and 200 mg base has been approved by US FDA, which is available at Drugs@ FDA under New Drugs Approval (NDA) 218922 as a Type 3 - New Dosage Form submission. The approval letter from US FDA bears date 02/19/2025. Furthermore, the firm has also submitted long-term stability data for 24 months. US FDA has mentioned in its approval letter that “Based on the stability data submitted to date, the expiry dating period for Nilotinib Capsules shall be 24 months from the date of manufacture when stored at USP controlled room temperature conditions i.e., 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30°C (59°F to 86°F).”

Decision

Approved

5	Case Category	New License (Abdul Mughees)
	Name, address of Applicant.	Well Go Pharmaceuticals (Pvt) Ltd 5-km, Raiwind Manga Road Lahore (001004)
	Application Form Dy. No / Tracking ID & date of submission	(LJS-XBX-A3D6, 2025-07-24)
	Detail of Fee Submitted	37000.0, 2025-07-14,
	The proposed proprietary name / brand name	WELLOCTA 3gm Sachet
	Label Claim	Each Sachet Contains: Dioctahedral Smectite ... 3 g. (Innovator’s Specs).
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C and dry place.
	For generic drugs (me-too Status)	Smecta by Atco Laboratories Ltd.
	Pharmacotherapeutic Group of (API)	Anti-diarrhoeal / Intestinal adsorbents

Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Shangdong Xianhe Pharmaceuticals Co., Ltd. The Xianhe town of Hekou, County of Dongying of Shangdong Province.
Detail of stability batches of drug product	100 Sachet for each batch.
Documents for the procurement of API with approval from DRAP (in case of Import)	Attached.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and Comparative Dissolution is taken place Against Smecta by Atco Laboratories Ltd.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability submitted of zone iv A.
The status in reference regulatory authorities	ANSM Smecta M/s IPSEN Industrie. France
GMP status of the firm	Attached.
Evidence of approval of manufacturing facility	Attached.
Evaluation Remarks	
Product has been developed by using API taken on loan from GT pharma private limited, Lahore. Stability studies have been performed for 06 months. Pharmaceutical Equivalence and Comparative Dissolution is taken place Against Smecta by Atco Laboratories Ltd.	
Decision	
Approved	
6 Case Category	New Section (Abdul Mughees)
Name, address of Applicant.	Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi (000333)
Application Form Dy. No / Tracking ID & date of submission	(AHS-JAG-Z4G1, 2025-07-21)
Detail of Fee Submitted	37000.0, 2025-05-22,
The proposed proprietary name / brand name	NUBIN 10mg/ml Injection
Label Claim	Each ampoule (1ml) contains:Nalbuphine HCl.....10mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	2x5's(1ml)-As per SRO
Shelf Life (Unit)	2 Yearstore below 30
For generic drugs (me-too Status)	Nalbin 10mg/ml injection
Pharmacotherapeutic Group of (API)	Opoid agonist antagonist
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	micro Orgo Chem
Detail of stability batches of drug product	182NS02-182NS03-182NS04
Documents for the procurement of API with approval from DRAP (in case of Import)	29-11-2024
Pharmaceutical Equivalence and Comparative Dissolution Profile	NUBAIN 10mg/ml Injection
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	MO/NBP/1401-MO/NBP/1402/MO/NBP/1403
The status in reference regulatory authorities	NUBAIN 10mg/ml Injection
GMP status of the firm	20th feb,2024
Evidence of approval of manufacturing facility	28th march 2025

	Evaluation Remarks	
	Applicant has performed PE and submitted 06 months stability data according to provided specifications.	
	Decision	
	Approved	
7	Case Category	New License (Abdul Mughees)
	Name, address of Applicant.	Well Go Pharmaceuticals (Pvt) Ltd 5-km, Raiwind Manga Road Lahore (001004)
	Application Form Dy. No / Tracking ID & date of submission	(TTB-V1P-79GD, 2025-07-24)
	Detail of Fee Submitted	37000.0, 2025-07-14,
	The proposed proprietary name / brand name	Well-D3 5mg/ml Injection
	Label Claim	Well-D3 5mg/ml Injection Each 1ml ampoule contains: - Cholecalciferol (Vitamin D3)....5mg (Innovator's Specification).
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C and dry place.
	For generic drugs (me-too Status)	Indrop-D Injection
	Pharmacotherapeutic Group of (API)	for healthy bones, muscles, nerves, and to support the immune system
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhejiang Jinlangbo Pharmaceutical Co., Ltd. Yulin Road, 53#, Yulin Street, Xinchang, Zhejiang Province China
	Detail of stability batches of drug product	300 Ampoules is for each batch.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and Comparative Dissolution is taken place Against Indrop-D Injection
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability submitted of zone iv A.
	The status in reference regulatory authorities	ANSM France Approved VITAMIN D3 GOOD 200,000 IU/1 ml, IM injection solution in ampoule ANSM (France) Approved
	GMP status of the firm	Attached.
	Evidence of approval of manufacturing facility	Attached.
	Evaluation Remarks	
	Each 1ml contains 5 mg (200,000 IU/ml) of Cholecalciferol. Control of DS is based on BP specs. The final liquid is 5mg Cholecalciferol in 1ml ampoule with medium-chain triglyceride oil i.e. Palmester Oil (MCT) – pharmacopeial grade. Comparative data with Indrop-D (innovator) has been provided. Chromatographic conditions for Assay have been mentioned as LC with UV detection at 280 nm while using Mobile Phase of Methanol: Acetonitrile (80:20) with an acceptance criteria of 90% to 20%.	
	Decision	
	Approved	
8	Case Category	New License (Abdul Mughees)
	Name, address of Applicant.	Well Go Pharmaceuticals (Pvt) Ltd 5-km, Raiwind Manga Road Lahore (001004)

Application Form Dy. No / Tracking ID & date of submission	(9J2-AS9-2ZED, 2025-07-24)
Detail of Fee Submitted	37000.0, 2025-07-14,
The proposed proprietary name / brand name	Welltro 500mg/100ml IV Infusion
Label Claim	Welltro 500mg/100ml IV Infusion Each 100ml contains: Metronidazole.....500mg (BP Specs.)
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	as per SRO-As per SRO
Shelf Life (Unit)	2 YearStore below 30°C and dry place.
For generic drugs (me-too Status)	Flagyl injection by Hoechst Pakistan Limited
Pharmacotherapeutic Group of (API)	Antibiotic /Antiprotozoal
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	AARTI DRUGS LIMITED E120/105/106,MIDC,TARAPUR,VIA BOISAR, DIST:THANE.MAHARASHTRA.INDIA (India).
Detail of stability batches of drug product	100 Vails is for each batch.
Documents for the procurement of API with approval from DRAP (in case of Import)	Attached.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and Comparative Dissolution is taken place Against Flagyl injection by Hoechst Pakistan Limited
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability submitted of zone iv A.
The status in reference regulatory authorities	Metronidazole 500mg/100ml MHRA Approved
GMP status of the firm	Attached.
Evidence of approval of manufacturing facility	Attached.
Evaluation Remarks	
Welltro 500mg/100ml IV Infusion is Clear, light yellow solution. Comparative analysis was done with Flagyl. It follows BP specifications: pH 4.5–6.0, assay 95–110%, endotoxin ≤0.5 EU/mg. Type-I glass vial is used. The API was on loan from Fahmir Pharma however no intimation to DRAP was provided.	
Decision	
Approved	
9 Case Category	Routine (Abdul Mughees)
Name, address of Applicant.	Nabiqasim Industries (Pvt) Ltd., 17/24, Korangi Industrial Area, Karachi. (000105)
Application Form Dy. No / Tracking ID & date of submission	(38D-3MS-BJRW, 2024-03-14)
Detail of Fee Submitted	30000.0, 2024-01-08,
The proposed proprietary name / brand name	Tapen IR Tablet 75mg
Label Claim	Each film coated tablet contains; Tapentadol hydrochloride eq. to Tapentadol.... 75mg (Innovator's Specification)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	10's, 14's, 20's,28'-As per SRO
Shelf Life (Unit)	2 Year(s)Store below 30 Degree Celsius Temperature
For generic drugs (me-too Status)	Tapenta IR 75mg (Sami Pharmaceuticals)
Pharmacotherapeutic Group of (API)	N02AX06 strong analgesic

Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Arene life sciences, Plot No. 48, 49 & 50, 209, 210 & 211 Phase-II, IDA, Pashamylaram Sangareddy Telangana, India.
Detail of stability batches of drug product	Provided
Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
Pharmaceutical Equivalence and Comparative Dissolution Profile	Tapento IR 75 tablet by Sami
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
The status in reference regulatory authorities	Nucynta tablet 75mg (FDA Approved)
GMP status of the firm	Provided
Evidence of approval of manufacturing facility	Provided
Evaluation Remarks	
Decision	
Approved	
The Registration Board approved the grant of registration of the applied product with the condition that manufacturer shall ensure the following directions for use on the labelling of the drug product in a clear manner:	
"To be used by patients 18 years of age or older for the management of moderate to severe chronic pain."	
Case Category	Routine (Abdul Mughees)
Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
Application Form Dy. No / Tracking ID & date of submission	(GY4-242-X6BM, 2024-03-12)
Detail of Fee Submitted	30000.0, 2024-01-26,
The proposed proprietary name / brand name	Empamet 12.5mg/1000mg XR Tablet (EMPAGLIFLOZIN+METFORMINHCl)
Label Claim	Each Film Coated Extended Release tablet contains: Empagliflozin.....12.5mg (Immediate release coat) Metformin HCl.....1000mg (Extended release core)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
Shelf Life (Unit)	2 Year(s)Store at cool &dry place below 30
For generic drugs (me-too Status)	Empaa M XR(Empagliflozin + Metformin HCl) 12.5mg/1000mg M/s Weather Folds PHARMACEUTICALS Registration # 105282
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	
Detail of stability batches of drug product	Provided for 3 batches long-term and accelerated as per Zone IV-a
Documents for the procurement of API with approval from DRAP (in case of Import)	Provided

Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP data but not complete report																																				
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided for both APIs																																				
The status in reference regulatory authorities	SYNJARDY XR- empagliflozin, metformin hydrochloride tablet, extended release 12.5mg/1000mg M/s BOEHR																																				
GMP status of the firm	Provided																																				
Evidence of approval of manufacturing facility	Provided																																				
Evaluation Remarks																																					
The applicant was asked to provide audit trail, required under the stability data (section 3.2.P.8.3). on 19th Feb 2024 however, they replied as follows: "System is not 21CFR complaint"																																					
Decision																																					
Deferred																																					
The Registration Board directed to conduct a Product Specific Inspection to verify the audit trail by a panel constituted by the Chairman, Registration Board.																																					
11	<table> <tr> <td>Case Category</td><td>Routine (Abdul Mughees)</td></tr> <tr> <td>Name, address of Applicant.</td><td>Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)</td></tr> <tr> <td>Application Form Dy. No / Tracking ID & date of submission</td><td>(J31-8S2-A29E, 2024-03-12)</td></tr> <tr> <td>Detail of Fee Submitted</td><td>30000.0, 2024-01-26,</td></tr> <tr> <td>The proposed proprietary name / brand name</td><td>Empamet 25mg/1000mg XR Tablet (EMPAGLIFLOZIN+METFORMINHCl)</td></tr> <tr> <td>Label Claim</td><td>Each Film Coated Extended Release tablet contains: Empagliflozin.....25mg (Immediate release coat) Metformin HCl.....1000mg (Extended release core)</td></tr> <tr> <td>Reference to Finished product specifications</td><td>As per Innovators Specification</td></tr> <tr> <td>Proposed Pack Size</td><td>1x10's, 2x7's, 2x10'-As per SRO</td></tr> <tr> <td>Shelf Life (Unit)</td><td>2 Year(s)Store at cool &dry place below 30</td></tr> <tr> <td>For generic drugs (me-too Status)</td><td>Empaa M XR(Empagliflozin + Metformin HCl) 25mg/1000mg M/s Weather Folds PHARMACEUTICALS Registration # 105282</td></tr> <tr> <td>Pharmacotherapeutic Group of (API)</td><td></td></tr> <tr> <td>Name, address of Manufacturing site:</td><td>Self Manufacturing</td></tr> <tr> <td>Name & address of API manufacturer</td><td></td></tr> <tr> <td>Detail of stability batches of drug product</td><td>Provided for 3 batches for long-term and accelerated studies at Zone IV-a</td></tr> <tr> <td>Documents for the procurement of API with approval from DRAP (in case of Import)</td><td>Provided</td></tr> <tr> <td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>CDP data but not the report</td></tr> <tr> <td>Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)</td><td>Provided for both APIs</td></tr> <tr> <td>The status in reference regulatory authorities</td><td>SYNJARDY XR- empagliflozin, metformin hydrochloride tablet, extended release 25mg/1000mg M/s BOEHRIN</td></tr> </table>	Case Category	Routine (Abdul Mughees)	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)	Application Form Dy. No / Tracking ID & date of submission	(J31-8S2-A29E, 2024-03-12)	Detail of Fee Submitted	30000.0, 2024-01-26,	The proposed proprietary name / brand name	Empamet 25mg/1000mg XR Tablet (EMPAGLIFLOZIN+METFORMINHCl)	Label Claim	Each Film Coated Extended Release tablet contains: Empagliflozin.....25mg (Immediate release coat) Metformin HCl.....1000mg (Extended release core)	Reference to Finished product specifications	As per Innovators Specification	Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO	Shelf Life (Unit)	2 Year(s)Store at cool &dry place below 30	For generic drugs (me-too Status)	Empaa M XR(Empagliflozin + Metformin HCl) 25mg/1000mg M/s Weather Folds PHARMACEUTICALS Registration # 105282	Pharmacotherapeutic Group of (API)		Name, address of Manufacturing site:	Self Manufacturing	Name & address of API manufacturer		Detail of stability batches of drug product	Provided for 3 batches for long-term and accelerated studies at Zone IV-a	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP data but not the report	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided for both APIs	The status in reference regulatory authorities	SYNJARDY XR- empagliflozin, metformin hydrochloride tablet, extended release 25mg/1000mg M/s BOEHRIN
Case Category	Routine (Abdul Mughees)																																				
Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)																																				
Application Form Dy. No / Tracking ID & date of submission	(J31-8S2-A29E, 2024-03-12)																																				
Detail of Fee Submitted	30000.0, 2024-01-26,																																				
The proposed proprietary name / brand name	Empamet 25mg/1000mg XR Tablet (EMPAGLIFLOZIN+METFORMINHCl)																																				
Label Claim	Each Film Coated Extended Release tablet contains: Empagliflozin.....25mg (Immediate release coat) Metformin HCl.....1000mg (Extended release core)																																				
Reference to Finished product specifications	As per Innovators Specification																																				
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Pharmacotherapeutic Group of (API)																																					
Name, address of Manufacturing site:	Self Manufacturing																																				
Name & address of API manufacturer																																					
Detail of stability batches of drug product	Provided for 3 batches for long-term and accelerated studies at Zone IV-a																																				
Documents for the procurement of API with approval from DRAP (in case of Import)	Provided																																				
Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP data but not the report																																				
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided for both APIs																																				
The status in reference regulatory authorities	SYNJARDY XR- empagliflozin, metformin hydrochloride tablet, extended release 25mg/1000mg M/s BOEHRIN																																				

	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	Provided
	Evaluation Remarks	
	The applicant was asked to provide audit trail, required under the stability data (section 3.2.P.8.3). on 19th Feb 2024 however, they replied as follows: "System is not 21CFR complaint"	
	Decision	
	Deferred	
	The Registration Board directed to conduct a Product Specific Inspection to verify the audit trail by a panel constituted by the Chairman, Registration Board.	
12	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(JXW-TZH-AS56, 2024-03-12)
	Detail of Fee Submitted	30000.0, 2024-01-26,
	The proposed proprietary name / brand name	Empamet 10/1000mg XR Tablet
	Label Claim	Each film coated extended release tablet contains: Empagliflozin.....10mg (Immediate release coat) Metformin HCl.....1000mg (Extended release core)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature below 30
	For generic drugs (me-too Status)	Xengl-Met 10mg/1000mg XR tablet by M/s Hilton Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Provided for 3 batches for long-term and accelerated at Zone IV-a
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP data but no report
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided for both APIs
	The status in reference regulatory authorities	Synjardy 10mg/1000mg XR tablet by M/sBoehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT06877
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	Provided
	Evaluation Remarks	
	The applicant was asked to provide audit trail, required under the stability data (section 3.2.P.8.3). on 19th Feb 2024 however, they replied as follows: "System is not 21CFR complaint"	
	Decision	
	Deferred	

The Registration Board directed to conduct a Product Specific Inspection to verify the audit trail by a panel constituted by the Chairman, Registration Board.

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Case Category	Routine (Abdul Mughees)	
Name, address of Applicant.	AGP Limited B-23-C, S.I.T.E., Karachi (000348)	
Application Form Dy. No / Tracking ID & date of submission	(JSY-Z4L-JHT1, 2024-03-18)	
Detail of Fee Submitted	75000.0, 2024-01-08,	
The proposed proprietary name / brand name	Emoglip Met XR	
Label Claim	Each Film Coated Tablet Contains: Empagliflozin.....5mg Linagliptin.....2.5mg Metformin HCl.....1000mg (as extended release core)"	
Reference to Finished product specifications	As per Innovators Specification	
Proposed Pack Size	10's, 20's, 30's & 4-As per SRO	
Shelf Life (Unit)	2 Year(s)Store below 30°C	
For generic drugs (me-too Status)	New Chemical Entity	
Pharmacotherapeutic Group of (API)		
Name, address of Manufacturing site:	Self Manufacturing	
Name & address of API manufacturer	AARTI DRUGS LIMITED,RUYUAN HEC PHARM CO.,LTD.,Zhejiang Hongyuan Pharmaceutical Co.Ltd	
Detail of stability batches of drug product	Provided	
Documents for the procurement of API with approval from DRAP (in case of Import)	Provided	
Pharmaceutical Equivalence and Comparative Dissolution Profile	Trijardy XR by BIP Germany	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided for all 3 APIs	
The status in reference regulatory authorities	FDA approved Trijardy XR Tablet by Boehringer Ingelheim Pharmaceuticals, Inc	
GMP status of the firm	Provided	
Evidence of approval of manufacturing facility	Provided	
Evaluation Remarks		
Sr.No	Shortcoming	Response of the firm
1	Submit valid DML/GMP certificate of drug substance manufacturer of Empagliflozin and Linagliptin, issued by relevant regulatory authority of country of origin	The DML & written confirmation for GMP Certificate for Empagliflozin & written confirmation for GMP Certificate of Linagliptin uploaded provided in Module 3 section 1.6.5. However, copy uploaded as Annex A
2	Details of general properties and solubility profile of Empagliflozin shall be submitted.	Detail of general properties and solubility profile of Empagliflozin provided in Module 3, section 3.2.S.1. However, copy uploaded in Annex B
3	Justification shall be submitted for the variation in analytical procedure for Assay test of Empagliflozin and Linagliptin as proposed by Drug substance manufacturer and as submitted by the drug product manufacturer.	Please find enclosed updated Standard testing of Empagliflozin & Linagliptin in Annex C.
4	COA of reference/working standard of drug substances shall be submitted.	Provided in Module 3 section 3.2.S.5. However, copy provided in Annex D.
5	Long term stability data of Empagliflozin shall be submitted till claimed shelf. (SUPPLY CHAIN)	We have requested the stability data from our API manufacturer. We hereby commit you to provide the stability studies as received from the manufacturer.

6	Justification shall be submitted on the product development data basis for the proposed excess quantities of Empagliflozin and Linagliptin coating solutions.	Justification provided in Annex E.
7	Clarification shall be submitted regarding the in-process controls applied for establishing the dissolution profile of Metformin HCl core tablet before processing it further for the active coating.	Based on the satisfactory dissolution testing results of Metformin HCl core tablets of trial batch (Report enclosed in Annex F).
8	Justification shall be submitted for not including test of moisture content in drug product specifications, as recommended by the Innovator drug product literature. Limits of the test for Arginine content shall be declared. (metformin content remains same in all strengths) 3.2.P.5.1	Water determination performed on Drug product because Water content specifically quantifies the actual water present in the finished product. In contrast, moisture content includes both water and other volatile components, making it a broader measurement however as per drug product literature on page no 9 (uploaded sequence). Link: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/212614Orig1s000ChemR.pdf The water determination/moisture content has performed (Annex-G attached for reference) The moisture content analysis conducted on the current test sample has demonstrated results consistent with the water determination assessment. Conversely, for commercial batch testing, the moisture content parameter has been integrated into testing to ensure compliance. (Uploaded as Annex -G) Limit of arginine has been revised to incorporate a defined limit for arginine content in the specification and already mentioned in stability sheet. (Uploaded as Annex -G
9	Performance of parameters of Robustness and range shall be submitted in the drug product analytical method validation studies. As evident from the submitted analytical record the analytical method validation studies have been performed at different wavelengths of UV detector from that recommended in the analytical procedure for Empagliflozin and Metformin HCl. Justification shall be submitted in this regard.	The chromatogram shows peak retention (RT) as follows: Metformin Hydrochloride at 1.4 min (230 nm), Linagliptin at 4.21 min (294 nm), and Empagliflozin at 15.02 min (224 nm). The Standard Chromatogram Report presents the peak trend in the order of Empagliflozin, Metformin Hydrochloride and Linagliptin. However, in the Sample Report format, the trend appears as Empagliflozin, Linagliptin, followed by Metformin Hydrochloride separately. (Annex H (Standard) & Annex I (Sample) uploaded. The evaluation of column temperature and solution stability has been conducted as part of the robustness assessment document already submitted, ensuring the reliability and consistency of analytical results. This study examines the impact of varying temperature conditions and solution stability on method performance, confirming that the analytical procedure remains unaffected by these influences.
10	The peak areas reported in the analytical record of drug product stability studies does not coincide with those reported in analytical method validation studies. Justification shall be submitted in this regard.	Please note that two different HPLC systems (HPLC-001 and HPLC-003) were used for analysis of molecule (Empagliflozin, Linagliptin and Metformin HCl), different peak areas were seen as a result of the UV lamp & its efficacy while RRT's produce on same time and result concluded that are in acceptable range, the UV lamp life gradually decreased, due to performed multiple analysis on HPLC by using UV lamp.

However, two different peak areas can be observed two different systems on same time.

Decision

Approved

14

Case Category	Routine (Abdul Mughees)	
Name, address of Applicant.	AGP Limited B-23-C, S.I.T.E., Karachi (000348)	
Application Form Dy. No / Tracking ID & date of submission	(TJT-UYD-AWEG, 2024-03-12)	
Detail of Fee Submitted	75000.0, 2024-01-08,	
The proposed proprietary name / brand name	Emoglip Met XR	
Label Claim	Each Film Coated Tablet contains: Empagliflozin.....10mg Linagliptin.....5mg Metformin HCl.....1000mg (as extended release core)	
Reference to Finished product specifications	As per Innovators Specification	
Proposed Pack Size	10s, 20s, 30s & 40s-As per SRO	
Shelf Life (Unit)	2 Year(s)Store below 30°C	
For generic drugs (me-too Status)	New Chemical Entity	
Pharmacotherapeutic Group of (API)		
Name, address of Manufacturing site:	Self Manufacturing	
Name & address of API manufacturer	Zhejiang Hongyuan Pharmaceutical Co.Ltd ,AARTI DRUGS LIMITED ,RUYUAN HEC PHARM CO.,LTD	
Detail of stability batches of drug product	Provided	
Documents for the procurement of API with approval from DRAP (in case of Import)	Provided	
Pharmaceutical Equivalence and Comparative Dissolution Profile	Trijardy XR by BIP Germany	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided	
The status in reference regulatory authorities	FDA approved Trijardy XR Tablet by Boehringer Ingelheim Pharmaceuticals, Inc	
GMP status of the firm	Provided	
Evidence of approval of manufacturing facility	Provided	
Evaluation Remarks		
Sr.No	Shortcoming	Response of the firm
1	Submit valid DML/GMP certificate of drug substance manufacturer of Empagliflozin and Linagliptin, issued by relevant regulatory authority of country of origin	The DML & written confirmation for GMP Certificate for Empagliflozin & written confirmation for GMP Certificate of Linagliptin uploaded provided in Module 3 section 1.6.5. However, copy uploaded as Annex A
2	Details of general properties and solubility profile of Empagliflozin shall be submitted.	Detail of general properties and solubility profile of Empagliflozin provided in Module 3, section 3.2.S.1. However, copy uploaded in Annex B
3	Justification shall be submitted for the variation in analytical procedure for Assay test of Empagliflozin and Linagliptin as proposed by Drug substance manufacturer and as submitted by the drug product manufacturer.	Please find enclosed updated Standard testing of Empagliflozin & Linagliptin in Annex C.
4	COA of reference/working standard of drug substances shall be submitted.	Provided in Module 3 section 3.2.S.5. However, copy provided in Annex D.

5	Long term stability data of Empagliflozin shall be submitted till claimed shelf. (SUPPLY CHAIN)	We have requested the stability data from our API manufacturer. We hereby commit you to provide the stability studies as received from the manufacturer.
6	Justification shall be submitted on the product development data basis for the proposed excess quantities of Empagliflozin and Linagliptin coating solutions.	Justification provided in Annex E.
7	Clarification shall be submitted regarding the in-process controls applied for establishing the dissolution profile of Metformin HCl core tablet before processing it further for the active coating.	Based on the satisfactory dissolution testing results of Metformin HCl core tablets of trial batch (Report enclosed in Annex F).
8	Justification shall be submitted for not including test of moisture content in drug product specifications, as recommended by the Innovator drug product literature. Limits of the test for Arginine content shall be declared. (metformin content remains same in all strengths) 3.2.P.5.1	Water determination performed on Drug product because Water content specifically quantifies the actual water present in the finished product. In contrast, moisture content includes both water and other volatile components, making it a broader measurement however as per drug product literature on page no 9 (uploaded sequence). Link: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/212614Orig1s000ChemR.pdf The water determination/moisture content has performed (Annex-G attached for reference) The moisture content analysis conducted on the current test sample has demonstrated results consistent with the water determination assessment. Conversely, for commercial batch testing, the moisture content parameter has been integrated into testing to ensure compliance. (Uploaded as Annex -G) Limit of arginine has been revised to incorporate a defined limit for arginine content in the specification and already mentioned in stability sheet. (Uploaded as Annex -G
9	Performance of parameters of Robustness and range shall be submitted in the drug product analytical method validation studies. As evident from the submitted analytical record the analytical method validation studies have been performed at different wavelengths of UV detector from that recommended in the analytical procedure for Empagliflozin and Metformin HCl. Justification shall be submitted in this regard.	The chromatogram shows peak retention (RT) as follows: Metformin Hydrochloride at 1.4 min (230 nm), Linagliptin at 4.21 min (294 nm), and Empagliflozin at 15.02 min (224 nm). The Standard Chromatogram Report presents the peak trend in the order of Empagliflozin, Metformin Hydrochloride and Linagliptin. However, in the Sample Report format, the trend appears as Empagliflozin, Linagliptin, followed by Metformin Hydrochloride separately. (Annex H (Standard) & Annex I (Sample) uploaded. The evaluation of column temperature and solution stability has been conducted as part of the robustness assessment document already submitted, ensuring the reliability and consistency of analytical results. This study examines the impact of varying temperature conditions and solution stability on method performance, confirming that the analytical procedure remains unaffected by these influences.
10	The peak areas reported in the analytical record of drug product stability studies does not coincide with those reported in analytical method validation studies. Justification shall be submitted in this regard.	Please note that two different HPLC systems (HPLC-001 and HPLC-003) were used for analysis of molecule (Empagliflozin, Linagliptin and Metformin HCl), different peak areas were seen as a result of the UV lamp & its efficacy while RRT's produce on same time and result concluded that are in acceptable range, the

		UV lamp life gradually decreased, due to performed multiple analysis on HPLC by using UV lamp. However, two different peak areas can be observed two different systems on same time.
Decision		
Approved		
15	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	AGP Limited B-23-C, S.I.T.E., Karachi (000348)
	Application Form Dy. No / Tracking ID & date of submission	(MTL-QL4-4UUR, 2024-03-12)
	Detail of Fee Submitted	75000.0, 2024-01-08,
	The proposed proprietary name / brand name	Emoglip Met XR 12.5/2.5/1000mg
	Label Claim	Each Film Coated Tablet contains: Empagliflozin.....12.5mg Linagliptin.....2.5mg Metformin HCl.....1000mg (as extended release core)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10s, 20s, 30s & 40s-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	New Chemical Entity
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhejiang Hongyuan Pharmaceutical Co.Ltd ,AARTI DRUGS LIMITED ,RUYUAN HEC PHARM CO.,LTD
	Detail of stability batches of drug product	Provided
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Trijardy XR Tablet by Boehringer Ingelheim Pharmaceuticals, Inc Germany
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
	The status in reference regulatory authorities	FDA approved Trijardy XR Tablet by Boehringer Ingelheim Pharmaceuticals, Inc
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	Provided
Evaluation Remarks		
	Sr.No	Shortcoming
	1	Submit valid DML/GMP certificate of drug substance manufacturer of Empagliflozin and Linagliptin, issued by relevant regulatory authority of country of origin
	2	Details of general properties and solubility profile of Empagliflozin shall be submitted.
	3	Justification shall be submitted for the variation in analytical procedure for Assay test of Empagliflozin and Linagliptin as proposed by Drug substance manufacturer and as submitted by the drug product manufacturer.
		Response of the firm
		The DML & written confirmation for GMP Certificate for Empagliflozin & written confirmation for GMP Certificate of Linagliptin uploaded provided in Module 3 section 1.6.5. However, copy uploaded as Annex A
		Detail of general properties and solubility profile of Empagliflozin provided in Module 3, section 3.2.S.1. However, copy uploaded in Annex B
		Please find enclosed updated Standard testing of Empagliflozin & Linagliptin in Annex C.

4	COA of reference/working standard of drug substances shall be submitted.	Provided in Module 3 section 3.2.S.5. However, copy provided in Annex D.
5	Long term stability data of Empagliflozin shall be submitted till claimed shelf. (SUPPLY CHAIN)	We have requested the stability data from our API manufacturer. We hereby commit you to provide the stability studies as received from the manufacturer.
6	Justification shall be submitted on the product development data basis for the proposed excess quantities of Empagliflozin and Linagliptin coating solutions.	Justification provided in Annex E.
7	Clarification shall be submitted regarding the in-process controls applied for establishing the dissolution profile of Metformin HCl core tablet before processing it further for the active coating.	Based on the satisfactory dissolution testing results of Metformin HCl core tablets of trial batch (Report enclosed in Annex F).
8	Justification shall be submitted for not including test of moisture content in drug product specifications, as recommended by the Innovator drug product literature. Limits of the test for Arginine content shall be declared. (metformin content remains same in all strengths) 3.2.P.5.1	Water determination performed on Drug product because Water content specifically quantifies the actual water present in the finished product. In contrast, moisture content includes both water and other volatile components, making it a broader measurement however as per drug product literature on page no 9 (uploaded sequence). Link: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/212614Orig1s000ChemR.pdf The water determination/moisture content has performed (Annex-G attached for reference) The moisture content analysis conducted on the current test sample has demonstrated results consistent with the water determination assessment. Conversely, for commercial batch testing, the moisture content parameter has been integrated into testing to ensure compliance. (Uploaded as Annex -G) Limit of arginine has been revised to incorporate a defined limit for arginine content in the specification and already mentioned in stability sheet. (Uploaded as Annex -G
9	Performance of parameters of Robustness and range shall be submitted in the drug product analytical method validation studies. As evident from the submitted analytical record the analytical method validation studies have been performed at different wavelengths of UV detector from that recommended in the analytical procedure for Empagliflozin and Metformin HCl. Justification shall be submitted in this regard.	The chromatogram shows peak retention (RT) as follows: Metformin Hydrochloride at 1.4 min (230 nm), Linagliptin at 4.21 min (294 nm), and Empagliflozin at 15.02 min (224 nm). The Standard Chromatogram Report presents the peak trend in the order of Empagliflozin, Metformin Hydrochloride and Linagliptin. However, in the Sample Report format, the trend appears as Empagliflozin, Linagliptin, followed by Metformin Hydrochloride separately. (Annex H (Standard) & Annex I (Sample) uploaded. The evaluation of column temperature and solution stability has been conducted as part of the robustness assessment document already submitted, ensuring the reliability and consistency of analytical results. This study examines the impact of varying temperature conditions and solution stability on method performance, confirming that the analytical procedure remains unaffected by these influences.
10	The peak areas reported in the analytical record of drug product stability studies does not coincide with those reported in analytical	Please note that two different HPLC systems (HPLC-001 and HPLC-003) were used for analysis of molecule (Empagliflozin, Linagliptin and Metformin HCl), different peak areas were seen as a result of the UV

method validation studies. Justification shall be submitted in this regard.

lamp & its efficacy while RRT's produce on same time and result concluded that are in acceptable range, the UV lamp life gradually decreased, due to performed multiple analysis on HPLC by using UV lamp. However, two different peak areas can be observed two different systems on same time.

Decision

Approved

16	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	AGP Limited B-23-C, S.I.T.E., Karachi (000348)
	Application Form Dy. No / Tracking ID & date of submission	(QLR-TWA-X175, 2024-03-12)
	Detail of Fee Submitted	75000.0, 2024-01-08,
	The proposed proprietary name / brand name	Emoglip Met XR 25/5/1000mg
	Label Claim	Each Film Coated Tablet contains: Empagliflozin.....25mg Linagliptin.....5mg Metformin HCl.....1000mg (as extended release core)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10s, 20s, 30s & 40s-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	New Chemical Entity
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	RUYUAN HEC PHARM CO.,LTD, Zhejiang Hongyuan Pharmaceutical Co.Ltd ,AARTI DRUGS LIMITED
	Detail of stability batches of drug product	Provided
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Trijardy XR Tablet by Boehringer Ingelheim Pharmaceuticals, Inc Germany
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
	The status in reference regulatory authorities	FDA approved Trijardy XR Tablet by Boehringer Ingelheim Pharmaceuticals, Inc
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	Provided

Evaluation Remarks

Sr.No	Shortcoming	Response of the firm
1	Submit valid DML/GMP certificate of drug substance manufacturer of Empagliflozin and Linagliptin, issued by relevant regulatory authority of country of origin	The DML & written confirmation for GMP Certificate for Empagliflozin & written confirmation for GMP Certificate of Linagliptin uploaded provided in Module 3 section 1.6.5. However, copy uploaded as Annex A
2	Details of general properties and solubility profile of Empagliflozin shall be submitted.	Detail of general properties and solubility profile of Empagliflozin provided in Module 3, section 3.2.S.1. However, copy uploaded in Annex B
3	Justification shall be submitted for the variation in analytical procedure for Assay test of Empagliflozin and Linagliptin as proposed by Drug substance manufacturer	Please find enclosed updated Standard testing of Empagliflozin & Linagliptin in Annex C.

	and as submitted by the drug product manufacturer.	
4	COA of reference/working standard of drug substances shall be submitted.	Provided in Module 3 section 3.2.S.5. However, copy provided in Annex D.
5	Long term stability data of Empagliflozin shall be submitted till claimed shelf. (SUPPLY CHAIN)	We have requested the stability data from our API manufacturer. We hereby commit you to provide the stability studies as received from the manufacturer.
6	Justification shall be submitted on the product development data basis for the proposed excess quantities of Empagliflozin and Linagliptin coating solutions.	Justification provided in Annex E.
7	Clarification shall be submitted regarding the in-process controls applied for establishing the dissolution profile of Metformin HCl core tablet before processing it further for the active coating.	Based on the satisfactory dissolution testing results of Metformin HCl core tablets of trial batch (Report enclosed in Annex F).
8	Justification shall be submitted for not including test of moisture content in drug product specifications, as recommended by the Innovator drug product literature. Limits of the test for Arginine content shall be declared. (metformin content remains same in all strengths) 3.2.P.5.1	Water determination performed on Drug product because Water content specifically quantifies the actual water present in the finished product. In contrast, moisture content includes both water and other volatile components, making it a broader measurement however as per drug product literature on page no 9 (uploaded sequence). Link: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/212614Orig1s000ChemR.pdf The water determination/moisture content has performed (Annex-G attached for reference) The moisture content analysis conducted on the current test sample has demonstrated results consistent with the water determination assessment. Conversely, for commercial batch testing, the moisture content parameter has been integrated into testing to ensure compliance. (Uploaded as Annex -G) Limit of arginine has been revised to incorporate a defined limit for arginine content in the specification and already mentioned in stability sheet. (Uploaded as Annex -G
9	Performance of parameters of Robustness and range shall be submitted in the drug product analytical method validation studies. As evident from the submitted analytical record the analytical method validation studies have been performed at different wavelengths of UV detector from that recommended in the analytical procedure for Empagliflozin and Metformin HCl. Justification shall be submitted in this regard.	The chromatogram shows peak retention (RT) as follows: Metformin Hydrochloride at 1.4 min (230 nm), Linagliptin at 4.21 min (294 nm), and Empagliflozin at 15.02 min (224 nm). The Standard Chromatogram Report presents the peak trend in the order of Empagliflozin, Metformin Hydrochloride and Linagliptin. However, in the Sample Report format, the trend appears as Empagliflozin, Linagliptin, followed by Metformin Hydrochloride separately. (Annex H (Standard) & Annex I (Sample) uploaded. The evaluation of column temperature and solution stability has been conducted as part of the robustness assessment document already submitted, ensuring the reliability and consistency of analytical results. This study examines the impact of varying temperature conditions and solution stability on method performance, confirming that the analytical procedure remains unaffected by these influences.
10	The peak areas reported in the analytical record of drug product stability studies does	Please note that two different HPLC systems (HPLC-001 and HPLC-003) were used for analysis of molecule

not coincide with those reported in analytical method validation studies. Justification shall be submitted in this regard.

(Empagliflozin, Linagliptin and Metformin HCl), different peak areas were seen as a result of the UV lamp & its efficacy while RRT's produce on same time and result concluded that are in acceptable range, the UV lamp life gradually decreased, due to performed multiple analysis on HPLC by using UV lamp. However, two different peak areas can be observed two different systems on same time.

Decision

Approved

17	Case Category	Short Availability Drugs (Abdul Mughees)
	Name, address of Applicant.	OBS AGP (Private) Limited Plot no. B-23-C, 2nd Floor S.I.T.E., Karachi (024)
	Application Form Dy. No / Tracking ID & date of submission	(THY-RWH-GM9G, 2025-09-18)
	Detail of Fee Submitted	300000.0, 2024-02-22,
	The proposed proprietary name / brand name	Amphonex 50mg
	Label Claim	Each vial contains: Liposomal Amphotericin B.....50mg.
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1 x 20ml-As per SRO
	Shelf Life (Unit)	24 Month(s) 2 C to 8 C
	For generic drugs (me-too Status)	Anfogen Ferozsos Laboratories Ltd.
	Pharmacotherapeutic Group of (API)	Antifungal
	Name, address of Manufacturing site:	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
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	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
	Details of Certificates (CoPP/FSC/cGMP):	Provided valid upto 29 March 2025
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
	The status in reference regulatory authorities	USFDA Approved (AMBISOME ASTELLAS PHARMA US INC)

Evaluation Remarks

Authority in its 211th meeting accorded priority to Amphotericin. DS is Manufactured at Synbiotics Limited Plot No. 570, 571 & 576/A, Maitry Marg, Effluent Canal Road, Village : Luna , Taluka : Padra, Dist/City : Vadodara State : Gujarat, Country : India where as Determination of Particle size in the Final API Batches, Analytical Method Validation for the Particle size is performed at contract laboratory Baroda Analytical Services 78/2/3 – GIDC-Makarpura, Vadsar Main Road,B/H-VCCI Complex, Vadodara – 390010. Hydrogenated soybean phosphatidylcholine (HSPC), distearoyl phosphatidylglycerol (DSPG) quantification is performed in FP with acceptance criteria of HSPC: 191. 7 - 255.6 mg /vial & DSPG: 75.6- 100.8 mg / vial. Acceptance criteria for Cholesterol: 46.8 - 62.4 mg I vial & Alpha Tocopherol: 0.448 - 0.768 mg I vial. The average vesicle size is NMT

150 nm. The potency of Amphotericin B is NL T 90.0% and NMT 120.0 % through microbiological method that is 45.0 mg to 60.0 mg /vial as per EP specs.

Decision

Deferred

Deferred to explain the scientific basis for adopting the particle size specification of NLT 75 nm and NMT 150 nm, whereas the innovator has stated that AmBisome contains liposomes of less than 100 nm. As the batch results of the particle size test are all above 100 nm, and considering that liposome size is a critical determinant of pharmacokinetic performance, the applicant is required to justify the proposed limit.

18	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	High-Q Pharmaceuticals Plot# 224 and 225/1, sector 23, Korangi Industrial area, Karachi (000597)
	Application Form Dy. No / Tracking ID & date of submission	(J35-R32-XJGD, 2024-03-12)
	Detail of Fee Submitted	30000.0, 2023-12-07,
	The proposed proprietary name / brand name	ErtagMet
	Label Claim	Each film coated tablet contains: Ertugliflozin L- Pyroglutamic acid eq. to Ertugliflozin 7.5mg Metformin HCl.....
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	10's-As per SRO,14's-As per SRO,20's-As per SRO,28's- As per SRO,30's-As per SRO,7's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Ertuvia-M 7.5/1000mg Tablet (Ferozsans Laboratories Limited)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Aarti Drugs Limited,Chifeng Arker Pharmaceutical Technology Co., Ltd
	Detail of stability batches of drug product	Provided.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP is performed against Ertuvia of Ferozsans
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
	The status in reference regulatory authorities	SEGLUROMET 7.5mg/1000mg Tablet (USFDA Approved)
	GMP status of the firm	Not provided
	Evidence of approval of manufacturing facility	DML is provided
	Evaluation Remarks	
	The applicant was asked to attach GMP certificate of the DS Ertugliflozin manufacturer, as previously they attached certificate issued by Jiangsu Food and Drug Administration Changzhou Pharmaceutic Professional Association valid until Jun. 27, 2023. In response, the applicant has attached a letter by the DS manufacturer with the following statement:	
	Decision	
	Approved	

19	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(7SP-NHV-459J, 2024-03-12)
	Detail of Fee Submitted	30000.0, 2024-01-26,
	The proposed proprietary name / brand name	Empamet 5/1000mg XR Tablet
	Label Claim	Each film coated extended release tablet contains: Empagliflozin.....5mg (Immediate release coat) Metformin HCl.....1000mg (Extended release core)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Xenglu-Met 5mg/1000mg XR tablet by M/s Hilton Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Synjardy 5mg/1000mg XR tablet by M/s Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT06877
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
20	Evaluation Remarks	
	The applicant was asked to provide audit trail, required under the stability data (section 3.2.P.8.3). on 19th Feb 2024 however, they replied as follows: "System is not 21CFR complaint"	
	Decision	
	Deferred	
	The Registration Board directed to conduct a Product Specific Inspection to verify the audit trail by a panel constituted by the Chairman, Registration Board.	
	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	AGP Limited B-23-C, S.I.T.E., Karachi (000348)
	Application Form Dy. No / Tracking ID & date of submission	(PYT-THL-AWH2, 2024-03-18)
	Detail of Fee Submitted	30000.0, 2023-11-20,
	The proposed proprietary name / brand name	Tadol 50mg XR Tablet
	Label Claim	Each film coated extended release tablet contains Tapentadol(as hydrochloride)...50mg
	Reference to Finished product specifications	As per Innovators Specification

Proposed Pack Size	5x10s-As per SRO
Shelf Life (Unit)	2 Year(s)Store below 30°C
For generic drugs (me-too Status)	Tapendol by Searle
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	SYMED LABS LIMITED
Detail of stability batches of drug product	Provided
Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP with Tapentadol Mylan Portugal
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
The status in reference regulatory authorities	Belgium (AFMPS) approved Tapentadol by Laboratorios Liconsa SA
GMP status of the firm	Provided
Evidence of approval of manufacturing facility	Provided

Evaluation Remarks

US FDA has reviewed and stated for the 200533Orig1s000 Nucynta™ (tapentadol) Extended Release Tablets that the labeling indicates that the drug product is to be used by patients 18 years of age or older for the management of moderate to severe chronic pain.

Decision

Approved

The Registration Board approved the grant of registration of the applied product with the condition that manufacturer shall ensure the following directions for use on the labelling of the drug product in a clear manner:

"To be used by patients 18 years of age or older for the management of moderate to severe chronic pain."

21	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	AGP Limited B-23-C, S.I.T.E., Karachi (000348)
	Application Form Dy. No / Tracking ID & date of submission	(1TG-VU1-9N7G, 2024-03-18)
	Detail of Fee Submitted	30000.0, 2023-11-20,
	The proposed proprietary name / brand name	Tadol 150mg XR Tablet
	Label Claim	Each film coated extended release tablet contains Tapentadol (as Hydrochloride)...150mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x10s-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Tapento by SAMI Pharmaceuticals (Pvt) Limited
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	SYMED LABS LIMITED
	Detail of stability batches of drug product	Provided
	Documents for the procurement of API with approval from DRAP	Provided

(in case of Import)																																					
Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided																																				
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided																																				
The status in reference regulatory authorities	Belgium (AFMPS) approved Tapentadol by Laboratorios Liconsa SA																																				
GMP status of the firm	Provided																																				
Evidence of approval of manufacturing facility	Provided																																				
Evaluation Remarks																																					
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Decision																																					
Approved																																					
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22	<table> <tr> <td>Case Category</td><td>Routine (Abdul Mughees)</td></tr> <tr> <td>Name, address of Applicant.</td><td>Nabiqasim Industries (Pvt) Ltd., 17/24, Korangi Industrial Area, Karachi. (000105)</td></tr> <tr> <td>Application Form Dy. No / Tracking ID & date of submission</td><td>(6D8-57M-SLLE, 2024-02-02)</td></tr> <tr> <td>Detail of Fee Submitted</td><td>75000.0, 2023-12-20,</td></tr> <tr> <td>The proposed proprietary name / brand name</td><td>Reliefal OD Tablet</td></tr> <tr> <td>Label Claim</td><td>Each orodispersible tablet contains: Paracetamol BP 500mg</td></tr> <tr> <td>Reference to Finished product specifications</td><td>British Pharmacopeia</td></tr> <tr> <td>Proposed Pack Size</td><td>as per DPC-Controlled</td></tr> <tr> <td>Shelf Life (Unit)</td><td>2 Year(s)Store below 30 degree</td></tr> <tr> <td>For generic drugs (me-too Status)</td><td>not available</td></tr> <tr> <td>Pharmacotherapeutic Group of (API)</td><td>Antipyretic</td></tr> <tr> <td>Name, address of Manufacturing site:</td><td>Self Manufacturing</td></tr> <tr> <td>Name & address of API manufacturer</td><td>Citi Pharma Private Limited, Lahore</td></tr> <tr> <td>Detail of stability batches of drug product</td><td>Batch No: 623DS01, 623DS02 2 batches of 5000 units each</td></tr> <tr> <td>Documents for the procurement of API with approval from DRAP (in case of Import)</td><td>Paracetamol Lot No 489, Batch No. PGP21-489 (3 Kg) commercial invoice no.CP21-9343 dated 30-11-2021</td></tr> <tr> <td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Reference Product: Dafalgan ODIS 500mg Tablets Batch No: A0960 Exp. Date: 8-2024 Test Product: Paracetamol OD 50mg Tablet Batch No.: 623DS01 Mfg. Date: 09-2022 Exp. Date: 09-2024</td></tr> <tr> <td>Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)</td><td>Submitted as per Zone IV</td></tr> <tr> <td>The status in reference regulatory authorities</td><td>Paracetamol MAE 500mg, dispersible tablets, MAE Holding B.V, approved by Netherlands</td></tr> </table>	Case Category	Routine (Abdul Mughees)	Name, address of Applicant.	Nabiqasim Industries (Pvt) Ltd., 17/24, Korangi Industrial Area, Karachi. (000105)	Application Form Dy. No / Tracking ID & date of submission	(6D8-57M-SLLE, 2024-02-02)	Detail of Fee Submitted	75000.0, 2023-12-20,	The proposed proprietary name / brand name	Reliefal OD Tablet	Label Claim	Each orodispersible tablet contains: Paracetamol BP 500mg	Reference to Finished product specifications	British Pharmacopeia	Proposed Pack Size	as per DPC-Controlled	Shelf Life (Unit)	2 Year(s)Store below 30 degree	For generic drugs (me-too Status)	not available	Pharmacotherapeutic Group of (API)	Antipyretic	Name, address of Manufacturing site:	Self Manufacturing	Name & address of API manufacturer	Citi Pharma Private Limited, Lahore	Detail of stability batches of drug product	Batch No: 623DS01, 623DS02 2 batches of 5000 units each	Documents for the procurement of API with approval from DRAP (in case of Import)	Paracetamol Lot No 489, Batch No. PGP21-489 (3 Kg) commercial invoice no.CP21-9343 dated 30-11-2021	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference Product: Dafalgan ODIS 500mg Tablets Batch No: A0960 Exp. Date: 8-2024 Test Product: Paracetamol OD 50mg Tablet Batch No.: 623DS01 Mfg. Date: 09-2022 Exp. Date: 09-2024	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per Zone IV	The status in reference regulatory authorities	Paracetamol MAE 500mg, dispersible tablets, MAE Holding B.V, approved by Netherlands
Case Category	Routine (Abdul Mughees)																																				
Name, address of Applicant.	Nabiqasim Industries (Pvt) Ltd., 17/24, Korangi Industrial Area, Karachi. (000105)																																				
Application Form Dy. No / Tracking ID & date of submission	(6D8-57M-SLLE, 2024-02-02)																																				
Detail of Fee Submitted	75000.0, 2023-12-20,																																				
The proposed proprietary name / brand name	Reliefal OD Tablet																																				
Label Claim	Each orodispersible tablet contains: Paracetamol BP 500mg																																				
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Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per Zone IV																																				
The status in reference regulatory authorities	Paracetamol MAE 500mg, dispersible tablets, MAE Holding B.V, approved by Netherlands																																				

GMP status of the firm		26-07-2023: GMP certificate issued including Tablet general section
Evidence of approval of manufacturing facility		26-07-2023: GMP certificate issued including Tablet general section
Evaluation Remarks		
First list of questions which were replied as follows:		
Sr.No	Shortcoming/ observation	Response of the firm
1	Justification shall be submitted for claiming BP monograph for the applied formulation.	We have revised the claim of Finished Product monograph from BP specifications to Innovator Specifications for QC commercial release batches enclosed in Annexure-A. . We have developed the orodispersible tablets as per reference product "Dafalgan ODIS tablet" and select ' the analytical test method from BP pharmacopeia for dispersible tablet with respect to identification, impurities and assay testing and also perform Analytical Method verification for the product which indicates that method is suitable for intended use
2	Justification shall be submitted for using sodium bicarbonate, sodium carbonate and citric acid in the applied formulation, since the same has not been used in the innovator's formulation. Role of sodium benzoate lubricant shall be justified.	As per the query by DRAP Evaluator, dated 22nd April, 2025 for registration of Reliefal OD Tablet 500mg. For above subject query, it is stated that orally disintegrating ,,,/ : tablets are designed to disintegrate quickly in the mouth, offering advantages like faster onset of action and ease of swallowing, especially for patients with difficulty swallowing or those requiring rapid drug absorption. Sodium bicarbonate and sodium carbonate, when combined with citric acid, create an effervescent reaction, leading to a rapid disintegration of tablets when they come into contact with water or saliva. This is why they are often used in orally disintegrating tablets (ODTs). The reaction produces carbon dioxide, which helps the tablet to dissolve quickly and provides a pleasant mouthfeel. Sodium Benzoate is used as a water-soluble lubricant in tablet manufacturing, particularly for fast-dissolving pharmaceuticals and nutritional supplements. Also it is functionally categorized as tablet and capsule lubricant in Handbook of Pharmaceutical excipients (Sixth Edition).
3	Justification shall be provided for not submitting CDP studies. Details of the drug product manufacturer and country of origin of the reference product against which PE has been submitted, shall be provided.	CDP protocol and report is submitted for your reference enclosed in Annexure-B. Dafalgan ODI S Tablets (odispersible) registration number 55 1 38 (Swissmedic), Authorization Holder UPSA Switzerland AG, Zug is used to conduct equivalence studies

4	Justification shall be submitted including test of dissolution drugs product specifications. for not in the	Revised Finished product specifications with dissolution test is enclosed in Annexure-A
5	Complete batch manufacturing record for drug product stability batches shall be submitted	Complete batch manufacturing record for drug product stability batches are enclosed in Annexure-C

Second list of questions which were replied as

Sr. No	Shortcoming / Observation	Summary to Response of the firm
1	The analytical verification study of a drug substance doesn't meet the standards set by the British Pharmacopoeia (BP). The specifications, acceptance criteria and sample/standard concentration while studying parameters such as accuracy, precision, specificity are not in line with BP. The analytical testing method of drug substance along with analytical verification studies need to be justified w.r.t BP monograph.	Previously we adopted HPLC from USP monograph. Now we have adopted BP specs in which test by UV is performed.
	Analytical testing method of finished need also need to be justified against BP. Under Dissolution and Assay method UV spectroscopic analysis has been performed as compare to Chromatographic (as provided in BP). The lambda max (257nm) need to be justified w.r.t BP.	We developed product in 2022 and hence followed BP 2022. In 2025 BP revised monograph.
	Under analytical validation study of Drug Product, results are mentioned in % instead of peak areas in precision, accuracy and system suitability while specificity parameter has not been performed. Moreover the specifications, acceptance criteria and sample/ standard concentration while studying parameters such as accuracy, precision and system suitability need to be justified w.r.t BP.	Complete verification report is enclosed.
	Accordingly stability studies need to be justified accordingly	BP monograph is for orodispersible tablets.

Third list of questions which were replied as follows:

Sr. No	Shortcomings/ Observations	Response of the firm
1	Regarding your reply submitted on July 14th, please clarify & provide: basis for not including calibration curves and correlation coefficients in your provided analytical method protocols and reports for DS and DP to show that your method produces results that are directly proportional to the concentration of paracetamol across a specified range	As per USP Chapter (1225) VALIDATION OF COMpendial PROCEDURES "Assessment of accuracy can be accomplished in a variety of ways, including evaluating the recovery of the analyte (percent recovery) across the range of the assay, or evaluating the

		linearity of the relationship between estimated and actual concentrations." Previously we have calculated accuracy through evaluating the recovery of the analyte (percent recovery) across the range of the assay furthermore we have revised the analytical method verification protocols and reports of DS and DP also incorporate the calibration curves and values of correlation coefficients in reports. Values are enclosed in table below: Verification Parameter Values of correlation coefficient for DS Values of correlation coefficient for DP Accuracy 1.000 0.999 Protocols and Reports are enclosed in Annexure-I.
2	basis for not including LOD and LOQ quantification with acceptable precision and accuracy	As per USP Chapter "VALIDATION OF COMPENDIAL PROCEDURES" in table 2 for Category-I (For example validation of a quantitative spectroscopic method) it is mentioned that for Analytical Performance Characteristics (Detection limit and Quantitation limit) is not necessary to determine,
3	basis for not including data, discussion and conclusion on including parameters like resolution, tailing factor and %RSD of replicate injections while performing system suitability testing	The testing method for Drug Substance is Titration based analysis, and for Drug Product the testing method is UV-Spectrophotometer (by A1%) based analysis, that's why parameters like resolution, tailing factor is not included. However, %RSD is being previously calculated and reported in case of Drug Product
4	Certificate of Analysis (CoA) for Reference Standards used in these reports	Annexure-II
5	BP 2022 Monograph compliance mapping to exactly pinpoint variations and deviations	BP 2022 monograph comparison with Drug product manufacturer monograph and BP 2025 monograph is enclosed in Annexure-III for compliance mapping. NOTE: M/S Nabiqasim Industries (Pvt.) Ltd. has incorporated additional tests of Dissolution & Uniformity of Dosage Unit in Finished Product, while other test complies with BP 2022 monograph

Decision

Approved

The firm shall submit requisite fee for revision of specifications.

23	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	High-Q Pharmaceuticals Plot# 224 and 225/1, sector 23, Korangi Industrial area, Karachi (000597)
	Application Form Dy. No / Tracking ID & date of submission	(643-4YW-ET35, 2024-03-26)

Detail of Fee Submitted	30000.0, 2024-03-14,
The proposed proprietary name / brand name	Empaglin-Met
Label Claim	Each film-coated tablet contains: Empagliflozin (as immediate release) 12.5mg Linagliptin (as immediate release) 2.5mg Metformin HC1 (as extended release).... 1000mg
Reference to Finished product specifications	Manufacturer Specification
Proposed Pack Size	10's-As per SRO,14's-As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO,50's-As per SRO,7's-As per SRO
Shelf Life (Unit)	2 Year(s)Store below 30°C
For generic drugs (me-too Status)	TRIGLEM-LIN XR Tablet (Nabiqasim Industries)
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Fuxin Long Rui Pharmaceutical Co., Ltd,Shouguang Fukang Pharmaceutical Co., Ltd.,Venkata Narayana Active Ingredients Private Limited
Detail of stability batches of drug product	Provided
Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
The status in reference regulatory authorities	TRIJARDY XR Tablet 12.5mg/2.5mg/1000mg (US FDA Approved)
GMP status of the firm	Provided
Evidence of approval of manufacturing facility	Provided

Evaluation Remarks

Sr. No	Shortcomings/ Observations	Response of the firm
1	Submit valid DML/GMP certificate of drug substance manufacturer of Empagliflozin and Linagliptin, issued by relevant regulatory authority of country of origin	Attached
2	Solubility profile of Empagliflozin in water shall declared as "Practically insoluble" shall be justified with reference to the innovator drug product literature.	Water solubility test has been added in Empagliflozin specs and testing method.
3	Justification shall be submitted for the variation in analytical procedure for Assay test of Empagliflozin as proposed by Drug substance manufacturer and as submitted by the drug product manufacturer.	In this regard, we would like to apprise you that erroneously alternate method for Assay of Empagliflozin included instead of the one supplied by the DS manufacturer. Please note that we had used the manufacture's method after validation, as an evidence please see the Analytical Method validation protocol of Empagliflozin in the dossier submitted.

4	Justification shall be submitted for different limits for the test of S-Isomer, as proposed by Drug substance manufacturer and as submitted by the drug product manufacturer. Limits of test of S -Isomer reported in the COA of Linagliptin is different from that declared in the drugs substance specifications from the manufacturer. Justification shall be submitted in this regard.	The S-isomer limit stated in the DMF is the correct limit. The specification of the Linagliptin has been amended.
5	COA of reference/working standard of drug substances shall be submitted.	Attached
6	Long term stability data of Empagliflozin shall be submitted till claimed shelf.	Attached
7	Justification shall be submitted on the product development data basis for the proposed overage quantities of Empagliflozin and Linagliptin in the submitted formulation.	The overages are added to compensate for the process loss during coating of empagliflozin and linagliptin.
8	The dissolution profile reported in submitted CDP studies shall be justified against the innovator drug product literature.	Remaining three CDP points (30 min, 45 min, and 60 min) were missed to submit at the time of application, which are provided now with reports.
9	Justification shall be submitted for not including test of moisture content and arginine content in drug product specifications, as recommended by the Innovator drug product literature.	L-arginine was used as an excipient in the formulation therefore assay was not performed at that time. Revised Finished Product Specification including L-arginine content and moisture content are attached.
10	Limits of dissolution test shall be justified against the recommendations of innovator drug product literature.	Dissolution limits are revised according to ICH Q6 guidelines and time points of Empagliflozin and Linagliptin are revised according to public assessment report of US FDA.

Decision

Approved

24	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	High-Q Pharmaceuticals Plot# 224 and 225/1, sector 23, Korangi Industrial area, Karachi (000597)
	Application Form Dy. No / Tracking ID & date of submission	(R5M-4Y5-R68E, 2024-03-27)
	Detail of Fee Submitted	30000.0, 2024-03-14,
	The proposed proprietary name / brand name	Empaglin-Met
	Label Claim	Each Film -Coated Tablet Contains: Empagliflozin (Immediate release).....25mg Linagliptin (Immediate release).....5mg Metformin HCl (Extended release).....1000mg (Manufa
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	10's-As per SRO,14's-As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO,50's-As per SRO,7's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C

For generic drugs (me-too Status)	Triglem-Lin XR 25mg/5mg/1000mg (Nabi Qasim Industries Pvt Ltd)
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Fuxin Long Rui Pharmaceuticals Co., Ltd, Shougang Fukang Pharmaceutical Co., Ltd, Venkata Narayana Active Ingredients Pvt Ltd
Detail of stability batches of drug product	Provided
Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
The status in reference regulatory authorities	Trijardy XR 25mg/5mg/1000mg Tablet (USFDA Approved)
GMP status of the firm	Provided
Evidence of approval of manufacturing facility	Provided

Evaluation Remarks

Sr. No	Shortcomings/ Observations	Response of the firm
1	Submit valid DML/GMP certificate of drug substance manufacturer of Empagliflozin and Linagliptin, issued by relevant regulatory authority of country of origin	Attached
2	Solubility profile of Empagliflozin in water shall declared as "Practically insoluble" shall be justified with reference to the innovator drug product literature.	Water solubility test has been added in Empagliflozin specs and testing method.
3	Justification shall be submitted for the variation in analytical procedure for Assay test of Empagliflozin as proposed by Drug substance manufacturer and as submitted by the drug product manufacturer.	In this regard, we would like to apprise you that erroneously alternate method for Assay of Empagliflozin included instead of the one supplied by the DS manufacturer. Please note that we had used the manufacture's method after validation, as an evidence please see the Analytical Method validation protocol of Empagliflozin in the dossier submitted.
4	Justification shall be submitted for different limits for the test of S-Isomer, as proposed by Drug substance manufacturer and as submitted by the drug product manufacturer. Limits of test of S -Isomer reported in the COA of Linagliptin is different from that declared in the drugs substance specifications from the manufacturer. Justification shall be submitted in this regard.	The S-isomer limit stated in the DMF is the correct limit. The specification of the Linagliptin has been amended.
5	COA of reference/working standard of drug substances shall be submitted.	Attached

6	Long term stability data of Empagliflozin shall be submitted till claimed shelf.	Attached
7	Justification shall be submitted on the product development data basis for the proposed overage quantities of Empagliflozin and Linagliptin in the submitted formulation.	The overages are added to compensate for the process loss during coating of empagliflozin and linagliptin.
8	The dissolution profile reported in submitted CDP studies shall be justified against the innovator drug product literature.	Remaining three CDP points (30 min, 45 min, and 60 min) were missed to submit at the time of application, which are provided now with reports.
9	Justification shall be submitted for not including test of moisture content and arginine content in drug product specifications, as recommended by the Innovator drug product literature.	L-arginine was used as an excipient in the formulation therefore assay was not performed at that time. Revised Finished Product Specification including L-arginine content and moisture content are attached.
10	Limits of dissolution test shall be justified against the recommendations of innovator drug product literature.	Dissolution limits are revised according to ICH Q6 guidelines and time points of Empagliflozin and Linagliptin are revised according to public assessment report of US FDA.

Decision

Approved

25	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	High-Q Pharmaceuticals Plot# 224 and 225/1, sector 23, Korangi Industrial area, Karachi (000597)
	Application Form Dy. No / Tracking ID & date of submission	(Q7V-D61-PXP4, 2024-03-27)
	Detail of Fee Submitted	30000.0, 2024-03-14,
	The proposed proprietary name / brand name	Empaglin-Met
	Label Claim	Each film coated contains: Empagliflozin (as immediate release) 5mg Linagliptin (as immediate release) 2.5mg Metformin HCl (as extended release) 1000mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	10's-As per SRO,14's-As per SRO,20's-As per SRO,28's-Free of Cost,30's-As per SRO,50's-As per SRO,7's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	TRIGLEM-LIN XR 5mg/2.5mg/1000mg Tablet manufactured by NABIQASIM INDUSTRIES (PVT) LTD. Approved in 324th meeting of Registration Board
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Fuxin Long Rui Pharmaceutical CO., Ltd,Shouguang Fukang Pharmaceutical Co., Ltd.,Venkata Narayana Active Ingredients Private Limited.
	Detail of stability batches of drug product	Provided
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided

Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
The status in reference regulatory authorities	TRIJARDY XR 5/2.5/1000mg TABLET is being marketed by Boehringer Ingelheim Pharmaceuticals, Inc. and
GMP status of the firm	Provided
Evidence of approval of manufacturing facility	Provided

Evaluation Remarks

Sr. No	Shortcomings/ Observations	Response of the firm
1	Submit valid DML/GMP certificate of drug substance manufacturer of Empagliflozin and Linagliptin, issued by relevant regulatory authority of country of origin	Attached
2	Solubility profile of Empagliflozin in water shall declared as "Practically insoluble" shall be justified with reference to the innovator drug product literature.	Water solubility test has been added in Empagliflozin specs and testing method.
3	Justification shall be submitted for the variation in analytical procedure for Assay test of Empagliflozin as proposed by Drug substance manufacturer and as submitted by the drug product manufacturer.	In this regard, we would like to apprise you that erroneously alternate method for Assay of Empagliflozin included instead of the one supplied by the DS manufacturer. Please note that we had used the manufacture's method after validation, as an evidence please see the Analytical Method validation protocol of Empagliflozin in the dossier submitted.
4	Justification shall be submitted for different limits for the test of S-Isomer, as proposed by Drug substance manufacturer and as submitted by the drug product manufacturer. Limits of test of S -Isomer reported in the COA of Linagliptin is different from that declared in the drugs substance specifications from the manufacturer. Justification shall be submitted in this regard.	The S-isomer limit stated in the DMF is the correct limit. The specification of the Linagliptin has been amended.
5	COA of reference/working standard of drug substances shall be submitted.	Attached
6	Long term stability data of Empagliflozin shall be submitted till claimed shelf.	Attached
7	Justification shall be submitted on the product development data basis for the proposed overage quantities of Empagliflozin and Linagliptin in the submitted formulation.	The overages are added to compensate for the process loss during coating of empagliflozin and linagliptin.
8	The dissolution profile reported in submitted CDP studies shall be justified against the innovator drug product literature.	Remaining three CDP points (30 min, 45 min, and 60 min) were missed to submit at the time of application, which are provided now with reports.

9	Justification shall be submitted for not including test of moisture content and arginine content in drug product specifications, as recommended by the Innovator drug product literature.	L-arginine was used as an excipient in the formulation therefore assay was not performed at that time. Revised Finished Product Specification including L-arginine content and moisture content are attached.
10	Limits of dissolution test shall be justified against the recommendations of innovator drug product literature.	Dissolution limits are revised according to ICH Q6 guidelines and time points of Empagliflozin and Linagliptin are revised according to public assessment report of US FDA.

Decision

Approved

26

Case Category	Routine (Abdul Mughees)
Name, address of Applicant.	High-Q Pharmaceuticals Plot# 224 and 225/1, sector 23, Korangi Industrial area, Karachi (000597)
Application Form Dy. No / Tracking ID & date of submission	(HEE-V3T-94YS, 2024-04-18)
Detail of Fee Submitted	30000.0, 2024-03-14,
The proposed proprietary name / brand name	Empaglin-Met
Label Claim	Each film coated tablet contains: Empagliflozin (as immediate release) ... 10mg Linagliptin (as immediate release) 5mg Metformin HCl (as extended release) .. 1000mg
Reference to Finished product specifications	Manufacturer Specification
Proposed Pack Size	10's-As per SRO,14's-As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO,50's-As per SRO,7's-As per SRO
Shelf Life (Unit)	2 Year(s)Store below 30°C
For generic drugs (me-too Status)	TRIGLEM-LIN XR 10mg/5mg/1000mg Tablet manufactured by NABIQASIM INDUSTRIES (PVT) LTD. Approved in 324th meeting of Registration Board
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Fuxin Long Rui Pharmaceutical CO., Ltd,Shouguang Fukang Pharmaceutical Co., Ltd.,Venkata Narayana Active Ingredients Private Limited.
Detail of stability batches of drug product	Provided
Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
The status in reference regulatory authorities	TRIJARDY XR 10/5/1000mg TABLET is being marketed by Boehringer Ingelheim Pharmaceuticals, Inc. and E
GMP status of the firm	Provided
Evidence of approval of manufacturing facility	Provided

Evaluation Remarks

Sr. No	Shortcomings/ Observations	Response of the firm
1	Submit valid DML/GMP certificate of drug substance manufacturer of Empagliflozin and Linagliptin, issued by relevant regulatory authority of country of origin	Attached
2	Solubility profile of Empagliflozin in water shall declared as "Practically insoluble" shall be justified with reference to the innovator drug product literature.	Water solubility test has been added in Empagliflozin specs and testing method.
3	Justification shall be submitted for the variation in analytical procedure for Assay test of Empagliflozin as proposed by Drug substance manufacturer and as submitted by the drug product manufacturer.	In this regard, we would like to apprise you that erroneously alternate method for Assay of Empagliflozin included instead of the one supplied by the DS manufacturer. Please note that we had used the manufacture's method after validation, as an evidence please see the Analytical Method validation protocol of Empagliflozin in the dossier submitted.
4	Justification shall be submitted for different limits for the test of S-Isomer, as proposed by Drug substance manufacturer and as submitted by the drug product manufacturer. Limits of test of S -Isomer reported in the COA of Linagliptin is different from that declared in the drugs substance specifications from the manufacturer. Justification shall be submitted in this regard.	The S-isomer limit stated in the DMF is the correct limit. The specification of the Linagliptin has been amended.
5	COA of reference/working standard of drug substances shall be submitted.	Attached
6	Long term stability data of Empagliflozin shall be submitted till claimed shelf.	Attached
7	Justification shall be submitted on the product development data basis for the proposed overage quantities of Empagliflozin and Linagliptin in the submitted formulation.	The overages are added to compensate for the process loss during coating of empagliflozin and linagliptin.
8	The dissolution profile reported in submitted CDP studies shall be justified against the innovator drug product literature.	Remaining three CDP points (30 min, 45 min, and 60 min) were missed to submit at the time of application, which are provided now with reports.
9	Justification shall be submitted for not including test of moisture content and arginine content in drug product specifications, as recommended by the Innovator drug product literature.	L-arginine was used as an excipient in the formulation therefore assay was not performed at that time. Revised Finished Product Specification including L-arginine content and moisture content are attached.
10	Limits of dissolution test shall be justified against the recommendations of innovator drug product literature.	Dissolution limits are revised according to ICH Q6 guidelines and time points of Empagliflozin and Linagliptin are revised according to public assessment report of US FDA.

	Decision	
	Approved	
	The firm shall submit fee for revision of specifications.	
27	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	The Searle Company Limited Plot No. F-319, Sindh Industrial Trading Estate (SITE) (000016)
	Application Form Dy. No / Tracking ID & date of submission	(AWS-2YS-XT8E, 2024-04-17)
	Detail of Fee Submitted	30000.0, 2024-03-21,
	The proposed proprietary name / brand name	HOSPICAINE SPINAL (Bupivacaine HCl 5mg in Dextrose Injection) HEAVY 0.
	Label Claim	Each mL contains: Bupivacaine Hydrochloride 5mg in Dextrose Injection
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per DPC-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 C
	For generic drugs (me-too Status)	Sensocaine Spinal 0.5% Injection by M/s Brookes Pharma (Reg. No.: 057745)
	Pharmacotherapeutic Group of (API)	intrathecal (subarachnoid) spinal anaesthesia for surgery
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Nortec Química S.A
	Detail of stability batches of drug product	Provided
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Marcain Heavy Steripack 0.5% w/v Solution for Injection Cenexi, 52 Rue Marcel et Jacques Gaucher, 94120 Fontenay sous Bois, France
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
	The status in reference regulatory authorities	Bupivacaine 0.5% w/v with glucose solution for injection by M/s Aspen Pharma Trading Limited (https:
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	Provided
	Evaluation Remarks	
	Decision	
	Approved	
28	Case Category	New Molecule/Formulation (Abdul Mughees)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(E6B-345-VQ6M, 2025-08-25)
	Detail of Fee Submitted	75000.0, 2025-07-23,
	The proposed proprietary name / brand name	Varda 5mg Tablets
	Label Claim	Vardenafil 5mg/Tablet

Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	2, 4, 6, 8, 10, 14, 28, 20, 30, 40, 50, 60, 70, 80-As per SRO
Shelf Life (Unit)	2 Year(s)Below 30°C
For generic drugs (me-too Status)	NA
Pharmacotherapeutic Group of (API)	Vardenafil HCl: Urologicals, Drugs used in erectile dysfunction, ATC code: G04BE09. Vardenafil is an oral therapy for the improvement of erectile function in men with erectile dysfunction
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	CENTURY PHARMACEUTICALS LIMITED 103-106, GIDC, Halol Dist. Panchmahals- 389 350, India
Detail of stability batches of drug product	Attached in Module 3 in section 3.2.P.8
Documents for the procurement of API with approval from DRAP (in case of Import)	Attached in Module 3 in section 3.2.P.8
Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP performed with Levitra Batch BXHNZE77
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached in Module 3 in section 3.2. S.7
The status in reference regulatory authorities	LEVITRA® (Vardenafil HCl) tablets, for oral use Tablets: 2.5mg, 5mg, 10mg, 20mg Initial U.S. Approval: 2003 Manufactured By: Bayer Healthcare Bayer Pharmaceutical Corporation 400 Morgan Lane, West Haven CT 06516 Made in Germany
GMP status of the firm	Attached in Module 1 in section 1.3.5
Evidence of approval of manufacturing facility	Attached in Module 1 in section 1.3.5

Evaluation Remarks

Sr. No.	Shortcoming/ Observation	Reply of the firm
1	1.5.2: In label claim, please justify how you claimed Vardenafil HCL to be equivalent to Vardenafil 5 mg per tablet (Factor 1.1852). Provide corrected claim (by calculating content of Vardenafil in Vardenafil HCL trihydrate) according to BP monograph and providing evidence of this calculation in the testing method). For example, the label claim for Levitra (your reference product) is 5.926 mg of vardenafil hydrochloride trihydrate.	Vardenafil HCl Trihydrate 5.926 is equivalent to Vardenafil 5mg because 1.1852 factor of Hydrochloride with trihydrate is involved in the composition.· i- This is further practically explained in Module 3 (3.2. Drug Product, Section 3.2. P.1 * * Description and Composition of Drug Product) (Picture attached) ii- Revised Module 1 is also attached for your kind perusal.
2	The system suitability in BP monograph for performing Assay (content uniformity) states that the test is not valid unless, in the chromatogram obtained with solution (3), the resolution between the peak	Impurity A is not procured, therefore we had not used during analysis that is why no peak observed with vardenafil which is our Peak of interest, as it is not essential requirement from the DRAP.

	due to vardenafil and impurity A is not less than 4.0. Please provide evidence for purchase and use of said impurity while performing all the tests.	
3	The BP monograph specifies that for tablets less than 20 mg use the average individual results obtained in content uniformity and gives separate chromatographic conditions with mentioning a retention time of 5 minutes. Please clarify why this has not been included in the provided testing method, analytical verification protocol or report	As per BP Monograph of Vardenafil Tablets (attached also) explained the conditions of Uniformity of Content with respect to 2mg and/or 2% w/w of Vardenafil and the product under discussion in 5mg and/or 2.7% w/w of Vardenafil, that is why we have not followed content Uniformity and went for Weight Variation option.

Decision

Approved

The Registration Board approved the product subject to the report of Product Specific Inspection (PSI) for verification of submitted data by a panel constituted by Chairman, Registration Board.

29	Case Category	New Molecule/Formulation (Abdul Mughees)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(HD4-MJT-RXQL, 2025-08-25)
	Detail of Fee Submitted	75000.0, 2025-07-21,
	The proposed proprietary name / brand name	Varda 10mg Tablets
	Label Claim	Vardenafil 10mg/Tablet
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	2, 4, 6, 8, 10, 14, 20, 28, 30, 40, 50, 60, 70, 80-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Vardenafil HCl: Urologicals, Drugs used in erectile dysfunction, ATC code: G04BE09. Vardenafil is an oral therapy for the improvement of erectile function in men with erectile dysfunction
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CENTURY PHARMACEUTICALS LIMITED 103-106, GIDC, Halol Dist. Panchmahals- 389 350, India
	Detail of stability batches of drug product	Attached in Module 3 in section 3.2.P.8
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached in Module 3 in section 3.2.P.8
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Levitra Batch BXHNEZ39
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached in Module 3 in section 3.2. S.7

	The status in reference regulatory authorities	LEVITRA® (Vardenafil HCl) tablets, for oral use Tablets: 2.5mg, 5mg, 10mg, 20mg Initial U.S. Approval: 2003 Manufactured By: Bayer Healthcare Bayer Pharmaceutical Corporation 400 Morgan Lane, West Haven CT 06516 Made in Germany
	GMP status of the firm	Attached in Module 1 in section 1.3.5
	Evidence of approval of manufacturing facility	Attached in Module 1 in section 1.3.5
	Evaluation Remarks	
	In lower strength the firm has submitted to revise label claim in line with reference product.	
	Decision	
	Approved	
	The Registration Board approved the product subject to the report of Product Specific Inspection (PSI) for verification of submitted data by a panel constituted by Chairman, Registration Board.	
30	Case Category	New Molecule/Formulation (Abdul Mughees)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(PZX-LDU-MJ97, 2025-08-25)
	Detail of Fee Submitted	75000.0, 2025-07-21,
	The proposed proprietary name / brand name	Varda 20mg Tablets
	Label Claim	Vardenafil 20mg/Tablet
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	2, 4, 6, 8, 10, 14, 20, 28, 30, 40, 50, 60, 70, 80-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Vardenafil HCl: Urologicals, Drugs used in erectile dysfunction, ATC code: G04BE09. Vardenafil is an oral therapy for the improvement of erectile function in men with erectile dysfunction
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CENTURY PHARMACEUTICALS LIMITED 103-106, GIDC, Halol Dist. Panchmahals- 389 350, India
	Detail of stability batches of drug product	Attached in Module 3 in section 3.2.P.8
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached in Module 3 in section 3.2.P.8
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Levitra BXK0U21
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached in Module 3 in section 3.2. S.7
	The status in reference regulatory authorities	LEVITRA® (Vardenafil HCl) tablets, for oral use Tablets: 2.5mg, 5mg, 10mg, 20mg Initial U.S. Approval: 2003 Manufactured By: Bayer Healthcare Bayer Pharmaceutical Corporation 400 Morgan Lane, West Haven CT 06516 Made in Germany
	GMP status of the firm	Attached in Module 1 in section 1.3.5
	Evidence of approval of manufacturing facility	Attached in Module 1 in section 1.3.5
	Evaluation Remarks	

In lower strength the firm has submitted to revise label claim in line with reference product.

Decision

Approved

The Registration Board approved the product subject to the report of Product Specific Inspection (PSI) for verification of submitted data by a panel constituted by Chairman, Registration Board.

31	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Platinum Pharmaceuticals A-20,North Western Industrial Zone Bin Qasim,Karachi (000415)
	Application Form Dy. No / Tracking ID & date of submission	(HQT-G5H-BYXJ, 2024-04-17)
	Detail of Fee Submitted	30000.0, 2023-11-29,
	The proposed proprietary name / brand name	Piracetam 800mg tablet
	Label Claim	Piracetam 800mg Tablet
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-20's-30's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30C in a dry place, and protect from s
	For generic drugs (me-too Status)	Nootropil 800mg tablet (GSK Pakistan)
	Pharmacotherapeutic Group of (API)	ATC code: N06BX03; Psychostimulant and nootropics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Jiangxi Yuehua Pharmaceutical CO., Ltd.
	Detail of stability batches of drug product	Batches 1,2 and 3 of 1000 tablets each with stability conditions of Zone IV-a .
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP is performed against Nootropil of GSK.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability of DS is provided.
	The status in reference regulatory authorities	Nootropil 800mg Tablet (MHRA)
	GMP status of the firm	GMP certificate dated16th June 2023 by DRAP Karachi office is submitted that concludes that firm is found complying with cGMP.
	Evidence of approval of manufacturing facility	DML is provided.
	Evaluation Remarks	
	White, oblong biconvex film-coated tablet with “P” logo on one side & break line on reverse, Contains 800 mg of Piracetam -PH.EUR specs as API and excipients including Polyethylene Glycol-6000 , Colloidal Silicon Dioxide, Magnesium Stearate, Croscarmellose Sodium, PVA coating. Specs include Dissolution NLT 85 % (Q+5%) of labeled amount dissolved in 30min. and Assay is performed on LC at 205 nm with an acceptance criteria of 98-102% on dried basis. Stability of DP was performed for long term and accelerated conditions according to Zone-IVa.	
	Decision	
	Approved	
32	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	AGP Limited B-23-C, S.I.T.E., Karachi (000348)

Application Form Dy. No / Tracking ID & date of submission	(4RW-8PP-DN5H, 2024-04-18)
Detail of Fee Submitted	75000.0, 2024-03-26,
The proposed proprietary name / brand name	Lasmitan 50mg Tablet
Label Claim	Each film coated tablet contains 50mg Lasmiditan (equivalent to 57.824mg Lasmiditan Hemisuccinate)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As approved by DRAP-As per SRO
Shelf Life (Unit)	2 Year(s)Store below 30°C
For generic drugs (me-too Status)	New Chemical Entity
Pharmacotherapeutic Group of (API)	N02CC08; Nervous system anti migraine; 5HT1 Agonist
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Enantiotech Corporation Limited
Detail of stability batches of drug product	Provided
Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed against Reyvow by Lilly del Caribe
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
The status in reference regulatory authorities	FDA approved Reyvow by Lilly del Caribe
GMP status of the firm	Provided
Evidence of approval of manufacturing facility	Provided
Evaluation Remarks	
57.824mg of Lasmiditan Hemisuccinate is equivalent to 50.0mg Lasmiditan. It is determined that Lasmitan 50 mg tablets (Lasmiditan) meets all applicable standards regarding identity, strength, quality, and purity.	
Decision	
Approved	

33	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	AGP Limited B-23-C, S.I.T.E., Karachi (000348)
	Application Form Dy. No / Tracking ID & date of submission	(7TL-PZ6-2XQY, 2024-04-18)
	Detail of Fee Submitted	75000.0, 2024-03-26,
	The proposed proprietary name / brand name	Lasmitan 100mg Tablet
	Label Claim	Each film coated tablet contains 100mg Lasmiditan (equivalent to 115.650mg Lasmiditan Hemisuccinate)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As approved by DRAP-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	New Chemical Entity
	Pharmacotherapeutic Group of (API)	Anti-migraine; 5HT1 agonists
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Enantiotech Corporation Limited
	Detail of stability batches of drug product	Provided
	Documents for the procurement of API with approval from DRAP	Provided

	(in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reyvow by Lilly del Caribe
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
	The status in reference regulatory authorities	FDA approved Reyvow by Lilly del Caribe
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	Provided
	Evaluation Remarks	
	From a quality perspective, it is determined that Lasmitan 100 mg tablets (Lasmiditan) meets all applicable standards regarding identity, strength, quality, and purity	
	Decision	
	Approved	
34	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Platinum Pharmaceuticals A-20,North Western Industrial Zone Bin Qasim,Karachi (000415)
	Application Form Dy. No / Tracking ID & date of submission	(97G-WGJ-DHH6, 2024-04-29)
	Detail of Fee Submitted	75000.0, 2024-01-19,
	The proposed proprietary name / brand name	Piracetam 33% oral solution
	Label Claim	33%
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	120ml-As per SRO,125ml-As per SRO,150ml-As per SRO,300ml-As per SRO,30ml-As per SRO,60ml-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30C in a dry place and protect from sunlight
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Provided
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
	The status in reference regulatory authorities	Nootropil 33% oral solution (MHRA)
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	Provided
	Evaluation Remarks	
	From a quality perspective, it is determined that Piracetam 33 % oral solution meets all applicable standards regarding identity, strength, quality, and purity.	
	Decision	
	Approved	

35	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Nabiqasim Industries (Pvt) Ltd., 17/24, Korangi Industrial Area, Karachi. (000105)
	Application Form Dy. No / Tracking ID & date of submission	(5TQ-11R-NHB2, 2024-04-29)
	Detail of Fee Submitted	30000.0, 2024-01-16,
	The proposed proprietary name / brand name	Normisar-AM
	Label Claim	Each bilayer tablet contains: Telmisartan USP 80mg Amlodipine (as Besylate) USP 10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's, 14's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 Degree Celsius Temperature
	For generic drugs (me-too Status)	Telarb-Plus tablet 80mg/5mg
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Smruthi Organics Ltd.,Zhejiang Tianyu Pharmaceutical Co.
	Detail of stability batches of drug product	Provided
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Telarb by Sami Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
	The status in reference regulatory authorities	TGA Approved
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	Provided
	Evaluation Remarks	
	From a quality perspective, it is determined that Normisar-AM tablet meets all applicable standards regarding identity, strength, quality, and purity.	
	Decision	
	Approved	
36	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Nabiqasim Industries (Pvt) Ltd., 17/24, Korangi Industrial Area, Karachi. (000105)
	Application Form Dy. No / Tracking ID & date of submission	(EPP-M7P-BXMX, 2024-04-29)
	Detail of Fee Submitted	30000.0, 2024-04-04,
	The proposed proprietary name / brand name	RIVAS
	Label Claim	Each capsule contains Rivastigmine hydrogen tartrate corresponding to Rivastigmine
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	7s, 14s, 28s, 30s, 6-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 degree
	For generic drugs (me-too Status)	Exelon 1.5mg capsule, Novartis

Pharmacotherapeutic Group of (API)	Alzheimer's Disease: Rivastigmine is indicated for the treatment of mild-to-moderate dementia of the Alzheimer's type (AD). Parkinson's Disease: Dementia Rivastigmine is indicated for the treatment of mild-to-moderate dementia associated with Parkinson's disease (PD)
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Shodhana Laboratories Limited
Detail of stability batches of drug product	Provided
Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
Pharmaceutical Equivalence and Comparative Dissolution Profile	Exelon Capsule 1.5mg Novartis Batch BDLV2
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
The status in reference regulatory authorities	EMA Aproved - Rivastigmine Sandoz 1.5 mg hard capsules Sandoz GmbH, Austria
GMP status of the firm	Provided
Evidence of approval of manufacturing facility	Provided
Evaluation Remarks	
From a quality perspective, it is determined that RIVAS (Capsules) meets all applicable standards regarding identity, strength, quality, and purity.	
Decision	
Approved	
37	
Case Category	Routine (Abdul Mughees)
Name, address of Applicant.	Nabiqasim Industries (Pvt) Ltd., 17/24, Korangi Industrial Area, Karachi. (000105)
Application Form Dy. No / Tracking ID & date of submission	(G1V-W8N-D2XP, 2024-04-30)
Detail of Fee Submitted	30000.0, 2024-04-04,
The proposed proprietary name / brand name	Rivas Capsule 4.5mg
Label Claim	Each capsule contains: Rivastigmine Hydrogen Tartrate BP corresponding to Rivastigmine.....4.5mg (BP Specifications)
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	7s, 14s, 28s, 30s, 6-As per SRO
Shelf Life (Unit)	2 Year(s)Store below 30°C
For generic drugs (me-too Status)	Yes
Pharmacotherapeutic Group of (API)	Parkinsons and Alzheimer
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Shodhana Laboratories Limited
Detail of stability batches of drug product	Provided
Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
Pharmaceutical Equivalence and Comparative Dissolution Profile	Exelon 4.5 mg hard capsules by Novartis Pharmaceuticals UK Limited, United Kingdom

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
	The status in reference regulatory authorities	MHRA Approved (Exelon 4.5 mg hard capsules by Novartis Pharmaceuticals UK Limited, United Kingdom)
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	Attached in Module 1 in section 1.3.5
	Evaluation Remarks	
	From a quality perspective, it is determined that Rivas Capsule 4.5 mg meets all applicable standards regarding identity, strength, quality, and purity.	
	Decision	
	Approved	
38	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Scilife Pharma Private Limited FD-57/58-A2, Korangi Creek Industrial Park (KCIP) (000837)
	Application Form Dy. No / Tracking ID & date of submission	(BHW-7WH-5EYW, 2024-04-30)
	Detail of Fee Submitted	30000.0, 2024-04-17,
	The proposed proprietary name / brand name	M-Tor 5mg/10mg Tablet
	Label Claim	Each film coated tablet contains: Amlodipine (as Amlodipine Besylate) 5mg Atorvastatin (as Atorvastatin Calcium).....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO,14's-As per SRO,15's-As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO,50's-As per SRO,7's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 25°C (Excursions permitted between 15°C to 30°C). Protect from sunlight & moisture.
	For generic drugs (me-too Status)	VASTOR-AM Tablet by ATCO
	Pharmacotherapeutic Group of (API)	Calcium channel blocker with lipid modifying agent
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	JPR Labs Pvt Ltd India,Prudence pharma chem India
	Detail of stability batches of drug product	3 batches: 5000 Tablet
	Documents for the procurement of API with approval from DRAP (in case of Import)	Amlodipine: 04-04-2023 Clearance certificate, Atorvastatin: 11-05-2023 clerance certificate
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Caduet Tablet: PE and CDP performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IV-A
	The status in reference regulatory authorities	CADUET TABLET 5 MG/10 MG (USFDA Approved)
	GMP status of the firm	22-02-2023: GMP certificate inspection date
	Evidence of approval of manufacturing facility	22-02-2023: GMP certificate Tablet (General) section
	Evaluation Remarks	
	From a quality perspective, it is determined that M-Tor meets all applicable standards regarding identity, strength, quality, and purity	
	Decision	
	Approved	
39	Case Category	New Section (Abdul Mughees)

Name, address of Applicant.	Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi (000333)
Application Form Dy. No / Tracking ID & date of submission	(NGJ-J3B-GQL4, 2024-10-10)
Detail of Fee Submitted	30000.0, 7000.0 2024-08-26, 2024-09-20
The proposed proprietary name / brand name	ZONEX 4mg/100ml Infusion
Label Claim	each 100mL vial contains:Zoledronic acid monohydrate 4.264mg equivalent to zoledronic acid anhydrous 4mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's (100ml)-As per SRO
Shelf Life (Unit)	2 Year(s)store in a cool and dry place below 30
For generic drugs (me-too Status)	Zometa 4mg/100ml(Novartis)
Pharmacotherapeutic Group of (API)	M05BA08; osteoclastic bone resorption
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Synnat Pharma Private Limited
Detail of stability batches of drug product	Provided
Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
The status in reference regulatory authorities	zometa 4mg/100ml Novartis
GMP status of the firm	Provided
Evidence of approval of manufacturing facility	Attached in Module 1 in section 1.3.5
Evaluation Remarks	
Section approval 24th May 2024. From a quality perspective, it is determined that the product meets all applicable standards regarding identity, strength, quality, and purity	
Decision	
Approved	
40	Case Category
Name, address of Applicant.	Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi (000333)
Application Form Dy. No / Tracking ID & date of submission	(QPA-DV2-9U8V, 2024-10-23)
Detail of Fee Submitted	30000.0, 7000.0 2024-08-26, 2024-09-20
The proposed proprietary name / brand name	ZONEX 5mg/100ml Infusion
Label Claim	Each 100mL vial contains:Zoledronic acid monohydrate 5.33mg equivalent to zoledronic acid anhydrous 5mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's (100ml)-As per SRO
Shelf Life (Unit)	2 Year(s)store in a cool and dry place below 30
For generic drugs (me-too Status)	EDONEX 5mg/100ml
Pharmacotherapeutic Group of (API)	osteoclastic bone resorption
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Synnat Pharma Private Limited

	Detail of stability batches of drug product	Provided
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
	The status in reference regulatory authorities	Reclast 5mg/100ml (Novartis)
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	Attached in Module 1 in section 1.3.5
	Evaluation Remarks	
	Section approval 24th May 2024. From a quality perspective, it is determined that the product meets all applicable standards regarding identity, strength, quality, and purity.	
	Decision	
	Approved	
41	Case Category	New Section (Abdul Mughees)
	Name, address of Applicant.	Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi (000333)
	Application Form Dy. No / Tracking ID & date of submission	(L2Q-257-9XEU, 2024-10-09)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-26, 2024-10-07
	The proposed proprietary name / brand name	METNI 500mg/100ml infusion
	Label Claim	each 100ml ready to use bottle contains: Metronidazole 500mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's (100ml)-As per SRO
	Shelf Life (Unit)	2 Year(s)store in a cool and dry place below 30
	For generic drugs (me-too Status)	flagyl 500mg/100ml
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Aartin drugs limited
	Detail of stability batches of drug product	Provided
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
	The status in reference regulatory authorities	flagyl 0.55 w/v (500mg/100ml) solution for infusion (snofi aventis ireland
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	Attached in Module 1 in section 1.3.5
	Evaluation Remarks	
	Section approval 24th May, 2024. From a quality perspective, it is determined that the product meets all applicable standards regarding identity, strength, quality, and purity	
	Decision	

	Approved	
42	Case Category	New Section (Abdul Mughees)
	Name, address of Applicant.	Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi (000333)
	Application Form Dy. No / Tracking ID & date of submission	(S2Z-74X-YG3D, 2025-04-29)
	Detail of Fee Submitted	37000.0, 2024-09-20,
	The proposed proprietary name / brand name	FLUZIN 200mg/100ml Infusion
	Label Claim	Each mL contains: Fluconazole.....2mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's (100ml)-As per SRO
	Shelf Life (Unit)	2 Year(s)store in a cool and dry place below 30
	For generic drugs (me-too Status)	Diflucan 2mg/ml (100ml)
	Pharmaceutical Group of (API)	Anti-fungal
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Synergene Active Ingredients Pvt Ltd.
	Detail of stability batches of drug product	Provided
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
	The status in reference regulatory authorities	Diflucan 2mg/ml infusion (100ml) Pfizer healthcare Ireland
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	Attached in Module 1 in section 1.3.5
	Evaluation Remarks	
	Section approval dated 24th May, 2024. From a quality perspective, it is determined that the product meets all applicable standards regarding identity, strength, quality, and purity	
	Decision	
	Approved	
43	Case Category	Export Facilitation (Abdul Mughees)
	Name, address of Applicant.	Ferozsons Laboratories Limited PO Ferozsons, Amangarh (000038)
	Application Form Dy. No / Tracking ID & date of submission	(Q3G-7E3-T2H4, 2024-10-24)
	Detail of Fee Submitted	75000.0, 2024-10-22,
	The proposed proprietary name / brand name	Verigard Tablets 2.5mg
	Label Claim	Each film-coated tablet contains: Vericiguat.....2.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,14's-As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO,7's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C in a dry place
	For generic drugs (me-too Status)	NA

Pharmacotherapeutic Group of (API)	vasodilator used in cardiac diseases
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	NA
Detail of stability batches of drug product	Provided
Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
The status in reference regulatory authorities	Brand Name: Verquvo Tablets 2.5mg Manufacturer: Bayer AG, Kaiser-Wilhelm-Allee, 51368 Leverkusen, Germany
GMP status of the firm	Provided
Evidence of approval of manufacturing facility	Attached in Module 1 in section 1.3.5
Evaluation Remarks	
From a quality perspective, it is determined that the product meets all applicable standards regarding identity, strength, quality, and purity	
Decision	
Approved	
44	Case Category
	Export Facilitation (Abdul Mughees)
	Name, address of Applicant.
	Ferozsons Laboratories Limited PO Ferozsons, Amangarh (000038)
	Application Form Dy. No / Tracking ID & date of submission
	(6QX-4M7-BP15, 2024-10-24)
	Detail of Fee Submitted
	75000.0, 2024-10-22,
	The proposed proprietary name / brand name
	Verigard Tablets 5mg
	Label Claim
	Each film-coated tablet contains: Vericiguat.....5mg
	Reference to Finished product specifications
	As per Innovators Specification
	Proposed Pack Size
	10's-As per SRO,14's-As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO,7's-As per SRO
	Shelf Life (Unit)
	2 Year(s)Store below 30°C in a dry place
	For generic drugs (me-too Status)
	NA
	Pharmacotherapeutic Group of (API)
	vasodilator used in cardiovascular diseases
	Name, address of Manufacturing site:
	Self Manufacturing
	Name & address of API manufacturer
	NA
	Detail of stability batches of drug product
	Provided
	Documents for the procurement of API with approval from DRAP (in case of Import)
	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile
	Provided
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)
	Provided
	The status in reference regulatory authorities
	Brand Name: Verquvo Tablets 5mg Manufacturer: Bayer AG, Kaiser-Wilhelm-Allee, 51368 Leverkusen, Germany
	GMP status of the firm
	Provided

	Evidence of approval of manufacturing facility	Attached in Module 1 in section 1.3.5
	Evaluation Remarks	
	From a quality perspective, it is determined that the product meets all applicable standards regarding identity, strength, quality, and purity	
	Decision	
	Approved	
45	Case Category	Export Facilitation (Abdul Mughees)
	Name, address of Applicant.	Ferozsons Laboratories Limited PO Ferozsons, Amangarh (000038)
	Application Form Dy. No / Tracking ID & date of submission	(U77-27T-NPYS, 2025-01-30)
	Detail of Fee Submitted	37000.0, 2025-01-08,
	The proposed proprietary name / brand name	Rapsil Capsules 4mg
	Label Claim	Each Capsule contains: Silodosin.....4mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,14's-As per SRO,20's -As per SRO,28's-As per SRO,30's-As per SRO,7's-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store above 30°C
	For generic drugs (me-too Status)	Brand Name: Silorap Capsules 4mg Manufacturer: Getz Pharma Private Limited-Karachi
	Pharmacotherapeutic Group of (API)	alpha-adrenoreceptor antagonist within the Urologicals therapeutic group. G
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	NA
	Detail of stability batches of drug product	Provided
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
	The status in reference regulatory authorities	Brand Name: Rapaflo Capsules 4mg Manufacturer: Watson Laboratories, Inc. Corona, CA 92880 -USFDA
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	Provided
	Evaluation Remarks	
	From a quality perspective, it is determined that the product meets all applicable standards regarding identity, strength, quality, and purity	
	Decision	
	Approved	
46	Case Category	Export Facilitation (Abdul Mughees)
	Name, address of Applicant.	Ferozsons Laboratories Limited PO Ferozsons, Amangarh (000038)
	Application Form Dy. No / Tracking ID & date of submission	(P61-PZX-W216, 2025-01-30)
	Detail of Fee Submitted	37000.0, 2025-01-08,

The proposed proprietary name / brand name	Rapsil Capsules 8mg																								
Label Claim	Each capsule contains: Silodosin.....8mg																								
Reference to Finished product specifications	As per Innovators Specification																								
Proposed Pack Size	10's-As per SRO,14's-As per SRO,20's -As per SRO,28's-As per SRO,30's-As per SRO,7's-As per SRO																								
Shelf Life (Unit)	2 Year(s)Do not store above 30°C																								
For generic drugs (me-too Status)	Brand Name: Silorap Capsules 8mg Manufacturer: Getz Pharma Private Limited-Karachi																								
Pharmacotherapeutic Group of (API)	alpha-adrenoreceptor antagonist within the Urologicals therapeutic group. G																								
Name, address of Manufacturing site:	Self Manufacturing																								
Name & address of API manufacturer	NA																								
Detail of stability batches of drug product	Provided																								
Documents for the procurement of API with approval from DRAP (in case of Import)	Provided																								
Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided																								
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided																								
The status in reference regulatory authorities	Brand Name: Rapaflo Capsules 8mg Manufacturer: Watson Laboratories, Inc. Corona, CA 92880 -USFDA																								
GMP status of the firm	Provided																								
Evidence of approval of manufacturing facility	Provided																								
Evaluation Remarks																									
From a quality perspective, it is determined that the product meets all applicable standards regarding identity, strength, quality, and purity																									
Decision																									
Approved																									
47	<table> <tr> <td>Case Category</td><td>New License (Abdul Mughees)</td></tr> <tr> <td>Name, address of Applicant.</td><td>Fast Pharmaceuticals (Pvt) Ltd. Plot no.55, Street No. S-4, National Industrial Zone, RCCI-Rawat, Pakistan. (000954)</td></tr> <tr> <td>Application Form Dy. No / Tracking ID & date of submission</td><td>(91T-9UJ-5GXD, 2025-03-11)</td></tr> <tr> <td>Detail of Fee Submitted</td><td>37000.0, 2025-01-28,</td></tr> <tr> <td>The proposed proprietary name / brand name</td><td>FASBACT 500mg IM/IV Injection</td></tr> <tr> <td>Label Claim</td><td>FASBACT 500mg IM/IV Injection Each vial contains: (Powder for reconstitution) Cefoperazone as Sodium 250mg Sulbactam as Sodium 250mg (MANUFACTURER'S Specification).</td></tr> <tr> <td>Reference to Finished product specifications</td><td>Manufacturer Specification</td></tr> <tr> <td>Proposed Pack Size</td><td>As per SRO-As per SRO</td></tr> <tr> <td>Shelf Life (Unit)</td><td>2 YearStore below 30 C.</td></tr> <tr> <td>For generic drugs (me-too Status)</td><td>2SUM 500mg Injection by Healthtek Pvt. Ltd.</td></tr> <tr> <td>Pharmacotherapeutic Group of (API)</td><td></td></tr> <tr> <td>Name, address of Manufacturing site:</td><td>Self Manufacturing</td></tr> </table>	Case Category	New License (Abdul Mughees)	Name, address of Applicant.	Fast Pharmaceuticals (Pvt) Ltd. Plot no.55, Street No. S-4, National Industrial Zone, RCCI-Rawat, Pakistan. (000954)	Application Form Dy. No / Tracking ID & date of submission	(91T-9UJ-5GXD, 2025-03-11)	Detail of Fee Submitted	37000.0, 2025-01-28,	The proposed proprietary name / brand name	FASBACT 500mg IM/IV Injection	Label Claim	FASBACT 500mg IM/IV Injection Each vial contains: (Powder for reconstitution) Cefoperazone as Sodium 250mg Sulbactam as Sodium 250mg (MANUFACTURER'S Specification).	Reference to Finished product specifications	Manufacturer Specification	Proposed Pack Size	As per SRO-As per SRO	Shelf Life (Unit)	2 YearStore below 30 C.	For generic drugs (me-too Status)	2SUM 500mg Injection by Healthtek Pvt. Ltd.	Pharmacotherapeutic Group of (API)		Name, address of Manufacturing site:	Self Manufacturing
Case Category	New License (Abdul Mughees)																								
Name, address of Applicant.	Fast Pharmaceuticals (Pvt) Ltd. Plot no.55, Street No. S-4, National Industrial Zone, RCCI-Rawat, Pakistan. (000954)																								
Application Form Dy. No / Tracking ID & date of submission	(91T-9UJ-5GXD, 2025-03-11)																								
Detail of Fee Submitted	37000.0, 2025-01-28,																								
The proposed proprietary name / brand name	FASBACT 500mg IM/IV Injection																								
Label Claim	FASBACT 500mg IM/IV Injection Each vial contains: (Powder for reconstitution) Cefoperazone as Sodium 250mg Sulbactam as Sodium 250mg (MANUFACTURER'S Specification).																								
Reference to Finished product specifications	Manufacturer Specification																								
Proposed Pack Size	As per SRO-As per SRO																								
Shelf Life (Unit)	2 YearStore below 30 C.																								
For generic drugs (me-too Status)	2SUM 500mg Injection by Healthtek Pvt. Ltd.																								
Pharmacotherapeutic Group of (API)																									
Name, address of Manufacturing site:	Self Manufacturing																								

	Name & address of API manufacturer	Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co., Ltd West Side of Yanbin Road, Economic Development Zone, Feixian, Linyi, Shandong, China
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Cefoperazone + Sulbactam 500mg injection, Approved by PMDA of Japan
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Clarify your sample solution preparation method without any detail of reconstitution and further dilutions. Provide complete elaborative method of sample preparation. Attached Submit in-use stability studies. Attached You have not specified "run-time" in your submitted SAP for Finished Product Analysis of Fasbact 500mg Injection dated 02-05-2024. Please Justify As the chromatographic run-time is not specified in any official pharmacopoeia, and no monograph is available for this product in either the British Pharmacopoeia (BP) or United States Pharmacopeia (USP), we have adopted the analytical method and specifications based on the innovator product.	
48	Decision	
	Approved	
	Case Category	New Molecule/Formulation (Abdul Mughees)
	Name, address of Applicant.	Solaris Life Sciences Private Limited , Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992)
	Application Form Dy. No / Tracking ID & date of submission	(GZJ-E16-SQJN, 2025-06-25)
	Detail of Fee Submitted	75000.0, 2025-04-08,
	The proposed proprietary name / brand name	Velif 20mg Tablets
	Label Claim	Each film coated tablet contains; Vardenafil as Hydrochloride trihydrate 20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s) Below 30°C
	For generic drugs (me-too Status)	N/A (New Molecule)
	Pharmacotherapeutic Group of (API)	Drugs used in erectile dysfunction ATC code: G04BE09.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	03 batches having batch size of 1500 Tablets each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate, however, not in readable form.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and PE studies are performed against innovator product i.e. Levitra 20 mg Tablet, B. No. BXKOU52, Exp. date 12-2025 manufactured by M/s Bayer Pharma. Both innovator product and applied product have shown more than 85% release within 15 minutes at acidic
	Minutes of 351st Meeting of Registration Board (23rd – 24th September, 2025)	

	medium while in acetate buffer and phosphate buffer mediums of CDP values of F2 are also in acceptable range.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of 3 batches of drug substance as per Zone IV-B is submitted. Accelerated 06 months and real time for 60 months.
The status in reference regulatory authorities	LEVITRA® (Vardenafil HCl) tablets, USFDA approved. Vardenafil 10 mg & 20mg tablets, MHRA approved.
GMP status of the firm	Copy of GMP certificate No. 3-128/2024-Addl. Dir. (QA<-FO)-11 dated 04-02-2025 issued on the basis of inspection conducted on 15-01-2025 is submitted..
Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-18/2015-Lic (Pt.) dated 17-01-2024 mentioning Tablet Section-I (General) and Tablet section-II (General).

Evaluation Remarks

Sr. No	Observations	Reply of the firm
1	Section 1.5.6 has mentioned USP specifications. Clarification shall be submitted.	Specification of Velif 20mg are developed form USP, and Monograph of Verdenafil tablets is available in USP 2025.
2	Complete analytical procedures of the drug substance from drug substance manufacturer shall be submitted as most of the pages are missing in the provided analytical procedures.	Complete analytical procedures of the drug substance from drug substance manufacturer are added in revised Module-III, the analytical procedure and revised Module-II is enclosed for your kind consideration.
3	As per USP monograph, system suitability requires use of 7-methyl Vardenafil, while the performed system suitability does not indicate any use of impurity. Clarification shall be submitted.	The Reference standard of Impurity of 7-methyl Vardenafil is not yet purchased from USP and hence the System Suitability is performed on Vardenafil Working Standard.
4	Justification shall be submitted for altering the real time stability data of the drug substance as the condition are clearly altered	Stability data of API was previously submitted from DMF and the condition was not clearly mentioned on the stability studies provided in DMF. Manufacturer of API is provided stability studies according to Zone IV-A and resubmitted here for your kind consideration.
5	Justification shall be mentioning assay limit of 90-110% in PE studies while BP monograph has mentioned 95-105%	As the product specifications are according to USP monograph the USP monograph is mentioned 90-110% limit for Assay determination. USP Monograph is attached for your kind consideration
6	Pictorial evidence of the innovator product, against which the CDP & PE studies are performed, with visible details of the batch number, manufacturing date and name of manufacturer etc. shall be submitted.	13 Packs (4's) of Verdenafil 20mg Tablets (Levitra) having following is purchased as reference and used in CDP & PE studies. Batch No: B XKOU52 Mfg.Date: 12-2022 Date: 12-2025 evidence of the innovator product, are attached for your kind consideration.
7	Provide USP monograph for Vardenafil tablet as the specification and analytical procedures are as per USP method.	USP monograph for Vardenafil tablet enclosed for your kind consideration.
8	As per provided analytical procedure, system suitability requires use of 7-methyl Vardenafil, while the performed system suitability does not indicate any use of impurity.	Clarification shall be submitted. Impurity of Vardenafil is not yet purchased from USP and hence the System Suitability is performed on Vardenafil Working Standard.
8	Six-month time point stability data along with raw data sheets and chromatograms shall be submitted.	Six-month time point stability data along with raw data sheets and chromatograms is added in Module-

		III 3.2.P.8.3. revised Module-III enclosed for your kind consideration
10	Procurement document in readable form shall be submitted.	Procurement document in readable form enclosed for your kind consideration.

Decision

Approved

The Registration Board approved the product subject to the report of Product Specific Inspection (PSI) for verification of submitted data by a panel constituted by Chairman, Registration Board.

49	Case Category	New Molecule/Formulation (Abdul Mughees)
	Name, address of Applicant.	Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (000644)
	Application Form Dy. No / Tracking ID & date of submission	(M3B-RPA-HE1W, 2025-07-22)
	Detail of Fee Submitted	75000.0, 2025-04-18,
	The proposed proprietary name / brand name	Verion-OD 10mg Tablet
	Label Claim	Each Orodispersible Tablet Contains: Vardenafil as Hydrochloride Trihydrate 10MG
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Drugs used in erectile dysfunction ATC code: G04BE09.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	03 batches having batch size of 450 tablets each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of loan letter from M/s WnsFeild pharma wherein they give 100gm of Vardenafil to M/s Weather Folds pharma for the purpose of stability and dossier submission to DRAP dated 01-07-2024. They also submitted loan intimation to DRAP dated 15-07-2024 as per notification. They also submitted copy of GD and invoice. However, neither any license to import nor any clearance certificate is provided.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies are performed against innovator product i.e. Staxyn 10mg Tablet, B. No. VF4482, Mfg. date 02-2023.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of 3 batches of drug substance as per Zone IV-B is submitted. Accelerated 06 months and real time for 60 months.
	The status in reference regulatory authorities	Levatik® 10mg Orodispersible tablet, CIMA Spain approved.
	GMP status of the firm	Not submitted.
	Evidence of approval of manufacturing facility	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.

Evaluation Remarks

Sr. No.	Observation/ Shortcoming	Reply of the firm
1	Section 1.5.6 has mentioned innovator specifications. Clarification shall be	It was typographical error. We shall follow the official monograph.

	submitted 08 Analytical method validation protocol along with results shall be submitted. Analytical method validation protocol along with results attached in Annexure-3	
2	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 of the applicant shall be submitted. Valid GMP Attached.
3	Specifications and analytical procedures of the drug substance from drug product manufacturer shall be submitted.	Specifications and analytical procedures of the drug substance Attached in Annexure-1.
4	As per USP monograph, system suitability requires use of 7- methyl Vardenafil, while the performed system suitability does not indicate any use of impurity. Clarification shall be submitted.	As we have exemption of impurities, and we used pharmacopial method which show no impurities in both standard and sample .
5	COA of the working standard submitted in section 3.2.S.5 has expiry of 05-04-2023. Clarification shall be submitted with respect to trial batch manufacturing i.e. 08-2024.	Working Standard COA from Product Part attached.
6	Qualitative composition is different from the innovator product. Justification shall be submitted. Justify the applied formulation as Orodispersible tablet without using any super disintegrant in the formulation.	Mistakenly incorrect formulation was attached previously. Revised and correct formulation is Attached in Annexure-2
7	Pictorial evidence of the innovator product, against which PE studies are performed, with visible details of the batch number, manufacturing date and name of the manufacturer shall be submitted.	Attached.
8	Documents for procurements of API i.e. license to import and clearance certificate with approval from DRAP shall be submitted.	The Goods Declaration certificate dated 13th June,2024 on the Name of M/s Wnsfeild Pharmaceuticals attached as proof of import. Loan letter and DRAP intimated was already attached.
9	Submitted chromatograms have no wavelength. Clarification shall be submitted.	As we used Empower 2 software in which no option of wavelength. We are updating software and next time wavelength will be included.
10	Raw data sheets as per calculation formula shall be submitted.	Raw data sheets as per calculation formula ATTACHED IN Annexure-4

Decision

Approved

The Registration Board approved the product subject to the report of Product Specific Inspection (PSI) for verification of submitted data by a panel constituted by Chairman, Registration Board.

50	Case Category	New Molecule/Formulation (Abdul Mughees)
	Name, address of Applicant.	Martin Dow Marker Limited 7, Jail Road Quetta. (000028)
	Application Form Dy. No / Tracking ID & date of submission	(TRR-BWS-WBRR, 2024-11-20)
	Detail of Fee Submitted	75000.0, 2024-10-24,

The proposed proprietary name / brand name	Ibatin 5mg
Label Claim	Each film-coated tablet contains Elobixibat monohydrate 5.13mg equivalent to Elobixibat.....5mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	10s-As per SRO
Shelf Life (Unit)	2 Year(s) Below 30
For generic drugs (me-too Status)	Not applicable
Pharmacotherapeutic Group of (API)	selective inhibitor of the ileal bile acid transporter (IBAT)
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Metrochem API Private limited Unit-IV, Plot No 34B, 40B & 60B, J.N. Pharma City, Thanam Village, Parawada Mandal, Vosakhapatnam District, Andhra Pradesh, 531021, India (IND)
Detail of stability batches of drug product	3 Batches, 8000 tablets per batch
Documents for the procurement of API with approval from DRAP (in case of Import)	Qty: 1.85 kg via Form 6 issued on 13-09-2023
Pharmaceutical Equivalence and Comparative Dissolution Profile	Goofice tablet 5 mg manufactured by Eisai Japan. (PE & CDP)
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 batches at Zone IV-B
The status in reference regulatory authorities	Pharmaceuticals and Medical Devices Agency (PMDA)
GMP status of the firm	GMP certificate dated 18-03-2024 (valid for three years)
Evidence of approval of manufacturing facility	Tablet (General) Section regularized in 280th meeting of Central Licensing Board

Evaluation Remarks

The instant application was deferred in 345th Meeting of the Registration Board being new molecule for the following: "Following shortcomings has been communicated to the company. Please submit summary of stability batches of drug product according to table available in DRAP's guidance document of CTD submission (Page 37-38) at following link <https://www.dra.gov.pk/wp-content/uploads/2022/01/Guidance-Document-on-CTD-Doc-No.-PER-GL-AF-004.pdf>." The firm has now submitted shortcomings.

Decision

Approved

51	Case Category	Export Facilitation (Abdul Mughees)
	Name, address of Applicant.	Martin Dow Marker Limited 7, Jail Road Quetta. (000028)
	Application Form Dy. No / Tracking ID & date of submission	(953-P3R-PULJ, 2025-02-10)
	Detail of Fee Submitted	75000.0, 2025-01-31,
	The proposed proprietary name / brand name	Resmin
	Label Claim	Each Film-coated Tablet contains: Resmetirom 80mg (Innovator's Specification).
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per DPC-Controlled
	Shelf Life (Unit)	2 Year(s) Below 30°C
	For generic drugs (me-too Status)	N.A
	Pharmacotherapeutic Group of (API)	hepatic and biliary diseases
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	

	Detail of stability batches of drug product	Provided
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
	The status in reference regulatory authorities	Rezdiffra Tablets 80mg (USFDA)
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	Provided
	Evaluation Remarks	
	The applicant was asked to submit the following which they complied: Submit 06 month stability data alongwith chromatograms.Include time for dissolution in the acceptance criteria in the DP specifications based on your PD analysis and validation of dissolution method. The firm has now submitted shortcomings.	
	Decision	
	Approved	
52	Case Category	Export Facilitation (Abdul Mughees)
	Name, address of Applicant.	Martin Dow Limited Plot no. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan (000267)
	Application Form Dy. No / Tracking ID & date of submission	(9EB-DW3-V67H, 2025-03-04)
	Detail of Fee Submitted	93000.0, 2025-01-29,
	The proposed proprietary name / brand name	Resmidow Tablet 80mg
	Label Claim	Each film coated tablet contains: Resmetirom.....80mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,20's-As per SRO,30's-As per SRO,40's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	A05BA11; Lipotropic agent
	Name, address of Manufacturing site:	Martin Dow Market Limited-07-Jail Road, Quetta, Pakistan.-
	Name & address of API manufacturer	Not Applicable
	Detail of stability batches of drug product	Provided
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
	The status in reference regulatory authorities	US-FDA Rezdiffra Tablet 80mg by Medrigal Pharmaceuticals Inc
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	Provided
	Evaluation Remarks	

From a quality perspective, it is determined that the product meets all applicable standards regarding identity, strength, quality, and purity.

Decision

Approved

53

Case Category	Export Facilitation (Abdul Mughees)
Name, address of Applicant.	Martin Dow Marker Limited 7, Jail Road Quetta. (000028)
Application Form Dy. No / Tracking ID & date of submission	(YB3-TDJ-JHV9, 2025-02-12)
Detail of Fee Submitted	75000.0, 2025-02-06,
The proposed proprietary name / brand name	Resmin Tablet
Label Claim	Each Film-coated Tablet contains: Resmetirom 100mg (Innovator's Specification)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per DPC-As per SRO
Shelf Life (Unit)	2 Year(s)Below 30
For generic drugs (me-too Status)	NA
Pharmacotherapeutic Group of (API)	A05BA11; lipotropic
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Shandong Chenghuishuangda Pharmaceutical Co., Ltd. Economic Development Zone, Pingyuan County, Dezhou, Shandong, China
Detail of stability batches of drug product	Provided
Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
The status in reference regulatory authorities	Rezdiffra Tablets 100mg (USFDA)
GMP status of the firm	Provided
Evidence of approval of manufacturing facility	Provided

Evaluation Remarks

From a quality perspective, it is determined that the product meets all applicable standards regarding identity, strength, quality, and purity.

Decision

Approved

54

Case Category	Export Facilitation (Abdul Mughees)
Name, address of Applicant.	Martin Dow Limited Plot no. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan (000267)
Application Form Dy. No / Tracking ID & date of submission	(MW4-APE-PA7B, 2025-03-04)
Detail of Fee Submitted	93000.0, 2025-01-29,
The proposed proprietary name / brand name	Resmidow Tablet 100mg
Label Claim	Each film coated tablet contains: Resmetirom.....100mg

Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	10's-As per SRO,20's-As per SRO,30's-As per SRO,40's-As per SRO
Shelf Life (Unit)	2 Year(s)Store below 30°C
For generic drugs (me-too Status)	Not Applicable
Pharmacotherapeutic Group of (API)	A05BA11; Lipotropic
Name, address of Manufacturing site:	Martin Dow Marker Limited-07-Jail Road, Quetta, Pakistan.-
Name & address of API manufacturer	Not Applicable
Detail of stability batches of drug product	Provided
Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
The status in reference regulatory authorities	US-FDA Rezdiffra Tablet 100mg by Medrigal Pharmaceuticals Inc
GMP status of the firm	Provided
Evidence of approval of manufacturing facility	Provided

Evaluation Remarks

From a quality perspective, it is determined that the product meets all applicable standards regarding identity, strength, quality, and purity.

Decision

Approved

55	Case Category	Export Facilitation (Abdul Mughees)
	Name, address of Applicant.	Martin Dow Marker Limited 7, Jail Road Quetta. (000028)
	Application Form Dy. No / Tracking ID & date of submission	(Q7B-APH-GRZU, 2025-04-21)
	Detail of Fee Submitted	75000.0, 2025-02-06,
	The proposed proprietary name / brand name	Resmin Tablet 60mg
	Label Claim	Each Film-coated Tablet contains: Resmetirom 60mg (Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per DPC-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	A05BA11; Lipotropic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Chenghuishuangda Pharmaceutical Co., Ltd. Economic Development Zone, Pingyuan County, Dezhou, Shandong, China
	Detail of stability batches of drug product	Provided
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
	The status in reference regulatory authorities	Rezdiffra Tablets 60mg (USFDA)
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	Provided
	Evaluation Remarks	
	From a quality perspective, it is determined that the product meets all applicable standards regarding identity, strength, quality, and purity.	
	Decision	
	Approved	
56	Case Category	New Section (Abdul Mughees)
	Name, address of Applicant.	Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi (000333)
	Application Form Dy. No / Tracking ID & date of submission	(7GS-744-LQZS, 2024-06-10)
	Detail of Fee Submitted	30000.0, 2023-12-19,
	The proposed proprietary name / brand name	wolide infusion
	Label Claim	Each 100ml contains: Linezolid.....200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's (100ml)-As per SRO
	Shelf Life (Unit)	2 Year(s)store in a cool and dry place below 30
	For generic drugs (me-too Status)	barizold infusion
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Benova Labs Private Limited
	Detail of stability batches of drug product	03 batches of 150 vials on Zone IVa conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
	The status in reference regulatory authorities	Zyvox infusion
	GMP status of the firm	DS: DCA Govt of Telangana India dated 03.01.2022 DP: Panel inspection and GMP 28 December 2021
	Evidence of approval of manufacturing facility	DML provided
	Evaluation Remarks	
	From a quality perspective, it is determined that the product meets all applicable standards regarding identity, strength, quality, and purity.	
	Decision	
	Approved	
57	Case Category	New Section (Abdul Mughees)
	Name, address of Applicant.	Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi (000333)

Application Form Dy. No / Tracking ID & date of submission	(DNQ-NTM-73BM, 2025-07-21)
Detail of Fee Submitted	37000.0, 2025-05-07,
The proposed proprietary name / brand name	IBUFEN 400mg/100ml Infusion
Label Claim	Each 100ml vial contains:Ibuprofen.....400mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1x1's 100ml-As per SRO
Shelf Life (Unit)	2 Year(s)store below 30
For generic drugs (me-too Status)	Boscofen 400mg/100ml I.V infusion
Pharmacotherapeutic Group of (API)	NSAID's
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Hubei Biocause Heilon Pharmaceuticals Co,Ltd
Detail of stability batches of drug product	177NS02,177NS03,177NS04
Documents for the procurement of API with approval from DRAP (in case of Import)	Ibuprofen BP 0.3300 Kg 05-11-2024
Pharmaceutical Equivalence and Comparative Dissolution Profile	Ibuprofen 400mg/100ml infusion
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	C100-0911122M,C100-0911123M,C100-0911124M,C100-1507197M,C100-1507198M,C100-1507199M
The status in reference regulatory authorities	Ibuprofen 400mg/100ml infusion Germany
GMP status of the firm	20th feb,2024
Evidence of approval of manufacturing facility	28th march 2025
Evaluation Remarks	
From a quality perspective, it is determined that the product meets all applicable standards regarding identity, strength, quality, and purity.	
Decision	
Approved	
58	Case Category
	Name, address of Applicant.
	Application Form Dy. No / Tracking ID & date of submission
	Detail of Fee Submitted
	The proposed proprietary name / brand name
	Label Claim
	Reference to Finished product specifications
	Proposed Pack Size
	Shelf Life (Unit)
	For generic drugs (me-too Status)
	Pharmacotherapeutic Group of (API)
	Name, address of Manufacturing site:
	Name & address of API manufacturer
	Detail of stability batches of drug product
	Documents for the procurement of API with approval from DRAP
	New Section (Abdul Mughees)
	Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi (000333)
	(DAZ-MBT-ZVJQ, 2025-07-21)
	37000.0, 2025-05-20,
	NUBIN 20mg/ml Injection
	Each ampoule (1ml) contains:Nalbuphine HCl.....20mg
	As per Innovators Specification
	2x5's(1ml)-As per SRO
	2 Year(s)store below 30
	Nalbin 20mg/ml injection
	Opioid agonist antagonist
	Self Manufacturing
	micro Orgo Chem
	183NS02-183NS03-183NS04
	29-11-2024

	(in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	NUBAIN 20mg/ml Injection
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	MO/NBP/1401-MO/NBP/1402/MO/NBP/1403
	The status in reference regulatory authorities	NUBAIN 20mg/ml Injection
	GMP status of the firm	20th feb,2024
	Evidence of approval of manufacturing facility	28th march 2025
	Evaluation Remarks	
	From a quality perspective, it is determined that the product meets all applicable standards regarding identity, strength, quality, and purity.	
	Decision	
	Approved	
59	Case Category	New Section (Abdul Mughees)
	Name, address of Applicant.	Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi (000333)
	Application Form Dy. No / Tracking ID & date of submission	(G99-6ZP-SQWQ, 2025-07-21)
	Detail of Fee Submitted	37000.0, 2025-06-17,
	The proposed proprietary name / brand name	TRULAC 30mg/ml Injection
	Label Claim	Ech 1ml ampoule contains: Ketorolac Tromethamine.....30mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x5's-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30
	For generic drugs (me-too Status)	Kydor injection
	Pharmacotherapeutic Group of (API)	NSAID's
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Satyadivis Pharmaceuticals Pvt Ltd
	Detail of stability batches of drug product	184NS02-184NS03-184NS04
	Documents for the procurement of API with approval from DRAP (in case of Import)	29-11-2024
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Ketarolac tromethamine injection
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	KET-V/001/20-KET-V/002/20-KET/003/20
	The status in reference regulatory authorities	Ketorolac Tromethamine 30mg/ml injection Bexter Healthcare USA
	GMP status of the firm	20th feb,2024
	Evidence of approval of manufacturing facility	28th march 2025
	Evaluation Remarks	
	From a quality perspective, it is determined that the product meets all applicable standards regarding identity, strength, quality, and purity.	
	Decision	
	Approved	
60	Case Category	Contract Manufacturing (Abdul Mughees)

Name, address of Applicant.	Solaris Life Sciences Private Limited , Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992)
Application Form Dy. No / Tracking ID & date of submission	(9ZY-ELB-9GWX, 2024-06-11)
Detail of Fee Submitted	75000.0, 2024-02-02,
The proposed proprietary name / brand name	SOLPIME-500MG INJECTION IV/IM
Label Claim	Each vial contains: Cefepime as hydrochloride (with L arginine) 500mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	As Per SRO-As per SRO
Shelf Life (Unit)	2 Year30°C
For generic drugs (me-too Status)	ROSIPINE-500MG Injection By Genome Pharmaceuticals
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Seraph Pharmaceuticals-Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad-PAKISTAN.-
The status in reference regulatory authorities	Cefepime hydrochloride 500mg Powder for Solution for Injection By QILU PHARMACEUTICAL (FDA Approved)
Detail of previous approval	PRV-100 of Genome Pharmaceuticals By the Name of ROSIPINE-500MG Injection.

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. However, in 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer.

Decision

Approved

61	Case Category	Contract Manufacturing (Abdul Mughees)
	Name, address of Applicant.	Solaris Life Sciences Private Limited , Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992)
	Application Form Dy. No / Tracking ID & date of submission	(BHY-N52-G5U5, 2024-06-11)
	Detail of Fee Submitted	75000.0, 2024-02-02,
	The proposed proprietary name / brand name	SOLPIME-1GM INJECTION IV/IM
	Label Claim	Each vial contains: Cefepime as hydrochloride (with L arginine) 1000mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year30°C
	For generic drugs (me-too Status)	ROSIPINE-1GM Injection By Genome Pharmaceuticals
	Pharmacotherapeutic Group of (API)	

Name, address of Manufacturing site:	Seraph Pharmaceuticals-Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad-PAKISTAN.-
The status in reference regulatory authorities	Cefepime hydrochloride 1000mg Powder for Solution for Injection By QILU PHARMACEUTICAL (FDA Approved
Detail of previous approval	PRV-100 of Genome Pharmaceuticals By the Name of ROSIPINE-1GM Injection.

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. However, in 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer.

Decision

Approved

62	Case Category	Contract Manufacturing (Abdul Mughees)
	Name, address of Applicant.	FAAS Pharmaceuticals (Pvt)Ltd F-748 L, S.I.T.E, Karachi (000767)
	Application Form Dy. No / Tracking ID & date of submission	(T72-BJ8-6VV1, 2024-08-16)
	Detail of Fee Submitted	75000.0, 22200.0 2024-06-25, 2025-09-02
	The proposed proprietary name / brand name	FAAS-D 5mg/ml Injection
	Label Claim	Each ampoule contains: Cholecalciferol (200,000IU) 5mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearstore below 30 C.
	For generic drugs (me-too Status)	Brand Name: Novel-D Injection Oral/ I.M Registration holder: DANAS Pharmaceuticals Islamabad
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Seraph Pharmaceutical-Plot # 210, Industrial Triangle, Kahuta Road, Islamabad, Pakistan-
	The status in reference regulatory authorities	MHRA approved drug
	Detail of previous approval	Seraf-D 5mg/ml Injection , Meeting No. PRVC 119
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. However, in 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer.	
	Decision	

Approved

63	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	NovaMed Pharmaceuticals(Pvt.)Ltd 28-KM Ferozepur Road Lahore (000590)
	Application Form Dy. No / Tracking ID & date of submission	(GY4-G5E-5GEL, 2024-04-30)
	Detail of Fee Submitted	75000.0, 2024-04-04,
	The proposed proprietary name / brand name	Mirogab
	Label Claim	Each film coated tablet contains: Mirogabalin besylate eq to mirogabalin.....5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's,10's,14's,20's,2-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store away from direct sunlight, heat and moisture below 30C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	N02BF03; Nervous system analgesics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Kehui Pharmaceutical Co, Ltd
	Detail of stability batches of drug product	Provided
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Tarlige 5mg Tablet batch number YBA 1293
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
	The status in reference regulatory authorities	Tarlige tablet by Daiichi sankyo company
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	Attached in Module 1 in section 1.3.5
	Evaluation Remarks	
	The firm was asked to provide 06 month stability data and API procurement data. To which, the firm has submitted stability data which is assessed. However, they have informed that API was on the loan basis from Hihg-Q and have not included loan intimation letter to DRAP.	
	Decision	
	Approved	
	The Registration Board approved the product subject to verification of API loan letter from High-Q Pharma.	
64	Case Category	Contract Manufacturing (Abdul Mughees)
	Name, address of Applicant.	FAAS Pharmaceuticals (Pvt)Ltd F-748 L, S.I.T.E, Karachi (000767)
	Application Form Dy. No / Tracking ID & date of submission	(PLR-XLR-6PE2, 2024-08-28)
	Detail of Fee Submitted	75000.0, 2024-07-04,
	The proposed proprietary name / brand name	Fastcure 100mg/5ml Injection
	Label Claim	Each 5ml ampoule contains: Iron (III) hydroxide sucrose equivalent to elemental iron..... 100mg
	Reference to Finished product specifications	United States Pharmacopeia

Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 Yearstore below 30 C.
For generic drugs (me-too Status)	Brand Name: G-FER Injection Registration holder: Global Pharma
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Seraph Pharmaceutical-Plot # 210, Industrial Triangle, Kahuta Road, Islamabad, Pakistan-
The status in reference regulatory authorities	MHRA approved drug
Detail of previous approval	Seros , PRVC 119th

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. However, in 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer.

Decision

Approved

65	Case Category	Contract Manufacturing (Abdul Mughees)
	Name, address of Applicant.	Pine Pharmaceuticals Plot No, 40, S-4, Rawat Industrial Estate, Islamabad (000955)
	Application Form Dy. No / Tracking ID & date of submission	(J9U-L5Q-538N, 2024-09-13)
	Detail of Fee Submitted	75000.0, 18000.0 2024-08-09, 2024-09-12
	The proposed proprietary name / brand name	Pritam 100mg/ml Injection
	Label Claim	Each ml contains; Levetiracetam 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30 ° C
	For generic drugs (me-too Status)	Lerace 100mg/ml injection, Hilton pharma Lahore Pakistan.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	SERAPH PHARMACEUTICAL-Plot no 210 Seraph pharma Model Town Kahuta Road Islamabad-
	The status in reference regulatory authorities	UCB Pharma Limited 208 Bath Road Slough Berkshire SL1 3WE UK, Approved in FDA
	Detail of previous approval	PRVC 119th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. However, in 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer.	

	Decision	
	Approved	
66	Case Category	Contract Manufacturing (Abdul Mughees)
	Name, address of Applicant.	Medwell Pharmaceuticals 1 km, terbella road, lawrencepur, faqirabad Attock (000699)
	Application Form Dy. No / Tracking ID & date of submission	(M43-S6G-H3HE, 2024-10-21)
	Detail of Fee Submitted	75000.0, 18000.0 2024-05-23, 2024-10-09
	The proposed proprietary name / brand name	Ceftramed 250mg Injection IM
	Label Claim	Each vial contains: Ceftriaxone Sodium eq. to Ceftriaxone.....250mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1-As per SRO
	Shelf Life (Unit)	2 YearStore below 25 Degree Centigrade
	For generic drugs (me-too Status)	Rocephin Injection 250mg (Manufactured by Martin Dow Pvt. Ltd)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE, Super Highway, Phase II, Karachi-
	The status in reference regulatory authorities	Ceftriaxone for Injection 250mg USP (Manufactured by Sandoz Pvt. Ltd.)
	Detail of previous approval	Shelzone 250mg Injection (F-106-PRVC/2023)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. However, in 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer.	
	Decision	
	Approved	
67	Case Category	Contract Manufacturing (Abdul Mughees)
	Name, address of Applicant.	Medwell Pharmaceuticals 1 km, terbella road, lawrencepur, faqirabad Attock (000699)
	Application Form Dy. No / Tracking ID & date of submission	(3AE-UAW-DMR9, 2025-01-22)
	Detail of Fee Submitted	75000.0, 18000.0 2024-05-23, 2024-10-09
	The proposed proprietary name / brand name	Ceftramed 500mg Injection
	Label Claim	Each vial contains: Ceftriaxone Sodium eq. to Ceftriaxone.....500mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-Free of Cost
	Shelf Life (Unit)	2 YearStore below 25 Degree Centigrade

For generic drugs (me-too Status)	Rocephin Injection 500mg (Manufactured by Martin Dow Pvt. Ltd)
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE, Super Highway, Phase II, Karachi-
The status in reference regulatory authorities	Ceftriaxone for Injection 500mg USP (Manufactured by Sandoz Pvt. Ltd.)
Detail of previous approval	Shelzone 500mg Injection 106th PRVC

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. However, in 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer.

Decision

Approved

68	Case Category	Contract Manufacturing (Abdul Mughees)
	Name, address of Applicant.	Novins International (PVT) Ltd E-37 & 38, Port Bin Qasim Authority, Karachi-Pakistan. (000541)
	Application Form Dy. No / Tracking ID & date of submission	(6L2-JWX-DPGM, 2025-03-06)
	Detail of Fee Submitted	75000.0, 18000.0 2024-08-28, 2024-10-30
	The proposed proprietary name / brand name	NOVIXONE 1000mg INJECTION IV
	Label Claim	Each vial contains: Ceftriaxone Sodium eq. to Ceftriaxone.....1000mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearStore below 25 Degree Centigrade
	For generic drugs (me-too Status)	Rocephin Injection 1000mg (Manufactured by Martin Dow Pvt. Ltd)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE, Super Highway, Phase II, Karachi-
	The status in reference regulatory authorities	Ceftriaxone for Injection 1000mg USP (Manufactured by Sandoz Pvt. Ltd.)
	Detail of previous approval	Shelzone 1000mg Injection in 106th Meeting of PRVC
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. However, in 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer.	

	Decision	
	Approved	
69	Case Category	Contract Manufacturing (Abdul Mughees)
	Name, address of Applicant.	Evolution Pharmaceuticals (Pvt.) Ltd. Plot no. 25,26 & 27, Street S-3, National Industrial Zone, Rawat, Islamabad. (000867)
	Application Form Dy. No / Tracking ID & date of submission	(41D-REQ-J6N1, 2024-10-17)
	Detail of Fee Submitted	93000.0, 2024-09-24,
	The proposed proprietary name / brand name	EVOCOBAL 500mcg/ml Injection
	Label Claim	Mecobalamin solution for Injection 500mcg/ml Each ampoule contains Mecobalamin.....500mcg/ml (Innovator specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	2 Yeartore below 30°C. Protect from light. Reconstituted solution may be stored at 25°C for 24 hours or between 2-8°C for 7 days.
	For generic drugs (me-too Status)	Brand Name: Mecomax Injection I.V/ I.M 500mcg/ml injection Registration holder: Global Pharmaceuticals Pakistan
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	SERAPH PHARMACEUTICAL -Plot No 210, Industrial triangle, Kahuta road, Islamabad-Pakistan-
	The status in reference regulatory authorities	Brand Name Mecobalamin (500mcg) injection Marketing Authorization holder: PMDA Approved
	Detail of previous approval	Reg No,115262, Product Name: Adenomin
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. However, in 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer.	
	Decision	
	Approved	
70	Case Category	Contract Manufacturing (Abdul Mughees)
	Name, address of Applicant.	Evolution Pharmaceuticals (Pvt.) Ltd. Plot no. 25,26 & 27, Street S-3, National Industrial Zone, Rawat, Islamabad. (000867)
	Application Form Dy. No / Tracking ID & date of submission	(HBL-6RV-NUEB, 2025-03-04)
	Detail of Fee Submitted	93000.0, 2024-10-08,
	The proposed proprietary name / brand name	Evoket 30mg/ml Injection

Label Claim	Each ml contains: Ketorolac tromethamine 30mg (USP Specs.)
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	1s-As per SRO
Shelf Life (Unit)	2 YearStore at 20° to 25° C (68° to 77°F). Keep container closed tightly. Protect from light and moisture. Store away from foodstuffs.
For generic drugs (me-too Status)	Brand Name: Toralac 30mg/ml injection Registration holder: Global Pharmaceuticals Pakistan
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Name: SERAPH PHARMACEUTICAL DMLNo: 000860 Address-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
The status in reference regulatory authorities	Brand Name Toradol 30mg/ml injection Marketing Authorization holder: Roche Palo Alto LLC , California, US Regulatory Authority: FDA Approved drugs
Detail of previous approval	11170 Cilokat30mg/mlinjection,No.F-119-PRVC/2024(PR-II)

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. However, in 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer.

Decision

Approved

71	Case Category	Contract Manufacturing (Abdul Mughees)
	Name, address of Applicant.	Evolution Pharmaceuticals (Pvt.) Ltd. Plot no. 25,26 & 27, Street S-3, National Industrial Zone, Rawat, Islamabad. (000867)
	Application Form Dy. No / Tracking ID & date of submission	(9UB-RRY-E1A2, 2025-03-04)
	Detail of Fee Submitted	93000.0, 2024-10-08,
	The proposed proprietary name / brand name	Nalbin 10mg/ml injection
	Label Claim	Each Ampoule(1ml) contains; Nalbuphine hydrochloride 10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	2 YearStore at 20° to 25° C (68° to 77°F). Keep container closed tightly. Protect from light and moisture. Store away from foodstuffs.
	For generic drugs (me-too Status)	Brand Name: Bunail 10mg/ml injection Registration holder: Bosch pharmaceuticals (pvt) ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	SERAPH PHARMACEUTICAL Plot # 210, Industrial Trian- Plot # 210, Industrial Triangle, Kahuta Road,

	Islamabad, Pakistan-
The status in reference regulatory authorities	Brand Name: NUBAIN Injection.....10mg/ml Registration holder: Par Pharmaceutical USA, Approved in FDA.
Detail of previous approval	111997 Sernaib10mg/lmlInjection, No.F-119-PRVC/2024(PR-II)

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. However, in 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer.

Decision

Approved

72	Case Category	Contract Manufacturing (Abdul Mughees)
	Name, address of Applicant.	Evolution Pharmaceuticals (Pvt.) Ltd. Plot no. 25,26 & 27, Street S-3, National Industrial Zone, Rawat, Islamabad. (000867)
	Application Form Dy. No / Tracking ID & date of submission	(DGE-7E1-15ZM, 2025-03-21)
	Detail of Fee Submitted	93000.0, 2024-10-08,
	The proposed proprietary name / brand name	Nalbin 20mg/ml injection,
	Label Claim	Each Ampoule(1ml) contains; Nalbuphine hydrochloride 20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	2 YearStore at 20° to 25° C (68° to 77°F). Keep container closed tightly. Protect from light and moisture. Store away from foodstuffs.
	For generic drugs (me-too Status)	Brand Name: Bunail 20mg/ml injection Registration holder: Bosch pharmaceuticals (pvt) ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	SERAPH PHARMACEUTICAL -Plot No 210, Industrial triangle, Kahuta road, Islamabad-Pakistan-
	The status in reference regulatory authorities	Brand Name: NUBAIN Injection.....20mg/ml Registration holder: Par Pharmaceutical USA, Approved in FDA.
	Detail of previous approval	111998 Sernaib20mg/lml InjectionNo.F-119-PRVC/2024(PR-II)

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. However, in 250th meeting, the Board

decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer.

Decision

Approved

73	Case Category	Export Facilitation (Abdul Mughees)
	Name, address of Applicant.	Nabiqasim Industries (Pvt) Ltd., 17/24, Korangi Industrial Area, Karachi. (000105)
	Application Form Dy. No / Tracking ID & date of submission	(2GW-V55-6JMA, 2025-04-09)
	Detail of Fee Submitted	37000.0, 2025-03-11,
	The proposed proprietary name / brand name	Tebact Tablet 200mg
	Label Claim	Each film-coated tablet contains: Tedizolid Phosphate.....200mg (Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	6's, 10's, 12's, 20'-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Yes
	Pharmacotherapeutic Group of (API)	J01XX11: Anti-bacterials for systemic use
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Yibin Hongguang Pharmaceutical Co.,Ltd.
	Detail of stability batches of drug product	03 batches on Zone IV-a conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
	The status in reference regulatory authorities	US FDA Approved (Sivextro Tablet 200mg by Cubist Pharmaceuticals U.S.)
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	Provided
	Evaluation Remarks	
	The instant application is priority under export facilitation as per letter No.F.1-6/2019-PR-I (EFD) dated 12.08.2025.. From a quality perspective, it is determined that the product meets all applicable standards regarding identity, strength, quality, and purity.	
	Decision	
	Approved	
74	Case Category	New License (Abdul Mughees)
	Name, address of Applicant.	Well Go Pharmaceuticals (Pvt) Ltd 5-km, Raiwind Manga Road Lahore (001004)
	Application Form Dy. No / Tracking ID & date of submission	(V64-Q7V-SHYE, 2025-07-14)
	Detail of Fee Submitted	37000.0, 2025-06-24,
	The proposed proprietary name / brand name	Parawell 1G/100ML INFUSION

Label Claim	PARAWELL 1G/100ML INFUSION Each 100ml Contains: Paracetamol.....1g (BP Specification).
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	as per SRO-As per SRO
Shelf Life (Unit)	2 YearStore below 30°C and dry place.
For generic drugs (me-too Status)	Provas infusion by M/s Sami pharmaceuticals.
Pharmacotherapeutic Group of (API)	Analgesic; antipyretic
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	PHARMAGEN LIMITED Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore.
Detail of stability batches of drug product	100 vials of each Batch.
Documents for the procurement of API with approval from DRAP (in case of Import)	PHARMAGEN LIMITED Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and Comparative Dissolution is taken place Against Paracetamol Infusion by BOSCH Pharma.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability submitted of zone iv A.
The status in reference regulatory authorities	Paracetamol 10 mg/ml solution for infusion B. Braun Melsungen AG Carl-Braun-Strasse 1 34212 Melsungen, Germany
GMP status of the firm	Attached.
Evidence of approval of manufacturing facility	Attached.

Evaluation Remarks

Decision

Approved

75

Case Category	Short Availability Drugs (Abdul Mughees)
Name, address of Applicant.	Nimrall Laboratories Plot No. 24, Street SS-3, Rawat Industrial Estate, Rawat (000611)
Application Form Dy. No / Tracking ID & date of submission	(BR1-9NB-EEMZ, 2025-07-18)
Detail of Fee Submitted	75000.0, 2025-07-11,
The proposed proprietary name / brand name	Rhythm 200mg Capsules
Label Claim	Each Capsule contains: Mexiletine HCl.....200mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	100's in HDPE bottle with secure cap-As per SRO
Shelf Life (Unit)	2 YearRoom Temperature
For generic drugs (me-too Status)	NDP
Pharmacotherapeutic Group of (API)	Anti Arrhythmic
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Alembic Pharmaceuticals
Detail of stability batches of drug product	Module 3 (3.2.P.8.3), 2 batches of 7500 Capsules/Units each, as per DRAP Guidelines.
Documents for the procurement of API with approval from DRAP (in case of Import)	Attached module 3, from Alembic Pharmaceuticals, India.

Pharmaceutical Equivalence and Comparative Dissolution Profile	Module 3 (3.2.P.2.2.1)
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Module 3 (3.2S.7.3)
The status in reference regulatory authorities	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=074377
GMP status of the firm	GMP Certified. Valid Certificate issued by DRAP. 28-10-2025
Evidence of approval of manufacturing facility	DML 000611 Validity 21-03-2027
Evaluation Remarks	
The applicant was asked to clarify: 1. Signed copy of Analytical method verification as per claimed specifications. 2. Signed copy of Comparative Dissolution Profile Report along with relevant data including chromatograms. 3. Evidence of FTIR. 4. The HPLC documents attached from page 171 to page 215 in Module 3 does not show any peak. Please clarify. 5. As per information provided by you on page 108 of submitted module 3, the stability batches of your product were manufactured in 02-2024 using API lot 2302027465 with the stability initiation date 02-2024, whereas the accelerated stability table on the same page shows stability time points date as 02-2022 for 0 months, 05-2023 for 03 months and 08-2024 for 06 months. Please justify how you have tested a batch before its manufacturing? 6. Also provide stability summary as per applicable CTD guidelines along with relevant data including chromatograms for testing on all time points. They have submitted response to the queries and for point 5 they have informed "this was a typo error",	
Decision	
Approved	
The Registration Board approved the product subject to Product Specific Inspection (PSI) for verification of submitted data by a panel constituted by the Chairman, Registration Board.	
76	Case Category
	New Section (Abdul Mughees)
	ICU Pharmaceuticals (SMC-Private) Limited Khewat No. 13/13, Khatooni 57/66, Mouza Mirpur Kehna, Tehsil Sharakpur, District Sheikhpura, (000956)
	Name, address of Applicant.
	Application Form Dy. No / Tracking ID & date of submission
	(AH7-624-Z2ZU, 2025-07-23)
	Detail of Fee Submitted
	37000.0, 2025-07-02,
	The proposed proprietary name / brand name
	CPX 200mg/100ml IV INFUSION
	Label Claim
	Each 100ml solution in glass vial contains: Ciprofloxacin (as Lactate) 200 mg (BP Specs.)
	Reference to Finished product specifications
	British Pharmacopeia
	Proposed Pack Size
	1's-As per SRO
	Shelf Life (Unit)
	2 Year(s)Store below 30°C and dry place.
	For generic drugs (me-too Status)
	Novidate 200mg/100ml by Sami Pharmaceuticals
	Pharmacotherapeutic Group of (API)
	Antibiotic
	Name, address of Manufacturing site:
	Self Manufacturing
	Name & address of API manufacturer
	Shangyu Jingxin Pharmaceuticals Co., Ltd. No.31 Weisan Road Hangzhou Bay Shangyu Economic and Technological Development Area Shangyu Zhejiang Province China 312369.
	Detail of stability batches of drug product
	100 Vails is for each batch.
	Documents for the procurement of API with approval from DRAP (in case of Import)
	Attached.

Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and Comparative Dissolution is taken place Against Novidate 200mg/100ml by Sami Pharmaceuticals
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability submitted of zone iv A.
The status in reference regulatory authorities	Ciprofloxacin 2 mg/ml Solution for infusion. MHRA Approved.
GMP status of the firm	Attached.
Evidence of approval of manufacturing facility	Attached.
Evaluation Remarks	
Decision	
Deferred	
For submission of 06 months stability studies.	
77 Case Category	New Section (Abdul Mughees)
Name, address of Applicant.	ICU Pharmaceuticals (SMC-Private) Limited Khewat No. 13/13, Khatooni 57/66, Mouza Mirpur Kehna, Tehsil Sharakpur, District Sheikhpura, (000956)
Application Form Dy. No / Tracking ID & date of submission	(BMJ-VMR-63NG, 2025-07-23)
Detail of Fee Submitted	37000.0, 2025-07-02,
The proposed proprietary name / brand name	JELVO 500mg/100ml Infusion
Label Claim	Each 100ml contains: Levofloxacin hemihydrate eq. to Levofloxacin.....500mg (BP Specs.)
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	as per SRO-As per SRO
Shelf Life (Unit)	2 YearStore below 30°C and dry place.
For generic drugs (me-too Status)	Leflox 500MG/100ML Infusion BY Getz Pharmaceuticals.
Pharmacotherapeutic Group of (API)	Antibiotic
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Citi Pharma Ltd. 3 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan.
Detail of stability batches of drug product	100 Vails is for each batch.
Documents for the procurement of API with approval from DRAP (in case of Import)	Attached.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and Comparative Dissolution is taken place Against Leflox 500MG/100ML Infusion BY Getz Pharmaceuticals.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability submitted of zone iv A.
The status in reference regulatory authorities	evofloxacin 5mg/ml solution for infusion By Mercury Pharmaceuticals Limited Dashwood House, 69 Old Broad Street, London, EC2M 1QS, United Kingdom MHRA APPROVED
GMP status of the firm	Attached.
Evidence of approval of manufacturing facility	Attached.

Evaluation Remarks																																															
Decision																																															
Deferred																																															
For submission of 06 months stability studies.																																															
78	<table> <tr> <td>Case Category</td><td>New License (Abdul Mughees)</td></tr> <tr> <td>Name, address of Applicant.</td><td>Well Go Pharmaceuticals (Pvt) Ltd 5-km, Raiwind Manga Road Lahore (001004)</td></tr> <tr> <td>Application Form Dy. No / Tracking ID & date of submission</td><td>(JA1-GVX-5W4M, 2025-07-24)</td></tr> <tr> <td>Detail of Fee Submitted</td><td>37000.0, 2025-07-14,</td></tr> <tr> <td>The proposed proprietary name / brand name</td><td>WELL-DONE 7.5% Solution</td></tr> <tr> <td>Label Claim</td><td>Well-done 7.5% Solution Each 1ml Contains: - Povidone Iodine 75mg equivalent to 7.5mg Iodine. (USP Specification).</td></tr> <tr> <td>Reference to Finished product specifications</td><td>United States Pharmacopeia</td></tr> <tr> <td>Proposed Pack Size</td><td>as per SRO-As per SRO</td></tr> <tr> <td>Shelf Life (Unit)</td><td>2 Year(s)Store below 30°C and dry place.</td></tr> <tr> <td>For generic drugs (me-too Status)</td><td>C-Pyidine Scrub Care 7.5 by Cortex Pharmaceuticals Islamabad</td></tr> <tr> <td>Pharmacotherapeutic Group of (API)</td><td>Antiseptic</td></tr> <tr> <td>Name, address of Manufacturing site:</td><td>Self Manufacturing</td></tr> <tr> <td>Name & address of API manufacturer</td><td>Caliber Chemicals Pvt. Ltd. Plot No. 901/A, 901/B, 903, 905, 907, 1002, 1004, & 1006, GIDC Sarigam, Tal, Umbergaon, Sarigam, Valsad, Gujrat India</td></tr> <tr> <td>Detail of stability batches of drug product</td><td>100 bottles is for each batch.</td></tr> <tr> <td>Documents for the procurement of API with approval from DRAP (in case of Import)</td><td>Attached.</td></tr> <tr> <td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical Equivalence and Comparative Dissolution is taken place Against C-Pyidine Scrub Care 7.5 by Cortex Pharmaceuticals Islamabad</td></tr> <tr> <td>Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)</td><td>Stability submitted of zone iv A.</td></tr> <tr> <td>The status in reference regulatory authorities</td><td>Povidone-Iodine 0.75% w/w (MHRA Approved)</td></tr> <tr> <td>GMP status of the firm</td><td>Attached.</td></tr> <tr> <td>Evidence of approval of manufacturing facility</td><td>Attached.</td></tr> <tr> <td colspan="2">Evaluation Remarks</td></tr> <tr> <td colspan="2">Decision</td></tr> <tr> <td colspan="2">Approved</td></tr> </table>	Case Category	New License (Abdul Mughees)	Name, address of Applicant.	Well Go Pharmaceuticals (Pvt) Ltd 5-km, Raiwind Manga Road Lahore (001004)	Application Form Dy. No / Tracking ID & date of submission	(JA1-GVX-5W4M, 2025-07-24)	Detail of Fee Submitted	37000.0, 2025-07-14,	The proposed proprietary name / brand name	WELL-DONE 7.5% Solution	Label Claim	Well-done 7.5% Solution Each 1ml Contains: - Povidone Iodine 75mg equivalent to 7.5mg Iodine. (USP Specification).	Reference to Finished product specifications	United States Pharmacopeia	Proposed Pack Size	as per SRO-As per SRO	Shelf Life (Unit)	2 Year(s)Store below 30°C and dry place.	For generic drugs (me-too Status)	C-Pyidine Scrub Care 7.5 by Cortex Pharmaceuticals Islamabad	Pharmacotherapeutic Group of (API)	Antiseptic	Name, address of Manufacturing site:	Self Manufacturing	Name & address of API manufacturer	Caliber Chemicals Pvt. Ltd. Plot No. 901/A, 901/B, 903, 905, 907, 1002, 1004, & 1006, GIDC Sarigam, Tal, Umbergaon, Sarigam, Valsad, Gujrat India	Detail of stability batches of drug product	100 bottles is for each batch.	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached.	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and Comparative Dissolution is taken place Against C-Pyidine Scrub Care 7.5 by Cortex Pharmaceuticals Islamabad	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability submitted of zone iv A.	The status in reference regulatory authorities	Povidone-Iodine 0.75% w/w (MHRA Approved)	GMP status of the firm	Attached.	Evidence of approval of manufacturing facility	Attached.	Evaluation Remarks		Decision		Approved	
Case Category	New License (Abdul Mughees)																																														
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Pharmacotherapeutic Group of (API)	Antiseptic																																														
Name, address of Manufacturing site:	Self Manufacturing																																														
Name & address of API manufacturer	Caliber Chemicals Pvt. Ltd. Plot No. 901/A, 901/B, 903, 905, 907, 1002, 1004, & 1006, GIDC Sarigam, Tal, Umbergaon, Sarigam, Valsad, Gujrat India																																														
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Approved																																															
79	<table> <tr> <td>Case Category</td><td>New License (Abdul Mughees)</td></tr> <tr> <td>Name, address of Applicant.</td><td>Well Go Pharmaceuticals (Pvt) Ltd 5-km, Raiwind Manga Road Lahore (001004)</td></tr> <tr> <td>Application Form Dy. No / Tracking ID & date of submission</td><td>(UUY-46D-6P7H, 2025-07-24)</td></tr> </table>	Case Category	New License (Abdul Mughees)	Name, address of Applicant.	Well Go Pharmaceuticals (Pvt) Ltd 5-km, Raiwind Manga Road Lahore (001004)	Application Form Dy. No / Tracking ID & date of submission	(UUY-46D-6P7H, 2025-07-24)																																								
Case Category	New License (Abdul Mughees)																																														
Name, address of Applicant.	Well Go Pharmaceuticals (Pvt) Ltd 5-km, Raiwind Manga Road Lahore (001004)																																														
Application Form Dy. No / Tracking ID & date of submission	(UUY-46D-6P7H, 2025-07-24)																																														

	Detail of Fee Submitted	37000.0, 2025-07-14,
	The proposed proprietary name / brand name	Well-done 10% Solution
	Label Claim	Well-done 10% Solution Each 1ml Contains: - Povidone Iodine 100mg equivalent to 10mg Iodine (USP Specification).
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C and dry place.
	For generic drugs (me-too Status)	PYODINE 10% solution BY Brookes Pharma
	Pharmacotherapeutic Group of (API)	Antiseptic, germicidal
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Caliber Chemicals Pvt. Ltd. Plot No. 901/A, 901/B, 903, 905, 907, 1002, 1004, & 1006, GIDC Sarigam, Tal, Umbergaon, Sarigam, Valsad, Gujrat India
	Detail of stability batches of drug product	100 bottles is for each batch.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and Comparative Dissolution is taken place Against PYODINE 10% solution BY Brookes Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability submitted of zone iv A.
	The status in reference regulatory authorities	Povidone-Iodine 10% w/w (MHRA Approved)
	GMP status of the firm	Attached.
	Evidence of approval of manufacturing facility	Attached.
	Evaluation Remarks	
	Decision	
	Approved	
80	Case Category	Priority As Per 257-M of RB (Abdul Mughees)
	Name, address of Applicant.	REVIVE HEALTH CARE 503, 5TH FLOOR EDEN HEIGHTS 6 MAIN GULBERG JAIL ROAD (05-352-0065)
	Application Form Dy. No / Tracking ID & date of submission	(7WV-SZD-2TUN, 2025-09-04)
	Detail of Fee Submitted	313500.0, 2025-08-25,
	The proposed proprietary name / brand name	PACLIXA Injection 100 mg
	Label Claim	Each Vial Contains: Paclitaxel (Albumin Bound) 100 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's Vial-As per SRO
	Shelf Life (Unit)	24 Month(s)Store below 30 degree centigrade
	For generic drugs (me-too Status)	Registration No:114196, NAB Paclid 100mg Injection
	Pharmacotherapeutic Group of (API)	Antineoplastic agent, ATC Code: L01CD01
	Name, address of Manufacturing site:	Qilu Pharmaceutical (Hainan) Co., Ltd.-No.273-A, Nanhai Avenue, National High-Tech Zone, Haikou, Hainan, 570314, China-China

Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence study performed by Comparison of Innovator’s product (ABRAXANE, paclitaxel protein-bound particles for injectable suspension 100 mg) with QILU’s Paclitaxel (Albumin Bound) lyophilized powder for injection 100 mg
Name, address of Marketing Authorization Holder:	Qilu Pharmaceutical (Hainan) Co., Ltd., No.273-A, Nanhai Avenue, National High-Tech Zone, Haikou, Hainan, 570314, China, China
Details of Certificates (CoPP/FSC/cGMP):	Valid Eudra GMP Certificate No. ES/106HV/24
Details of Authorization Letter :	Imported product- Not applicable
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies performed on four commercial batches B# 902-1612411, 902-1701411, 902-1701401, 902-1701402 of paclitaxel on accelerated (6M) & long-term (36M) conditions. Stability data provided in 3.2.S.7.3
The status in reference regulatory authorities	ABRAXANE for Injectable Suspension 100mg (paclitaxel protein-bound particles for injectable suspension), USFDA Approved
Evaluation Remarks	
CoPP issued by Hainan Provincial medical Products China bearing certificate number 20250168 and GMP by Spanish Agency for medicines and medical devices.	
Decision	
Approved	
Case Category	New Section (Adil Saeed)
Name, address of Applicant.	Kaizen Pharmaceuticals (Pvt) Ltd Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi (000755)
Application Form Dy. No / Tracking ID & date of submission	(Y4A-5QD-JRQD, 2025-07-18)
Detail of Fee Submitted	37000.0, 2025-05-02,
The proposed proprietary name / brand name	Imanib 400mg Tablet
Label Claim	Each film coated tablet contains: Imatinib mesylate equivalent to imatinib..... 400mg
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	30's-As per SRO,60's-As per SRO,90's-As per SRO
Shelf Life (Unit)	2 Year(s)Store in a cool and dry place. Below 30°C
For generic drugs (me-too Status)	IM-Tab Tablet 400mg Manufactured by: Werrick Pharmaceuticals
Pharmacotherapeutic Group of (API)	L01EA01 Protein-tyrosine kinase inhibitor
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Anhui Haikang Pharmaceu- tical Co. Ltd. Address: No. 21 Huancheng West Road, Daguan District, Anqing, Anhui, 246000 China.
Detail of stability batches of drug product	3 batches, 500 tablets each.
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Gleevec 400mg Batch No. C145290 Mfg Novartis Pharma UK
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submttd.

	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	Inspection report dated 20.11.2024 is submitted
	Evidence of approval of manufacturing facility	Copy of section approval letter is submitted.
	Evaluation Remarks	
82	Decision	
	Approved	
	Case Category	New Section (Adil Saeed)
	Name, address of Applicant.	Kaizen Pharmaceuticals (Pvt) Ltd Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi (000755)
	Application Form Dy. No / Tracking ID & date of submission	(1LD-H8E-XADG, 2025-07-18)
	Detail of Fee Submitted	37000.0, 2025-05-02,
	The proposed proprietary name / brand name	Imanib 100mg Tablet
	Label Claim	Each film coated tablet contains: Imatinib mesylate equivalent to imatinib..... 100mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	30's-As per SRO,60's-As per SRO,90's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a cool and dry place. Below 30°C
	For generic drugs (me-too Status)	IM-Tab Tablet 100mg Manufactured by: Werrick Pharmaceuticals
	Pharmacotherapeutic Group of (API)	L01EA01 BCR-ABL tyrosine kinase inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Anhui Haikang Pharmaceu- tical Co. Ltd. Address: No. 21 Huancheng West Road, Daguang District, Anqing, Anhui, 246000 China.
	Detail of stability batches of drug product	3 batches, 500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate mentioning 1kg drug substance is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Gleevec 100mg Tablet B. No. S301411 Mfg M/s Novartis UK
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa up to 24 months.
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	Inspection report dated 20.11.2024 is submitted
	Evidence of approval of manufacturing facility	Section approval letter dated 10.05.2024 is submitted
	Evaluation Remarks	
	Decision	
	Approved	
83	Case Category	Priority As Per 257-M of RB (Adil Saeed)
	Name, address of Applicant.	Macter International Limited F-216 S.I.T.E. Karachi-Pakistan. (022)
	Application Form Dy. No / Tracking ID & date of submission	(E68-PSM-Z8SH, 2025-08-05)

Detail of Fee Submitted	300000.0, 2025-07-02,
The proposed proprietary name / brand name	TGO-1
Label Claim	Each hard capsule contains: Tegafur.....20 mg Gimeracil..... 5.8 mg Oteracil (as salt)..... 15.8 mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	42's-As per SRO
Shelf Life (Unit)	2 Year(s)Store below 30°C
For generic drugs (me-too Status)	Not Applicable since this is a new drug
Pharmacotherapeutic Group of (API)	Antineoplastic
Name, address of Manufacturing site:	Shandong New Time Pharmaceuticals Co., Ltd.-No.1 North Outer Ring Road, Feixian County, Shandong 273400, China.-China
Pharmaceutical Equivalence and Comparative Dissolution Profile	performed against product of M/s Taiho Pharmaceutical Co Ltd. batch No. 4H77
Name, address of Marketing Authorization Holder:	Macter International Limited , Plot No. F 217, F-217-A S.I.T.E. Karachi Pakistan., Pakistan
Details of Certificates (CoPP/FSC/cGMP):	It is mentioned on the COPP that facility and operations conform to GMP as recommended by the WHO
Details of Authorization Letter :	Copy of Licensing and Distribution agreement is submitted. As per agreement Macter is authorized for territory of Pakistan and Afghanistan by Shandong New times Pharma Co for sale of mentioned product.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
The status in reference regulatory authorities	Teysuno 20/5.8/15.8mg Capsules, Nordic Group, EMA Approved

Evaluation Remarks

Decision

Approved

As per policy for inspection abroad.

84	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	Allmed (Pvt.) Ltd Plot # 590 Sunder Industrial Estate Raiwind Road Lahore-Pakistan (000645)
	Application Form Dy. No / Tracking ID & date of submission	(4E5-7HZ-RUXD, 2024-03-19)
	Detail of Fee Submitted	30000.0, 2023-11-13,
	The proposed proprietary name / brand name	Thioran Tablet 50mg
	Label Claim	Each Film Coated Tablet Contains Azathioprine ----- 50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	120's-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Imuran Tablet 50mg Reg. # 010058
	Pharmacotherapeutic Group of (API)	L04AX01 Other immunosuppressants
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rakshit Pharmaceuticals Limited

Detail of stability batches of drug product	2 Batches, 5000 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate of 2Kg drug substance is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Imuran 50mg Tablet Lot No. A895315 Mfg Aspen South Africa.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
The status in reference regulatory authorities	Azathioprine Tablet 50mg by Generics [UK] Limited t/a Mylan
GMP status of the firm	GMP certificate issued o basis of inspection dated 11.06.2021 is submitted
Evidence of approval of manufacturing facility	Section approval letter dated 27.08.2008 is submitted

Evaluation Remarks

Decision

Approved

85	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	Neutro Pharma (Pvt.) Ltd., 9.5-Km, Sheikhpura Road, Lahore (000576)
	Application Form Dy. No / Tracking ID & date of submission	(THE-215-BZ84, 2024-03-18)
	Detail of Fee Submitted	30000.0, 2024-03-04,
	The proposed proprietary name / brand name	Neuzyl Cream 4%
	Label Claim	Each gram contains: Benzoyl peroxide.....40mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	40gm-As per SRO
	Shelf Life (Unit)	2 Year(s)Store between 15 - 30°C in a dry place, protect from light.
	For generic drugs (me-too Status)	Oxyzole 4%w/w Cream by Valor Pharma
	Pharmacotherapeutic Group of (API)	D10AE01 ANTI-ACNE PREPARATIONS FOR TOPICAL USE
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Name: Cambrex Karlskoga AB Address: SE-691 85 Karlskoga Sweden Telephone: +46 586783000
	Detail of stability batches of drug product	3 batches, 25 tubes each
	Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested invoice mentioning 350grams drug substance is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brevoxyl 4% cream B. No. BHG7V Mfg Stiefel Laboratories
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Brevoxyle 4% w/w Cream HPRA Ireland Approved
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 14.04.2022 is submitted
	Evidence of approval of manufacturing facility	Section approval is submitted

Evaluation Remarks

	Decision	
	Approved	
86	Case Category	New Section (Adil Saeed)
	Name, address of Applicant.	Kaizen Pharmaceuticals (Pvt) Ltd Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi (000755)
	Application Form Dy. No / Tracking ID & date of submission	(6TH-YB6-GRZT, 2025-07-18)
	Detail of Fee Submitted	37000.0, 2025-05-02,
	The proposed proprietary name / brand name	Nilonib 50mg Capsule
	Label Claim	Each capsule contains: Nilotinib Hydrochloride monohydrate eq. to Nilotinib ---- 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	120 Capsules-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a cool and dry place. Below 30°C
	For generic drugs (me-too Status)	Nilotinib Imported By: Novartis Pharma (Pakistan) Limited, Manufacturer: Novartis Pharma Stein AG,
	Pharmacotherapeutic Group of (API)	L01EA03 Kinase Inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	ANHUI HAIKANG PHARMACEUTICAL CO., LTD, Address NO.21 HUANCHENG WEST ROAD, ANQING CITY, ANHUI PROVINCE,246000 CHINA
	Detail of stability batches of drug product	3 batches, 400 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Tasigna 50mg Capsule Batch No. A30254 M/s Novartis Pharma Stein AG
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa Conditions, up to 36 months
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	Valid GMP certificate is submitted
	Evidence of approval of manufacturing facility	Section approval letter is submitted.
	Evaluation Remarks	
	Decision	
	Approved	
87	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	AsianContinental (Pvt.) Ltd. D-32, S.I.T.E II, Super Highway, Karachi (000643)
	Application Form Dy. No / Tracking ID & date of submission	(VQA-A18-NE1T, 2024-04-22)
	Detail of Fee Submitted	30000.0, 2024-03-19,
	The proposed proprietary name / brand name	Dapasian 5mg
	Label Claim	Each Film coated Tablet contains: Dapagliflozin Propanediol Monohydrate equivalent to Dapagliflozin.....5mg

Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	2 x 7 's-As per SRO
Shelf Life (Unit)	2 Year(s)Store below 30 °C
For generic drugs (me-too Status)	Daplyza 5mg Tablet (Getz Pharma Pvt. Ltd.)
Pharmacotherapeutic Group of (API)	A10BK01 Sodium-glucose co-transporter 2 (SGLT2) inhibitors
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Fuxin Long Rui Pharmaceutical. Co.,Ltd.
Detail of stability batches of drug product	3 batches 3000 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 (License to import) is submitted
Pharmaceutical Equivalence and Comparative Dissolution Profile	Forxiga 5mg Tablet B. No. RX644 M/s AstraZeneca
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
The status in reference regulatory authorities	Farxiga 5mg Tablet (AstraZeneca Pharm. LP Wilmington) US
GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 27.09.2022 is submitted
Evidence of approval of manufacturing facility	Section approval letter dated 22.06.2019 is submitted

Evaluation Remarks

Decision

Approved

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Case Category	Contract Manufacturing (Adil Saeed)
Name, address of Applicant.	Welwink Pharmaceuticals G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751)
Application Form Dy. No / Tracking ID & date of submission	(EYT-2QG-7R86, 2024-03-25)
Detail of Fee Submitted	75000.0, 2024-02-03,
The proposed proprietary name / brand name	FWH 2% + 1% Cream
Label Claim	Each gm Contains: Fusidic acid 20mg (2% w/w) Hydrocortisone Acetate.....10mg (1%w/w) (Product complies Innovators Specs)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 Year(s)store below 25°c
For generic drugs (me-too Status)	Fosic-H Cream by Metro Pharmaceuticals
Pharmacotherapeutic Group of (API)	Hydrocortisone and antibiotics, ATC code: D 07 CA 01
Name, address of Manufacturing site:	Winbrains Research Laboratories-Plot No.69/1 Block B, Phase I-II, Industrial Estate, Hattar Pakistan-
Name & address of API manufacturer	HENAN LINHUA PHARMACEUTICAL CO., LTD. MIDDLE OF HUANGHE STREET, ANYANG HI-TECH, INDUSTRY DEVELOPMENT ZONE, CHINA,NORTH CHINA PHARMACEUTICAL HUASHENG CO., LTD. NO. 8, YANGZI ROAD, SHIJIAZHUANG ECONOMIC & TECHNOLOGICAL DEVELOPMENT ZONE, CHINA.

Detail of stability batches of drug product	3 batches, 200 tubes each
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted AD attested invoice.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Fusiderm H 2%+1% Cream Batch No. FI041 Mfg: Seatl Limited Lahore
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
The status in reference regulatory authorities	UK MHRA APPROVED
GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 28.07.2022 is submitted
Evidence of approval of manufacturing facility	Section approval letter dated 11.04.2017 is submitted

Evaluation Remarks

Decision

Approved

89	Case Category	Priority As Per 257-M of RB (Adil Saeed)
	Name, address of Applicant.	HIMMEL PHARMACEUTICALS (PVT.) LTD Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Zazaria e Pakistan Lahore (05-352-0065)
	Application Form Dy. No / Tracking ID & date of submission	(T91-3QB-X41M, 2025-03-23)
	Detail of Fee Submitted	300000.0, 2024-12-30,
	The proposed proprietary name / brand name	Eribulin AqVida 0.44mg/ml Solution for Injection
	Label Claim	Each 2ml vial contains. Eribulin Mesilate equivalent to Eribulin.....0.88mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C.
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	L01XX41 Other antineoplastic agents
	Name, address of Manufacturing site:	AqVida GmbH -Werkstr.21 23942 Dassow-Germany
	Name & address of API manufacturer	Wisdom Pharmaceuticals Co., Ltd
	Detail of stability batches of drug product	Zone IVb 24 months, 6 bacthes, 0.88mg/2ml vials, batch size 5 to 10 litre
	Documents for the procurement of API with approval from DRAP (in case of Import)	Letter of authorization for Eribulin 0.44mg/ml Solution for injection is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Halaven 0.44mg/ml Solution for injection 2ml and 3 ml vial.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Long term -20C 36 months, Accelerated 5C 6 months.
	The status in reference regulatory authorities	Halaven 0.44mg/ml Solution for Injection (Eribulin Mesylate), Germany
	GMP status of the firm	Copy of COPP issued by Pharmaziewesen und Medizinprodukte Hamburg Germany is submitted. As per COPP product is being marketed in Germany and manufacturing facility is inspected every 3 years.
	Evidence of approval of manufacturing facility	Copy of COPP and GMP certificate is provided.

Evaluation Remarks		
Decision		
Approved		
As per policy for inspection abroad.		
90	Case Category	Priority As Per 257-M of RB (Adil Saeed)
	Name, address of Applicant.	ATCO LIFE SCIENCES (PRIVATE) LIMITED B-18 S.I.T.E. Karachi (051)
	Application Form Dy. No / Tracking ID & date of submission	(Z8L-6P3-SA9N, 2025-08-21)
	Detail of Fee Submitted	300000.0, 2025-07-07,
	The proposed proprietary name / brand name	ABECLIB 200mg Tablet
	Label Claim	Each film coated tablet contains: Abemaciclib 200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2 x 7's-De-Controlled
	Shelf Life (Unit)	24 Year(s) Do not store & transport above 30oC. Protect from light, heat & moisture. Keep out of the reach of children. To be sold on the prescription of a registered medical practitioner only.
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	L01EF03 Cyclin-dependent kinase (CDK) inhibitors
	Name, address of Manufacturing site:	Eskayef Pharmaceuticals Limited-Murapara, Rupganj, Narayanganj 1464, Bangladesh.-Bangladesh
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Verzenios 200mg Mfg Eli Lilly (Suisse) B No. D658410A
	Name, address of Marketing Authorization Holder:	Eskayef Pharmaceuticals Limited, Murapara, Rupganj, Narayanganj 1464, Bangladesh., Bangladesh
	Details of Certificates (CoPP/FSC/cGMP):	Copy of GMP certificate issued by DG of Drug Administration Bangladesh valid till 05.03.2027 is submitted. Copy of COPP is also submitted
	Details of Authorization Letter :	Copy of letter of Authorization is submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted. As per Zone IVa conditions.
	The status in reference regulatory authorities	Abemaciclib 200 Film Coated Tablets manufactured by Eli Lilly and Company Limited, UK.
	Evaluation Remarks	
	Decision	
	Approved	
	As per policy for inspection abroad.	
91	Case Category	Priority As Per 257-M of RB (Adil Saeed)
	Name, address of Applicant.	ATCO LIFE SCIENCES (PRIVATE) LIMITED B-18 S.I.T.E. Karachi (051)
	Application Form Dy. No / Tracking ID & date of submission	(DXG-NP8-46TE, 2025-08-21)

Detail of Fee Submitted	300000.0, 2025-06-05,
The proposed proprietary name / brand name	ABECLIB Tablet 150mg
Label Claim	Each film coated tablet contains: Abemaciclib..... 150 mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	30's-De-Controlled
Shelf Life (Unit)	2 Year(s)Don't store & transport above 30degree centigrade
For generic drugs (me-too Status)	Yulareb tablet by Eli Lilly and Company Limited
Pharmacotherapeutic Group of (API)	L01EF03 Cyclin-dependent kinase (CDK) inhibitors
Name, address of Manufacturing site:	Eskayef Pharmaceuticals Limited-Rupganj Plant: Murapara, Rupganj, Narayanganj 1464, Bangladesh- Bangladesh
Pharmaceutical Equivalence and Comparative Dissolution Profile	Ramiven 150mg Mfg Lilly S.A Avenida Spain B No. D823210
Name, address of Marketing Authorization Holder:	Atco Life Sciences (Private) Limited, B-18, S.I.T.E., Karachi , Pakistan
Details of Certificates (CoPP/FSC/cGMP):	Copy of GMP certificate issued by DG of Drug Administration Bangladesh valid till 05.03.2027 is submitted. Copy of COPP is also submitted
Details of Authorization Letter :	Copy of letter of Authorization is submitted
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted. As per Zone IVa conditions.
The status in reference regulatory authorities	Abemaciclib 150 Film Coated Tablets by Eli Lilly and Company Limited
Evaluation Remarks	
Decision	
Approved	
As per policy for inspection abroad	
92	
Case Category	Export Facilitation (Adil Saeed)
Name, address of Applicant.	CCL Pharmaceuticals (Pvt.) Ltd. 62-Quaid-e-Azam Industrial Estate, Kot Lakhpat (000052)
Application Form Dy. No / Tracking ID & date of submission	(W17-J29-T3AQ, 2024-10-09)
Detail of Fee Submitted	75000.0, 2024-07-24,
The proposed proprietary name / brand name	Imemin 500mg Tablets
Label Claim	Each film coated contains Imeglimin hydrochloride..... 500mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	10's-De-Controlled,100's-De-Controlled,14's-De- Controlled,20's-De-Controlled,28's-De-Controlled,30's- De-Controlled,5's-De-Controlled,50's-De-Controlled,7's- De-Controlled
Shelf Life (Unit)	2 Year(s)Not more than 30C
For generic drugs (me-too Status)	Not available

Pharmacotherapeutic Group of (API)	A10BX15 Other blood glucose lowering drugs, excl. insulins
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Ami Lifesciences Private Limited. Address: Block No. 82/B, ECP Road, At & post Karakhadi, Taluka: Padra, District: Vadodara, Gujarat,
Detail of stability batches of drug product	3 batches, 1000 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	TWYMEEG 500mg Tablet B. No. 1587C Mfg: Sumitomo Pharma Japan
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted.
The status in reference regulatory authorities	TWYMEEG - Sumitomo Dainippon Pharma Co., Ltd. (PMDA, JAPAN.)
GMP status of the firm	GMP certificate issued on basis of inspection dated 21.03.2023 is submitted.
Evidence of approval of manufacturing facility	Copy of renewal letter dated 08.06.2021 is submitted
Evaluation Remarks	
Decision	
Approved	
Case Category	Export Facilitation (Adil Saeed)
Name, address of Applicant.	CCL Pharmaceuticals (Pvt.) Ltd. 62-Quaid-e-Azam Industrial Estate, Kot Lakhpat (000052)
Application Form Dy. No / Tracking ID & date of submission	(JZA-L73-XTA1, 2024-11-14)
Detail of Fee Submitted	75000.0, 2024-10-03,
The proposed proprietary name / brand name	Sodif 200mg Tablets
Label Claim	Each film coated tablet contains Sotagliflozin..... 200mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	10's-De-Controlled,100's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled,40's-De-Controlled,5's-De-Controlled,50's-De-Controlled,7's-De-Controlled
Shelf Life (Unit)	2 Year(s)Do not store more than 30C
For generic drugs (me-too Status)	Not available
Pharmacotherapeutic Group of (API)	A10BK06 Sodium-glucose co-transporter 2 (SGLT2) inhibitors
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Fuxin Long Rui Pharmaceutical CO., Ltd Fluoride Industrial Park, Fumeng County (YiMaTu), Fuxin City, Liaoning Province, China
Detail of stability batches of drug product	3 batches, 1000 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate of 4.5kg Drug substance is submitted.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Infepa 200mg Tablet B. No. CPMBF Mfg Lexicon
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Impefa - USFDA Approved
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 21.03.2023 is submitted
	Evidence of approval of manufacturing facility	Renewal letter dated 08.06.2021 is submitted
	Evaluation Remarks	
	Decision	
	Approved	
94	Case Category	Export Facilitation (Adil Saeed)
	Name, address of Applicant.	CCL Pharmaceuticals (Pvt.) Ltd. 62-Quaid-e-Azam Industrial Estate, Kot Lakhpat (000052)
	Application Form Dy. No / Tracking ID & date of submission	(DX4-Z8S-2YN6, 2024-11-14)
	Detail of Fee Submitted	75000.0, 2024-10-03,
	The proposed proprietary name / brand name	Sodif 400mg Tablets
	Label Claim	Each film coated tablet contains Sotagliflozin..... 400mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,100's-De-Controlled,14's-De-Controlled,20's-De-Controlled,21's-De-Controlled,28's-De-Controlled,30's-De-Controlled,5's-De-Controlled,50's-De-Controlled,7's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Do not store more than 30C
	For generic drugs (me-too Status)	Not available
	Pharmacotherapeutic Group of (API)	A10BK06 Sodium-glucose co-transporter 2 (SGLT2) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Fuxin Long Rui Pharmaceutical CO., Ltd Fluoride Industrial Park, Fumeng County (YiMaTu), Fuxin City, Liaoning Province, China
	Detail of stability batches of drug product	3 batches, 1000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate of 4.5kg Drug substance is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Infepa 400mg Tablet B. No. CPXXH Mfg Lexicon
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Impefa - USFDA Approved
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 21.03.2023 is submitted
	Evidence of approval of manufacturing facility	Renewal letter dated 08.06.2021 is submitted
	Evaluation Remarks	
	Decision	

	Approved	
95	Case Category	Export Facilitation (Adil Saeed)
	Name, address of Applicant.	High-Q Pharmaceuticals Plot# 224 and 225/1, sector 23, Korangi Industrial area, Karachi (000597)
	Application Form Dy. No / Tracking ID & date of submission	(QT8-EU1-6588, 2024-05-22)
	Detail of Fee Submitted	30000.0, 9400.0 2024-05-08, 2025-08-21
	The proposed proprietary name / brand name	Racidro 30mg sachet
	Label Claim	Each sachet contains: Racecadotril 30mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled, 16's-De-Controlled
	Shelf Life (Unit)	2 Year(s) Store below 30°C
	For generic drugs (me-too Status)	Hidrasec 30mg Sachet (MAH import - Abbott Laboratories Pakistan Ltd)
	Pharmacotherapeutic Group of (API)	A07XA04 Other antidiarrheals
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s SYMED LABS LIMITED PLOT NO. 25/B, PHASE-I II, IDA, JEEDIMETLA, HYDERABAD, JEEDIMETLA (VILLAGE), QUTHBULLAPUR (MANDAL), MEDCHAL - MALKAJGIRI (DIST.), TELANGANA, INDIA
	Detail of stability batches of drug product	3 batches, 333 sachet each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 (License to import drugs) is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Hidrasec 20mg Sachet Batch No. SXE2758 Mfg: Abbott
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	upto 60 months, Zone IVb conditions.
	The status in reference regulatory authorities	HIDRASEC 30mg Sachet (Manufactured by Laboratories Sophartex by France and MAH is Bioproject Europe Ltd) MHRA approved
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 17.05.2023 is submitted.
	Evidence of approval of manufacturing facility	Copy of renewal letter dated 17.09.2021 wherein Sachet general section is mentioned.
96	Evaluation Remarks	
	Decision	
	Approved	
	Case Category	Export Facilitation (Adil Saeed)
	Name, address of Applicant.	High-Q Pharmaceuticals Plot# 224 and 225/1, sector 23, Korangi Industrial area, Karachi (000597)
	Application Form Dy. No / Tracking ID & date of submission	(NYE-9PW-RDW3, 2024-05-22)
	Detail of Fee Submitted	30000.0, 9400.0 2024-05-08, 2025-08-21
	The proposed proprietary name / brand name	Racidro 10mg Sachet

Label Claim	Each sachet contains: Racecadotril 10mg
Reference to Finished product specifications	Manufacturer Specification
Proposed Pack Size	10's-De-Controlled,16's-De-Controlled
Shelf Life (Unit)	2 Year(s)Store below 30°C
For generic drugs (me-too Status)	Hidrasec 10mg Sachet (MAH import - Abbott Laboratories Pakistan Ltd)
Pharmacotherapeutic Group of (API)	A07XA04 Other antidiarrheals
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	M/s SYMED LABS LIMITED PLOT NO. 25/B, PHASE-I II, IDA, JEEDIMETLA, HYDERABAD,JEEDIMETLA(VILLAGE), QUTHBULLAPUR(MANDAL), MEDCHAL - MALKAJGIRI(DIST.),TELANGANA,INDIA
Detail of stability batches of drug product	3 batches, 333 sachet each.
Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 (License to import drugs) is submitted
Pharmaceutical Equivalence and Comparative Dissolution Profile	Hidrasec 20mg Sachet Batch No. SXE2758 Mfg: Abbott
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	upto 60 months, Zone IVb conditions.
The status in reference regulatory authorities	HIDRASEC 10mg Sachet (Manufactured by Laboratories Sophartex by France and MAH is Bioproject Europe Ltd) MHRA approved
GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 17.05.2023 is submitted.
Evidence of approval of manufacturing facility	Copy of renewal letter dated 17.09.2021 wherein Sachet general section is mentioned.

Evaluation Remarks

Decision

Approved

97	Case Category	Export Facilitation (Adil Saeed)
	Name, address of Applicant.	High-Q Pharmaceuticals Plot# 224 and 225/1, sector 23, Korangi Industrial area, Karachi (000597)
	Application Form Dy. No / Tracking ID & date of submission	(R29-MPU-AU8H, 2024-05-15)
	Detail of Fee Submitted	30000.0, 9400.0 2024-05-08, 2025-08-21
	The proposed proprietary name / brand name	Racidro 100mg capsule
	Label Claim	Each capsule contains: Racecadotril 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-De-Controlled,10's-De-Controlled,14's-De-Controlled,16's-De-Controlled,20's-De-Controlled,21's-De-Controlled,30's-De-Controlled,9's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Hidrasec 100mg Capsule (MAH import - Abbott Laboratories Pakistan Ltd)
	Pharmacotherapeutic Group of (API)	A07XA04 Other antidiarrheals
	Name, address of Manufacturing site:	Self Manufacturing

Name & address of API manufacturer	M/s SYMED LABS LIMITED PLOT NO. 25/B, PHASE-I II, IDA, JEEDIMETLA, HYDERABAD,JEEDIMETLA(VILLAGE), QUTHBULLAPUR(MANDAL), MEDCHAL - MALKAJGIRI(DIST.),TELANGANA,INDIA
Detail of stability batches of drug product	3 batches, 4000 capsules each
Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Hidrasec 100mg capsule Batch No. SX600A Mfg M/s Abbott
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
The status in reference regulatory authorities	HIDRASEC 100mg CAPSULE (Manufactured by Laboratories Sophartex by France and MAH is Bioproject Europe Ltd) MHRA approved
GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 17.05.2023 is submitted
Evidence of approval of manufacturing facility	Renewal letter dated 17.09.2021 is submitted wherein capsule general section is mentioned.
Evaluation Remarks	
Decision	
Approved	
Case Category	Priority As Per 257-M of RB (Adil Saeed)
Name, address of Applicant.	Amgomed Office No.5, First Floor, Rose-1 Plaza, I-8 Markaz (DHO-ISB-188)
Application Form Dy. No / Tracking ID & date of submission	(ZU8-T4U-9XSY, 2025-06-17)
Detail of Fee Submitted	300000.0, 2025-04-10,
The proposed proprietary name / brand name	Axinib 5 mg film-coated tablets
Label Claim	Each Film-coated Tablet contains Axitinib..... 5 mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	56 Tablets-De-Controlled,60 Tablets-De-Controlled
Shelf Life (Unit)	36 Month(s)30 degree
For generic drugs (me-too Status)	Axinix film coated tablets M/s Himmel Pharma
Pharmacotherapeutic Group of (API)	Tyrosine Kinase Inhibitor
Name, address of Manufacturing site:	Synthon Hispania S.L.-Caste 1161 Polgono Las Salinas 088830 Sant Boi de Llobregat, Spain-Spain
Pharmaceutical Equivalence and Comparative Dissolution Profile	Bioequivalence studies of 7mg (highest) strength were performed and CDP of lower strengths was performed against 7mg strengths.
Name, address of Marketing Authorization Holder:	Synthon B.V., Microweg 22 6545 CM Nijmegen The Netherlands, Netherlands
Details of Certificates (CoPP/FSC/cGMP):	EUDRA GMP Copy of COPP No. 2205 issued by Ministry of Health Welfare and Support Netherlands is submitted
Details of Authorization Letter :	Letter of Authorization is submitted

Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached, studies conducted at 25C / 60 % RH
The status in reference regulatory authorities	EMA, USFDA

Evaluation Remarks

The firm has not submitted CDP with any reference product. Bioequivalence study (Phase 1) is performed against Inlyta 7mg tablet, of 7mg strength (Highest strength). CDP of lower strengths is performed against 7mg strength at 4 different pH.

The firm has not submitted CDP with any reference product. Bioequivalence study (Phase 1) is performed against Inlyta 7mg tablet, of 7mg strength (Highest strength). CDP of lower strengths is performed against 7mg strength at 4 different pH.

The USFDA Guidance document "Dissolution Testing of immediate Release Solid Oral Dosage Forms" in Section VII states that For multiple strengths of IR products with linear kinetics, the bioequivalence study may be performed at the highest strength and waivers of in vivo studies may be granted on lower strengths, based on an adequate dissolution test, provided the lower strengths are proportionately similar in composition (21 CFR 320.22(d)(2)). Similar may also be interpreted to mean that the different strengths of the products are within the scope of changes permitted under the category "Components and Composition," discussed in the SUPAC-IR guidance. In all cases, the approval of additional strengths is based on dissolution profile comparisons between these additional strengths and the strength of the batch used in the pivotal bioequivalence study.

Firm has quoted above USFDA guidance document and EMA GUIDELINE ON THE INVESTIGATION OF BIOEQUIVALENCE and have requested to consider their application in light of these international guidelines.

Decision

Approved

As per policy for inspection abroad,

99

Case Category	Priority As Per 257-M of RB (Adil Saeed)
Name, address of Applicant.	Amgomed Office No.5, First Floor, Rose-1 Plaza, I-8 Markaz (DHO-ISB-188)
Application Form Dy. No / Tracking ID & date of submission	(93H-MAB-84RX, 2025-06-17)
Detail of Fee Submitted	300000.0, 2025-04-10,
The proposed proprietary name / brand name	Axinib 1 mg film-coated tablets
Label Claim	Each film-coated tablet contains Axitinib..... 1 mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	56 Tablets-De-Controlled, 60 Tablets-De-Controlled
Shelf Life (Unit)	36 Month(s) 30 degree
For generic drugs (me-too Status)	Axinix film coated tablets M/s Himmel Pharma
Pharmacotherapeutic Group of (API)	Vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitors L01EK01
Name, address of Manufacturing site:	Synthon Hispania S.L.-Caste 1161 Polgono Las Salinas 088830 Sant Boi de Llobregat, Spain-Spain
Pharmaceutical Equivalence and Comparative Dissolution Profile	Bioequivalence studies of 7mg (highest) strength were performed and CDP of lower strengths was performed against 7mg strengths.
Name, address of Marketing Authorization Holder:	Synthon B.V, Microweg 22 6545 CM Nijmegen The Netherlands, Netherlands
Details of Certificates (CoPP/FSC/cGMP):	EUDRA GMP Copy of COPP No. 2204 issued by Ministry of Health Welfare and Support Netherlands is submitted
Details of Authorization Letter :	Letter of Authorization is submitted

Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached, studies conducted at 25C / 60 % RH
The status in reference regulatory authorities	EMA, USFDA

Evaluation Remarks

The firm has not submitted CDP with any reference product. Bioequivalence study (Phase 1) is performed against Inlyta 7mg tablet, of 7mg strength (Highest strength). CDP of lower strengths is performed against 7mg strength at 4 different pH.

The firm has not submitted CDP with any reference product. Bioequivalence study (Phase 1) is performed against Inlyta 7mg tablet, of 7mg strength (Highest strength). CDP of lower strengths is performed against 7mg strength at 4 different pH.

The USFDA Guidance document "Dissolution Testing of immediate Release Solid Oral Dosage Forms" in Section VII states that For multiple strengths of IR products with linear kinetics, the bioequivalence study may be performed at the highest strength and waivers of in vivo studies may be granted on lower strengths, based on an adequate dissolution test, provided the lower strengths are proportionately similar in composition (21 CFR 320.22(d)(2)). Similar may also be interpreted to mean that the different strengths of the products are within the scope of changes permitted under the category "Components and Composition," discussed in the SUPAC-IR guidance. In all cases, the approval of additional strengths is based on dissolution profile comparisons between these additional strengths and the strength of the batch used in the pivotal bioequivalence study.

Firm has quoted above USFDA guidance document and EMA GUIDELINE ON THE INVESTIGATION OF BIOEQUIVALENCE and have requested to consider their application in light of these international guidelines.

Decision

Approved

As per policy for inspection abroad.

100	Case Category	Contract Manufacturing (Adil Saeed)
	Name, address of Applicant.	Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (000644)
	Application Form Dy. No / Tracking ID & date of submission	(AZB-6AS-GXBR, 2024-04-30)
	Detail of Fee Submitted	75000.0, 2024-01-10,
	The proposed proprietary name / brand name	FWH Cream
	Label Claim	Each gm Contains: Fusidic acid (BP).....20mg (2% w/w) Hydrocortisone Acetate (USP).....10mg (1%w/w) (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°C
	For generic drugs (me-too Status)	Fosic-H Cream by Metro Pharma
	Pharmacotherapeutic Group of (API)	Hydrocortisone and antibiotics, ATC code: D 07 CA 01
	Name, address of Manufacturing site:	Winbrains Research Laboratories-Plot No. 69/1, Phase I-II, Industrial Estate, hattar, KPK-
	Name & address of API manufacturer	HENAN LINHUA PHARMACEUTICAL CO., LTD. MIDDLE OF HUANGHE STREET, ANYANG HI-TECH, INDUSTRY DEVELOPMENT ZONE, CHINA,NORTH CHINA PHARMACEUTICAL HUASHENG CO., LTD. NO. 8, YANGZI ROAD, SHIJIAZHUANG ECONOMIC & TECHNOLOGICAL DEVELOPMENT ZONE, CHINA.
	Detail of stability batches of drug product	3 batches, 200 tubes each
	Documents for the procurement of API with approval from DRAP	AD attested invoice mentioning 5kg and 1kg drug substance is submitted respectively.

	(in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Fusiderm H 2%+1% Cream Batch No. FI041 Mfg: Seattle Limited Lahore
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 28.07.2022 is submitted
	Evidence of approval of manufacturing facility	Section approval letter dated 11.04.2017 is submitted
	Evaluation Remarks	
	Decision	
	Approved	
101	Case Category	New License (Adil Saeed)
	Name, address of Applicant.	Oncogen Pharma (Pvt) Limited WH-26 & 27-A3 , Korangi Creek Industrial Park (KCIP) (000960)
	Application Form Dy. No / Tracking ID & date of submission	(J3L-4TA-W7V4, 2025-07-24)
	Detail of Fee Submitted	37000.0, 2025-06-03,
	The proposed proprietary name / brand name	Lenvagen Capsule 4mg
	Label Claim	Each capsule contains: Lenvatinib Mesylate equivalent to Lenvatinib..... 4mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's & 30's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Do not store above 30°C. Protect from sunlight and moisture.
	For generic drugs (me-too Status)	Lenvima Capsule 4mg
	Pharmacotherapeutic Group of (API)	L01EX08 Antineoplastic agents, protein kinase inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Loncom Pharma No 127, Qizhong Avenue, Yanbei Sub-district, Qihe County, Dezhou City, Shandong Province, 251100 Chinaceutical Co., Ltd.
	Detail of stability batches of drug product	Stability study of 03 batches i.e 011NS07-4, 011NS08-4 & 011NS09-4 2572 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	clearance certificate is attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Lenvatinib Capsule 4mg is equivalent to the reference product Lenvanix Capsule 4mg
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	stability studies of 36 months is enclosed in module 3
	The status in reference regulatory authorities	US-FDA Approved
	GMP status of the firm	Last GMP Inspection was carried on 07th december 2023
	Evidence of approval of manufacturing facility	Capsule (Oncology) approved on 04th July 2022
	Evaluation Remarks	
	The firm has used EGC (Gelatin) capsule shell whereas innovator product uses Hypromellose capsule shells. The firm was asked about this difference and in response they have submitted compatibility studies between Lenvatinib Mesylate and EGC shells. The results of compatibility studies have shown that EGC shells doesn't have any negative effect on product quality.	

	Decision	
	Approved	
102	Case Category	New License (Adil Saeed)
	Name, address of Applicant.	Oncogen Pharma (Pvt) Limited WH-26 & 27-A3 , Korangi Creek Industrial Park (KCIP) (000960)
	Application Form Dy. No / Tracking ID & date of submission	(8WM-Z6W-YG2W, 2025-07-24)
	Detail of Fee Submitted	37000.0, 2025-06-03,
	The proposed proprietary name / brand name	Lenvagen Capsule 10mg
	Label Claim	Each capsule contains: Lenvatinib Mesylate equivalent to Lenvatinib..... 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's & 30's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Do not store above 30°C. Protect from sunlight and moisture.
	For generic drugs (me-too Status)	Lenvima Capsule 10mg
	Pharmacotherapeutic Group of (API)	L01EX08 Antineoplastic agents, protein kinase inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Loncom Pharma No 127, Qizhong Avenue, Yanbei Sub-district, Qihe County, Dezhou City, Shandong Province, 251100 Chinaceutical Co., Ltd.
	Detail of stability batches of drug product	3 batches, 2400 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 and clearance certificate is attached in module 3
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Lenvanix Capsule 10mg Batch No. 24050190 M/s Beacon Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	US-FDA Approved
	GMP status of the firm	Last GMP Inspection was carried on 07th december 2023
	Evidence of approval of manufacturing facility	Capsule (Oncology) approved on 04th July 2022
	Evaluation Remarks	
	The firm has used EGC (Gelatin) capsule shell whereas innovator product uses Hypromellose capsule shells. The firm was asked about this difference and in response they have submitted compatibility studies between Lenvatinib Mesylate and EGC shells. The results of compatibility studies have shown that EGC shells doesn't have any negative effect on product quality.	
	Decision	
	Approved	
103	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (000790)
	Application Form Dy. No / Tracking ID & date of submission	(QRZ-3BQ-96T6, 2024-03-05)
	Detail of Fee Submitted	30000.0, 2023-03-30,
	The proposed proprietary name / brand name	DAMET 5/1000mg TABLET

Label Claim	Each Film Coated Tablet Contains: Metformin Hydrochloride 1000mg Dapagliflozin as Propanediol Monohydrate.....5mg (Product complies Innovator's Specs)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As Per SRO-As per SRO
Shelf Life (Unit)	2 Year(s)20-25C
For generic drugs (me-too Status)	DAPLYZA TABLET 5/1000mg by Getz Pharma
Pharmacotherapeutic Group of (API)	A10BD15 Combinations of oral blood glucose lowering drugs
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	AARTI DRUGS LTD Mahendra Industrial Estate Plot No. – 109 – D Road No.29, Sion (East), Mumbai – 400 022. INDIA,M/s. Precise Biopharma Pvt Ltd, , E-311 & E-312, 3rd Fir, Eastern Business District, Neptune Mall, L.B.S Road, Bhandup (W), Mumbai - 400078, India(India
Detail of stability batches of drug product	3 batches, 1200 tabs each.
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate mentioning 500kg metformin is submitted Dapagliflozin: Clearance certificate mentioning 2kg drug substance is submitted. Taken loan from M/s Welmark
Pharmaceutical Equivalence and Comparative Dissolution Profile	DAPA-Met 5mg+1000mg Batch No. 148949 Mfg: M/s Hilton
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
The status in reference regulatory authorities	MHRA Approved
GMP status of the firm	Copy of GMP certificate is submitted
Evidence of approval of manufacturing facility	Section approval letter dated 20.02.2014 is submitted for
Evaluation Remarks	
Decision	
Approved	
104	Case Category
	Routine (Adil Saeed)
	Name, address of Applicant.
	Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (000790)
	Application Form Dy. No / Tracking ID & date of submission
	(9R8-HSX-HHM6, 2024-03-26)
	Detail of Fee Submitted
	30000.0, 2023-03-30,
	The proposed proprietary name / brand name
	DAMET 5/850mg TABLET
Label Claim	Each Film Coated Tablet Contains: Metformin Hydrochloride 850mg Dapagliflozin as Propanediol Monohydrate.....5mg (Product complies Innovator's Specs)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As Per SRO-As per SRO
Shelf Life (Unit)	2 Year(s)20-25C
For generic drugs (me-too Status)	DAPLYZA TABLET 5/850mg by Getz Pharma

	Pharmacotherapeutic Group of (API)	A10BD15 Combinations of oral blood glucose lowering drugs
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	AARTI DRUGS LTD Mahendra Industrial Estate Plot No. – 109 – D Road No.29, Sion (East), Mumbai – 400 022. INDIA,M/s. Precise Biopharma Pvt Ltd, , E-311 & E-312, 3rd Flr, Eastern Business District, Neptune Mall, L.B.S Road, Bhandup (W), Mumbai - 400078, India(India
	Detail of stability batches of drug product	3 batches, 1200 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificates of both metformin and Dapagliflozin are submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Dapa-Met 5/850mg Batch No. 150340 Mfg: M/s Hilton
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	MHRA Approved
	GMP status of the firm	GMP certificate is submitted
	Evidence of approval of manufacturing facility	Section approval letter dated 20.02.2014 is submitted.
	Evaluation Remarks	
	Decision	
	Approved	
105	Case Category	New Section (Adil Saeed)
	Name, address of Applicant.	Kaizen Pharmaceuticals (Pvt) Ltd Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi (000755)
	Application Form Dy. No / Tracking ID & date of submission	(H7G-SYB-ZMTP, 2025-07-18)
	Detail of Fee Submitted	37000.0, 2025-05-02,
	The proposed proprietary name / brand name	Lenvanib (Lenvatinib Mesylate) 10mg Capsule
	Label Claim	Each capsule contains: Lenvatinib Mesylate 12.25mg eq. to Lenvatinib.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,20's-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30°C in a cool and dry place
	For generic drugs (me-too Status)	Lenvanix 10mg capsule
	Pharmacotherapeutic Group of (API)	Receptor tyrosine kinase (RTK) inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Kaifeng Pharmaceutical (Group) Company Limited/ Address.No.1, Yunan Street, Kaifeng,Henan Province, China
	Detail of stability batches of drug product	3 batches, 1500 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is submitted. FedEx Delivery note is also attached.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Lenvima 10mg Capsule B. No. S25240 Mfg. Patheon

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	FOOD & DRUG ADMINISTRATION (FDA)
	GMP status of the firm	New Section
	Evidence of approval of manufacturing facility	Section approval letter dated 10.05.2024 is submitted
	Evaluation Remarks	
	The firm has used EGC (Gelatin) capsule shell whereas innovator product uses Hypromellose capsule shells. The firm was asked about this difference and in response they have submitted compatibility studies between Lenvatinib Mesylate and EGC shells. The results of compatibility studies have shown that EGC shells doesn't have any negative effect on product quality.	
	Decision	
	Approved	
106	Case Category	New Section (Adil Saeed)
	Name, address of Applicant.	Kaizen Pharmaceuticals (Pvt) Ltd Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi (000755)
	Application Form Dy. No / Tracking ID & date of submission	(SHA-VD7-TBJY, 2025-07-18)
	Detail of Fee Submitted	37000.0, 2025-05-02,
	The proposed proprietary name / brand name	Lenvanib (Lenvatinib) 4mg Capsule
	Label Claim	Each capsule contains: Lenvatinib Mesylate 4.9mg eq. to Lenvatinib.....4mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,20's-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30°C in a cool and dry place
	For generic drugs (me-too Status)	Lenvanix 4mg capsule
	Pharmacotherapeutic Group of (API)	Receptor tyrosine kinase (RTK) inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Kaifeng Pharmaceutical (Group) Company Limited. Address: No.1, Yunan Street, Kaifeng, Henan Province, China
	Detail of stability batches of drug product	3 batches, 1500 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Lenvima 4mg Capsules Batch No. A11042 M/s Patheon Inc
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	FOOD & DRUG ADMINISTRATION (FDA)
	GMP status of the firm	Valid GMP certificate is submitted
	Evidence of approval of manufacturing facility	Section approval letter is submitted
	Evaluation Remarks	
	The firm has used EGC (Gelatin) capsule shell whereas innovator product uses Hypromellose capsule shells. The firm was asked about this difference and in response they have submitted compatibility studies between Lenvatinib Mesylate and EGC shells. The results of compatibility studies have shown that EGC shells doesn't have any negative effect on product quality.	
	Decision	

Approved

107	Case Category	Export Facilitation (Adil Saeed)
	Name, address of Applicant.	Martin Dow Marker Limited 7, Jail Road Quetta. (000028)
	Application Form Dy. No / Tracking ID & date of submission	(E4U-X8J-5AWN, 2025-03-12)
	Detail of Fee Submitted	93000.0, 2025-01-27,
	The proposed proprietary name / brand name	Vydra 100mg Tablets
	Label Claim	Each Film Coated Tablet contains: Sildenafil citrate Equivalent to Sildenafil.....100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per DPC-Controlled
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	N.A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wimits Pharmaceutical (Pvt.) Ltd-Plot # 129, Sunder Industrial Estate, Lahore-Pakistan-
	Name & address of API manufacturer	Ultra Tech India Ltd. Add: Plot Nos. 24, 25 & 26, New Chemical Zone, M.I.D.C. Taloja, Tal. Panvel, Dist. Raigad-410208, Maharashtra, India
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	VIAGRA Tablets/USFDA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The application is of contract manufacturing from M/s Wimits. Data Submitted is similar to the application submitted by M/s Wimits vide tracking ID UY9-52T-BSMD.	
	Application of M/s Wimits vide tracking ID UY9-52T-BSMD was initially approved in 345th meeting of Registration Board and then was rejected in 349th meeting of Registration Board on basis of outcome of Product Specification Inspection.	
	This application has same data which could not be verified in the PSI.	
108	Decision	
	Rejected	
	As the application of M/s. Wimits for Sildenafil 100mg tablets had been rejected in 349th meeting of the Registration Board.	
108	Case Category	Export Facilitation (Adil Saeed)
	Name, address of Applicant.	Martin Dow Marker Limited 7, Jail Road Quetta. (000028)
	Application Form Dy. No / Tracking ID & date of submission	(U49-S87-T4U9, 2025-04-22)

Detail of Fee Submitted	93000.0, 2025-03-20,
The proposed proprietary name / brand name	Vydra 25mg Tablets
Label Claim	Each Film Coated Tablet contains: Sildenafil citrate Equivalent to Sildenafil.....25mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	As per DPC-As per SRO
Shelf Life (Unit)	2 YearBelow 30°C
For generic drugs (me-too Status)	Not Available
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	M/s Wimits Pharmaceutical (Pvt.) Ltd-Plot # 129, Sunder Industrial Estate, Lahore-Pakistan-
Name & address of API manufacturer	ULTRATECH INDIA LTD : Plot Nos. 24, 25 & 26, New Chemical Zone, M.I.D.C. Taloja, . Tal. Panvel, Dist Raigad-410208, Maharashtra, India
Detail of stability batches of drug product	
Documents for the procurement of API with approval from DRAP (in case of Import)	
Pharmaceutical Equivalence and Comparative Dissolution Profile	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
The status in reference regulatory authorities	VIAGRA Tablet 25MG/USFDA
GMP status of the firm	
Evidence of approval of manufacturing facility	

Evaluation Remarks

The application is of contract manufacturing from M/s Wimits. The firm M/s Wimits had submitted their own application vide tracking ID S3R-RYT-Y6NB which was initially approved in 345th meeting of the Board, then it was rejected in 349th meeting of the board on basis of the fact that data submitted could not be verified in PSI. This application contains same data which not verified in product specific inspection.

Decision

Rejected

As the application of M/s. Wimits for Sildenafil 25mg tablets had been rejected in 349th meeting of the Registration Board.

109	Case Category	Export Facilitation (Adil Saeed)
	Name, address of Applicant.	Martin Dow Marker Limited 7, Jail Road Quetta. (000028)
	Application Form Dy. No / Tracking ID & date of submission	(AJT-PJH-U35A, 2025-05-29)
	Detail of Fee Submitted	93000.0, 2025-03-20,
	The proposed proprietary name / brand name	Vydra 50mg Tablets
	Label Claim	Each Film Coated Tablet contains: Sildenafil citrate Equivalent to Sildenafil.....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per DPC-As per SRO
	Shelf Life (Unit)	2 YearBelow 30
	For generic drugs (me-too Status)	Not Available

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceutical (Pvt.) Ltd-Plot # 129, Sunder Industrial Estate, Lahore – Pakistan-
	Name & address of API manufacturer	ULTRATECH INDIA LTD : Plot Nos. 24, 25 & 26, New Chemical Zone, M.I.D.C. Taloja, . Tal. Panvel, Dist Raigad-410208, Maharashtra, India
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	VIAGRA Tablet 50MG/USFDA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The application is of contract manufacturing from M/s Wimits. The firm M/s Wimits had applied for same product with same data which was approved in 345th meeting of the Board. Then after PSI it was rejected in 349th meeting of the Board because submitted data could not be verified. In this application same data is submitted which was not verified in the product specific inspection.	
	Decision	
	Rejected	
	As the application of M/s. Wimits for Sildenafil 50mg tablets had been rejected in 349th meeting of the Registration Board.	
110	Case Category	Contract Manufacturing (Adil Saeed)
	Name, address of Applicant.	Wnsfeild Pharmaceuticals Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK (000610)
	Application Form Dy. No / Tracking ID & date of submission	(L8S-7M8-USS3, 2024-03-19)
	Detail of Fee Submitted	75000.0, 2024-01-03,
	The proposed proprietary name / brand name	Merozik 2gm Powder for Solution for Infusion.
	Label Claim	Each vial contains:- Meropenem trihydrate eq. to Meropenem.....2gm (Blended with sodium carbonate) (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	J01DH02 Carbapenems
	Name, address of Manufacturing site:	Wallace Pharma Evolutions-Kala Wala Stop 20-KM, LAHORE JARANWALA ROAD, LAHORE-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	335th RB. Meronim 2G injection
	Evaluation Remarks	
	Decision	

Approved

111	Case Category	Export Facilitation (Adil Saeed)
	Name, address of Applicant.	Welmark Pharmaceuticals Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan (000614)
	Application Form Dy. No / Tracking ID & date of submission	(7Z2-TL1-2JR6, 2025-08-22)
	Detail of Fee Submitted	93000.0, 2025-07-10,
	The proposed proprietary name / brand name	TADAFOLD 10mg TABLET
	Label Claim	Each Film Coated Tablet Contains: Tadalafil.....5 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 25 C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	G04BE08 Drugs used in erectile dysfunction
	Name, address of Manufacturing site:	M/S Weather Folds Pharmaceuticals, Hattar-Plot No.69/2, Phase - II, Industrial Estate, Hattar, KPK-
	Name & address of API manufacturer	Century Pharmaceuticals Limited 103-106, GIDC, Halol Dist. Panchmahals
	Detail of stability batches of drug product	3 batches, 600 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan from M/s Wnsfield, Invoice and GD is submitted. Invoice not AD attested.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Cialis 10mg Tablet B. No. Lis-631102223
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	https://www.medicines.org.uk/emc/product/10231/smpc#g
	GMP status of the firm	Inspection report dated 17.10.2023 is submitted
	Evidence of approval of manufacturing facility	section approval letter dated 05.05.2010 is submitted
112	Evaluation Remarks	
	The firm has not submitted either Form 6 or clearance of drug substance. Firm was asked to provide Clearance of the material, and the firm has replied as under;	
	"As the materials have already been imported and the Traceable Goods Declaration, being a legal government document is attached, we submitted the undertaking that, following the clear decision taken in the DRB 345th Meeting, no further materials will be imported without prior permission from DRAP and in this regard we have already intimated DRAP about already imported materials. Therefore, you are kindly requested to please proceed with the evaluation of our registration application."	
112	Decision	
	Approved	
	Letter shall be issued upon verification of procurement and loan of drug substance in PSI of similar product of M/s WNSFeild Pharmaceuticals.	
112	Case Category	Export Facilitation (Adil Saeed)
	Name, address of Applicant.	Welmark Pharmaceuticals Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan (000614)
	Application Form Dy. No / Tracking ID & date of submission	(XRS-6A3-YAZA, 2025-08-22)

Detail of Fee Submitted	93000.0, 2025-07-10,
The proposed proprietary name / brand name	TADAFOLD 20mg TABLET
Label Claim	Each Film Coated Tablet Contains: Tadalafil.....5 mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 Year(s)Below 25 C
For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	G04BE08 Drugs used in erectile dysfunction
Name, address of Manufacturing site:	M/S Weather Folds Pharmaceuticals, Hattar-Plot No.69/2, Phase - II, Industrial Estate, Hattar, KPK-
Name & address of API manufacturer	Century Pharmaceuticals Limited 103-106, GIDC, Halol Dist. Panchmahals
Detail of stability batches of drug product	3 batches, 600 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan from M/s Wnsfield, Invoice and GD is submitted. Invoice not AD attested.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Cialis 20mg Tab B. No. Lis-26130124
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
The status in reference regulatory authorities	https://www.medicines.org.uk/emc/product/10231/smpc#g
GMP status of the firm	Inspection report dated 17.10.2023 is submitted
Evidence of approval of manufacturing facility	section approval letter dated 05.05.2010 is submitted
Evaluation Remarks	
The firm has not submitted either Form 6 or clearance of drug substance. Firm was asked to provide Clearance of the material, and the firm has replied as under;	
"As the materials have already been imported and the Traceable Goods Declaration, being a legal government document is attached, we submitted the undertaking that, following the clear decision taken in the DRB 345th Meeting, no further materials will be imported without prior permission from DRAP and in this regard we have already intimated DRAP about already imported materials. Therefore, you are kindly requested to please proceed with the evaluation of our registration application."	
Decision	
Approved	
Letter shall be issued upon verification of import and loaning of drug substance by M/s WNSfeild Pharmaceuticals in Product Specific Inspection.	
113	Case Category
	Export Facilitation (Adil Saeed)
	Name, address of Applicant.
	Welmark Pharmaceuticals Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan (000614)
	Application Form Dy. No / Tracking ID & date of submission
	(7DE-LQZ-AEDD, 2025-08-22)
	Detail of Fee Submitted
	93000.0, 2025-07-10,
	The proposed proprietary name / brand name
	TADAFOLD 5mg TABLET
	Label Claim
	Each Film Coated Tablet Contains: Tadalafil 5 mg
	Reference to Finished product specifications
	United States Pharmacopeia

Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 Year(s)Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	G04BE08 Drugs used in erectile dysfunction
Name, address of Manufacturing site:	M/S Weather Folds Pharmaceuticals, Hattar-Plot No.69/2, Phase - II, Industrial Estate, Hattar, KPK-
Name & address of API manufacturer	Century Pharmaceuticals Limited 103-106, GIDC, Halol Dist. Panchmahals
Detail of stability batches of drug product	3 batches, 600 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan from M/s Wnsfield, Invoice and GD is submitted. Invoice not AD attested.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Cialis 5mg Tab Lis-21620423
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
The status in reference regulatory authorities	https://www.medicines.org.uk/emc/product/10231/smpc#g
GMP status of the firm	Inspection report dated 17.10.2023 is submitted
Evidence of approval of manufacturing facility	section approval letter dated 05.05.2010 is submitted
Evaluation Remarks	
The firm has not submitted either Form 6 or clearance of drug substance. Firm was asked to provide Clearance of the material, and the firm has replied as under;	
"As the materials have already been imported and the Traceable Goods Declaration, being a legal government document is attached, we submitted the undertaking that, following the clear decision taken in the DRB 345th Meeting, no further materials will be imported without prior permission from DRAP and in this regard we have already intimated DRAP about already imported materials. Therefore, you are kindly requested to please proceed with the evaluation of our registration application."	
Decision	
Approved	
Letter shall be issued upon verification of import and loaning of drug substance by M/s WNSfeild Pharmaceuticals in Product Specific Inspection.	
114	Case Category
	Priority As Per 257-M of RB (Adil Saeed)
	Name, address of Applicant.
	REVIVE HEALTH CARE 503, 5TH FLOOR EDEN HEIGHTS 6 MAIN GULBERG JAIL ROAD (05-352-0065)
	Application Form Dy. No / Tracking ID & date of submission
	(QQN-7GA-WP5D, 2025-09-04)
	Detail of Fee Submitted
	313500.0, 2025-09-01,
	The proposed proprietary name / brand name
	RETABIN Tablet 500 mg
	Label Claim
	Each film coated tablet contains: Capecitabine 500 mg
	Reference to Finished product specifications
	United States Pharmacopeia
	Proposed Pack Size
	120's HDPE Bottle Pack-As per SRO
	Shelf Life (Unit)
	36 Month(s)Store below 30 degree centigrade
	For generic drugs (me-too Status)
	Registration No: 081285, By Revive Health Care
	Pharmacotherapeutic Group of (API)
	Antineoplastic agent, ATC Code: L01BC06

Name, address of Manufacturing site:	Qilu Pharmaceutical Co., Ltd.-8888 Lvyou Road, High-tech Zone, Jinan, Shandong 250104-China
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence study (Through QC comparison & Comparative dissolution profile) performed between Innovator's product (XELODA Tab. 500mg B No. X4703X1 & SH 2539) VS QILU's Capecitabine Tablet 500mg
Name, address of Marketing Authorization Holder:	Qilu Pharmaceutical Co., Ltd., 8888 Lvyou Road, High-tech Zone, Jinan, Shandong 250104, China
Details of Certificates (CoPP/FSC/cGMP):	Valid Eudra GMP Certificate No. ES/046HV/25
Details of Authorization Letter :	Imported product- Not applicable
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 6 months Accelerated (40±2oC, 75% ± 5 % R.H) and 36 months of long- term (25±2oC, 60±5% R.H.) performed on three consecutive commercial batches (VY1001P, VY1002P and VY1003P). Stability data provided in section 3.2.S.7.3
The status in reference regulatory authorities	XELODA Tablet 500mg, USFDA Approved
Evaluation Remarks	
Copy of COPP No 20251221 dated 12.08.2025 is submitted. As per submitted COPP product is available in market of country of origin i.e. China. Copy of Eudra GMP is submitted. Agency agreement wherein Qilu Pharma Co Ltd. is authorized to import market and distribute the product in Pakistan	
Decision	
Approved	
As per policy for inspection abroad.	
115	Case Category
	Export Facilitation (Adil Saeed)
	Name, address of Applicant.
	Caraway Pharmaceuticals PLOT NO.12, STREET NO.3 NATIONAL INDUSTRIAL ZONE RAWAT, PAKISTAN (000629)
	Application Form Dy. No / Tracking ID & date of submission
	(ADB-8P8-B3ZH, 2025-07-18)
	Detail of Fee Submitted
	75000.0, 2025-02-24,
	The proposed proprietary name / brand name
	Cara-Sil 100mg Tablet
	Label Claim
	Each film coated tablet contains: Sildenafil Citrate equivalent to Sildenafil.....100mg
	Reference to Finished product specifications
	United States Pharmacopeia
	Proposed Pack Size
	2's, 4's, 6's, 8's, -De-Controlled
	Shelf Life (Unit)
	2 Year(s) Store Between 15° to 30°C.
	For generic drugs (me-too Status)
	Not available
	Pharmacotherapeutic Group of (API)
	G04BE03 Drugs used in erectile dysfunction
	Name, address of Manufacturing site:
	Self Manufacturing
	Name & address of API manufacturer
	Rakshit Drugs Private Limited. Survey no.10/B, IDA, Gaddapotaram (v), Jinnaram Mandal, Sangareddy Dist., Telangana, India
	Detail of stability batches of drug product
	3 batches, 1000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)
	Clearance certificate of 1.5kg drug substance is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile
	Viagra 100mg Tablets Batch No. 19990 5430 Mfg: Pfizer Brooklyn New York USA

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Viagra 100mg and 50mg Tablets (Sildenafil Citrate 100mg Tablet) By Upjohn UK Limited (MHRA approved)/pFizer USFDA Approved.
	GMP status of the firm	Copy of GMP certificate valid till 30.07.2027 is submitted
	Evidence of approval of manufacturing facility	Renewal letter dated 04.07.2022 is submitted for kind approval
	Evaluation Remarks	
	Decision	
	Approved	
116	Case Category	Export Facilitation (Adil Saeed)
	Name, address of Applicant.	Caraway Pharmaceuticals PLOT NO.12, STREET NO.3 NATIONAL INDUSTRIAL ZONE RAWAT, PAKISTAN (000629)
	Application Form Dy. No / Tracking ID & date of submission	(N6X-JLA-VMMD, 2025-04-22)
	Detail of Fee Submitted	75000.0, 2025-02-24,
	The proposed proprietary name / brand name	Cara-Sil 50mg Tablet
	Label Claim	Each film coated tablet contains: Sildenafil Citrate equivalent to Sildenafil.....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2's, 4's, 6's, 8's, -De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Between 15° to 30°C.
	For generic drugs (me-too Status)	Not available
	Pharmacotherapeutic Group of (API)	G04BE03 Drugs used in erectile dysfunction
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rakshit Drugs Private Limited. Survey no.10/B, IDA, Gaddapotaram (v), Jinnaram Mandal, Sangareddy Dist., Telangana, India
	Detail of stability batches of drug product	3 batches, 1000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate of 1.5kg drug substance is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra 50mg Tablets Batch No. 19990 543A Mfg: Pfizer Brooklyn New york USA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Viagra 50mg Tablets (Sildenafil Citrate) MHRA/USFDA Approved).
	GMP status of the firm	Copy of GMP certificate valid till 30.07.2027 is submitted
	Evidence of approval of manufacturing facility	Renewal letter dated 04.07.2022 is submitted for kind approval
	Evaluation Remarks	
	Decision	

	Approved	
117	Case Category	Contract Manufacturing (Adil Saeed)
	Name, address of Applicant.	Trigon Pharmaceuticals (Private) Ltd 8-k.m thokar raiwind road Lahore (000342)
	Application Form Dy. No / Tracking ID & date of submission	(14L-55R-J31S, 2024-03-12)
	Detail of Fee Submitted	75000.0, 2023-11-15,
	The proposed proprietary name / brand name	IMASTIN 500mg INJECTION
	Label Claim	Each vial Contains: Imipenem Monohydrate eq. to Imipenem..... 250mg Cilastatin Sodium eq. to Cilastatin.....250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°C
	For generic drugs (me-too Status)	Tienam Injection of OBS Pakistan Karachi
	Pharmacotherapeutic Group of (API)	Imipenem and Cilastatin is a new beta-lactam antibiotic belonging to the Carbapenem class.
	Name, address of Manufacturing site:	Wallace Pharma Evolutions-Kalalwala stop, 20-KM, Lahore Jaranwala Road Lahore.-
	The status in reference regulatory authorities	Primaxin Injection USFDA
	Detail of previous approval	323rd meeting. Nemcil 500mg/500mg Injection
	Evaluation Remarks	
	Decision	
	Approved	
118	Case Category	Export Facilitation (Adil Saeed)
	Name, address of Applicant.	Bio-Labs(Pvt) Ltd Plot 145, Industrial Triangle, Kahuta Road (000296)
	Application Form Dy. No / Tracking ID & date of submission	(VZU-6DU-A2EM, 2025-08-22)
	Detail of Fee Submitted	75000.0, 2025-01-13,
	The proposed proprietary name / brand name	Enafil 50mg
	Label Claim	Each film-coated tablet contains: Sildenafil Citrate eq. to Sildenafil..... 50mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	4'S & 10'S-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30C
	For generic drugs (me-too Status)	Hilagara 50mg tablet Hilton Pharma
	Pharmacotherapeutic Group of (API)	Urologicals; Drugs used in erectile dysfunction
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rakshit Drug Pvt Ltd
	Detail of stability batches of drug product	T25-SL50-014, T25-SL50-015, T25-SL50-016 1000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate of 50kg Sildenafil is submitted

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra 50mg Tablet B. No. 19659824AH Mfg. M/s Pfizer
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	USFDA Approved.
	GMP status of the firm	valid till 08-10-2025
	Evidence of approval of manufacturing facility	Section approval letter dated 24.03.2007
	Evaluation Remarks	
	The firm has submitted new data in this application after rejection of their first application in 349th meeting of the board based on outcomes of product specific inspection.	
	Decision	
	Approved	
	Letter shall be issued after verification of submitted data in Product Specific Inspection.	
119	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	AGP Limited B-23-C, S.I.T.E., Karachi (000348)
	Application Form Dy. No / Tracking ID & date of submission	(4TV-XPG-4YU3, 2024-04-29)
	Detail of Fee Submitted	30000.0, 2024-04-01,
	The proposed proprietary name / brand name	Bricetam
	Label Claim	Each Film coated Tablet contains: Brivaracetam.....50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-De-Controlled
	Shelf Life (Unit)	2 Year(s)store below 30 degree Centigrade
	For generic drugs (me-too Status)	Brivace Tablet 50mg, M/s Hilton Pharma, Reg. No. 110126.
	Pharmacotherapeutic Group of (API)	Antiepileptic. ATC code: N03AX23.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Ami Lifesciences Private Limited.
	Detail of stability batches of drug product	03 batches having batch size of 2500 tablets each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of Form-6 No. K-896964682895 dated 01-09-2022 mentioning 5 kg of Brivaracetam (Manufacturer Specifications) from M/s AMI life Sciences, India. Firm has also submitted copy of commercial invoice No. EXP/I/22-23/0279 dated 23-08-2022 mentioning 5kg of Brivaracetam 5kg, Batch No. BVR/90040722. However, commercial invoice is not attested by DRAP.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and PE studies are performed against comparator product i.e. Brivera 50mg tablets, B. No. 1961, Mfg. date 01-2023 manufactured by M/s Helix pharma and both reference and applied formulation have shown more than 85% release within 15 minute in all the three mediums i.e. 0.1N HCl, Acetate buffer and phosphate buffer.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of 3 batches of drug substance as per Zone IV-B is submitted. Accelerated 06 months and real time for 24 months.
	The status in reference regulatory authorities	Briviact 50mg tablets, USFDA approved.

	GMP status of the firm	Firm has submitted copy of GMP Certificate No. 43/2023-DRAP (K) dated 15-06-2023 issued on the basis of inspection conducted on 12-06-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-4/2010-Lic (Vol-I) dated 30-06-2020 mentioning Tablet (General) section.
	Evaluation Remarks	
	Decision	
	Approved	
120	Case Category	Priority As Per 257-M of RB (Adil Saeed)
	Name, address of Applicant.	Genix Pharma (Pvt) Ltd , Plot No. 44-45-B, Korangi Creek Road, Karachi (0640)
	Application Form Dy. No / Tracking ID & date of submission	(195-UQD-9EAT, 2025-09-10)
	Detail of Fee Submitted	300000.0, 2025-04-18,
	The proposed proprietary name / brand name	Nunilo 150mg Capsule
	Label Claim	Each capsule contain: Nilotinib.....150mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	56's-As per SRO
	Shelf Life (Unit)	2 Year(s)15°C - 30°C
	For generic drugs (me-too Status)	Tasigna Capsule 150mg
	Pharmacotherapeutic Group of (API)	L01EA03 BCR-ABL tyrosine kinase inhibitors
	Name, address of Manufacturing site:	Shilpa Medicare Limited -Plot No. S-20 to S26, Pharmaceutical formulations SEZ, TSIIIC, Green Industrial Park, Polepally, Jadcherla, Telangana, 509301, India -India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Tasigna 150mg KV7273
	Name, address of Marketing Authorization Holder:	Genix Pharma (Pvt) Ltd. Karachi, 44,45-B Korangi Creek Road, Karachi 75190 Pakistan , Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Copy of GMP certificate valid till 14.03.2026 issued by DCA Telangana India is submitted. Copy of COPP valid till 22.06.2026 is submitted. COPP issued by DCA Telangana India. As per COPP product is placed on market of country of origin (I.e. India)
	Details of Authorization Letter :	Letter of authorization is submitted,
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Tasigna Capsule 150mg
	Evaluation Remarks	
	Decision	
	Approved	
	As per policy for inspection abroad.	
121	Case Category	Priority As Per 257-M of RB (Adil Saeed)

Name, address of Applicant.	Genix Pharma (Pvt) Ltd , Plot No. 44-45-B, Korangi Creek Road, Karachi (0640)
Application Form Dy. No / Tracking ID & date of submission	(12L-XY4-9HSW, 2025-09-10)
Detail of Fee Submitted	300000.0, 2025-04-18,
The proposed proprietary name / brand name	Nunilo 200mg Capsule
Label Claim	Each Capsule Contains: Nilotinib.....200mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	56's-As per SRO
Shelf Life (Unit)	2 Year(s)15°C - 30°C
For generic drugs (me-too Status)	Tasigna Capsule 200mg
Pharmacotherapeutic Group of (API)	L01EA03 BCR-ABL tyrosine kinase inhibitors
Name, address of Manufacturing site:	Shilpa Medicare Limited -Plot No. S-20 to S26, Pharmaceutical formulations SEZ, TSIIC, Green Industrial Park, Polepally, Jadcherla, Telangana, 509301, India -India
Name & address of API manufacturer	Finished Product Import from Shilpa Medicare Limited
Detail of stability batches of drug product	3 batches, 50,000 capsules each. 30C 75%RH up to 24 months.
Documents for the procurement of API with approval from DRAP (in case of Import)	Letter of authorization is submitted,
Pharmaceutical Equivalence and Comparative Dissolution Profile	Tasgina 200mg LE4206
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
The status in reference regulatory authorities	Tasigna Capsule 200mg
GMP status of the firm	Copy of GMP certificate valid till 14.03.2026 issued by DCA Telangana India is submitted. Copy of COPP valid till 22.06.2026 is submitted. COPP issued by DCA Telangana India. As per COPP product is placed on market of country of origin (I.e. India)
Evidence of approval of manufacturing facility	copy of DML, COPP and GMP certificate are submitted.
Evaluation Remarks	
Decision	
Approved	
As per policy for inspection abroad.	
122 Case Category	Export Facilitation (Adil Saeed)
Name, address of Applicant.	AGP Limited B-23-C, S.I.T.E., Karachi (000348)
Application Form Dy. No / Tracking ID & date of submission	(ZLD-7PZ-Y15D, 2024-07-11)
Detail of Fee Submitted	30000.0, 2024-04-01,
The proposed proprietary name / brand name	Bricetam 100mg Tablet
Label Claim	Each Film coated Tablet contains: Brivaracetam.....100mg
Reference to Finished product specifications	As per Innovators Specification

Proposed Pack Size	14's-De-Controlled
Shelf Life (Unit)	2 Year(s)store below 30 degree Centigrade
For generic drugs (me-too Status)	Genric drug Product,Brivace 100mg Tablet by Hilton Pharma.
Pharmacotherapeutic Group of (API)	N03AX23 Other antiepileptics
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Ami Lifesciences Private Limited.
Detail of stability batches of drug product	3 batches, 1500 tables each
Documents for the procurement of API with approval from DRAP (in case of Import)	Copy of Form 6 is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Brivera 100mg Tablet M/s Helix Pharma B No. 2830
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
The status in reference regulatory authorities	USFDA approved Briviact (Brivaracetam) 100mg tablet.
GMP status of the firm	GMP certificate issued on basis of inspection dated 12.06.2023 is submitted
Evidence of approval of manufacturing facility	Section approval letter dated 30.06.2020 is submitted

Evaluation Remarks

Decision

Approved

123	Case Category	Export Facilitation (Adil Saeed)
	Name, address of Applicant.	AGP Limited B-23-C, S.I.T.E., Karachi (000348)
	Application Form Dy. No / Tracking ID & date of submission	(A97-29H-MAJ7, 2024-04-30)
	Detail of Fee Submitted	30000.0, 2024-04-01,
	The proposed proprietary name / brand name	Bricetam 25mg Tablet
	Label Claim	Each Film coated Tablet contains: Brivaracetam.....25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-De-Controlled
	Shelf Life (Unit)	2 Year(s)store below 30 degree Centigrade
	For generic drugs (me-too Status)	Genric drug Product,Brivace 25mg Tablet by Hilton Pharma.
	Pharmacotherapeutic Group of (API)	N03AX23: Other antiepileptics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Ami Lifesciences Private Limited.
	Detail of stability batches of drug product	3 batches, 4500 tables each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Copy of Form 6 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brivera 25mg Tablet M/s Helix Pharma B No. 1631
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	USFDA approved Briviact (Brivaracetam) 25mg tablet

	GMP status of the firm	https://eapp.dra.gov.pk/admin/admin_application.php?track=A97-29H-MAJ7&Refresh=66489
	Evidence of approval of manufacturing facility	Section approval letter dated 30.06.2020 is submitted
	Evaluation Remarks	
	Decision	
	Approved	
124	Case Category	Export Facilitation (Adil Saeed)
	Name, address of Applicant.	AGP Limited B-23-C, S.I.T.E., Karachi (000348)
	Application Form Dy. No / Tracking ID & date of submission	(D86-ZDH-2HD3, 2024-04-30)
	Detail of Fee Submitted	30000.0, 2024-04-01,
	The proposed proprietary name / brand name	Bricetam 10mg Tablet
	Label Claim	Each Film coated Tablet contains: Brivaracetam.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-De-Controlled
	Shelf Life (Unit)	2 Year(s)store below 30 degree Centigrade
	For generic drugs (me-too Status)	Generic drug Product,Brivace 10mg Tablet by Hilton Pharma.
	Pharmacotherapeutic Group of (API)	N03AX23: Other antiepileptics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Ami Lifesciences Private Limited.
	Detail of stability batches of drug product	3 batches, 5250 tables each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Copy of Form 6 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brivace 10mg Tablet M/s Hilton Pharma B No. 143934
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	USFDA approved Briviact (Brivaracetam) 10mg tablet
	GMP status of the firm	GMP certificate issued on basis of inspection dated 12.06.2023 is submitted
	Evidence of approval of manufacturing facility	Section approval letter dated 30.06.2020 is submitted
	Evaluation Remarks	
	Decision	
	Approved	
125	Case Category	Export Facilitation (Adil Saeed)
	Name, address of Applicant.	AGP Limited B-23-C, S.I.T.E., Karachi (000348)
	Application Form Dy. No / Tracking ID & date of submission	(Q3L-SWB-WRX8, 2024-05-07)
	Detail of Fee Submitted	30000.0, 2024-04-01,
	The proposed proprietary name / brand name	Bricetam 75mg tablet

Label Claim	Each Film coated Tablet contains: Brivaracetam.....75mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	14's-De-Controlled
Shelf Life (Unit)	2 Year(s)store below 30 degree Centigrade
For generic drugs (me-too Status)	Generic drug Product,Brivace 75mg Tablet by Hilton Pharma.
Pharmacotherapeutic Group of (API)	Antiepileptic. ATC code: N03AX23.
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Ami Lifesciences Private Limited.
Detail of stability batches of drug product	03 batches having batch size of 1500 tablets each.
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of Form-6 No. K-896964682895 dated 01-09-2022 mentioning 5 kg of Brivaracetam (Manufacturer Specifications) from M/s AMI life Sciences, India. Firm has also submitted copy of commercial invoice No. EXP/I/22-23/0279 dated 23-08-2022 mentioning 5kg of Brivaracetam 5kg, Batch No. BVR/90040722. However, commercial invoice is not attested by DRAP.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Cubriwa 75mg B No. 0001T510 M/s Genix
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of 3 batches of drug substance as per Zone IV-B is submitted. Accelerated 06 months and real time for 24 months.
The status in reference regulatory authorities	USFDA approved Briviact (Brivaracetam) 75mg tablet.
GMP status of the firm	Firm has submitted copy of GMP Certificate No. 43/2023-DRAP (K) dated 15-06-2023 issued on the basis of inspection conducted on 12-06-2023.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-4/2010-Lic (Vol-I) dated 30-06-2020 mentioning Tablet (General) section.
Evaluation Remarks	
Decision	
Approved	
126	Case Category
	Any Other (Adil Saeed)
	Name, address of Applicant.
	SAMI Pharmaceuticals Pvt. Ltd. F-95 Hub River Road S.I.T.E Karachi (000072)
	Application Form Dy. No / Tracking ID & date of submission
	(JXA-Y7U-1V4V, 2025-04-28)
	Detail of Fee Submitted
	75000.0, 2025-03-10,
	The proposed proprietary name / brand name
	STARDA 50mg Tablet
	Label Claim
	Each film coated tablet contains: Sildenafil citrate equivalent to Sildenafil....50mg
	Reference to Finished product specifications
	United States Pharmacopeia
	Proposed Pack Size
	1x2's, 1x4's, 1x6's-De-Controlled
	Shelf Life (Unit)
	2 Year(s)Donot store over 30°C
	For generic drugs (me-too Status)
	NA
	Pharmacotherapeutic Group of (API)
	G04BE03 Drugs used in erectile dysfunction

	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches, 2500 tablets each. Zone IVa, upto 24 months
	Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested invoice mentioning 2.5kg drug substance is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra 50mg B. No. 164712 Mfg Fareva Amboise France
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	VIAGRA 50mg Tablet (USFDA)
	GMP status of the firm	Copy of GMP certificate issued on basis inspection dated 01.07.2024 is submitted.
	Evidence of approval of manufacturing facility	Copy of section approval letter dated 13.10.2023 is submitted
	Evaluation Remarks	
	Considered on priority based on decision of 214th meeting of the Authority.	
	Decision	
	Approved	
127	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	shrooq pharmaceuticals pvt ltd 21km feorzpur road lahore (000577)
	Application Form Dy. No / Tracking ID & date of submission	(9HQ-94P-967L, 2025-08-22)
	Detail of Fee Submitted	37000.0, 2025-04-08,
	The proposed proprietary name / brand name	Vcra Tablet 100mg
	Label Claim	Each Film Coated Tablet Contains: Sildenafil Citrate eq. to Sildenafil.....100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at temperature below 25oC
	For generic drugs (me-too Status)	Viagra Tablet 100mg by M/s Pfizer & Co. Inc.,
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 (PDE5) inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rakshit Drugs Private Limited., Survey no.10/B, IDA, Gaddapotaram (v), Jinnaram Mandal, Sangareddy Dist., Telangana, India. Phone no:+91-40-23810385, 23818158 Fax:+91-40-23812709. E-mail: Planthead@rakshitdrugspvtltd.com
	Detail of stability batches of drug product	The three stability batches of Sildenafil Table 100mg is T-001, T-002, T-003 manufcaturing/expiry is 07-2024/07-2026 having batch size 1000 Tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	The loan request letter for the API Sildenafil citrate from M/s Novamed Pharmaceuticals along with Form 6 and Clearance certificate for procurement of API from M/s Novamed Pharmaceuticals attached in Module III Section 3.2.P.8.3
	Pharmaceutical Equivalence and Comparative Dissolution Profile	“Viagra Tablet 100mg Batch # B851106 mfg Pfizer

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Viagra Tablet 100mg USFDA Approved
	GMP status of the firm	GMP certificate issued based upon evaluation conducted on 01-12-2023 and valid for three years from date of inspection
	Evidence of approval of manufacturing facility	Tablet Section General approved with grant of DML
	Evaluation Remarks	
	Considered on priority, as per decision of 214th meeting of the Authority.	
	Decision	
	Approved	
128	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	shrooq pharmaceuticals pvt ltd 21km feorzpur road lahore (000577)
	Application Form Dy. No / Tracking ID & date of submission	(SXE-RUW-8SE7, 2025-08-22)
	Detail of Fee Submitted	37000.0, 2025-04-08,
	The proposed proprietary name / brand name	Vera Tablet 25mg
	Label Claim	Each Film Coated Tablet contains: Sildenafil as Citrate.....25mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x8's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at temperature below 25oC
	For generic drugs (me-too Status)	Viagra Tablet 25mg by M/s Pfizer & Co. Inc.,
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 (PDE5) inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rakshit Drugs Private Limited., Survey no.10/B, IDA, Gaddapotaram (v), Jinnaram Mandal, Sangareddy Dist., Telangana, India. Phone no:+91-40-23810385, 23818158 Fax:+91-40-23812709. E-mail: Planthead@rakshitdrugspvtltd.com
	Detail of stability batches of drug product	The three stability batches of Sildenafil Tablet 25mg is T-001, T-002, T-003 manufcaturing/expiry is 07-2024/07-2026 having batch size 1000 Tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	The loan request letter for the API Sildenafil citrate from M/s Novamed Pharmaceuticals along with Form 6 and Clearance certificate for procurement of API from M/s Novamed Pharmaceuticals attached in Module III Section 3.2.P.8.3
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The Pharmaceutical Equivalence and Comparative Dissolution Profile Report performed between developed product "Sildenafil Tablet 25mg" Batch # T-001 and Reference Product "Viagra Tablet 25mg Batch # B819321 and attached in Module 3 section 3.2.P.2.2.1
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Viagra Tablet 25mg USFDA Approved
	GMP status of the firm	GMP certificate issued based upon evaluation conducted on 01-12-2023 and valid for three years from date of inspection

	Evidence of approval of manufacturing facility	Tablet Section General
	Evaluation Remarks	
	Priority as per decision of 214th meeting of the Authority.	
	Decision	
	Approved	
129	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	shrooq pharmaceuticals pvt ltd 21km feorzpur road lahore (000577)
	Application Form Dy. No / Tracking ID & date of submission	(Y8P-876-N9RQ, 2025-08-22)
	Detail of Fee Submitted	37000.0, 2025-04-08,
	The proposed proprietary name / brand name	Vcra Tablet 50mg
	Label Claim	Each Film Coated Tablet contains: Sildenafil as Citrate.....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at temperature below 25oC
	For generic drugs (me-too Status)	Viagra Tablet 50mg by M/s Pfizer & Co. Inc.,
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 (PDE5) inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rakshit Drugs Private Limited., Survey no.10/B, IDA, Gaddapotaram (v), Jinnaram Mandal, Sangareddy Dist., Telangana, India. Phone no:+91-40-23810385, 23818158 Fax:+91-40-23812709. E-mail: Planthead@rakshitdrugspvtltd.com
	Detail of stability batches of drug product	The three stability batches of Sildenafil Tablet 50mg are T-001, T-002, T-003 manufcaturing/expiry is 07-2024/07-2026 having batch size 1000 Tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	The loan request letter for the API Sildenafil citrate from M/s Novamed Pharmaceuticals along with Form 6 and Clearance certificate for procurement of API from M/s Novamed Pharmaceuticals attached in Module III Section 3.2.P.8.3
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The Pharmaceutical Equivalence and Comparative Dissolution Profile Report performed between developed product "Sildenafil Tablet 50mg" Batch # T-001 and Reference Product "Viagra Tablet 50mg Batch # B637809 and attached in Module 3 section 3.2.P.2.2.1
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Viagra Tablet 50mg USFDA Approved
	GMP status of the firm	GMP certificate issued based upon evaluation conducted on 01-12-2023 and valid for three years from date of inspection
	Evidence of approval of manufacturing facility	Tablet Section General
	Evaluation Remarks	
	Priority as per Decision of 214th meeting of the Authority.	
	Decision	

	Approved	
130	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	Dyson Research Laboratories (Pvt.) Ltd 28-Km Ferozpur Road Lahore (000559)
	Application Form Dy. No / Tracking ID & date of submission	(X67-QUY-VE2H, 2025-09-15)
	Detail of Fee Submitted	38700.0, 2025-08-19,
	The proposed proprietary name / brand name	Pulmosil 100mg tablet
	Label Claim	Each film coated tablet contains: Sildenafil citrate Equivalent to Sildenafil.....100mg.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 x 4's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30C.
	For generic drugs (me-too Status)	Ripple Tablet 100mg by Solaris Life Sciences Private Limited.
	Pharmacotherapeutic Group of (API)	Selective Inhibitor of cyclic GMP-specific phosphodiesterase (Type V) with vasodilator action; Urological; Drugs used in erectile dysfunction.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rakshit Pharmaceuticals Limited., situated at Plot number 68/A, Jawaharlal Nehru Pharma City, Parawada Mandal, Anakapalli district, Andhra Pradesh, India. 531021.
	Detail of stability batches of drug product	3 batches, 1000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	ADC Computerized No: E-10722560409128, dated: 09 October, 2024.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra 100mg tablet B. No B768003U
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated Stability Studies Batch No: SP/11/18/368, SP/11/18/369 and SP/11/18/370 Real Time Stability Studies Batch No: SP/11/18/368, SP/11/18/369 and SP/11/18/370.
	The status in reference regulatory authorities	Viagra Tablet 100mg, approved by USFDA.
	GMP status of the firm	cGMP certificate is granted or valid having Reference No: 222/2024-DRAP (AD-7243533001) dated: 17-12-2024.
	Evidence of approval of manufacturing facility	Grant of letter by DRAP of section/facilities approval vide letter no: F. 1-7/2003-Lic (Vol-IV) dated: 08-06-2021.
Evaluation Remarks		
Priority as per decision of 214th meeting of the Authority.		
Decision		
Approved		
131	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	Scotmann Pharmaceuticals Plot #5D , Industrial Area, I-10/3 Islamabad (000498)

Application Form Dy. No / Tracking ID & date of submission	(BNU-Y6L-X6RN, 2025-09-15)
Detail of Fee Submitted	37000.0, 2025-05-02,
The proposed proprietary name / brand name	Sildiva Tablet 50mg
Label Claim	Each film coated tablet contains: Sildenafil citrate equivalent to sildenafil..... 50mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	10's-As per SRO,12's-As per SRO,14's-As per SRO,15's-As per SRO,16's-As per SRO,2's-As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO,4's-As per SRO,5's-As per SRO,6's-As per SRO,7's-As per SRO,8's-As per SRO
Shelf Life (Unit)	2 Year(s)Store below 30°C
For generic drugs (me-too Status)	Hilsil Tablet 50mg, Manufactured by: Hilton Pharma (Pvt) Ltd.
Pharmacotherapeutic Group of (API)	Selective inhibitor of cyclic GMP-specific phosphodiesterase (Type V)
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Source of Drug Substance: Century Pharmaceuticals Limited Address: 103-106, GIDC, Halol Dist. Panchmahals- 389 350, India.
Detail of stability batches of drug product	Accelerated & Long term stability studies performed on Batch No. T-01, T-02 & T-03, Batch Size: 1000 Tablets on initial,3 months testing intervals
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance Certificate no. RO-0A0ECC dated: 07-02-2025 mentioning 3 kg of Sildenafil citrate from M/s Century Pharmaceuticals, India.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence has been performed with comparator product "Viagra Tablet 50mg" Batch No. B601303 and Dissolution profile of both products (Viagra Tablet 50mg & Sildenafil Tablet 50mg) was compared at three pH (1.2, 4.5 & 6.8) graphically and statistically.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of 3 batches of drug substance as per Zone IV-A is submitted. Accelerated 06 months and real time for 60 months
The status in reference regulatory authorities	Viagra Tablet 50mg, Registered in Food and Drug Administration (FDA)
GMP status of the firm	GMP certificate no. F. 3-14/2018-Addl. Dir. (QA & LT-I)-13 valid till 21-02-2027
Evidence of approval of manufacturing facility	Tablet (General) Section approved & renewed by CLB dated 26-04-2024
Evaluation Remarks	
Priority as per decision of 214th meeting of Authority	
Decision	
Approved	
132 Case Category	Any Other (Adil Saeed)
Name, address of Applicant.	Scotmann Pharmaceuticals Plot #5D , Industrial Area, I-10/3 Islamabad (000498)

Application Form Dy. No / Tracking ID & date of submission	(EE4-S68-5HJ8, 2025-09-15)
Detail of Fee Submitted	37000.0, 2025-05-02,
The proposed proprietary name / brand name	Sildiva Tablet 100mg
Label Claim	Each film coated tablet contains: Sildenafil citrate equivalent to sildenafil..... 100mg (USP Specifications)
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	10's-As per SRO,12's-As per SRO,14's-As per SRO,15's-As per SRO,16's-As per SRO,2's-As per SRO,20's-As per SRO,21's-As per SRO,28's-As per SRO,30's-As per SRO,4's-As per SRO,5's-As per SRO,6's-As per SRO,7's-As per SRO,8's-As per SRO
Shelf Life (Unit)	2 YearBelow 30°C
For generic drugs (me-too Status)	Hilsil Tablet 100mg, Manufactured by: Hilton Pharma (Pvt) Ltd.
Pharmacotherapeutic Group of (API)	Selective inhibitor of cyclic GMP-specific phosphodiesterase (Type V)
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Source of Drug Substance: Century Pharmaceuticals Limited Address: 103-106, GIDC, Halol Dist. Panchmahals- 389 350, India.
Detail of stability batches of drug product	Accelerated & Long term stability studies performed on Batch No. T-01, T-02 & T-03, Batch Size: 1000 Tablets on initial,3 months testing intervals.
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance Certificate no. RO-0A0ECC dated: 07-02-2025 mentioning 3 kg of Sildenafil citrate from M/s Century Pharmaceuticals, India.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence has been performed with comparator product "Viagra Tablet 100mg" Batch No. B740103 and Dissolution profile of both products (Viagra Tablet 100mg & Sildenafil Tablet 100mg) was compared at three pH (1.2, 4.5 & 6.8) graphically and statistically.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of 3 batches of drug substance as per Zone IV-B is submitted. Accelerated 06 months and real time for 60 months
The status in reference regulatory authorities	Viagra Tablet 100mg, Registered in Food and Drug Administration (FDA)
GMP status of the firm	GMP certificate no. F. 3-14/2018-Addl. Dir. (QA & LT-I)-13 valid till 21-02-2027
Evidence of approval of manufacturing facility	Tablet (General) Section approved & renewed by CLB dated 26-04-2024
Evaluation Remarks	
Priority as per decision of 214th meeting of Authority	
Decision	
Approved	
133 Case Category	Any Other (Adil Saeed)
Name, address of Applicant.	Martin Dow Limited Plot no. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan (000267)

Application Form Dy. No / Tracking ID & date of submission	(9LY-RUZ-9DT5, 2025-05-05)
Detail of Fee Submitted	75000.0, 2025-04-23,
The proposed proprietary name / brand name	Viridio Tablet 100mg
Label Claim	Each film coated tablet contains: Sildenafil Citrate is equivalent to Sildenafil.....100mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	10's-As per SRO,2's-As per SRO,4's-As per SRO,8's-As per SRO
Shelf Life (Unit)	2 Year(s)Store below 30°C
For generic drugs (me-too Status)	Not Applicable
Pharmacotherapeutic Group of (API)	Phosphodiesterase inhibitor
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Century Pharmaceuticals Limited 103-106, GIDC, Halol Dist. Panchmahals
Detail of stability batches of drug product	Batch No: NPD-T-2703-S, Batch No: NPD-T-2724-S, Batch No: NPD-T-2725-S 2500 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted for 4.6kg drug substance.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence established with Innovator Product Viagra 100mg FC Tablet B No. 3189217 Mfg Pfizer Egypt
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
The status in reference regulatory authorities	Viagra Tablet 100mg by US-FDA
GMP status of the firm	GMP certificate valid till 15th August 2027
Evidence of approval of manufacturing facility	Tablet (General) section approval is submitted.
Evaluation Remarks	
Priority as per decision of 214th meeting of Authority.	
Decision	
Approved	
134	Case Category
	New Section (Adil Saeed)
	Name, address of Applicant.
	AHSONS Drug Company T/1 S.I.T.E Tando Adam (000138)
	Application Form Dy. No / Tracking ID & date of submission
	(1MD-VQM-3D5B, 2025-01-14)
	Detail of Fee Submitted
	37000.0, 2024-11-12,
	The proposed proprietary name / brand name
	Cefra Injection 1gm
	Label Claim
	Each vial of dry substance contains: Sterile Cephradine (with L – Arginine) USP.....1gm
	Reference to Finished product specifications
	United States Pharmacopeia
	Proposed Pack Size
	1's-As per SRO
	Shelf Life (Unit)
	2 Year(s)Store bellows 30°C. Protect from light. Improper storage may deteriorate the medicine.
	For generic drugs (me-too Status)
	Brand Name: Velosef Injection Strength: 1gm Dosage Form: IV /IM Injection Pack Size: 1's Regn No.001869 Manufacturer: GlaxoSmithKline Pakistan Limited.

Pharmacotherapeutic Group of (API)	J01DB09 First-generation cephalosporins
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Pharmagen Limited 5-A,Zafer Ali Road, Gulberg-V, Lahore, Pakistan.
Detail of stability batches of drug product	3 batches 500 vials each
Documents for the procurement of API with approval from DRAP (in case of Import)	Local purchased from Pharmagen
Pharmaceutical Equivalence and Comparative Dissolution Profile	Velosef 1g B858
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
The status in reference regulatory authorities	Brand Name: Velosef Injection Strength: 1gm Market Authorization: M/s Apothecon Reference Regulatory Authority: USFDA Approved medicine.
GMP status of the firm	----
Evidence of approval of manufacturing facility	Renewal letter dated 11.05.2022 is submitted
Evaluation Remarks	
3.2.P.5 In Assay the its mentioned that only peak of Cephadrine will be calculated, the monograph of older version of USP (which is followed as evident from your submission) states that quantity of Cephadrine and Cephalexin both needs to be considered. Further in chromatograms submitted, peak of cephalixin is not present. Please justify these deviations in analytical method and performance of assay.	
Response: The firm has stated that; "No cephalixin peak is observed because cephalixin is not present in the tested samples. The assay for Cephadrine for injection is conducted strictly as per USP Monograph with quantification based only on the Cephadrine peak. Cephalixin is not included in assay calculations but is approximately controlled as a specified impurity under the related substances procedure. The absence of a cephalixin peak in assay chromatograms is consistent with validated method sensitivity, stability data and product quality."	
The USP 2021 has monograph of Cephadrine for injection. The definition of product given in monograph is;"Cephadrine for Injection contains not less than 90.0 percent and not more than 115.0 percent of the labeled amount of cephradrine, calculated as the sum of cephradrine (C16H19N3O4S) and cephalixin (C16H17 N3O4S)"	
Under heading of assay, procedure to calculate quantity is give as "Calculate the quantity, in mg, of cephradrine (sum of cephradrine and cephalixin) withdrawn from the container, or in the portion of constituted solution taken by the formula"Further the COA of drug substance lot No. 00401/22-02/002 (used in manufacturing of drug product) does indicate cephalixin content. Drug substance manufacturer (M/s Pharmagen) has quantified it as 2.48% whereas drug product manufacturer has quantified it as 2.59%. But in their response firm is claiming that "No Cephalixin peak is observed because cephalixin is not present in the tested samples."	
Firm was asked to justify that their application falls under category of new section as in renewal section Ceph dry powder inj section is not mentioned as new. The firm has replied as under;	
"We M/s Ahsons Drug Company Plot No: T/1, S.I.T.E Tando Adam Sindh, wish to bring in your kind notice that, our newly established section of "Dry Powder Injection Section (Cephalosporin)" was inspected and recommended for grant on 22/02/2022 by the panel constituted by chairman Central Licensing Board. Subsequently renewal of DML was granted by the CLB with inclusion of new section of "Dry Powder Injection Section (Cephalosporin)" on 11/05/2022. Since the date of approval of our new section of "Dry Powder Injection Section (Cephalosporin)" by CLB we haven't applied for any product of the said section to the Registration Board"	
Decision	
Deferred	
for clarification from the firm for queries of evaluator.	
135	Case Category
	Any Other (Adil Saeed)
	Name, address of Applicant.
	Focus & Rulz Pharmaceuticals (Pvt) Ltd 44 - Industrial Triangle, Kahuta Road (000628)

Application Form Dy. No / Tracking ID & date of submission	(NBD-H7L-L7G7, 2025-09-15)
Detail of Fee Submitted	38700.0, 2025-08-07,
The proposed proprietary name / brand name	Blupil 50mg Tablets
Label Claim	Eachfilm coatedtablet contains; Sildenafil citrate eq. to Sildenafil.....50mg (USP Specification)
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	As Per SRO-As per SRO
Shelf Life (Unit)	24 Year(s)Room temperature
For generic drugs (me-too Status)	Ripple 50mg Tablet by SLS pharma
Pharmacotherapeutic Group of (API)	G04BE03 Drugs used in erectile dysfunction
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Century Pharmaceuticals Limited
Detail of stability batches of drug product	3 batches, 1000 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate mentioning 50 kg drug substance is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra 50mg M/s Viatris Egypt B. No. 240522
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
The status in reference regulatory authorities	Viagra 50mgTablets -NetherlandsApproved
GMP status of the firm	GMP certificate issued on basis of inspection dated 12.05.2023
Evidence of approval of manufacturing facility	DML Attached
Evaluation Remarks	
Priority as per decision of 214th meeting of the Authority Firm has submitted fresh application. First application was rejected in 349th meeting of RB after PSI.	
Decision	
Approved	
Letter shall be issued after verification of submitted data by Product Specific Inspection.	
136	Case Category
	Any Other (Adil Saeed)
	Name, address of Applicant.
	Focus & Rulz Pharmaceuticals (Pvt) Ltd 44 - Industrial Triangle, Kahuta Road (000628)
	Application Form Dy. No / Tracking ID & date of submission
	(GGQ-31Z-UPQP, 2025-09-15)
	Detail of Fee Submitted
	38700.0, 2025-08-07,
	The proposed proprietary name / brand name
	Blupil 100mg Tablets
	Label Claim
	Each film coated tablet contains; Sildenafil citrate eq. to Sildenafil.....100mg (USP Specification)
	Reference to Finished product specifications
	United States Pharmacopeia
	Proposed Pack Size
	As Per SRO-As per SRO
	Shelf Life (Unit)
	24 Year(s)Room temperature
	For generic drugs (me-too Status)
	Ripple 100mg Tablet by SLS pharma
	Pharmacotherapeutic Group of (API)
	G04BE03 Drugs used in erectile dysfunction
	Name, address of Manufacturing site:
	Self Manufacturing

Name & address of API manufacturer	Century Pharmaceuticals Limited
Detail of stability batches of drug product	3 batches, 1000 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate mentioning 50 kg drug substance is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra 100mg Viatris Egypt B. No. 230531
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
The status in reference regulatory authorities	Viagra 100mg Tablets -Netherlands Approved
GMP status of the firm	GMP certificate issued on basis of inspection dated 12.05.2023
Evidence of approval of manufacturing facility	DML Attached

Evaluation Remarks

Priority as per decision of 214th meeting of the Authority. Firm has submitted fresh application. First application was rejected in 349th meeting of RB after PSI.

Decision

Approved

Letter shall be issued after verification of submitted data by product specific inspection (PSI).

137	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (000644)
	Application Form Dy. No / Tracking ID & date of submission	(TWJ-2Q4-RQ8V, 2025-07-22)
	Detail of Fee Submitted	75000.0, 2025-03-15,
	The proposed proprietary name / brand name	Siltrate 25mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Sildenafil Citrate eq. to Sildenafil.....25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s) Store below 25°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	G04BE03 Drugs used in erectile dysfunction
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches having batch size of 1200 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan from M/s WNSfeild, GD and unattested invoice is submitted,
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra 25mg Tablet B.No. VS106911 Mfg Pfizer Ireland
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	Copy of GMP certificate is submitted
	Evidence of approval of manufacturing facility	Section approval letter dated 05.05.2010 is submitted

Evaluation Remarks

Priority as per decision of 214th meeting of Authority

Decision		
Approved		
Letter shall be issued upon verification of import and loaning of drug substance by M/s WNSFeild Pharmaceuticals.		
138	Case Category	Export Facilitation (Adil Saeed)
	Name, address of Applicant.	CCL Pharmaceuticals (Pvt.) Ltd. 62-Quaid-e-Azam Industrial Estate, Kot Lakhpat (000052)
	Application Form Dy. No / Tracking ID & date of submission	(UVR-SZZ-RMPA, 2025-02-07)
	Detail of Fee Submitted	75000.0, 2024-12-27,
	The proposed proprietary name / brand name	Bexavy 20mg Tablets
	Label Claim	Each film coated tablet contains: Bexagliflozin..... 20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,12's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,7's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Do not store more than 30C
	For generic drugs (me-too Status)	Not available
	Pharmacotherapeutic Group of (API)	A10BK08 Sodium-glucose co-transporter 2 (SGLT2) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhejiang Hongyuan Pharmaceutical Co., Ltd No.6 Donghai Fourth Avenue , Zhejiang Toudenggang Economic Development Zone , Linhai City , Taizhou , Zhejiang Province P.R of China 317016 China
	Detail of stability batches of drug product	3 batches, 1000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Drug Import license is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brenzavvy 20mg Tablet B. No. B31170, Mfg HracosBio
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	BRENZAVVY tablets- USFDA Approved
	GMP status of the firm	Copy of GMP certificate valid till 20.03.2025 is submitted
	Evidence of approval of manufacturing facility	Renewal letter dated 08.06.2021 is submitted wherein Tablet (General) section is mentioned
Evaluation Remarks		
Decision		
Approved		
139	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	Scotmann Pharmaceuticals Plot #5D , Industrial Area, I-10/3 Islamabad (000498)

Application Form Dy. No / Tracking ID & date of submission	(8WG-51H-RAZ6, 2025-09-18)
Detail of Fee Submitted	75000.0, 2024-12-13,
The proposed proprietary name / brand name	Sildiva Tablet 25mg
Label Claim	Each film coated tablet contains: Sildenafil citrate equivalent to sildenafil..... 25mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	10's-As per SRO,12's-As per SRO,14's-As per SRO,15's-As per SRO,16's-As per SRO,2's-As per SRO,20's-As per SRO,21's-As per SRO,28's-As per SRO,30's-As per SRO,4's-As per SRO,5's-As per SRO,6's-As per SRO,7's-As per SRO,8's-As per SRO
Shelf Life (Unit)	2 Year(s)Below 30°C
For generic drugs (me-too Status)	Hilsil Tablet 25mg, Manufactured by: Hilton Pharma (Pvt) Ltd.
Pharmacotherapeutic Group of (API)	G04BE03 Drugs used in erectile dysfunction
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Source of Drug Substance: Century Pharmaceuticals Limited Address: 103-106, GIDC, Halol Dist. Panchmahals- 389 350, India.
Detail of stability batches of drug product	Accelerated & Long term stability studies performed on Batch No. T-01, T-02 & T-03, Batch Size: 1000 Tablets on initial & 3 months testing intervals.
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance Certificate no. RO-0A0ECC dated: 07-02-2025 mentioning 3 kg of Sildenafil citrate from M/s Century Pharmaceuticals, India.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Ripple 25mg tablet B. No. 25G005 M/s Solaris Life Sciences
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of 3 batches of drug substance as per Zone IV-B is submitted. Accelerated 06 months and real time for 60 months.
The status in reference regulatory authorities	Viagra Tablet 25mg, Registered in Food and Drug Administration (USFDA)
GMP status of the firm	GMP certificate no. F. 3-14/2018-Addl. Dir. (QA & LT-I)-13 valid till 21-02-2027
Evidence of approval of manufacturing facility	Tablet (General) Section approved & renewed by CLB dated 26-04-2024
Evaluation Remarks	
Priority as per decision of 214th meeting of Authority.	
Decision	
Approved	
140	Case Category
	Any Other (Adil Saeed)
	Name, address of Applicant.
	Dyson Research Laboratories (Pvt.) Ltd 28-Km Ferozpur Road Lahore (000559)
	Application Form Dy. No / Tracking ID & date of submission
	(7X9-1UN-S5HX, 2025-04-24)
	Detail of Fee Submitted
	75000.0, 2025-04-14,
	The proposed proprietary name / brand name
	Pulmosil 25mg Tablet

Label Claim	Each film coated tablet contains: Sildenafil citrate Equivalent to Sildenafil.....25mg.
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	3 x 4's-As per SRO
Shelf Life (Unit)	2 Year(s)Store below 30C.
For generic drugs (me-too Status)	Not Applicable.
Pharmacotherapeutic Group of (API)	Selective Inhibitor of cyclic GMP-specific phosphodiesterase (Type V) with vasodilator action; Urological; Drugs used in erectile dysfunction.
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Rakshit Pharmaceuticals Limited., situated at Plot number 68/A, Jawaharlal Nehru Pharma City, Parawada Mandal, Anakapalli district, Andhra Pradesh, India. 531021.
Detail of stability batches of drug product	Accelerated Stability Studies (40C ± 2C, 75 ± 5% RH) Batch No: T01, T02 and T03, Real Time Stability Studies (30°C ± 2°C, 65 ± 5%RH) Batch No: T01, T02 and T03.
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance Certificate is granted/valid having computerized No: E-10722560409128 dated: 09-10-2024.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra 25mg B No. B819314U Mfg Fareva France
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated Stability Studies (40C ± 2C, 75 ± 5% RH) Batch No: SP/11/18/368, SP/11/18/369 and SP/11/18/370., Real Time Stability Studies (30°C ± 2°C, 65 ± 5%RH) Batch No: SP/11/18/368, SP/11/18/369 and SP/11/18/370.
The status in reference regulatory authorities	Viagra Tablet 25mg Applied formulation is registered in United States Food and Drug Administration (USFDA).
GMP status of the firm	cGMP certificate is granted or valid having Reference No: 222/2024-DRAP (AD-7243533001) dated: 17-12-2024.
Evidence of approval of manufacturing facility	Grant of letter by DRAP of section/facilities approval vide letter no: F. 1-7/2003-Lic (Vol-IV) dated: 08-06-2021.
Evaluation Remarks	
Priority as per decision of 214th meeting of Authority	
Decision	
Approved	
141	Case Category
	Priority As Per 257-M of RB (Adil Saeed)
	Name, address of Applicant.
	Amgomed Office No.5, First Floor, Rose-1 Plaza, I-8 Markaz (DHO-ISB-188)
	Application Form Dy. No / Tracking ID & date of submission
	(X5N-U5G-YB6L, 2025-07-01)
	Detail of Fee Submitted
	300000.0, 2025-05-21,
	The proposed proprietary name / brand name
	Levaler 10 mg
	Label Claim
	Each capsule contains; Lenvatinib besylate eq. to Lenvatinib 10 mg
	Reference to Finished product specifications
	As per Innovators Specification
	Proposed Pack Size
	30 tablets-De-Controlled,60 tablets-De-Controlled

Shelf Life (Unit)	24 Month(s)30 degree
For generic drugs (me-too Status)	Lenvanix 10 mg capsules
Pharmacotherapeutic Group of (API)	L01EX08 Protein Kinase Inhibitor
Name, address of Manufacturing site:	Synthon Chile Ltda-ubicado en EL castano N 145 comuna de LAMPA Region Metropolitana de santiago Chile-Chile
Pharmaceutical Equivalence and Comparative Dissolution Profile	Lenvima 10mg Batch No. 1267043 USA
Name, address of Marketing Authorization Holder:	Amgomed Pharma, Office No. 4 First Floor, Ghausia Plaza, Jinnah Avenue, Blue Area, Islamabad, Pakistan 44000, Pakistan
Details of Certificates (CoPP/FSC/cGMP):	EUDRA GMP COPP No. 360/25 dated 01.04.2025 issued by Chilean health department is submitted
Details of Authorization Letter :	Authorization letter is submitted.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached, studies conducted at 2 to 8 degree
The status in reference regulatory authorities	EMA, USFDA
Evaluation Remarks	
Decision	
Approved	
As per policy for inspection abroad.	
142	Case Category
	Priority As Per 257-M of RB (Adil Saeed)
	Name, address of Applicant.
	Amgomed Office No.5, First Floor, Rose-1 Plaza, I-8 Markaz (DHO-ISB-188)
	Application Form Dy. No / Tracking ID & date of submission
	(B29-W1U-49YY, 2025-07-01)
	Detail of Fee Submitted
	300000.0, 2025-05-21,
	The proposed proprietary name / brand name
	Levaler 4 mg
	Label Claim
	Each capsules contains; Lenvatinib besylate eq. to lenvatinib..... 4 mg
	Reference to Finished product specifications
	As per Innovators Specification
	Proposed Pack Size
	30 tablets-De-Controlled
	Shelf Life (Unit)
	24 Month(s)30 degree
	For generic drugs (me-too Status)
	Lenvanix 4 mg capsules
	Pharmacotherapeutic Group of (API)
	L01EX08 Protein Kinase Inhibitor
	Name, address of Manufacturing site:
	Synthon Chile Ltda-ubicado en EL castano N 145 comuna de LAMPA Region Metropolitana de santiago Chile-Pakistan
	Pharmaceutical Equivalence and Comparative Dissolution Profile
	Lenvema 10mg B. No. 133269 & 1267043 European
	Name, address of Marketing Authorization Holder:
	Amgomed Pharma, Office No. 4 First Floor, Ghausia Plaza, Jinnah Avenue, Blue Area, Islamabad, Pakistan 44000, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):
	EUDRA GMP COPP No. CW N 359/25 dated 31.03.2025 issued by Chilean Institute of Public Health is submitted.
	Details of Authorization Letter :
	Letter of authorization is attached.

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	long term 2 to 8 C 36 months.
	The status in reference regulatory authorities	EMA, USFDA
	Evaluation Remarks	
	Decision	
	Approved	
	As per policy for inspection abroad.	
143	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	Wnsfeild Pharmaceuticals Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK (000610)
	Application Form Dy. No / Tracking ID & date of submission	(XST-GXS-69SL, 2025-07-22)
	Detail of Fee Submitted	75000.0, 2025-02-14,
	The proposed proprietary name / brand name	Viglo 25mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Sildenafil Citrate eq. to Sildenafil.....25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	G04BE03 Drugs used in erectile dysfunction
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited 103-106, GIDC, Halol Dist. Panchmahals- 389 350, India
	Detail of stability batches of drug product	3 batches having batch size of 1200 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 and clearance not submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra 25mg Tablet B. No. VS106911 Mfg Pfizer
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	Renewal in 2024
	Evidence of approval of manufacturing facility	Renewal letter dated 11.06.2024 is submitted
	Evaluation Remarks	
	As per decision of 214th meeting of Authority.Firm was asked to submitted clearance certificate and Form 6 for import of drug substance. firm has replied, "We would respectfully like to submit that prior to the DRB 345th Meeting new requirement of mandatory clearance certificates along with other import documents, some of the material imports were made via the Green Channel. Regarding proof of Import of Said Material we have attached Goods Declaration documents in relevant section, for your kind consideration. We fully acknowledge the decision made in DRB 345th Meeting regarding the compulsory submission of clearance certificates for all future imports. Therefore, we hereby undertake that from this point onward, all API imports whether for stability or commercial use, will be carried out strictly in compliance with the new directive, and clearance certificates from DRAP will be duly obtained prior to import onward."	
	Decision	

Approved

Letter shall be issued after verification of import of drug substance by PSI.

144	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	shrooq pharmaceuticals pvt ltd 21km feorzpur road lahore (000577)
	Application Form Dy. No / Tracking ID & date of submission	(8AR-5RB-N4ND, 2024-03-15)
	Detail of Fee Submitted	30000.0, 2023-08-03,
	The proposed proprietary name / brand name	Dantron Injection 4mg/2ml Injection
	Label Claim	Each 2ml ampoule contains; Ondansetron Hydrochloride dihydrate eq. to Ondansetron.....4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2 ml-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Pharmedic Laboratories (Pvt) Ltd.
	Pharmacotherapeutic Group of (API)	A04AA01 Serotonin (5HT3) antagonists
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Anugraha Chemicals
	Detail of stability batches of drug product	3 batches, 476 ampoules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested invoice mentioning 20kg drug substance is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Onset 4mg/2ml Injection B No. 549 M/s Pharmedic Laboratories Lahore
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	Copy of GMP certificate issued on basis inspection conducted on 01.12.2023 is submitted
	Evidence of approval of manufacturing facility	Injection General ampoule section approved vide letter dated 07.04.2014
	Evaluation Remarks	
	Decision	
	Approved	
145	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	Pharmedic Laboratories (Pvt.) Ltd Lahore 16-Km Multan Road, Lahore (000228)
	Application Form Dy. No / Tracking ID & date of submission	(U6V-R17-N7QV, 2024-04-17)
	Detail of Fee Submitted	30000.0, 2024-02-13,
	The proposed proprietary name / brand name	Regab Capsule 75mg
	Label Claim	Each capsule contains: Pregabalin....75mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10x 10's-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30C

For generic drugs (me-too Status)	Lyrica 75mg Capsule by Pfizer Pakistan
Pharmacotherapeutic Group of (API)	Antiepileptics, other antiepileptics ATC code: N02BF02
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	KOPRAN RESEARCH LABORATORIES LIMITED
Detail of stability batches of drug product	3 batches having batch size of 1000 capsule each
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate issued dated 05-01-2023 specifying 3.5kg Pregabalin.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Lyrica 75mg Capsule by M/s Pfizer Germany.,
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A
The status in reference regulatory authorities	Lyrica (Pregabalin) Capsules (Pfizer) https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/021227Orig1s01.pdf
GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 04-06-2025.
Evidence of approval of manufacturing facility	Firm has submitted copy of panel inspection report for renewal of DML dated 04-06-2025 specifying capsule (General) section. The panel recommended the Renewal of DML

Evaluation Remarks

Shortcomings	Firm's Response
Submit alternative brand name for applied product as the submitted brand name resemble with already registered product	Firm has submitted the suggested brand name for applied product. Lyrin, Lyrigab, Nervolin

Decision

Approved

146	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	Pharmedic Laboratories (Pvt.) Ltd Lahore 16-Km Multan Road, Lahore (000228)
	Application Form Dy. No / Tracking ID & date of submission	(A4Y-6U5-VPZW, 2024-04-29)
	Detail of Fee Submitted	30000.0, 2024-03-21,
	The proposed proprietary name / brand name	Artu Tablet
	Label Claim	Each Film coated Tablet contains: 19.43mg Ertugliflozin l-pyrogutamic acid which is eq. Ertugliflozin 15 mg.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	A blister pack of 1 -As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store above 30 C, store in the original package in order to protect from moisture.
	For generic drugs (me-too Status)	Ertuvia 15mg Tablet by Ferozsans Laboratories
	Pharmacotherapeutic Group of (API)	Sodium glucose co-transporter 2 (SGLT2) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhejiang Hongyuan Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	3 batches having batch size of 1000 tablets each
	Documents for the procurement of API with approval from DRAP	Firm has submitted copy of commercial invoice cleared dated 04-03-2020 specifying 918gm Ertugliflozin L-

(in case of Import)	pyroglutamic acid.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies and CDP performed against Steglatro tablet 15mg by Pfizer Manufacturing Deutschland GmbH, Frieberg, Germany..
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV
The status in reference regulatory authorities	STEGLATRO (5mg, 15mg) film coated tablets USFDA Approved
GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 04-06-2025.
Evidence of approval of manufacturing facility	Firm has submitted copy of panel inspection report for renewal of DML dated 04-06-2025 specifying Tablet (General) section. The panel recommended the Renewal of DML
Evaluation Remarks	
Shortcomings	Firm's Response
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 of API manufacturer issued by Zhejiang Food and Drug Administration China valid upto 30-10-2028
Decision	
Approved	
147	Case Category
	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.
	Nabiqasim Industries (Pvt) Ltd., 17/24, Korangi Industrial Area, Karachi. (000105)
	Application Form Dy. No / Tracking ID & date of submission
	(AR3-PUQ-2HB7, 2024-04-30)
	Detail of Fee Submitted
	30000.0, 2024-03-05,
	The proposed proprietary name / brand name
	Equlip 200mg capsule
	Label Claim
	Each capsule contains: Fenofibrate USP (micronized) 200mg (USP Specification)
	Reference to Finished product specifications
	United States Pharmacopeia
	Proposed Pack Size
	10's, 20's & 30's-As per SRO
	Shelf Life (Unit)
	2 Year(s)Store below 30 Degree Celsius Temperature
	For generic drugs (me-too Status)
	Fenoget capsule 200mg by M/s Getz Pharma
	Pharmacotherapeutic Group of (API)
	Antilipemic agents
	Name, address of Manufacturing site:
	Self Manufacturing
	Name & address of API manufacturer
	Everest organics Limited
	Detail of stability batches of drug product
	3 batches having batch size of 2000 capsule each
	Documents for the procurement of API with approval from DRAP (in case of Import)
	Firm has submitted copy of clearance certificate dated 15-08-2023 specifying 2.65kg Fenofibrate.
	Pharmaceutical Equivalence and Comparative Dissolution Profile
	PE and CDP studies performed against Fenoget 200mg capsules by M/s Getz Pharma.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)
	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV
	The status in reference regulatory authorities
	Fenofibrate 200mg Capsule MHRA Approved

GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 22-05-2023.																																		
Evidence of approval of manufacturing facility	Firm has submitted copy of letter for renewal of DML dated 27-04-2020 specifying Capsule (General) section.																																		
Evaluation Remarks																																			
Shortcomings	Firm's Response																																		
You have applied for innovator's specifications in module I while monograph for applied product is available in USP, clarify?	Corrected 1.5.6 Form 5F (Module I) with "USP Specifications", due to typographical error previously Innovator's Specifications was written in 1.5.6 Form 5F (Module I).																																		
Decision																																			
Approved																																			
The Registration Board further decided that the registration letter shall be issued after submission of the Pre-Registration Variation fee of Rs. 9,400/-, as per S.R.O. 1399(I)/2025 dated 01-08-2025.																																			
148	<table> <tr> <td>Case Category</td><td>Priority As Per 257-M of RB (Dr. Farhad Ullah)</td></tr> <tr> <td>Name, address of Applicant.</td><td>Al Habib Pharmaceuticals. Plot 81 SMCHS BLOCK B (0414)</td></tr> <tr> <td>Application Form Dy. No / Tracking ID & date of submission</td><td>(7J3-7TA-4Q4J, 2025-06-02)</td></tr> <tr> <td>Detail of Fee Submitted</td><td>300000.0, 2025-04-16,</td></tr> <tr> <td>The proposed proprietary name / brand name</td><td>SIMBIOTE</td></tr> <tr> <td>Label Claim</td><td>Each vial contains Bortezomib 2.5mg</td></tr> <tr> <td>Reference to Finished product specifications</td><td>Manufacturer Specification</td></tr> <tr> <td>Proposed Pack Size</td><td>1's (1 Vial)-As per SRO</td></tr> <tr> <td>Shelf Life (Unit)</td><td>2 Year(s)Store below 30 C</td></tr> <tr> <td>For generic drugs (me-too Status)</td><td>N/A (New Drug)</td></tr> <tr> <td>Pharmacotherapeutic Group of (API)</td><td>Antineoplastic agents, other antineoplastic Agents WHO ATC code; L01XG</td></tr> <tr> <td>Name, address of Manufacturing site:</td><td>JODAS EXPOIM PVT. LTD.-Plot No. 55, Phase III, Biotech Park, Karkapatla Village, Markook Mandal, Siddipet District, Telangana-502279, INDIA-India</td></tr> <tr> <td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>not submitted</td></tr> <tr> <td>Name, address of Marketing Authorization Holder:</td><td>JODAS EXPOIM PVT. LTD., Plot No. 55, Phase III, Biotech Park, Karkapatla Village, Markook Mandal, Siddipet District, Telangana-502279, INDIA.,</td></tr> <tr> <td>Details of Certificates (CoPP/FSC/cGMP):</td><td>GMP certificate: Firm has submitted copy of cGMP certificate of product manufacturer issued by Drug Control Administration, Government of Telangana India valid upto 04-06-2026. Certificate of Pharmaceutical Product: Firm has submitted copy of Certifica</td></tr> <tr> <td>Details of Authorization Letter :</td><td>Firm has submitted copy of letter of authorization from M/s JODAS EXPOIM PVT. LTD., Plot No. 55, Phase III, Biotech Park, Karkapatla (V), Markook (M), Siddipet (D), Telangana State-502279, India for applied product dated; 10-04-2025.</td></tr> <tr> <td>Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)</td><td>Stability study data of three batches is submitted Real time (24 months): 30°C ± 2 °C /75% ±5%RH Accelerated (6 months): 40°C±2 °C /75% ±5%RH</td></tr> </table>	Case Category	Priority As Per 257-M of RB (Dr. Farhad Ullah)	Name, address of Applicant.	Al Habib Pharmaceuticals. Plot 81 SMCHS BLOCK B (0414)	Application Form Dy. No / Tracking ID & date of submission	(7J3-7TA-4Q4J, 2025-06-02)	Detail of Fee Submitted	300000.0, 2025-04-16,	The proposed proprietary name / brand name	SIMBIOTE	Label Claim	Each vial contains Bortezomib 2.5mg	Reference to Finished product specifications	Manufacturer Specification	Proposed Pack Size	1's (1 Vial)-As per SRO	Shelf Life (Unit)	2 Year(s)Store below 30 C	For generic drugs (me-too Status)	N/A (New Drug)	Pharmacotherapeutic Group of (API)	Antineoplastic agents, other antineoplastic Agents WHO ATC code; L01XG	Name, address of Manufacturing site:	JODAS EXPOIM PVT. LTD.-Plot No. 55, Phase III, Biotech Park, Karkapatla Village, Markook Mandal, Siddipet District, Telangana-502279, INDIA-India	Pharmaceutical Equivalence and Comparative Dissolution Profile	not submitted	Name, address of Marketing Authorization Holder:	JODAS EXPOIM PVT. LTD., Plot No. 55, Phase III, Biotech Park, Karkapatla Village, Markook Mandal, Siddipet District, Telangana-502279, INDIA.,	Details of Certificates (CoPP/FSC/cGMP):	GMP certificate: Firm has submitted copy of cGMP certificate of product manufacturer issued by Drug Control Administration, Government of Telangana India valid upto 04-06-2026. Certificate of Pharmaceutical Product: Firm has submitted copy of Certifica	Details of Authorization Letter :	Firm has submitted copy of letter of authorization from M/s JODAS EXPOIM PVT. LTD., Plot No. 55, Phase III, Biotech Park, Karkapatla (V), Markook (M), Siddipet (D), Telangana State-502279, India for applied product dated; 10-04-2025.	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of three batches is submitted Real time (24 months): 30°C ± 2 °C /75% ±5%RH Accelerated (6 months): 40°C±2 °C /75% ±5%RH
Case Category	Priority As Per 257-M of RB (Dr. Farhad Ullah)																																		
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Proposed Pack Size	1's (1 Vial)-As per SRO																																		
Shelf Life (Unit)	2 Year(s)Store below 30 C																																		
For generic drugs (me-too Status)	N/A (New Drug)																																		
Pharmacotherapeutic Group of (API)	Antineoplastic agents, other antineoplastic Agents WHO ATC code; L01XG																																		
Name, address of Manufacturing site:	JODAS EXPOIM PVT. LTD.-Plot No. 55, Phase III, Biotech Park, Karkapatla Village, Markook Mandal, Siddipet District, Telangana-502279, INDIA-India																																		
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Details of Certificates (CoPP/FSC/cGMP):	GMP certificate: Firm has submitted copy of cGMP certificate of product manufacturer issued by Drug Control Administration, Government of Telangana India valid upto 04-06-2026. Certificate of Pharmaceutical Product: Firm has submitted copy of Certifica																																		
Details of Authorization Letter :	Firm has submitted copy of letter of authorization from M/s JODAS EXPOIM PVT. LTD., Plot No. 55, Phase III, Biotech Park, Karkapatla (V), Markook (M), Siddipet (D), Telangana State-502279, India for applied product dated; 10-04-2025.																																		
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of three batches is submitted Real time (24 months): 30°C ± 2 °C /75% ±5%RH Accelerated (6 months): 40°C±2 °C /75% ±5%RH																																		

The status in reference regulatory authorities	Bortezomib Sandoz 2.5 mg powder for solution for injection MHRA Approved, Netherlands Approved

Evaluation Remarks

Firm have stated that, "we are in the process of obtaining attestation for 1. Letter of Authorization 2. COPP 3. GMP Drug Product Manufacturer." We anticipate that the attestation and notarization from the Embassy of Pakistan will take approximately 150 days. We will submit the attested and legalized documents to DRAP immediately upon receipt.

Shortcomings	Firm's response
Submit label claim of applied product as per reference formulation in module I	The firm has submitted label claim as; Each vial contains 2.5 mg bortezomib
Results of Pharmaceutical Equivalence study against the innovator's/reference product shall be submitted	PE studies performed against RMP-Bortezomib Sandoz 2.5 Mg, Powder For Solution For Injection

Decision

Approved

Approved as per policy for inspection of manufacturer abroad. The Registration Board further decided that registration letter shall be issued upon submission of the original legalized COPP, GMP Certificate and notarized Letter of Authorization.

149	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	Martin Dow Marker Limited 7, Jail Road Quetta. (000028)
	Application Form Dy. No / Tracking ID & date of submission	(8UQ-G1V-PXXS, 2024-03-11)
	Detail of Fee Submitted	75000.0, 2023-12-26,
	The proposed proprietary name / brand name	Renocard
	Label Claim	Each film coated tablet contains: Finerenone.....10mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	As per DPC-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Mineralocorticoid receptor antagonists
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Henan JinHuaitang Biological Engineering., Co.,Ltd, Address: No.5329, Hesudadao Road Street Avenue, Wuzhi Country, Jiaozuo City, Henan Provice.,China
	Detail of stability batches of drug product	3 batches having batch size of 10000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of form 6 issued dated 11-05-2023 specifying 870gm Finerenone.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Kerendia 10mg tablet by M/s Bayer AG, Kaiser- Wilhelm-Allee 51368 Leverkusen, Germany.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A
	The status in reference regulatory authorities	Kerendia 10mg Film Coated Tablet
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 15th and 16th January 2024.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Regularization of Sections dated 31-05-2021 specifying Tablet (General) section.

Evaluation Remarks

Shortcomings	Firm's Response
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# YU20230200 of API manufacturer issued by Medical Products Administration valid upto 15-06-2028 is submitted
Justification shall be submitted for selection of different time of dissolution test (15min) in finished product specifications than innovators product (30 min)	The firm stated that we had followed innovator dissolution time point and submitted finished product specifications and analytical method documents for reference.
Stability study data of applied product at 6th month time point shall be submitted	Submitted
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 11-05-2023 specifying 870gm Finerenone. Firm has also submitted copy of goods declaration, invoice, packing list, form 3, form 7 and airway bill for procurement of API.

Decision**Approved**

150	Case Category	New Section (Dr. Farhad Ullah)
	Name, address of Applicant.	Kaizen Pharmaceuticals (Pvt) Ltd Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi (000755)
	Application Form Dy. No / Tracking ID & date of submission	(J66-JAL-1LU5, 2025-07-18)
	Detail of Fee Submitted	37000.0, 2025-02-14,
	The proposed proprietary name / brand name	OSIMER 80mg Tablet
	Label Claim	Each Film coated Tablet Contains: Osimertinib mesylate 95.4 mg eq. to Osimertinib.....80mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30°C in a cool and dry place
	For generic drugs (me-too Status)	Tagrix tablet 80mg Reg# 114222
	Pharmacotherapeutic Group of (API)	Protein kinase inhibitor (antineoplastic) ATC Code; L01E
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	GANSU HAOTIAN PHARMATECH CO., LTD Address: No.11 Chongqing Road,Baiyin District, Baiyin City, Gansu Province,
	Detail of stability batches of drug product	3 batches having batch size of 500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of form 6 issued dated 25-09-2024 specifying 0.500kg Osimertinib Mesylate.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against TAGRISSO 80mg Tablet by M/s AstraZeneca Pharmaceuticals
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A
	The status in reference regulatory authorities	TAGRISSO 80mg film coated tablets MHRA Approved (PLGB 17901/0341)

GMP status of the firm	New section																								
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 10-05-2024 specifying Tablet Cytotoxic (New) Section.																								
Evaluation Remarks																									
Shortcomings	Firm's response																								
Clarification shall be submitted for selecting different mobile phase composition in assay test of drug substance by drug product manufacturer than drug substance manufacturer	The firm has submitted that, we would like to clarify that the mobile phase composition used for the assay of the drug substance is the same for both the drug substance manufacturer and the drug product manufacturer. There is no variation in the mobile phase composition or test parameters. For your kind reference, we are resubmitting the assay test methods from both manufacturers, which were previously included in the initial dossier submission. Mobile phase composition is as follows: Mobile Phase A: Water:ACN:TFA=95:5:0.05(v/v) Mobile Phase B: Water:ACN:TFA=5:95:0.05(v/v)																								
The composition of mobile phase in testing method of drug substance manufacturer submitted in your reply is different than the one initially submitted in dossier. Clarification shall be submitted.	The firm submitted that we would like to intimate your good office that we have submitted the updated Method provided by Drug substance manufacturer in response to the query. We hereby resubmitting the updated method along with the AMV provided by Drug substance manufacturer.																								
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 25-09-2024 specifying 0.500kg Osimertinib Mesylate. Firm has submitted copy of commercial invoice for Osimertinib Mesylate not attested by AD I&E DRAP. Firm has also submitted copy of form 3 and FedEx courier receipt.																								
Decision																									
Approved																									
151	<table> <tr> <td>Case Category</td><td>New Section (Dr. Farhad Ullah)</td></tr> <tr> <td>Name, address of Applicant.</td><td>Kaizen Pharmaceuticals (Pvt) Ltd Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi (000755)</td></tr> <tr> <td>Application Form Dy. No / Tracking ID & date of submission</td><td>(R71-NT5-NRA9, 2025-07-18)</td></tr> <tr> <td>Detail of Fee Submitted</td><td>37000.0, 2025-05-19,</td></tr> <tr> <td>The proposed proprietary name / brand name</td><td>Osimer 40mg Tablet</td></tr> <tr> <td>Label Claim</td><td>Each Film Coated Tablet Contains: Osimertinib mesylate 47.7mg equivalent to Osimertinib..... 40mg</td></tr> <tr> <td>Reference to Finished product specifications</td><td>As per Innovators Specification</td></tr> <tr> <td>Proposed Pack Size</td><td>10's-As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO</td></tr> <tr> <td>Shelf Life (Unit)</td><td>2 Year(s)Store in a cool and dry place. Below 30°C</td></tr> <tr> <td>For generic drugs (me-too Status)</td><td>Tagrisso 40mg, Imported by: AstraZeneca Pharmaceuticals Pakistan Private Limit</td></tr> <tr> <td>Pharmacotherapeutic Group of (API)</td><td>Protein kinase inhibitor (antineoplastic) ATC Code; L01E</td></tr> <tr> <td>Name, address of Manufacturing site:</td><td>Self Manufacturing</td></tr> </table>	Case Category	New Section (Dr. Farhad Ullah)	Name, address of Applicant.	Kaizen Pharmaceuticals (Pvt) Ltd Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi (000755)	Application Form Dy. No / Tracking ID & date of submission	(R71-NT5-NRA9, 2025-07-18)	Detail of Fee Submitted	37000.0, 2025-05-19,	The proposed proprietary name / brand name	Osimer 40mg Tablet	Label Claim	Each Film Coated Tablet Contains: Osimertinib mesylate 47.7mg equivalent to Osimertinib..... 40mg	Reference to Finished product specifications	As per Innovators Specification	Proposed Pack Size	10's-As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO	Shelf Life (Unit)	2 Year(s)Store in a cool and dry place. Below 30°C	For generic drugs (me-too Status)	Tagrisso 40mg, Imported by: AstraZeneca Pharmaceuticals Pakistan Private Limit	Pharmacotherapeutic Group of (API)	Protein kinase inhibitor (antineoplastic) ATC Code; L01E	Name, address of Manufacturing site:	Self Manufacturing
Case Category	New Section (Dr. Farhad Ullah)																								
Name, address of Applicant.	Kaizen Pharmaceuticals (Pvt) Ltd Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi (000755)																								
Application Form Dy. No / Tracking ID & date of submission	(R71-NT5-NRA9, 2025-07-18)																								
Detail of Fee Submitted	37000.0, 2025-05-19,																								
The proposed proprietary name / brand name	Osimer 40mg Tablet																								
Label Claim	Each Film Coated Tablet Contains: Osimertinib mesylate 47.7mg equivalent to Osimertinib..... 40mg																								
Reference to Finished product specifications	As per Innovators Specification																								
Proposed Pack Size	10's-As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO																								
Shelf Life (Unit)	2 Year(s)Store in a cool and dry place. Below 30°C																								
For generic drugs (me-too Status)	Tagrisso 40mg, Imported by: AstraZeneca Pharmaceuticals Pakistan Private Limit																								
Pharmacotherapeutic Group of (API)	Protein kinase inhibitor (antineoplastic) ATC Code; L01E																								
Name, address of Manufacturing site:	Self Manufacturing																								

Name & address of API manufacturer	GANSU HAOTIAN PHARMATECH CO., LTD. Address: No.11 Chongqing Road, Baiyin District, Baiyin City, Gansu Province,
Detail of stability batches of drug product	3 batches having batch size of 500 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of Form 6 issued dated 25-09-2024 specifying 0.500kg Osimertinib Mesylate.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against TAGRISSO 40mg Tablet by M/s AstraZeneca Pharmaceuticals
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A
The status in reference regulatory authorities	TAGRISSO 40 mg film-coated tablets MHRA Approved (PLGB 17901/0340)
GMP status of the firm	New section
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 10-05-2024 specifying Tablet Cytotoxic (New) Section.
Evaluation Remarks	
Shortcomings	Firm's response
Clarification shall be submitted for selecting different mobile phase composition in assay test of drug substance by drug product manufacturer than drug substance manufacturer	The firm has submitted that, we would like to clarify that the mobile phase composition used for the assay of the drug substance is the same for both the drug substance manufacturer and the drug product manufacturer. There is no variation in the mobile phase composition or test parameters. For your kind reference, we are resubmitting the assay test methods from both manufacturers, which were previously included in the initial dossier submission. Mobile phase composition is as follows: Mobile Phase A: Water:ACN:TFA=95:5:0.05(v/v) Mobile Phase B: Water:ACN:TFA=5:95:0.05(v/v)
The composition of mobile phase in testing method of drug substance manufacturer submitted in your reply is different than the one initially submitted in dossier. Clarification shall be submitted.	The firm submitted that we would like to intimate your good office that we have submitted the updated Method provided by Drug substance manufacturer in response to the query .We hereby resubmitting the updated method along with the AMV provided by Drug substance manufacturer.
Submit copy of commercial invoice or clearance certificate for the procurement of API with approval from DRAP.	Firm has submitted form 6 issued dated 25-09-2024 specifying 0.500kg Osimertinib Mesylate. Firm has submitted copy of commercial invoice for Osimertinib Mesylate not attested by AD I&E DRAP. Firm has also submitted copy of form 3 and FedEx courier receipt.
Decision	
Approved	
152	
Case Category	New Section (Dr. Farhad Ullah)
Name, address of Applicant.	Kaizen Pharmaceuticals (Pvt) Ltd Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi (000755)
Application Form Dy. No / Tracking ID & date of submission	(MUH-148-DLBM, 2025-07-18)

Detail of Fee Submitted	37000.0, 2025-07-02,
The proposed proprietary name / brand name	OLARIB 100mg Tablet
Label Claim	Each film coated tablet contains: Olaparib.....100mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	120's-As per SRO,60's-As per SRO
Shelf Life (Unit)	2 Year(s)Store in a cool and dry place. Below 30°C
For generic drugs (me-too Status)	LYNPARZA 100mg tablet Imported By AstraZeneca Pharmaceuticals Pakistan Private Limited, C- 50, Block-2, Clifton, Karachi Pakistan Reg#125525
Pharmacotherapeutic Group of (API)	(ADP-ribose) polymerase (PARP) inhibitor ATC Code; L01XK01
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	ANHUI HAIKANG PHARMACEUTICAL CO., LTD.Address No. 21 Huancheng West Road Anqing city Anhui province 246000 China
Detail of stability batches of drug product	3 batches having batch size of 700 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of form 6 issued dated 27-11-2024 specifying 0.600kg Olaparib.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Lynparza 100mg tablets by M/s AstraZeneca Pharmaceuticals
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A
The status in reference regulatory authorities	LYNPARZA (100mg, 150mg) film coated tablets USFDA Approved
GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 20-11-2024.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 10-05-2024 specifying Tablet Cytotoxic (New) Section.
Evaluation Remarks	
Shortcomings	Firm's response
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 of API manufacturer issued by Anhui Provincial Medical Products Administration valid upto 31-12-2025.
Submit copy of commercial invoice or clearance certificate for the procurement of API with approval from DRAP.	Firm has submitted copy of Final clearance certificate issued dated 28-10-2024 specifying 0.600kg Olaparib.
Clarification shall be submitted since the clearance certificate of API is obtained prior to the issuance of drug import license (form6).	Firm has submitted copy of another form 6 issued dated 22-09-2024 specifying 1kg Olaparib.
Decision	
Approved	
153 Case Category	Routine (Dr. Farhad Ullah)
Name, address of Applicant.	TABROS PHARMA (PVT). LTD. Plot No. L-20/B, Sector 22, F.B. Industrial Area (000106)

Application Form Dy. No / Tracking ID & date of submission	(DTP-995-6A4X, 2024-04-23)
Detail of Fee Submitted	30000.0, 2024-03-27,
The proposed proprietary name / brand name	Linoxy-Met 2.5mg/500mg Tablet
Label Claim	Each film coated tablet contains: Linagliptin.....2.5mg Metformin HCl.....500mg Innovator's Specification
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	10's Tablet-As per SRO,14's Tablet-As per SRO,20's Tablet-As per SRO,28's Tablet-As per SRO,30's Tablet- As per SRO,60's Tablet-As per SRO
Shelf Life (Unit)	2 Year(s)Store below 30oC
For generic drugs (me-too Status)	Lina-Met 2.5mg/500mg Tablet, M/s. CCL Pharmaceuticals (Reg# 121629)
Pharmacotherapeutic Group of (API)	Blood Glucose Lowering Drugs
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Aarti Drugs Limited, Plot No. 211- 213, Road No 02. G.I.D.C., Sarigam, Dist: Valsad, Gujrat. India 396155,M/s Ruyuan HEC Pharm Co. Ltd., XIABA Development Zone Shaoguan City Guangdong Province P.R China
Detail of stability batches of drug product	3 batches having batch size of 1500 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of form 6 issued dated 01-02- 2023 specifying 0.51gm Linagliptin. Firm has submitted copy of clearance certificate dated 22-12-2022 specifying 1000kg Metformin HCl.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Trajenta Duo 2.5mg/500mg Tablet by M/s Boehringer Ingelheim.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV
The status in reference regulatory authorities	Jentaduetto,Boehringer Ingelheim Pharmaceuticals, USFDA Approved
GMP status of the firm	Firm has submitted copy of cGMP certificate issued based on inspection dated 28-03-2024.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter for renewal of DML dated 30-06-2020 specifying tablet (General) section.
Evaluation Remarks	
ANDA in USFDA has got tentative approval due to patent issue.	
Shortcomings	Firm's Response
Clarification shall be submitted for selecting USP specifications for metformin hydrochloride by drug product manufacturer since drug substance manufacturer claims for BP specifications	Yes, we have selected and followed the USP specifications for the testing of Metformin Hydrochloride. Although the drug substance manufacturer claims BP specifications, we opted for the USP monograph because its assay method is based on High-Performance Liquid Chromatography (HPLC), which is scientifically recognized as a more precise, accurate, and robust analytical technique compared to the titration-based method described in the BP monograph. Given the critical importance of assay precision in confirming product quality and compliance, the adoption of the USP method is justified and aligns with best industry practices.

Clarification shall be submitted for selecting different limit of assay test in drug substance specifications by drug product manufacturer (98%-102%) than drug substance manufacturer (98.5%-101%)	The assay limit specified by the drug substance manufacturer (98.5%–101.0%) is based on the BP monograph. However, as the drug product manufacturer, we have adopted the USP monograph for the testing of Metformin Hydrochloride, which specifies an assay limit of 98.0%–102.0%. Our selected specification aligns with the adopted analytical method and ensures consistency with the compendial requirements of the USP.
Submit copy of commercial invoice or clearance certificate for the procurement of linagliptin with approval from DRAP.	Firm has submitted copy of commercial Invoice and goods declaration along with form 6 for procurement of API linagliptin. Firm submitted that at the time of procurement of Linagliptin for the development of applied product the Custom Clearance was obtained based on Form 6 issued from DRAP ADC Office.

Decision

Approved

154	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	TABROS PHARMA (PVT). LTD. Plot No. L-20/B, Sector 22, F.B. Industrial Area (000106)
	Application Form Dy. No / Tracking ID & date of submission	(NN1-NSX-PNZZ, 2024-04-23)
	Detail of Fee Submitted	30000.0, 2024-03-27,
	The proposed proprietary name / brand name	Linoxy-Met 2.5mg/850mg Tablet
	Label Claim	Linoxy-Met 2.5mg/850mg Tablet Composition: Each film coated tablet contains: Linagliptin.....2.5mg Metformin HCl.....850mg Innovator's Specification
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's Tablet-As per SRO,14's Tablet-As per SRO,20's Tablet-As per SRO,28's Tablet-As per SRO,30's Tablet-As per SRO,60's Tablet-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30oC
	For generic drugs (me-too Status)	Lina-Met 2.5mg/850mg Tablet, M/s. CCL Pharmaceuticals (Reg#121630)
	Pharmacotherapeutic Group of (API)	Blood Glucose Lowering Drugs
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Aarti Drugs Limited Plot No. 211- 213, Road No 02. G.I.D.C., Sarigam, Dist: Valsad, Gujrat. India 396155.,Ruyuan HEC Pharm Co. Ltd. Xiaba Development Zone, Ruyuan Country, Shaoguan City, Guangdong Province, P.R. China, Postal Code: 512721
	Detail of stability batches of drug product	3 batches having batch size of 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of form 6 issued dated 01-02-2023 specifying 0.51gm Linagliptin. Firm has submitted copy of clearance certificate dated 22-12-2022 specifying 1000kg Metformin HCl.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Trajenta Duo 2.5mg/850mg Tablet by M/s Boehringer Ingelheim.

Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV
The status in reference regulatory authorities	Jentaducto,Boehringer Ingelheim Pharmaceuticals, USFDA Approved
GMP status of the firm	Firm has submitted copy of cGMP certificate issued based on inspection dated 28-03-2024.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter for renewal of DML dated 30-06-2020 specifying tablet (General) section.

Evaluation Remarks

ANDA in USFDA has got tentative approval due to patent issue.

Shortcomings	Firm's Response
Clarification shall be submitted for selecting USP specifications for metformin hydrochloride by drug product manufacturer since drug substance manufacturer claims for BP specifications	Yes, we have selected and followed the USP specifications for the testing of Metformin Hydrochloride. Although the drug substance manufacturer claims BP specifications, we opted for the USP monograph because its assay method is based on High-Performance Liquid Chromatography (HPLC), which is scientifically recognized as a more precise, accurate, and robust analytical technique compared to the titration-based method described in the BP monograph. Given the critical importance of assay precision in confirming product quality and compliance, the adoption of the USP method is justified and aligns with best industry practices.
Clarification shall be submitted for selecting different limit of assay test in drug substance specifications by drug product manufacturer (98%-102%) than drug substance manufacturer (98.5%-101%)	The assay limit specified by the drug substance manufacturer (98.5%–101.0%) is based on the BP monograph. However, as the drug product manufacturer, we have adopted the USP monograph for the testing of Metformin Hydrochloride, which specifies an assay limit of 98.0%–102.0%. Our selected specification aligns with the adopted analytical method and ensures consistency with the compendial requirements of the USP.
Submit copy of commercial invoice or clearance certificate for the procurement of linagliptin with approval from DRAP.	Firm has submitted copy of commercial Invoice and goods declaration along with form 6 for procurement of API linagliptin. Firm submitted that at that time clearance was granted on the basis of Form 6.

Decision

Approved

155	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	TABROS PHARMA (PVT). LTD. Plot No. L-20/B, Sector 22, F.B. Industrial Area (000106)
	Application Form Dy. No / Tracking ID & date of submission	(R97-W3V-NS3N, 2024-04-23)
	Detail of Fee Submitted	30000.0, 2024-03-27,
	The proposed proprietary name / brand name	Linoxy-Met 2.5mg/1000mg Tablet
	Label Claim	Composition: Each film coated tablet contains: Linagliptin.....2.5mg Metformin HCl.....1000mg Innovator's Specification
	Reference to Finished product specifications	As per Innovators Specification

Proposed Pack Size	10's Tablet-As per SRO,14's Tablet-As per SRO,20's Tablet-As per SRO,28's Tablet-As per SRO,30's Tablet-As per SRO,60's Tablet-As per SRO
Shelf Life (Unit)	2 Year(s)Store below 30oC
For generic drugs (me-too Status)	Lina-Met 2.5mg/1000mg Tablet, M/s. CCL Pharmaceuticals (Reg# 121631)
Pharmacotherapeutic Group of (API)	Blood Glucose Lowering Drugs
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Aarti Drugs Limited Plot No. 211- 213, Road No 02. G.I.D.C., Sarigam, Dist: Valsad, Gujrat. India 396155.,M/s Ruyuan HEC Pharm Co. Ltd., XIABA Development Zone Shaoguan City Guangdong Province P.R China
Detail of stability batches of drug product	3 batches having batch size of 1500 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of form 6 issued dated 01-02-2023 specifying 0.51gm Linagliptin. Firm has submitted copy of clearance certificate dated 22-12-2022 specifying 1000kg Metformin HCl.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Trajenta Duo 2.5mg/1000mg Tablet by M/s Boehringer Ingelheim.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV
The status in reference regulatory authorities	Jentaducto,Boehringer Ingelheim Pharmaceuticals, USFDA Approved
GMP status of the firm	Firm has submitted copy of cGMP certificate issued based on inspection dated 28-03-2024.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter for renewal of DML dated 30-06-2020 specifying tablet (General) section.

Evaluation Remarks

ANDA in USFDA has got tentative approval due to patent issue.

Shortcomings	Firm's Response
Clarification shall be submitted for selecting USP specifications for metformin hydrochloride by drug product manufacturer since drug substance manufacturer claims for BP specifications	Yes, we have selected and followed the USP specifications for the testing of Metformin Hydrochloride. Although the drug substance manufacturer claims BP specifications, we opted for the USP monograph because its assay method is based on High-Performance Liquid Chromatography (HPLC), which is scientifically recognized as a more precise, accurate, and robust analytical technique compared to the titration-based method described in the BP monograph. Given the critical importance of assay precision in confirming product quality and compliance, the adoption of the USP method is justified and aligns with best industry practices.
Clarification shall be submitted for selecting different limit of assay test in drug substance specifications by drug product manufacturer (98%-102%) than drug substance manufacturer (98.5%-101%)	The assay limit specified by the drug substance manufacturer (98.5%–101.0%) is based on the BP monograph. However, as the drug product manufacturer, we have adopted the USP monograph for the testing of Metformin Hydrochloride, which specifies an assay limit of 98.0%–102.0%. Our selected specification aligns with the adopted analytical method and ensures consistency with the compendial requirements of the USP.

	Submit copy of commercial invoice or clearance certificate for the procurement of linagliptin with approval from DRAP.	Firm has submitted copy of commercial Invoice and goods declaration along with form 6 for procurement of API linagliptin. Firm submitted that at that time clearance was granted on the basis of Form 6.
Decision		
Approved		
156	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	Maxitech Pharma (Pvt) Ltd. E-178, S.I.T.E., Super Highway Phase-II, Karachi (000851)
	Application Form Dy. No / Tracking ID & date of submission	(ER7-31X-BE5Y, 2024-03-22)
	Detail of Fee Submitted	30000.0, 9000.0 2024-01-11, 2025-07-02
	The proposed proprietary name / brand name	Empamet 12.5mg + 850mg tablet
	Label Claim	Each Film coated Tablet Contains: Empagliflozin.....12.5mg Metformin HCl.....850mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	14,s or as per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a cool, dry place below 30 degrees Celsius.
	For generic drugs (me-too Status)	Adrance-M 12.5mg + 850mg Tablet by ATCO Laboratories
	Pharmacotherapeutic Group of (API)	Biguanide/Reversible inhibitor of sodium-glucose co-transporter 2 (SGLT2)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Empagliflozin; Anhui Haikang Pharmaceutical Co., Ltd. China; Metformin HCl; Ningxia Hengkang Technology Co., Ltd. China
	Detail of stability batches of drug product	3 batches having batch size of 1000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of commercial invoice cleared dated 17-09-2020 specifying 02kg Empagliflozin. Firm has submitted copy of commercial invoice cleared dated 04-08-2021 specifying 25kg Metformin HCl.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies and CDP performed against Diampa-M 12.5mg/850mg Tablet manufactured by M/s Getz Pharma.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of 3 batches of drug substance at real time conditions as per Zone IV is not submitted
	The status in reference regulatory authorities	SYNJARDY (5mg/850mg, 5mg/1000mg, 12.5mg/850mg, and 12.5mg/1000mg) film-coated tablet EMA approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 23, 24 June and 04-July 2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 25-11-2016 specifying Tablet (General) section.
Evaluation Remarks		
	Shortcomings	Firm's Response

Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3	Copy of BMR for all the batches of drug product is submitted.
Stability study data of empagliflozin and metformin at real time conditions as per zone IV till claimed shelf life shall be submitted	Empagliflozin Stability study data of 3 batches of drug substance at real time conditions as per Zone IV-A till 36th month is submitted. Metformin Stability study data of 3 batches of drug substance at real time conditions as per Zone IV-A till 18th months is submitted.
Justification shall be submitted for selection of different time for dissolution test (30min) in finished product specifications than innovator product (20min)	We have revised our finished product specifications in accordance with the innovator's specification, which mentions a dissolution time of 20 minutes. A copy of our revised Specification and Testing Methods (STM), reflecting the updated dissolution time, is attached for reference. Furthermore, the required Change of Specification Fee of Rs. 9,000 has been submitted as per DRAP policy. The paid challan is also attached for your kind consideration.
Stability study data of applied product at 6th month time point shall be submitted	Submitted

Decision

Approved

157	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	Maxitech Pharma (Pvt) Ltd. E-178, S.I.T.E., Super Highway Phase-II, Karachi (000851)
	Application Form Dy. No / Tracking ID & date of submission	(GBA-B2Q-731T, 2024-03-25)
	Detail of Fee Submitted	30000.0, 9000.0 2024-01-11, 2025-07-02
	The proposed proprietary name / brand name	Empamet 5mg + 850 mg Tablet
	Label Claim	Each Film coated Tablet Contains: Empagliflozin.....5mg Metformin HCl.....850mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	14,s or as per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a cool, dry place below 30 degrees Celsius.
	For generic drugs (me-too Status)	Adrance-M 5mg + 850mg Tablet by ATCO Laboratories
	Pharmacotherapeutic Group of (API)	Biguanide/Reversible inhibitor of sodium-glucose co-transporter 2 (SGLT2)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Empagliflozin; Anhui Haikang Pharmaceutical Co., Ltd. China; Metformin HCl; Ningxia Hengkang Technology Co., Ltd. China
	Detail of stability batches of drug product	3 batches having batch size of 1000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of commercial invoice cleared dated 17-09-2020 specifying 02kg Empagliflozin. Firm has submitted copy of commercial invoice cleared dated 04-08-2021 specifying 25kg Metformin HCl.

Pharmaceutical Equivalence and Comparative Dissolution Profile	PE & CDP performed against Diampa-M 5mg/850mg Tablet manufactured by M/s Getz Pharma.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of 3 batches of drug substance at real time conditions as per Zone IV is not submitted
The status in reference regulatory authorities	SYNJARDY (5mg/850mg, 5mg/1000mg, 12.5mg/850mg, and 12.5mg/1000mg) film-coated tablet EMA approved
GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 23, 24 June and 04-July 2022.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 25-11-2016 specifying Tablet (General) section.

Evaluation Remarks

Shortcomings	Firm's Response
Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3	Copy of BMR for all the batches of drug product is submitted.
Stability study data of empagliflozin and metformin at real time conditions as per zone IV till claimed shelf life shall be submitted	Empagliflozin Stability study data of 3 batches of drug substance at real time conditions as per Zone IV-A till 36th month is submitted. Metformin Stability study data of 3 batches of drug substance at real time conditions as per Zone IV-A till 18th months is submitted.
Justification shall be submitted for selection of different time for dissolution test (30min) in finished product specifications than innovator product (20min)	We have revised our finished product specifications in accordance with the innovator's specification, which mentions a dissolution time of 20 minutes. A copy of our revised Specification and Testing Methods (STM), reflecting the updated dissolution time, is attached for reference. Furthermore, the required Change of Specification Fee of Rs. 9,000 has been submitted as per DRAP policy. The paid challan is also attached for your kind consideration.
Stability study data of applied product at 6th month time point shall be submitted	Submitted

Decision

Approved

158	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	Maxitech Pharma (Pvt) Ltd. E-178, S.I.T.E., Super Highway Phase-II, Karachi (000851)
	Application Form Dy. No / Tracking ID & date of submission	(RL5-LUG-7J7U, 2024-03-22)
	Detail of Fee Submitted	30000.0, 9000.0 2024-01-11, 2025-07-02
	The proposed proprietary name / brand name	Empamet 5mg + 500mg tablet
	Label Claim	Each Film coated Tablet Contains: Empagliflozin.....5mg Metformin HCl.....500mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	14,s or as per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a cool, dry place below 30 degrees Celsius.

For generic drugs (me-too Status)	Adrance-M 5mg + 500mg Tablet by ATCO Laboratories
Pharmacotherapeutic Group of (API)	Biguanide/Reversible inhibitor of sodium-glucose co-transporter 2 (SGLT2)
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Empagliflozin; Anhui Haikang Pharmaceutical Co., Ltd. China; Metformin HCl; Ningxia Hengkang Technology Co., Ltd. China
Detail of stability batches of drug product	3 batches having batch size of 1000 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of commercial invoice cleared dated 17-09-2020 specifying 02kg Empagliflozin. Firm has submitted copy of commercial invoice cleared dated 04-08-2021 specifying 25kg Metformin HCl.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies and CDP performed against Diampa-M 5mg/500mg Tablet manufactured by M/s Getz Pharma.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of 3 batches of drug substance at real time conditions as per Zone IV is not submitted
The status in reference regulatory authorities	SYNJARDY (5mg/500mg, 5mg/1000mg, 12.5mg/500mg, 12.5mg/1000mg) film-coated tablet USFDA approved
GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 23, 24 June and 04-July 2022.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 25-11-2016 specifying Tablet (General) section.
Evaluation Remarks	
Shortcomings	Firm's Response
Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3	Copy of BMR for all the batches of drug product is submitted.
Stability study data of empagliflozin and metformin at real time conditions as per zone IV till claimed shelf life shall be submitted	Empagliflozin Stability study data of 3 batches of drug substance at real time conditions as per Zone IV-A till 36th month is submitted. Metformin Stability study data of 3 batches of drug substance at real time conditions as per Zone IV-A till 18th months is submitted.
Justification shall be submitted for selection of different time for dissolution test (30min) in finished product specifications than innovator product (20min)	We have revised our finished product specifications in accordance with the innovator's specification, which mentions a dissolution time of 20 minutes. A copy of our revised Specification and Testing Methods (STM), reflecting the updated dissolution time, is attached for reference. Furthermore, the required Change of Specification Fee of Rs. 9,000 has been submitted as per DRAP policy. The paid challan is also attached for your kind consideration.
Stability study data of applied product at 6th month time point shall be submitted	Submitted
Decision	
Approved	
159	Case Category
	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.
	Maxitech Pharma (Pvt) Ltd. E-178, S.I.T.E., Super Highway Phase-II, Karachi (000851)

Application Form Dy. No / Tracking ID & date of submission	(TBA-NHW-M24U, 2024-03-25)
Detail of Fee Submitted	30000.0, 9000.0 2024-01-11, 2025-07-02
The proposed proprietary name / brand name	Empamet 12.5mg + 1000mg tablet
Label Claim	Each Film coated Tablet Contains: Empagliflozin.....12.5mg Metformin HCl.....1000mg
Reference to Finished product specifications	Manufacturer Specification
Proposed Pack Size	14,s or as per SRO-As per SRO
Shelf Life (Unit)	2 Year(s)Store in a cool, dry place below 30 degrees Celsius.
For generic drugs (me-too Status)	Adrance-M 12.5mg + 1000mg Tablet by ATCO Laboratories
Pharmacotherapeutic Group of (API)	Biguanide/Reversible inhibitor of sodium-glucose co-transporter 2 (SGLT2)
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Empagliflozin; Anhui Haikang Pharmaceutical Co., Ltd. China; Metformin HCl; Ningxia Henggang Technology Co., Ltd. China
Detail of stability batches of drug product	3 batches having batch size of 1000 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of commercial invoice cleared dated 17-09-2020 specifying 02kg Empagliflozin. Firm has submitted copy of commercial invoice cleared dated 04-08-2021 specifying 25kg Metformin HCl.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE & CDP performed against Diampa-M 12.5mg/1000mg Tablet manufactured by M/s Getz Pharma.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of 3 batches of drug substance at real time conditions as per Zone IV is not submitted
The status in reference regulatory authorities	SYNJARDY (5mg/500mg, 5mg/1000mg, 12.5mg/500mg, 12.5mg/1000mg) film-coated tablet USFDA approved
GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 23, 24 June and 04-July 2022.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 25-11-2016 specifying Tablet (General) section.
Evaluation Remarks	
Shortcomings	Firm's Response
Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3	Copy of BMR for all the batches of drug product is submitted.
Stability study data of empagliflozin and metformin at real time conditions as per zone IV till claimed shelf life shall be submitted	Empagliflozin Stability study data of 3 batches of drug substance at real time conditions as per Zone IV-A till 36th month is submitted. Metformin Stability study data of 3 batches of drug substance at real time conditions as per Zone IV-A till 18th months is submitted.
Justification shall be submitted for selection of different time for dissolution test (30min) in finished product specifications than innovator product (20min)	We have revised our finished product specifications in accordance with the innovator's specification, which mentions a dissolution time of 20 minutes. A copy of our revised Specification and Testing Methods (STM), reflecting the updated dissolution time, is attached for

	reference. Furthermore, the required Change of Specification Fee of Rs. 9,000 has been submitted as per DRAP policy. The paid challan is also attached for your kind consideration.
Stability study data of applied product at 6th month time point shall be submitted	Submitted

Decision

Approved

160	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	Maxitech Pharma (Pvt) Ltd. E-178, S.I.T.E., Super Highway Phase-II, Karachi (000851)
	Application Form Dy. No / Tracking ID & date of submission	(ZD1-8S7-18R3, 2024-03-25)
	Detail of Fee Submitted	30000.0, 9000.0 2024-01-11, 2025-07-02
	The proposed proprietary name / brand name	Empamet 12.5mg + 500mg tablet
	Label Claim	Each Film coated Tablet Contains: Empagliflozin.....12.5mg Metformin HCl.....500mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	14,s or as per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a cool, dry place below 30 degrees Celsius.
	For generic drugs (me-too Status)	Adrance-M 12.5mg + 500mg Tablet by ATCO Laboratories
	Pharmacotherapeutic Group of (API)	Biguanide/Reversible inhibitor of sodium-glucose co-transporter 2 (SGLT2)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Empagliflozin; Anhui Haikang Pharmaceutical Co., Ltd. China; Metformin HCl; Ningxia Hengkang Technology Co., Ltd. China
	Detail of stability batches of drug product	3 batches having batch size of 1000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of commercial invoice cleared dated 17-09-2020 specifying 02kg Empagliflozin. Firm has submitted copy of commercial invoice cleared dated 04-08-2021 specifying 25kg Metformin HCl.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies and CDP performed against Diampa-M 12.5mg/500mg Tablet manufactured by M/s Getz Pharma.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of 3 batches of drug substance at real time conditions as per Zone IV is not submitted
	The status in reference regulatory authorities	SYNJARDY (5mg/500mg, 5mg/1000mg, 12.5mg/500mg, 12.5mg/1000mg) film-coated tablet USFDA approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 23, 24 June and 04-July 2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 25-11-2016 specifying Tablet (General) section.

Evaluation Remarks

Shortcomings	Firm's Response
Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3	Copy of BMR for all the batches of drug product is submitted.
Stability study data of empagliflozin and metformin at real time conditions as per zone IV till claimed shelf life shall be submitted	Empagliflozin Stability study data of 3 batches of drug substance at real time conditions as per Zone IV-A till 36th month is submitted. Metformin Stability study data of 3 batches of drug substance at real time conditions as per Zone IV-A till 18th months is submitted.
Justification shall be submitted for selection of different time for dissolution test (30min) in finished product specifications than innovator product (20min)	We have revised our finished product specifications in accordance with the innovator's specification, which mentions a dissolution time of 20 minutes. A copy of our revised Specification and Testing Methods (STM), reflecting the updated dissolution time, is attached for reference. Furthermore, the required Change of Specification Fee of Rs. 9,000 has been submitted as per DRAP policy. The paid challan is also attached for your kind consideration.
Stability study data of applied product at 6th month time point shall be submitted	Submitted

Decision

Approved

161	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	Maxitech Pharma (Pvt) Ltd. E-178, S.I.T.E., Super Highway Phase-II, Karachi (000851)
	Application Form Dy. No / Tracking ID & date of submission	(T2D-MV1-12G9, 2024-04-26)
	Detail of Fee Submitted	30000.0, 2024-01-11,
	The proposed proprietary name / brand name	Empamet 5mg + 1000mg tablet
	Label Claim	Each Film coated Tablet Contains: Empagliflozin.....5mg Metformin HCl..... 1000mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	14,s or as per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a cool, dry place below 30 degrees Celsius.
	For generic drugs (me-too Status)	Adrance-M 5mg + 1000mg Tablet by ATCO Laboratories
	Pharmacotherapeutic Group of (API)	Biguanide/Reversible inhibitor of sodium-glucose co-transporter 2 (SGLT2)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Empagliflozin; Anhui Haikang Pharmaceutical Co., Ltd. China; Metformin HCl; Ningxia Hengchang Technology Co., Ltd. China
	Detail of stability batches of drug product	3 batches having batch size of 1000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of commercial invoice cleared dated 17-09-2020 specifying 02kg Empagliflozin.

Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies and CDP performed against Diampa-M 5mg/1000mg Tablet manufactured by M/s Getz Pharma.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of 3 batches of drug substance at real time conditions as per Zone IV is not submitted
The status in reference regulatory authorities	SYNJARDY (5mg/500mg, 5mg/1000mg, 12.5mg/500mg, 12.5mg/1000mg) film-coated tablet USFDA approved
GMP status of the firm	Firm has submitted copy of cGMP certificate based on inspection 30-04-2024.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 25-11-2016 specifying Tablet (General) section.

Evaluation Remarks

Shortcomings	Firm's Response
Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3	Copy of BMR for all the batches of drug product is submitted.
Stability study data of empagliflozin and metformin at real time conditions as per zone IV till claimed shelf life shall be submitted	Empagliflozin Stability study data of 3 batches of drug substance at real time conditions as per Zone IV-A till 36th month is submitted. Metformin Stability study data of 3 batches of drug substance at real time conditions as per Zone IV-A till 6th is submitted.
Justification shall be submitted for selection of different time for dissolution test (30min) in finished product specifications than innovator product (20min)	We have revised our finished product specifications in accordance with the innovator's specification, which mentions a dissolution time of 20 minutes. A copy of our revised Specification and Testing Methods (STM), reflecting the updated dissolution time, is attached for reference. Furthermore, the required Change of Specification Fee of Rs. 9,000 has been submitted vide receipt#0374264697 as per DRAP policy. The paid challan is also attached for your kind consideration.
Stability study data of applied product at 6th month time point shall be submitted	Submitted

Decision

Approved

162	Case Category	Export Facilitation (Dr. Farhad Ullah)
	Name, address of Applicant.	Hilton Pharma (Pvt) Limited. Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area (000136)
	Application Form Dy. No / Tracking ID & date of submission	(6GH-5DQ-BM4P, 2025-06-17)
	Detail of Fee Submitted	75000.0, 2025-03-05,
	The proposed proprietary name / brand name	Reluhil Tablets 40mg
	Label Claim	Each film-coated tablet contains: Relugolix 40mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled,7's-De-Controlled

Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect from sunlight . keep out of the reach of Children .
For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	Gonadotropin-releasing hormone (GnRH) Receptor Antagonist
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Nantong Chanyoo Pharmatech Co., Ltd.
Detail of stability batches of drug product	3 batches having batch size of 6250 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of form 6 issued dated 19-05-2024 specifying 02kg Relugolix. Firm has also submitted copy of commercial invoice, packing list, goods declaration, airway bill form 3 and form 7 for procurement of API.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Relumina Tablet 40mg by M/s Aska Pharmaceutical Company Limited.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A till 24th months
The status in reference regulatory authorities	Relumina 40mg Tablets PMDA Approved
GMP status of the firm	Firm has submitted copy of cGMP certificate issued based on inspection dated 09, 10-12-2024.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter for renewal of DML dated 06-02-2025 specifying Tablet (General) section.

Evaluation Remarks

Bioequivalence studies are required for this molecule effective from 17-07-2025; however, the receiving date of this application is 17-06-2025, which is before the notification date.

Shortcomings	Firm's Response
The address of applicant provided in section 1.3.1 is different than manufacturer. Clarification is required	In section 1.3.1, the address provided is for the Head Office of Hilton Pharma, located at 8th & 9th Floor, Progressive Plaza, Beaumont Road, Karachi, Pakistan. The manufacturing plant address of Hilton Pharma is Plot 13-14 & 43, Sector 15, Korangi Industrial Area, Karachi, Pakistan.
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 19-05-2024 specifying 02kg Relugolix. Firm has also submitted copy of commercial invoice, packing list, goods declaration, airway bill form 3 and form 7 for procurement of API.

Decision

Approved

163	Case Category	Export Facilitation (Dr. Farhad Ullah)
	Name, address of Applicant.	Hilton Pharma (Pvt) Limited. Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area (000136)
	Application Form Dy. No / Tracking ID & date of submission	(JNN-Y8T-48BR, 2025-05-12)
	Detail of Fee Submitted	75000.0, 2024-11-20,
	The proposed proprietary name / brand name	Hilostat Tablets 1mg
	Label Claim	Each film-coated tablet contains : Daprodustat 1mg

Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	20's-De-Controlled,10's-De-Controlled,14's-De-Controlled,28's-De-Controlled,30's-De-Controlled,5's-De-Controlled,7's-De-Controlled
Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect from sunlight .Keep out of the reach of Children .
For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	Hypoxia-inducible Factor Prolyl Hydroxylase Inhibitor
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Gansu Haotian Pharmaceutical Co., Ltd
Detail of stability batches of drug product	3 batches having batch size of 12500 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of form 6 issued dated 30-01-2024 specifying 1.1kg Daprodustat. Firm has also submitted copy of commercial invoice not attested by AD/DD I&E DRAP.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Duvroq Tablets 1mg by M/s GalaxoSmithKline K.K.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A
The status in reference regulatory authorities	PMDA Approved - Duvroq Tablets 1mg by GlaxoSmithKline K.K.
GMP status of the firm	Firm has submitted copy of cGMP certificate issued based on inspection dated 09, 10-12-2024.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter for renewal of DML dated 06-02-2025 specifying Tablet (General) section.
Evaluation Remarks	
Shortcomings	Firm's Response
The address of applicant in section 1.3.1 is different than manufacturer. Clarification is required	In section 1.3.1, the address provided is for the Head Office of Hilton Pharma, located at 8th & 9th Floor, Progressive Plaza, Beaumont Road, Karachi, Pakistan. The manufacturing plant address of Hilton Pharma is Plot 13-14 & 43, Sector 15, Korangi Industrial Area, Karachi, Pakistan.
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 30-01-2024 specifying 1.1kg Daprodustat. Firm has also submitted copy of Goods declaration and commercial invoice for procurement of API.
Justification shall be submitted for using a dissolution medium volume of 250mL instead of the 500mL recommended for the innovator's product.	The corrected dissolution medium is 500mL and 250mL was a typographical error. Specification after correction are enclosed as ready reference.
Decision	
Approved	
The Registration Board further decided that the registration letter shall be issued after submission of the Pre-Registration Variation fee of Rs. 9,400/-, as per S.R.O. 1399(I)/2025 dated 01-08-2025.	
164	Case Category
	Export Facilitation (Dr. Farhad Ullah)
	Name, address of Applicant.
	Hilton Pharma (Pvt) Limited. Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area (000136)
	Application Form Dy. No / Tracking ID & date of submission
	(9Y6-JNL-J4PA, 2025-06-17)

Detail of Fee Submitted	75000.0, 2024-11-20,
The proposed proprietary name / brand name	Hilostat Tablets 2mg
Label Claim	Each film-coated tablet contains: Daprodustat 2mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled,5's-De-Controlled,7's-De-Controlled
Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect from Sunlight and moisture.
For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	Hypoxia-inducible Factor Prolyl Hydroxylase Inhibitor
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Gansu Haotian Pharmaceutical Co., Ltd
Detail of stability batches of drug product	3 batches having batch size of 12500 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of form 6 issued dated 30-01-2024 specifying 1.1kg Daprodustat. Firm has also submitted copy of commercial invoice not attested by AD/DD I&E DRAP.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Duvroq Tablets 2mg by M/s GalaxoSmithKline K.K.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A
The status in reference regulatory authorities	PMDA Approved - Duvroq Tablets 2mg by GlaxoSmithKline K.K.
GMP status of the firm	Firm has submitted copy of cGMP certificate issued based on inspection dated 09, 10-12-2024.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter for renewal of DML dated 06-02-2025 specifying Tablet (General) section.

Evaluation Remarks

Shortcomings	Firm's Response
The address of applicant in section 1.3.1 is different than manufacturer. Clarification is required	In section 1.3.1, the address provided is for the Head Office of Hilton Pharma, located at 8th & 9th Floor, Progressive Plaza, Beaumont Road, Karachi, Pakistan. The manufacturing plant address of Hilton Pharma is Plot 13-14 & 43, Sector 15, Korangi Industrial Area, Karachi, Pakistan.
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 30-01-2024 specifying 1.1kg Daprodustat. Firm has also submitted copy of Goods declaration and commercial invoice for procurement of API.
As per the submitted batch analysis report and stability summary sheet, the manufacturing date of the trial batches is recorded as January 2024, whereas the executed BMR indicates May 2025. Furthermore, the submitted stability summary sheet shows the initiation date of the stability study as January 2024. Clarification is required for these discrepancies.	The discrepancy was due to a typographic error in the preparation of the batch analysis report & stability summary sheet. The correct manufacturing date of the trial batches is May 2024. The stability study was initiated accordingly in May 2024. Summary sheets after correction are enclosed.
The 3rd month stability study was conducted in October 2024 instead of the scheduled time in August 2024, and the 6th month stability study was carried out in January 2025 instead of November 2024. Clarification shall be	The stability study was initiated in May 2024. The 3rd month stability testing, which was originally due in August 2024, was performed on October 2025 & 6th month stability testing, which was originally due in

submitted for these deviations from the stability study protocol.	November 2024, was performed on January 2025. However, this deviation does not impact the overall stability evaluation & no impact on product quality even after extended time period.
Furthermore, the results for the 3rd month time point were reported in August 2024 and for the 6th month time point in November 2024 in the stability summary sheets, whereas the actual testing was conducted in October 2024 and January 2025, respectively. Clarification is required for this discrepancy	The discrepancy was due to a typographic error in the preparation of stability summary sheet. Summary sheets after correction are enclosed.

Decision

Deferred

Deferred for verification of the authenticity of the submitted stability data by the panel constituted by the Chairman, Registration Board.

165	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	Pharmedic Laboratories (Pvt.) Ltd Lahore 16-Km Multan Road, Lahore (000228)
	Application Form Dy. No / Tracking ID & date of submission	(9BS-M1P-S3P3, 2024-04-17)
	Detail of Fee Submitted	30000.0, 9400 2024-02-13, 2025-09-16
	The proposed proprietary name / brand name	Regab
	Label Claim	Each Capsule contains Pregabalin.....50mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10x 10's-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30C
	For generic drugs (me-too Status)	Xilica 50mg
	Pharmacotherapeutic Group of (API)	Antiepileptics, other antiepileptics ATC code: N02BF02
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	KOPRAN RESEARCH LABORATORIES LIMITED
	Detail of stability batches of drug product	3 batches having batch size of 1000 capsule each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate issued dated 05-01-2023 specifying 3.5kg Pregabalin.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Xilica 50mg Capsule by M/s PharmEvo (Pvt.) Ltd.,
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A
	The status in reference regulatory authorities	Lyrica (Pregabalin) Capsules (Pfizer) https://www.accessdata.fda.gov/drugsatfda_docs/label/20
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 04-06-2025.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for renewal of DML dated 01-08-2025 specifying capsule (General) section.
Evaluation Remarks		
	Shortcomings	Firm's Response
	Clarification is required as you have submitted details for 50mg strength in all modules of form 5F while provided label claim and evidence of me-too for 25mg strength in eApp	Its a typographical mistake during filling in eApp. Xilica 50mg by PharmEvo is Me-too reference for our product. Firm has also submitted fee Rs. 9400/- on deposit slip
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		No# 985096460883 for correction of label claim in E-App online portal
	Submit alternative brand name for applied product as the submitted brand name resemble with already registered product	Firm has submitted the suggested brand name for applied product. Lyrin, Lyrigab, Nervolin
	Decision	
	Approved	
166	Case Category	Priority As Per 257-M of RB (Dr. Farhad Ullah)
	Name, address of Applicant.	AJ Mirza Pharma Pvt Ltd 1st Floor, Shafi Court, Merewether Road, Civil Lines. Karachi–Pakistan. (235)
	Application Form Dy. No / Tracking ID & date of submission	(WWQ-TH7-TS29, 2025-08-01)
	Detail of Fee Submitted	300000.0, 2025-05-22,
	The proposed proprietary name / brand name	Imatinib Qilu Tablet 400 mg
	Label Claim	Each film-coated Tablet contains: Imatinib Mesylate equivalent to Imatinib 400mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	3x10's Blisters-As per SRO
	Shelf Life (Unit)	24 Month(s)stored at 25°C
	For generic drugs (me-too Status)	Glivec 400mg Tablet by M/s Novartis Pharma Limited
	Pharmacotherapeutic Group of (API)	Tyrosine-Kinase Inhibitors WHO ATC code; L01EA
	Name, address of Manufacturing site:	Qilu Pharmaceutical (Hainan) Co., Ltd.-No.273-A, Nanhai Avenue, National High-Tech Zone, Haikou, Hainan, 570314, China (CHN)-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against GLEEVEC 400mg tablet by M/s Novartis Pharmaceuticals
	Name, address of Marketing Authorization Holder:	A.J. Mirza Pharma (Pvt.) Ltd., 1st Floor, Shafi Court, Merewether Road, Civil Lines. Karachi–Pakistan., Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Certificate of Pharmaceutical Product: Firm has submitted copy of Certificate of Pharmaceutical Product 9FZP-T4NR issued by United States Food and Drug Administration valid upto 14-07-2027 for imatinib mesylate 400mg tablet.
	Details of Authorization Letter :	Firm has submitted copy of letter of authorization from M/s Qilu Pharmaceutical (Hainan) Co. Ltd., having its registered office at No.273-A, Nanhai Avenue, National High-Tech Zone, Haikou, Hainan, 570314, China for applied product dated; 16-07-2025 and valid for 5 years.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of three batches is submitted Real time (24 months): 30°C ± 2 °C /65% ±5%RH Accelerated (6 months): 40°C±2 °C /75% ±5%RH
	The status in reference regulatory authorities	Imatinib Mesylate (100mg, 400mg) film-coated tablets by M/s Qilu Pharm Hainan USFDA Approved
	Evaluation Remarks	
	Shortcomings	Firm's response
	You have claimed for USP specifications while monographfor applied product is not available in USP.	Firm submitted that there is an official BP monograph for Imatinib Mesylate Tablets, the specification of
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Clarification shall be submitted. However, Monograph for applied product is available in BP	Imatinib Mesylate Tablets is set based on BP monograph for Imatinib Tablets, and the results of our registration batches. Firm has also submitted BP specifications of applied product
Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required.	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted.
Comparative Dissolution Profile studies of applied product against the innovator/reference/comparator product in three BCS media shall be submitted	CDP studies performed against Glivec 400mg tablet
Process validation reports including the protocols and results for critical process steps shall be provided	Submitted

Decision

Approved

Approved with BP specifications and as per policy for inspection of manufacturer abroad. The Registration Board further decided that registration letter shall be issued upon submission of the original legalized COPP and notarized Letter of Authorization.

167	Case Category	Priority As Per 257-M of RB (Dr. Farhad Ullah)
	Name, address of Applicant.	AJ Mirza Pharma Pvt Ltd 1st Floor, Shafi Court, Merewether Road, Civil Lines. Karachi–Pakistan. (235)
	Application Form Dy. No / Tracking ID & date of submission	(22W-XJ6-76LX, 2025-07-28)
	Detail of Fee Submitted	300000.0, 2025-05-22,
	The proposed proprietary name / brand name	Imatinib Qilu Tablet 100 mg
	Label Claim	Each Film-Coated Tablet contains: Imatinib Mesylate equivalent to Imatinib 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	3x10's Blisters-As per SRO
	Shelf Life (Unit)	24 Month(s)stored at 25°C
	For generic drugs (me-too Status)	Glivec 100mg Tablet by M/s Novartis Pharma Limited
	Pharmacotherapeutic Group of (API)	Tyrosine-Kinase Inhibitors WHO ATC code; L01EA
	Name, address of Manufacturing site:	Qilu Pharmaceutical (Hainan) Co., Ltd.-No.273-A, Nanhai Avenue, National High-Tech Zone, Haikou, Hainan, 570314, China (CHN)-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against GLEEVEC 100mg tablet by M/s Novartis Pharmaceuticals
	Name, address of Marketing Authorization Holder:	A.J. Mirza Pharma (Pvt.) Ltd., 1st Floor, Shafi Court, Merewether Road, Civil Lines. Karachi–Pakistan., Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Certificate of Pharmaceutical Product: Firm has submitted copy of Certificate of Pharmaceutical Product 5GFP-6SQA issued by United States Food and Drug Administration valid upto 14-07-2027 for imatinib mesylate 100mg tablet.
	Details of Authorization Letter :	Firm has submitted copy of letter of authorization from M/s Qilu Pharmaceutical (Hainan) Co. Ltd., having its registered office at No.273-A, Nanhai Avenue, National High-Tech Zone, Haikou, Hainan, 570314, China for applied product dated; 16-07-2025 and valid for 5 years.

Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of three batches is submitted Real time (24 months): 30°C ± 2 °C /65% ±5%RH Accelerated (6 months): 40°C±2 °C /75% ±5%RH
The status in reference regulatory authorities	Imatinib Mesylate (100mg, 400mg) film-coated tablets by M/s Qilu Pharm Hainan USFDA Approved

Evaluation Remarks

Shortcomings	Firm's response
You have claimed for USP specifications while monograph for applied product is not available in USP. Clarification shall be submitted. However, Monograph for applied product is available in BP	Firm submitted that there is an official BP monograph for Imatinib Mesylate Tablets, the specification of Imatinib Mesylate Tablets is set based on BP monograph for Imatinib Tablets, and the results of our registration batches. Firm has also submitted BP specifications of applied product
Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required.	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted.
CDP studies of applied product against the innovator/reference/comparator product shall be submitted	CDP studies performed against Glivec 100mg tablet
Process validation reports including the protocols and results for critical process steps shall be provided	Submitted

Decision

Approved

Approved with BP specifications and as per policy for inspection of manufacturer abroad. The Registration Board further decided that registration letter shall be issued upon submission of the original legalized COPP and notarized Letter of Authorization.

168	Case Category	New Section (Dr. Farhad Ullah)
	Name, address of Applicant.	Hi-Med Pharmaceuticals 208C Sundar industrial estate Raiwind Road Lahore (000884)
	Application Form Dy. No / Tracking ID & date of submission	(71B-STA-TXZT, 2025-07-17)
	Detail of Fee Submitted	37000.0, 2025-05-14,
	The proposed proprietary name / brand name	Emetron Injection 4mg/2ml
	Label Claim	Each 2ml Contains: Ondansetron HCl eq. to Ondansetron..... 4mg.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 x 5's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store Below 25 degree celcius
	For generic drugs (me-too Status)	Onseron 2ml Injection (Indus Pharma)
	Pharmacotherapeutic Group of (API)	Serotonin 5HT-3 receptor Antagonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CTX Lifesciences Pvt. LTD.
	Detail of stability batches of drug product	3 batches having batch size of 2000 ampoules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy loan letter from M/s Trigon pharmaceuticals for procurement of API along with intimation of borrowing of API letter to PE&R division DRAP. Firm has also submitted copy of commercial invoice cleared by AD (I&E) DRAP Lahore dated 23-04-

	2021 specifying 5kg Ondansetron HCl USP (Injectable grade)
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Onseron 2ml Injection
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV
The status in reference regulatory authorities	ONDANSETRON SANDOZ 4MG/2ML SANDOZ (Sandoz Canada Inc. 110 Rue de Lauzon Boucherville, Québec, Canada J4B 1E6) Health Canada approved
GMP status of the firm	New section.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter for grant of additional section dated 02-12-2024 specifying Liquid Injectable (Small Volume Parenteral) (General)-New.

Evaluation Remarks

Shortcomings	Firm's Response
You have stated that we follow inhouse specifications for applied product in section 1.5.6 while monograph for applied product is available in USP. Clarification shall be submitted.	Firm submitted that we follow USP specifications
Revise the label claim of applied product as per innovator product (mentioning the hydrated form) along with submission of applicable fee.	While compiling the Dossier, due to an oversight, the DMF containing Ondansetron HCl dihydrate was attached instead of the Ondansetron HCl. However, our submission is in line with the innovator product, which contains Ondansetron HCl. Therefore, we confirm that the selected form is consistent with the reference product, and the submitted DMF reflects this alignment.
Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	Submitted. However GMP certificate is valid till 29-5-2025
Justification shall be submitted for not including the sterility test in finished product specifications for applied product	The sterility test has not been included in the submitted finished product specifications because we have strictly followed the official pharmacopeial monograph of the product, which does not mention sterility testing as a requirement. For your kind reference, a copy of the relevant monograph is attached herewith. Therefore, the submitted specifications are in full compliance with the referenced pharmacopeial standards.
The submitted monograph itself describes the product as sterile solution and states under heading of Other requirements—It meets the requirements under Injections and Implanted Drug Products <1>. As per USP General Chapter <1> Injections and Implanted Drug Products, it is mandatory to perform sterility test for applied products and to include sterility testing in the finished product specifications.	The sterility test has not been included in the submitted finished product specifications because we have strictly followed the official pharmacopeial monograph of the product, which does not mention sterility testing as a requirement. For your kind reference, a copy of the relevant monograph is attached herewith. Therefore, the submitted specifications are in full compliance with the referenced pharmacopeial standards.
Stability study data of applied product at 6th month time point shall be submitted	Submitted

Decision

Deferred

Deferred for following;

- Revision of the label claim of applied product as per innovator product (mentioning the hydrated form) along with submission of applicable fee.
- Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin
- Justification for not including the sterility test in finished product specifications for applied product.
- Submission of the Pre-Registration Variation fee as per S.R.O. 1399(I)/2025 dated 01-08-2025.

169	Case Category	New Section (Dr. Farhad Ullah)
	Name, address of Applicant.	Hi-Med Pharmaceuticals 208C Sundar industrial estate Raiwind Road Lahore (000884)
	Application Form Dy. No / Tracking ID & date of submission	(V1Y-N9D-DSQ9, 2025-07-17)
	Detail of Fee Submitted	37000.0, 2025-05-14,
	The proposed proprietary name / brand name	Emetron Injection 8mg/4ml
	Label Claim	Each 4ml contains: Ondansetron HCl eq. to Ondansetron.....8mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 x 5's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at below 25 degree celcius
	For generic drugs (me-too Status)	ONSERON 4ML INJECTION (Indus Pharma)
	Pharmacotherapeutic Group of (API)	Serotonin 5HT-3 receptor Antagonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CTX Lifesciences Pvt. Ltd.
	Detail of stability batches of drug product	3 batches having batch size of 2000 ampoules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy loan letter from M/s Trigon pharmaceuticals for procurement of API along with intimation of borrowing of API letter to PE&R division DRAP. Firm has also submitted copy of commercial invoice cleared by AD (I&E) DRAP Lahore dated 23-04-2021 specifying 5kg Ondansetron HCl USP (Injectable grade)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Onseron 8mg/4ml Injection
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV
	The status in reference regulatory authorities	ONDANSETRON SANDOZ 8MG/4ML (Sandoz Canada Inc. 110 Rue de Lauzon Boucherville, Québec, Canada J4B 1E6) Health Canada Approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate issued based on inspection dated 23-09-2024
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for grant of additional section dated 02-12-2024 specifying Liquid Injectable (Small Volume Parenteral) (General)-New.
Evaluation Remarks		
	Shortcomings	Firm's Response
	You have stated that we follow inhouse specifications for applied product in section 1.5.6 while monograph for applied product is available in USP. Clarification shall be submitted.	Firm submitted that we follow USP specifications
	Revise the label claim of applied product as per innovator product (mentioning the hydrated form) along	While compiling the Dossier, due to an oversight, the DMF containing Ondansetron HCl dihydrate was
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with submission of applicable fee.	attached instead of the Ondansetron HCl. However, our submission is in line with the innovator product, which contains Ondansetron HCl. Therefore, we confirm that the selected form is consistent with the reference product, and the submitted DMF reflects this alignment.
Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	Submitted. However GMP certificate is valid till 29-5-2025
Justification shall be submitted for not including the sterility test in finished product specifications for applied product	The sterility test has not been included in the submitted finished product specifications because we have strictly followed the official pharmacopeial monograph of the product, which does not mention sterility testing as a requirement. For your kind reference, a copy of the relevant monograph is attached herewith. Therefore, the submitted specifications are in full compliance with the referenced pharmacopeial standards.
The submitted monograph itself describes the product as sterile solution and states under heading of Other requirements—It meets the requirements under Injections and Implanted Drug Products <1>. As per USP General Chapter <1> Injections and Implanted Drug Products, it is mandatory to perform sterility test for applied products and to include sterility testing in the finished product specifications.	The sterility test has not been included in the submitted finished product specifications because we have strictly followed the official pharmacopeial monograph of the product, which does not mention sterility testing as a requirement. For your kind reference, a copy of the relevant monograph is attached herewith. Therefore, the submitted specifications are in full compliance with the referenced pharmacopeial standards.
Stability study data of applied product at 6th month time point shall be submitted	Submitted

Decision

Deferred

Deferred for following;

- Revision of the label claim of applied product as per innovator product (mentioning the hydrated form) along with submission of applicable fee.
- Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin
- Justification for not including the sterility test in finished product specifications for applied product.
- Submission of the Pre-Registration Variation fee as per S.R.O. 1399(I)/2025 dated 01-08-2025.

170	Case Category	New Section (Dr. Farhad Ullah)
	Name, address of Applicant.	Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (000790)
	Application Form Dy. No / Tracking ID & date of submission	(9QV-HGW-7NGE, 2024-10-29)
	Detail of Fee Submitted	30000.0, 7000.0 2024-05-16, 2024-10-21
	The proposed proprietary name / brand name	DEXAMETH 4MG/ML INJECTION
	Label Claim	Each Vial (1mL) Contains: Dexamethasone Phosphate as Dexamethasone Sodium Phosphate (USP).....4mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)20-25C

For generic drugs (me-too Status)	B.G Dexameth Injection by Biogen Pharma 072646
Pharmacotherapeutic Group of (API)	Corticosteroids for Systemic use;
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	
Detail of stability batches of drug product	3 batches having batch size of 500 vials each
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate issued dated 29-08-2023 specifying 35kg Dexamethasone sodium phosphate in name of M/s Trigon Pharmaceuticals., Firm has also submitted copy of loan letter from M/s Trigon Pharmaceuticals Pvt. Ltd.,
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Decadron 4mg/ml Injection
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-B till 24th months
The status in reference regulatory authorities	Decadron 4mg /ml Injection USFDA Approved **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 15-06-2022.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of additional Section dated 13-05-2024 specifying Dry Powder for Injection (steroid)-Additional.
Evaluation Remarks	
Shortcomings	Firm's response
Standardize the applied label claim as per the reference formulation considering the salt factor	Each 1 mL vial contains: 4.37 mg of dexamethasone sodium phosphate USP, equivalent to 4 mg of dexamethasone phosphate. (Product complies with USP specifications.)
Submit Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority.	Firm has submitted copy of letter of renewal of DML dated 06-02-2025 specifying Dry Powder for Injectable Section (Steroidal).The applied product is liquid injection.
You have applied for vial in label claim and other section of dossier while ampoule in executed BMR. Clarification is required	Firm submitted that Mistakenly the BMR was filled for ampoule, Now corrected (for vial) and revised BMR are submitted.
Copy of loan agreement for API between the firms and intimation of borrowing of API submitted in DRAP shall be submitted	Firm has submitted loan agreement between the firms and intimation of borrowing of API submitted in DRAP.
Decision	
Deferred	
Deferred for verification of the authenticity of the submitted stability data by the panel constituted by the Chairman, Registration Board.	
171 Case Category	New Section (Dr. Farhad Ullah)
Name, address of Applicant.	STARWAYS PHARMACEUTICALS Plot No. (Private Land), Near China Glassware, Nowshera Economic Zone, Risalpur, Nowshera, K.P.K, Pakistan (000999)
Application Form Dy. No / Tracking ID & date of submission	(E4V-NQL-GHSB, 2025-04-21)

Detail of Fee Submitted	37000.0, 9400 2025-01-22, 2025-09-17
The proposed proprietary name / brand name	Starlin 100mg capsule
Label Claim	Each capsule contains: Pregabalin 100mg
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	14's-As per SRO
Shelf Life (Unit)	2 Year(s)Store below 30 degree
For generic drugs (me-too Status)	Seipil 100mg Capsule, M/s Genix Pharma, Reg. No. 074872.
Pharmacotherapeutic Group of (API)	Gabapentinoids. ATC code: N02BF02.
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Progress life sciences pvt.ltd
Detail of stability batches of drug product	02 batches having batch size of 5000 capsules each.
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of loan letter from M/s Shaheen pharmaceutical, Swat wherein they have taken pregabalin as loan for the purpose of stability studies. Firm has also submitted copy of clearance certificate No. E-8910160683619 dated 08-04-2024 issued to M/s Shaheen pharmaceuticals, Swat mentioning 500kg of Pregabalin USP, B. No. PPR/23-24023 from M/s Yuvraj Chemicals, India.
Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and PE studies are performed against the comparator product i.e. Pre-Gax Capsules 100mg, B. No. 23F001, Mfg. Date 06/2023 manufactured by M/s Caraway Pharmaceuticals, and both reference and applied formulation have shown similar release pattern and Value of F2 in all the three medium is in acceptable range.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of 3 batches of drug substance as per Zone IV-B is submitted. Accelerated 06 months and real time for 24 months.
The status in reference regulatory authorities	Lyrica 75mg, 100mg capsule, USFDA approved.
GMP status of the firm	New DML issued dated 02-12-2024.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 3-1/2021-Lic dated 02-12-2024 mentioning Capsule (General) section.
Evaluation Remarks	
Shortcomings	Firm's Response
Specifications and analytical procedures of the drug substance from drug product manufacturer shall be submitted.	Specifications and analytical procedures of the drug substance from drug product manufacturer is submitted.
Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted
Link of relationship between progress life sciences and M/s Yuvraj chemicals, India shall be submitted.	We M/S Progress Life Sciences Pvt Ltd. Having office at: 225, Platinum Techno Park, Plot No. 17 and 18, Sector 30A, Vashi, Navi Mumbai - 400703, Maharashtra, India, would like to confirm that Yuvraj Chemicals Pvt. Ltd. Having address: J-311, MIDC, Bhosari, Pune -26 is our group company and Pregabalin USP is being manufactured at Yuvraj Chemicals Pvt. Ltd. J-311, MIDC, Bhosari, Pune -26 which ultimately is a product of Progress Life Sciences- parent organization. We

	hereby also confirm that Product, manufacturing Process and controls, quality systems, synthetic route, marketing, and sales in controlled by and belongs to Progress Life Sciences Pvt. Ltd.
Complete six-month time point stability data along with raw data sheets and chromatograms shall be submitted.	Submitted
Alternate brand name.	Firm has submitted alternate brands name for applied product; PROBEL, NEVON, HALORIX

Decision

Approved

Registration Board further decided that Registration letter will be issued after Verification of loan letter of API.

172	Case Category	New Section (Dr. Farhad Ullah)
	Name, address of Applicant.	STARWAYS PHARMACEUTICALS Plot No. (Private Land), Near China Glassware, Nowshera Economic Zone, Risalpur, Nowshera, K.P.K, Pakistan (000999)
	Application Form Dy. No / Tracking ID & date of submission	(TJ4-RN3-SUGP, 2025-04-21)
	Detail of Fee Submitted	37000.0, 2025-01-22,
	The proposed proprietary name / brand name	Starlin 75mg capsule
	Label Claim	Each capsule contains: Pregabalin 75mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 degree
	For generic drugs (me-too Status)	Seipil 75mg Capsule, M/s Genix Pharma, Reg. No. 074871.
	Pharmacotherapeutic Group of (API)	Gabapentinoids. ATC code: N02BF02.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Progress life sciences pvt.ltd
	Detail of stability batches of drug product	02 batches having batch size of 5000 capsules each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of loan letter from M/s Shaheen pharmaceutical, Swat wherein they have taken pregabalin as loan for the purpose of stability studies. Firm has also submitted copy of clearance certificate No. E-8910160683619 dated 08-04-2024 issued to M/s Shaheen pharmaceuticals, Swat mentioning 500kg of Pregabalin USP, B. No. PPR/23-24023 from M/s Yuvraj Chemicals, India.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and PE studies are performed against the comparator product i.e. Pre-Gax Capsules 75mg, B. No. 23M080, Mfg. Date 12/2023 manufactured by M/s Caraway Pharmaceuticals, and both reference and applied formulation have shown similar release pattern and Value of F2 in all the three medium is in acceptable range.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of 3 batches of drug substance as per Zone IV-B is submitted. Accelerated 06 months and real time for 24 months.
	The status in reference regulatory authorities	Lyrica 75mg, 100mg capsule, USFDA approved.

GMP status of the firm	New DML issued dated 02-12-2024.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 3-1/2021-Lic dated 02-12-2024 mentioning Capsule (General) section.
Evaluation Remarks	
Shortcomings	Firm's Response
Specifications and analytical procedures of the drug substance from drug product manufacturer shall be submitted.	Specifications and analytical procedures of the drug substance from drug product manufacturer is submitted.
Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Analytical method verification studies of the drug substance performed by the drug product manufacturer is submitted.
Link of relationship between progress life sciences and M/s Yuvraj chemicals, India shall be submitted.	We M/S Progress Life Sciences Pvt Ltd. Having office at: 225, Platinum Techno Park, Plot No. 17 and 18, Sector 30A, Vashi, Navi Mumbai - 400703, Maharashtra, India, would like to confirm that Yuvraj Chemicals Pvt. Ltd. Having address: J-311, MIDC, Bhosari, Pune -26 is our group company and Pregabalin USP is being manufactured at Yuvraj Chemicals Pvt. Ltd. J-311, MIDC, Bhosari, Pune -26 which ultimately is a product of Progress Life Sciences- parent organization. We hereby also confirm that Product, manufacturing Process and controls, quality systems, synthetic route, marketing, and sales in controlled by and belongs to Progress Life Sciences Pvt. Ltd.
Complete six-month time point stability data along with raw data sheets and chromatograms shall be submitted.	Submitted
Alternate brand name.	Firm has submitted alternate brands name for applied product; PROBEL, NEVON, HALORIX
Decision	
Approved	
Registration Board further decided that Registration letter will be issued after Verification of loan letter of API.	
173	Case Category
Name, address of Applicant.	New License (Dr. Farhad Ullah)
Application Form Dy. No / Tracking ID & date of submission	STARWAYS PHARMACEUTICALS Plot No. (Private Land), Near China Glassware, Nowshera Economic Zone, Risalpur, Nowshera, K.P.K, Pakistan (000999)
Detail of Fee Submitted	(7DQ-8UU-G6XN, 2025-07-16)
The proposed proprietary name / brand name	37000.0, 2025-01-31,
Label Claim	Tramastar 50mg Capsule
Reference to Finished product specifications	Tramastar 50mg Capsule Each Capsule contains: Tramadol As Hydrochloride).....50mg (BP Specification).
Proposed Pack Size	British Pharmacopeia
Shelf Life (Unit)	as per SRO-As per SRO
For generic drugs (me-too Status)	2 Year(s)Store below 30°C and dry place.
Pharmacotherapeutic Group of (API)	Tomogex 50mg Capsule, M/s Axis Pharmaceuticals, Reg. No. 115418.
	Analgesic/ Opioid Analgesic

Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Supriya Lifescience Limited A-5/2, Lote Parshuram Industrial Area, M.I.D.C Taluka – Khed, District – Ratnagiri, Maharashtra, India 415 722.
Detail of stability batches of drug product	03 batches having batch size of 1500 capsules each.
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of loan letter from M/s Medcraft pharmaceutical, Peshawar wherein they have given 500grams of Tramadol HCl as loan to M/s Starways Pharmaceuticals dated 20-09-2024 along with DML, attested invoices, COA of API, COA of impurities, COA of working standard, DMF and GMP certificate of the drug substance manufacturer for CTD dossier. Firm has also submitted copy of clearance certificate No. E-10546702483974 dated 02-09-2024 issued to M/s Medcraft pharmaceuticals, Peshawar mentioning 375kg of Tramadol HCl USP, B. No. SLL/TDM/0324030, Mfg. date 03-2024 from M/s Supriya Life sciences, India.
Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and PE studies are performed against the comparator product i.e. Tramal 50mg Capsule, B. No. GAG001, Mfg. Date 02/2025 manufactured by M/s The Searle Company Limited, and both reference and applied formulation have shown similar release pattern and Value of F2 in all the three medium is in acceptable range.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of 3 batches of drug substance as per Zone IV-A is submitted. Accelerated 06 months and real time for 60 months.
The status in reference regulatory authorities	Tramadol 50 mg Capsules., Each capsule contains 50 mg tramadol hydrochloride. MHRA approved.
GMP status of the firm	New DML issued dated 02-12-2024.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 3-1/2021-Lic dated 02-12-2024 mentioning Capsule (General) section.
Evaluation Remarks	
Shortcomings	Firm's Response
Justify the label claim of "Tramadol as HCl" with reference to the innovator or RRA product. As RRA has mentioned tramadol HCl instead of Tramadol as HCl. While the instant application has mentioned "Tramadol as HCl" in 1.5.2, 3.2.P.1 and in BMRs also.	Revised label claim is: Tramastar 50mg Capsule Each Capsule contains: Tramadol Hydrochloride..... 50mg (BP Specification). Fee for correction of label claim has been submitted, & attached. Challan form # is 87940155522
Specifications submitted by the drug product manufacturer has mentioned pregabalin. Justify?	As the documentation format was initially pre-set for the Common Technical Document (CTD), the reference to 'pregabalin' was mistakenly retained in the specification. This occurred due to the reuse of a template from a previous product, and was not identified during the initial review process. The error has since been corrected, and steps are being taken to strengthen the document review procedure to prevent recurrence
Analytical method has mentioned apparatus II and 0.01HCl as dissolution medium while the BP monograph has mentioned apparatus I and 0.1M HCl as dissolution medium. Clarification shall be submitted.	A typographical error was identified; therefore, the revised analytical procedure is submitted.
Analytical method verification studies are not performed as per BP monograph which states that "The test is not valid unless, in the chromatogram obtained with solution (4), the resolution between the peaks due to impurity A	System suitability was performed as per the BP monograph; however, during report compilation, the resolution parameter in system suitability was missed. The revised documents are attached for your reference

and tramadol is at least 3.0.” clarification shall be submitted.	
Raw data sheets and chromatograms for all the three trial batches and for both real time and accelerated conditions shall be submitted.	Submitted

Decision

Approved

Approved with following label claim;

Each Capsule contains:

Tramadol Hydrochloride.....50mg (BP Specification).

Registration Board further decided that Registration letter will be issued after Verification of loan letter of API.

174	Case Category	Export Facilitation (Dr. Farhad Ullah)
	Name, address of Applicant.	Hilton Pharma (Pvt) Limited. Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area (000136)
	Application Form Dy. No / Tracking ID & date of submission	(GRQ-YGJ-UYLD, 2024-09-25)
	Detail of Fee Submitted	75000.0, 2024-09-02,
	The proposed proprietary name / brand name	Silvial Powder for Oral Suspension 10mg/ml
	Label Claim	Each ml contains: Sildenafil Citrate, USP equivalent to sildenafil.....10mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	30ml-De-Controlled,60ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect form sunlight and moisture.
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	For pulmonary arterial hypertension (PAH)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited
	Detail of stability batches of drug product	3 batches having batch size of 86 bottles (30ml) and (60ml) each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of form 6 issued dated 30-03-2023 specifying 2.1kg Sildenafil Citrate. Firm has also submitted copy of form 3, form 7, invoice and packing list
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Revatio Powder for Oral Suspension 10mg/ml
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A
	The status in reference regulatory authorities	Rivatio 10mg/ml Powder for Oral Suspension (Pfizer), USFDA Approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate issued based on inspection dated 23-01-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for renewal of DML dated 30-06-2020 specifying Oral Dry Powder suspension (General).
	Evaluation Remarks	

Shortcomings	Firm's Response
You have applied for 30ml and 60ml volume while the reference product is of 112ml volume. Clarification shall be submitted since the applied volume may not contain the full dose	According to the recommended dose of the innovator product (Revatio for Oral Suspension 10mg/ml), our product maintains the same concentration as the innovator, i.e., 10 mg/mL. However, we have adjusted the total volume to 112 mL to align the administered volume with that of the reference product.
The address of applicant in section 1.3.1 is different than manufacturer. Clarification is required	In section 1.3.1, the address provided is for the Head Office of Hilton Pharma, located at 8th & 9th Floor, Progressive Plaza, Beaumont Road, Karachi, Pakistan. The manufacturing plant address of Hilton Pharma is Plot 13-14 & 43, Sector 15, Korangi Industrial Area, Karachi, Pakistan.
Pictorial evidence of the innovator product with visible details of batch number, manufacturing/expiry date and name of the manufacture shall be submitted	Pictorial evidence of the innovator product with visible details of batch number, manufacturing/expiry date and name of the manufacturer is submitted
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 30-03-2023 specifying 2.1kg Sildenafil Citrate. Firm has also submitted copy of goods declaration, airway bill, form 3, form 7, invoice and packing list
Justify the quantity of drug substance used in the trial batches of all the strengths of tablet and dry powder suspension with respect to the quantity of drug substance imported.	Firm has submitted complete details of quantity of drug substance used in the trial batches of all the strengths of tablet and dry powder suspension
Clarify the batch size of applied product in as you have mentioned the proposed batch size of 86 bottles while 57 bottles in yield statement of executed BMR	The actual batch size of the Silvial Powder for Oral Suspension is 1500gm. The powder has been divided into two portions: 1000gm for the 60mL pack size and 500gm for the 30mL pack size. The fill weight per bottle is 17.3gm for the 60mL pack and 8.65gm for the 30mL pack respectively. Calculation for 30mL pack: 30mL bottle contain = 8.65gm Batch size = 500gm No of bottle = Total weight of powder for 30mL / Target weight of 30mL bottle = 500gm / 8.65gm No of bottle = 57 bottles Calculation for 60mL pack: Calculation for 60mL pack: 30mL bottle contain = 17.3gm Batch size = 1000gm No of bottle = Total weight of powder for 60mL / Target weight of 60mL bottle = 1000gm / 17gm No of bottle = 57 bottles
In use stability study of reconstituted suspension shall be submitted	In use stability study of reconstituted suspension is submitted

Decision

Approved

Approved with pack size of 112ml volume

175	Case Category	Export Facilitation (Dr. Farhad Ullah)
	Name, address of Applicant.	Searle Pakistan Limited C-14, Manghopir Road, SITE, Karachi (000012)
	Application Form Dy. No / Tracking ID & date of submission	(QJT-HZU-AAM9, 2024-10-07)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-16, 2024-10-02
	The proposed proprietary name / brand name	Clomirate 50mg Tablet

Label Claim	Each tablet contains: Clomifene Citrate BP..... 50mg (BP Specifications)
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	As per DPC-Controlled
Shelf Life (Unit)	2 Year(s)Protect from moisture, freezing, excessive heat and sunlight.
For generic drugs (me-too Status)	Voi (Clomiphene Citrate) Tablets by Genix Pharma
Pharmacotherapeutic Group of (API)	Ovulation stimulants, synthetic
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Bioxera Pharma Pvt. Ltd.
Detail of stability batches of drug product	3 batches having batch size of 300000 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of commercial invoice cleared by AD I&E DRAP dated 01-01-2020 specifying 50kg Clomiphene Citrate.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Clomid 50mg, by Sanofi-Aventis, Patheon France, France.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A
The status in reference regulatory authorities	CLOMID 50mg tablets by sanofi-aventis U.S. LLC USFDA Approved
GMP status of the firm	Firm has submitted copy of cGMP certificate issued based on inspection dated 06-03-2024.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter for renewal of DML dated 26-10-2020 specifying Tablet (General) section and Tablet Hormone section.

Evaluation Remarks

Shortcomings	Firm's Response
Clarification shall be submitted for using Dissolution Apparatus II instead of Apparatus I for the applied product, as the BP monograph specifies the use of Apparatus I.	Dissolution Apparatus I (Basket Apparatus) is used in the procedure. Although, Dissolution Apparatus II is typographical error in method for the applied product procedure made by M/s Searle Pakistan Limited. We affix the problem by revising the procedure as attached
Clarification shall be submitted since you have claimed BP specifications whereas assay results have been provided is stability study using HPLC method, while BP recommends UV method	We, Searle Pakistan Limited situated at C-14, Manghopir Road, S.I.T.E, Karachi -75700, Pakistan would like to inform your kind authority that we have used our in-house developed validated alternated HPLC method for assay analysis during stability study of Clomirate 50mg Tablet which is Stability Indicating Method(SIM). Moreover, it is recommended by FDA in Guidance for Industry, Analytical Procedures and Methods Validation, FDA, 2000 that all assay procedures for stability should be performed on Stability Indicating Method(SIM) i.e. HPLC. HPLC method provides more detailed analysis than BP recommended UV method. Further to this, we commit to follow BP recommended analytical method during commercialization of subject product.
Justification shall be submitted for the use of 3% overage in the formulation of the applied product.	3% overage of Clomiphene Citrate is incorporated into the formulation to ensure that, after accounting for all potential process losses, the final product continues to meet the required assay and potency specifications. This overage is intended to compensate for any loss of the active pharmaceutical ingredient that may occur during manufacturing, packaging, or storage processes, thereby

	maintaining product efficacy and regulatory compliance throughout its shelf life.
Submit supporting data to justify the use of 3% overage, claimed to compensate for losses occurring during the manufacturing of Clomiphene Citrate tablets.	As per query regarding 3% overage in the formulation of the applied product, Clomifene Citrate Tablets was registered product on our former company name previously. However registration was transferred due to some business reasons. With reference to market potential, we have applied a new registration application of the product. We provided you the stability data of those previously manufactured commercial batches but as data demonstrates that a 3% overage is not required. We hereby confirm that the commercial batches of the newly registered product will be manufactured without the addition of any overage.

Decision

Approved

The Registration Board further decided that the registration letter shall be issued after submission of the Pre-Registration Variation fee of Rs. 9,400/-, as per S.R.O. 1399(I)/2025 dated 01-08-2025.

176	Case Category	Export Facilitation (Dr. Farhad Ullah)
	Name, address of Applicant.	Searle Pakistan Limited C-14, Manghopir Road, SITE, Karachi (000012)
	Application Form Dy. No / Tracking ID & date of submission	(2NP-RJG-B26T, 2025-09-03)
	Detail of Fee Submitted	37000.0, 9400 2025-06-04, 2025-09-18
	The proposed proprietary name / brand name	SINEMET PLUS (LEVODOPA + CARBIDOPA + ENTACAPONE) 200 MG + 50 MG + 200 MG TABLETS
	Label Claim	Each film-coated tablet contains 200 mg of Levodopa, 50 mg of Carbidopa and 200 mg of Entacapone.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per DPC/SRO-De-Controlled
	Shelf Life (Unit)	24 Month(s)Protect from sunlight, moisture and heat. Store below 30°C. Keep all medicines out of sight & reach of children.
	For generic drugs (me-too Status)	PARIDOPA 200 mg + 50 mg + 200 mg Tablets (Registration number: 092720)
	Pharmacotherapeutic Group of (API)	Anti-parkinson drugs
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Neuland Laboratories Limited,Shandong Xinhua Pharmaceutical Co., Ltd.,ZheJiang Wild Wind Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	3 batches having batch size of 3000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of commercial invoice cleared by AD I&E DRAP dated 16-07-2021 specifying 10kg Entacapone. Firm has submitted copy of clearance certificate dated 13-08-2022 specifying (200 piece/pack) of carbidopa. Firm has submitted copy of clearance certificate dated 25-07-2022 specifying (75 piece/pack, 500 piece/pack, 500 piece/pack, 500 piece/pack) of Levodopa

Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Stalevo 200+50+200mg tablets, by Orion Corporation, Finland for Exeltis Healthcare S.L Spain.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV
The status in reference regulatory authorities	STALEVO 200 film coated tablet USFDA Approved.
GMP status of the firm	Firm has submitted copy of cGMP certificate issued based on inspection dated 06-03-2024.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter for renewal of DML dated 26-10-2020 specifying Tablet (General) section.

Evaluation Remarks

Shortcomings	Firm's Response
Valid copy of cGMP certificate / DML of the Drug Substance manufacturer for Carbidopa and Entacapone issued by relevant regulatory authority of country of origin is required	Valid copy of cGMP/DML certificate of API manufacturer for both entacapone and carbidopa is submitted
Submit copies of the commercial invoice and goods declaration to clarify the weight of imported Carbidopa and Levodopa.	Firm has submitted copies of goods declaration and invoice specifying 1575kg levodopa and 200kg carbidopa
Clarification shall be submitted for selecting different dissolution time (60 minutes) compared to the innovator product (45 minutes)	We, Searle Pakistan Limited, C-14, Manghopir Road, S.I.T.E, Karachi-75700, Pakistan, hereby commit to align the dissolution time of Sinemet Plus (Levodopa + Carbidopa + Entacapone) Tablets with the innovator's specification of 45 minutes (instead of 60 minutes) for all product ranges at the time of commercialization. Enclosed are the revised specifications for all strengths of Sinemet Plus Tablets range reflecting the dissolution time of 45 minutes, which will be adopted during commercialization. Firm's has submitted fee Rs. 9400/- vide deposit slip No#00767738541 for revision of specifications

Decision

Approved

177	Case Category	Export Facilitation (Dr. Farhad Ullah)
	Name, address of Applicant.	Searle Pakistan Limited C-14, Manghopir Road, SITE, Karachi (000012)
	Application Form Dy. No / Tracking ID & date of submission	(9DS-Y2M-1ZSP, 2025-09-03)
	Detail of Fee Submitted	37000.0, 9400 2025-06-04, 2025-09-18
	The proposed proprietary name / brand name	SINEMET PLUS (LEVODOPA + CARBIDOPA + ENTACAPONE) 100 MG + 25 MG + 200 MG TABLETS
	Label Claim	Each film-coated tablet contains 100 mg of Levodopa, 25 mg of Carbidopa and 200 mg of Entacapone.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per DPC/SRO-De-Controlled
	Shelf Life (Unit)	24 Month(s)Protect from sunlight, moisture and heat. Store below 30°C. Keep all medicines out of sight & reach of children.

For generic drugs (me-too Status)	PARIDOPA 100 mg + 25 mg + 200 mg Tablets (Registration number: 092719)
Pharmacotherapeutic Group of (API)	Anti-parkinson drugs
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Neuland Laboratories Limited, Shandong Xinhua Pharmaceutical Co., Ltd., ZheJiang Wild Wind Pharmaceutical Co., Ltd.
Detail of stability batches of drug product	3 batches having batch size of 2500 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of commercial invoice cleared by AD I&E DRAP dated 16-07-2021 specifying 10kg Entacapone. Firm has submitted copy of clearance certificate dated 13-08-2022 specifying (200 piece/pack) of carbidopa. Firm has submitted copy of clearance certificate dated 25-07-2022 specifying (75 piece/pack, 500 piece/pack, 500 piece/pack, 500 piece/pack) of Levodopa
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Stalevo 100+25+200mg tablets, by Orion Corporation, Finland for Exeltis Healthcare S.L Spain.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV
The status in reference regulatory authorities	STALEVO 100 film coated tablet USFDA Approved.
GMP status of the firm	Firm has submitted copy of cGMP certificate issued based on inspection dated 06-03-2024.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter for renewal of DML dated 26-10-2020 specifying Tablet (General) section.

Evaluation Remarks

Shortcomings	Firm's Response
Valid copy of cGMP certificate / DML of the Drug Substance manufacturer for Carbidopa and Entacapone issued by relevant regulatory authority of country of origin is required	Valid copy of cGMP/DML certificate of API manufacturer for both entacapone and carbidopa is submitted
Submit copies of the commercial invoice and goods declaration to clarify the weight of imported Carbidopa and Levodopa.	Firm has submitted copies of goods declaration and invoice specifying 1575kg levodopa and 200kg carbidopa
Clarification shall be submitted for selecting different dissolution time (60 minutes) compared to the innovator product (45 minutes)	Firm has referred to USFDA dissolution database for adopting 60minutes dissolution time for applied product We, Searle Pakistan Limited, C-14, Manghopir Road, S.I.T.E, Karachi-75700, Pakistan, hereby commit to align the dissolution time of Sinemet Plus (Levodopa + Carbidopa + Entacapone) Tablets with the innovator's specification of 45 minutes (instead of 60 minutes) for all product ranges at the time of commercialization. Enclosed are the revised specifications for all strengths of Sinemet Plus Tablets range reflecting the dissolution time of 45 minutes, which will be adopted during commercialization. Firm's has submitted fee Rs. 9400/- vide deposit slip No#5478121360 for revision of specifications

Decision

Approved

Case Category	Export Facilitation (Dr. Farhad Ullah)
Name, address of Applicant.	Searle Pakistan Limited C-14, Manghopir Road, SITE, Karachi (000012)
Application Form Dy. No / Tracking ID & date of submission	(B1H-XXJ-M8QB, 2025-09-03)
Detail of Fee Submitted	37000.0, 9400 2025-06-04, 2025-09-18
The proposed proprietary name / brand name	SINEMET PLUS (LEVODOPA + CARBIDOPA + ENTACAPONE) 150 MG + 37.5 MG + 200 MG TABLETS
Label Claim	Each film-coated tablet contains 150 mg of Levodopa, 37.5 mg of Carbidopa and 200 mg of Entacapone.
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per DPC/SRO-De-Controlled
Shelf Life (Unit)	24 Month(s)Protect from sunlight, moisture and heat. Store below 30°C. Keep all medicines out of sight & reach of children.
For generic drugs (me-too Status)	PARIDOPA 150 mg + 37.5 mg + 200 mg Tablets (Reg. No. 088240)
Pharmacotherapeutic Group of (API)	Anti-parkinson drugs
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Neuland Laboratories Limited,Shandong Xinhua Pharmaceutical Co., Ltd.,ZheJiang Wild Wind Pharmaceutical Co., Ltd.
Detail of stability batches of drug product	3 batches having batch size of 2500 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of commercial invoice cleared by AD I&E DRAP dated 16-07-2021 specifying 10kg Entacapone. Firm has submitted copy of clearance certificate dated 13-08-2022 specifying (200 piece/pack) of carbidopa. Firm has submitted copy of clearance certificate dated 25-07-2022 specifying (75 piece/pack, 500 piece/pack, 500 piece/pack, 500 piece/pack) of Levodopa
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Stalevo 150+37.5+200mg tablets, by Orion Corporation, Finland for Exeltis Healthcare S.L Spain.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV
The status in reference regulatory authorities	STALEVO 150 film coated tablet USFDA Approved.
GMP status of the firm	Firm has submitted copy of cGMP certificate issued based on inspection dated 06-03-2024.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter for renewal of DML dated 26-10-2020 specifying Tablet (General) section.
Evaluation Remarks	
Shortcomings	Firm's Response
Valid copy of cGMP certificate / DML of the Drug Substance manufacturer for Carbidopa and Entacapone issued by relevant regulatory authority of country of origin is required	Valid copy of cGMP/DML certificate of API manufacturer for both entacapone and carbidopa is submitted
Submit copies of the commercial invoice and goods declaration to clarify the weight of imported Carbidopa	Firm has submitted copies of goods declaration and invoice specifying 1575kg levodopa and 200kg

	and Levodopa.	carbidopa
	Clarification shall be submitted for selecting different dissolution time (60 minutes) compared to the innovator product (45 minutes)	Firm has referred to USFDA dissolution database for adopting 60minutes dissolution time for applied product We, Searle Pakistan Limited, C-14, Manghopir Road, S.I.T.E, Karachi-75700, Pakistan, hereby commit to align the dissolution time of Sinemet Plus (Levodopa + Carbidopa + Entacapone) Tablets with the innovator's specification of 45 minutes (instead of 60 minutes) for all product ranges at the time of commercialization. Enclosed are the revised specifications for all strengths of Sinemet Plus Tablets range reflecting the dissolution time of 45 minutes, which will be adopted during commercialization. Firm's has submitted fee Rs. 9400/- vide deposit slip No#76245220786 for revision of specifications
	Decision	
	Approved	
179	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	Q. Track Pharma Plot No. D-90-91, Sector-D H.I.T.E Lasbella, Hub, Balochistan. (000982)
	Application Form Dy. No / Tracking ID & date of submission	(5ZD-4A7-4EES, 2024-04-02)
	Detail of Fee Submitted	75000.0, 2023-11-28,
	The proposed proprietary name / brand name	Trckexon 1000mg Injection IV
	Label Claim	Each vial contains: Ceftriaxone Sodium eq. to Ceftriaxone.....1000mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25 Degree Centigrade
	For generic drugs (me-too Status)	Rocephin Injection 1000mg (Manufactured by Martin Dow Pvt. Ltd)
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Name, address of Manufacturing site:	Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE, Super Highway, Phase II, Karachi-
	The status in reference regulatory authorities	Ceftriaxone 1g Powder for Solution for Injection MHRA Approved
	Detail of previous approval	Shelzone 1000mg Injection in 106th PRVC meeting
	Evaluation Remarks	
	Decision	
	Approved	
180	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	Q. Track Pharma Plot No. D-90-91, Sector-D H.I.T.E Lasbella, Hub, Balochistan. (000982)

	Application Form Dy. No / Tracking ID & date of submission	(ABZ-VWZ-BDXA, 2024-04-02)
	Detail of Fee Submitted	75000.0, 2023-11-28,
	The proposed proprietary name / brand name	Fixeipha Suspension 200mg
	Label Claim	Each 5ml of reconstituted suspension contains: Cefixime as trihydrate.....200mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	30ml-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25 Degree Centigrade
	For generic drugs (me-too Status)	Evofix Suspension 200mg (Reg No. 050396) Manufactured by PharmEvo Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Name, address of Manufacturing site:	Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE, Super Highway, Phase II, Karachi-
	The status in reference regulatory authorities	Suprax Suspension 200mg (USFDA Approved)
	Detail of previous approval	Ze-Xim DS 200mg dry powder for suspension in 106th PRVC meeting
	Evaluation Remarks	
	Decision	
	Approved	
181	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	Q. Track Pharma Plot No. D-90-91, Sector-D H.I.T.E Lasbella, Hub, Balochistan. (000982)
	Application Form Dy. No / Tracking ID & date of submission	(NEP-JS5-ABHD, 2024-04-02)
	Detail of Fee Submitted	75000.0, 2023-11-28,
	The proposed proprietary name / brand name	Fixeipha Suspension 100mg
	Label Claim	Each 5ml of reconstituted suspension contains: Cefixime as trihydrate.....100mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	30ml-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25 Degree Centigrade
	For generic drugs (me-too Status)	Evofix Suspension 100mg (Reg No. 029152) Manufactured by PharmEvo Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Name, address of Manufacturing site:	Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE, Super Highway, Phase II, Karachi-
	The status in reference regulatory authorities	Suprax 100mg/5ml powder for Suspension USFDA Approved Discontinued **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
	Detail of previous approval	Ze-Xim DS 100mg Oral powder for suspension in 106th PRVC meeting
	Evaluation Remarks	

	Decision	
	Approved	
182	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	Q. Track Pharma Plot No. D-90-91, Sector-D H.I.T.E Lasbella, Hub, Balochistan. (000982)
	Application Form Dy. No / Tracking ID & date of submission	(SYT-3VE-QH2D, 2024-04-02)
	Detail of Fee Submitted	75000.0, 2023-11-28,
	The proposed proprietary name / brand name	Fixeipha Capsule 400mg
	Label Claim	Each capsule contains: Cefixime as trihydrate.....400mg (Manufacturer's Specifications)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	5's-As per SRO
	Shelf Life (Unit)	2 YearStore below 25 Degree Centigrade
	For generic drugs (me-too Status)	Evofix Capsule 400mg (Reg No. 029151) Manufactured by PharmEvo Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE, Super Highway, Phase II, Karachi-
	The status in reference regulatory authorities	Suprax Capsule 400mg (USFDA Approved)
	Detail of previous approval	Ze-Xim Capsule 400mg in 106th PRVC meeting
	Evaluation Remarks	
	Decision	
	Approved	
183	Case Category	New Section (Dr. Farhad Ullah)
	Name, address of Applicant.	Hi-Med Pharmaceuticals 208C Sundar industrial estate Raiwind Road Lahore (000884)
	Application Form Dy. No / Tracking ID & date of submission	(HES-US7-HDEJ, 2025-07-17)
	Detail of Fee Submitted	37000.0, 9400 2025-05-14, 2025-09-17
	The proposed proprietary name / brand name	Citojet Injection 1000mg/4ml
	Label Claim	Each 4ml Contains: Citicoline Sodium.....1000mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at below 25 degree celcius
	For generic drugs (me-too Status)	CITOLIN 1G INJECTION (Global Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	Psychostimulants and nootropics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Dhanuka Laboratries Ltd
	Detail of stability batches of drug product	3 batches having batch size of 800 ampoules each
	Documents for the procurement of API with approval from DRAP	Firm has submitted copy loan letter from M/s Wimits pharmaceuticals for procurement of API along with

(in case of Import)	intimation of borrowing of API letter to PE&R division DRAP. Firm has also submitted copy of final clearance certificate issued dated 20-02-2025 specifying 25kg Citicoline sodium
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Citolin 1g Injection
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A
The status in reference regulatory authorities	GEROLIN 1gm/4ml solution for injection AIFA approved
GMP status of the firm	New section
Evidence of approval of manufacturing facility	Firm has submitted copy of letter for grant of additional section dated 02-12-2024 specifying Liquid Injectable (Small Volume Parenteral) (General)-New.
Evaluation Remarks	
Shortcomings	Firm's Response
Revise the label claim as per reference formulation considering the salt factor along with submission of applicable fee	The firm has revised the label claim along with submission of Rs. 9400/- on deposit slip No#22686579. The revised label claim is as under; Each 4ml Contain: Citicoline (as Sodium).....1000mg
The chromatographic conditions for assay test of API by drug product manufacturer is different than drug substance manufacturer, clarify	Firm has submitted revised analytical method in which chromatographic conditions are same as per drug substance manufacturer
Clarification shall be submitted for selecting different limit of pH test in batch analysis of drug substance by drug product manufacturer (2.5-3.5.) than drug substance manufacturer (6.5 to 7.5)	Firm has submitted revised drug substance specifications in which limit of pH test has been corrected as per drug substance manufacturer
Stability study data of applied product at 6th month time point shall be submitted	Submitted
Clarification shall be submitted since the manufacturing date of trial batches (03-01-2025) is prior to the import of API (20-02-2025).	With reference to the previous submission, it is noted that an incorrect ADC was attached due to a compilation error. Please find attached the revised ADC, which is the correct version. We kindly request that this corrected document be considered for further processing. Firm has also submitted copy of final clearance certificate issued dated 24-10-2024 specifying 25kg Citicoline sodium The batch number stated in the new clearance certificate differs from that provided in the batch analysis report, clarify.
Clarification shall be submitted since the intimation date of API (23-12-2024) is prior to the import of API (20-02-2025)	With reference to the previous submission, it is noted that an incorrect ADC was attached due to a compilation error. Please find attached the revised ADC, which is the correct version. We kindly request that this corrected document be considered for further processing. Firm has also submitted copy of final clearance certificate issued dated 24-10-2024 specifying 25kg Citicoline sodium The batch number stated in the new clearance certificate differs from that provided in the batch analysis report, clarify.
The batch number stated in the new clearance certificate differs from that provided in the batch analysis report, clarify.	Firm has submitted batch analysis report of new batch.
Decision	

Approved

Approved with following label claim;

Each 4ml Contain:

Citicoline (as Sodium).....1000mg

Registration Board, further decided that the Registration Letter shall be issued after:

- Verification of the loan letter of API.
- Verification of the authenticity of the submitted stability data by the panel constituted by the Chairman, Registration Board.

184	Case Category	New Section (Dr. Farhad Ullah)
	Name, address of Applicant.	Hi-Med Pharmaceuticals 208C Sundar industrial estate Raiwind Road Lahore (000884)
	Application Form Dy. No / Tracking ID & date of submission	(V28-J6Z-AUWS, 2025-07-17)
	Detail of Fee Submitted	37000.0, 9400 2025-05-14, 2025-09-17
	The proposed proprietary name / brand name	Citojet Injection 500mg/4ml
	Label Claim	Each 4ml Contain: Citicoline Sodium..... 500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	4ml x 10 Ampoules-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at below 25 degree celcius
	For generic drugs (me-too Status)	Cerecolin Injection 500mg/4ml (Pharmasol Pvt. Ltd.)
	Pharmacotherapeutic Group of (API)	Psychostimulants and nootropics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Dhanuka Laboratories Ltd
	Detail of stability batches of drug product	3 batches having batch size of 800 ampoules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy loan letter from M/s Wimits pharmaceuticals for procurement of API along with intimation of borrowing of API letter to PE&R division DRAP. Firm has also submitted copy of final clearance certificate issued dated 20-02-2025 specifying 25kg Citicoline sodium
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Neurizer Injection 500mg
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A
	The status in reference regulatory authorities	GEROLIN 500mg/4ml solution for injection AIFA approved
	GMP status of the firm	New section
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for grant of additional section dated 02-12-2024 specifying Liquid Injectable (Small Volume Parenteral) (General)-New.
Evaluation Remarks		
	Shortcomings	Firm's Response
	Revise the label claim as per reference formulation considering the salt factor along with submission of applicable fee	The firm has revised the label claim along with submission of Rs. 9400/- on deposit slip No#24025951145. The revised label claim is as under; Each 4ml Contain: Citicoline (as Sodium).....500mg
	The chromatographic conditions for assay test of API by drug product manufacturer is different than drug substance manufacturer, clarify	Firm has submitted revised analytical method in which chromatographic conditions are same as per drug substance manufacturer

Clarification shall be submitted for selecting different limit of pH test in batch analysis of drug substance by drug product manufacturer (2.5-3.5.) than drug substance manufacturer (6.5 to 7.5)	Firm has submitted revised drug substance specifications in which limit of pH test has been corrected as per drug substance manufacturer
Stability study data of applied product at 6th month time point shall be submitted	Submitted.
Clarification shall be submitted since the manufacturing date of trial batches (02-01-2025) is prior to the import of API (20-02-2025).	With reference to the previous submission, it is noted that an incorrect ADC was attached due to a compilation error. Please find attached the revised ADC, which is the correct version. We kindly request that this corrected document be considered for further processing. Firm has also submitted copy of final clearance certificate issued dated 24-10-2024 specifying 25kg Citicoline sodium The batch number stated in the new clearance certificate differs from that provided in the batch analysis report, clarify.
Clarification shall be submitted since the intimation date of API (23-12-2024) is prior to the import of API (20-02-2025)	With reference to the previous submission, it is noted that an incorrect ADC was attached due to a compilation error. Please find attached the revised ADC, which is the correct version. We kindly request that this corrected document be considered for further processing. Firm has also submitted copy of final clearance certificate issued dated 24-10-2024 specifying 25kg Citicoline sodium The batch number stated in the new clearance certificate differs from that provided in the batch analysis report, clarify.
The batch number stated in the new clearance certificate differs from that provided in the batch analysis report, clarify.	Firm has submitted batch analysis report of new batch.

Decision

Approved

Approved with following label claim;

Each 4ml Contain:

Citicoline (as Sodium).....500mg

Registration Board, further decided that the Registration Letter shall be issued after:

- Verification of the loan letter of API.
- Verification of the authenticity of the submitted stability data by the panel constituted by the Chairman, Registration Board.

185	Case Category	New Section (Dr. Farhad Ullah)
	Name, address of Applicant.	Hi-Med Pharmaceuticals 208C Sundar industrial estate Raiwind Road Lahore (000884)
	Application Form Dy. No / Tracking ID & date of submission	(WJQ-JWN-85T7, 2025-07-17)
	Detail of Fee Submitted	37000.0, 9400 2025-05-14, 2025-09-17
	The proposed proprietary name / brand name	Citojet Injection 250mg/2ml
	Label Claim	Each 2ml contains: Citicoline Sodium.....250mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2ml x 5's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store Below 25 degree celcius

For generic drugs (me-too Status)	Citolin 250mg Injection 2ml (Global Pharmaceuticals)
Pharmacotherapeutic Group of (API)	Psychostimulants and nootropics
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Dhanuka Laboratories Ltd.
Detail of stability batches of drug product	3 batches having batch size of 800 ampoules each
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy loan letter from M/s Wimits pharmaceuticals for procurement of API along with intimation of borrowing of API letter to PE&R division DRAP. Firm has also submitted copy of final clearance certificate issued dated 20-02-2025 specifying 25kg Citicoline sodium
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Citolin Injection 250mg
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A
The status in reference regulatory authorities	CIDILIN 250mg/2ml solution for injection AIFA approved
GMP status of the firm	New section
Evidence of approval of manufacturing facility	Firm has submitted copy of letter for grant of additional section dated 02-12-2024 specifying Liquid Injectable (Small Volume Parenteral) (General)-New.

Evaluation Remarks

Shortcomings	Firm's Response
Revise the label claim as per reference formulation considering the salt factor along with submission of applicable fee	The firm has revised the label claim along with submission of Rs. 9400/- on deposit slip No#3142050316. The revised label claim is as under; Each 2ml Contain: Citicoline (as Sodium).....500mg
The chromatographic conditions for assay test of API by drug product manufacturer is different than drug substance manufacturer, clarify	Firm has submitted revised analytical method in which chromatographic conditions are same as per drug substance manufacturer
Clarification shall be submitted for selecting different limit of pH test in batch analysis of drug substance by drug product manufacturer (2.5-3.5.) than drug substance manufacturer (6.5 to 7.5)	Firm has submitted revised drug substance specifications in which limit of pH test has been corrected as per drug substance manufacturer
Stability study data of applied product at 6th month time point shall be submitted	Submitted
Clarification shall be submitted since the manufacturing date of trial batches (01-01-2025) is prior to the import of API (20-02-2025).	With reference to the previous submission, it is noted that an incorrect ADC was attached due to a compilation error. Please find attached the revised ADC, which is the correct version. We kindly request that this corrected document be considered for further processing. Firm has also submitted copy of final clearance certificate issued dated 24-10-2024 specifying 25kg Citicoline sodium The batch number stated in the new clearance certificate differs from that provided in the batch analysis report, clarify.
Clarification shall be submitted since the intimation date of API (23-12-2024) is prior to the import of API (20-02-2025)	With reference to the previous submission, it is noted that an incorrect ADC was attached due to a compilation error. Please find attached the revised ADC, which is the correct version. We kindly request that this corrected document be considered for further processing. Firm has also submitted copy of final clearance certificate issued dated 24-10-2024 specifying 25kg Citicoline sodium The

		batch number stated in the new clearance certificate differs from that provided in the batch analysis report, clarify.
	The batch number stated in the new clearance certificate differs from that provided in the batch analysis report, clarify.	Firm has submitted batch analysis report of new batch.
Decision		
Approved Approved with following label claim; Each 2ml Contain: Citicoline (as Sodium).....250mg Registration Board, further decided that the Registration Letter shall be issued after: • Verification of the loan letter of API. • Verification of the authenticity of the submitted stability data by the panel constituted by the Chairman, Registration Board.		
186	Case Category	Export Facilitation (Dr. Farhad Ullah)
	Name, address of Applicant.	Swiss Pharmaceuticals Pvt. Ltd. A/159, S.I.T.E.-II, Super Highway (000438)
	Application Form Dy. No / Tracking ID & date of submission	(SVE-EUE-94S7, 2024-10-09)
	Detail of Fee Submitted	37000.0, 2024-09-27,
	The proposed proprietary name / brand name	CO-OLANZA 3mg/25mg CAPSULE
	Label Claim	Each Capsule contains: Olanzapine.....3mg Fluoxetine as Hydrochloride.....25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's, 14's, 20's, 28-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Olanzagat Capsule by M/s Getz Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Atypical Antipsychotic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. Vision Drugs Limited Hyderabad, India.
	Detail of stability batches of drug product	3 batches having batch size of 1000 capsule each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of loan letter from M/s Seraph Pharmaceutical for procurement of API along with intimation of borrowing of API letter to PE&R division DRAP. Firm has also submitted copy of clearance certificate for fluoxetine HCl issued dated 07-10-2022 specifying 25kg fluoxetine. Firm has also submitted copy of clearance certificate for Olanzapine issued dated 05-08-2020 specifying 05kg olanzapine.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Olanzagat 3mg/25mg Capsule by M/s Getz Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A
	The status in reference regulatory authorities	Symbyax 3mg/25mg Capsule by Eli Lilly and Company Indianapolis, IN 46285, USA
	GMP status of the firm	Firm has submitted copy of cGMP certificate issued based on inspection dated 26-10-2023.

Evidence of approval of manufacturing facility	Firm has submitted panel inspection report dated 31-07-2025 & 04-08-2025 for renewal of DML specifying Capsule (General) section

Evaluation Remarks

Shortcomings	Firm's Response
Stability study data of applied product at 6th month time point shall be submitted	Stability study data of applied product at 6th month time point is submitted
The retest date of olanzapine API as per submitted COA is May-2023 while manufacturing date of trial batches is 06-2024. Clarification shall be submitted as manufacturing of trial batches is subsequent to retest date of API.	The firm submitted that the date "May-2023" mentioned on the certificate of analysis of olanzapine is the "Retest date" not the date of expiry of raw material. According to ICH Q7 guidelines "Good Manufacturing Practice for API" under sub section 11.61 defines that: "An API expiry or retest date should be based on an evaluation of data derived from stability studies. Common practice is to use a retest date, not an expiration date". Based on above guidelines the material was analyzed at the retest date and the results were found within the specifications and then used for trial batches. Moreover the API manufacturer has performed and provided the real time stability study up to 60 months (5years). The results are satisfactory and concordant to the specifications, which indicate that the material is stable for up to 5 years.
Since reference has been made to ICH Q7 'Good Manufacturing Practice for API' under subsection 11.61 regarding retesting of APIs, it is noted that as per WHO guidelines (Annex 10: Stability testing of active pharmaceutical ingredients and finished pharmaceutical products, subsection 2.1.10), 'after this retest period a batch of API destined for use in the manufacture of FPP could be retested and then, if in compliance with the specification, could be used immediately (e.g. within 30 days). Complete testing of API should be done.' However, it is observed that the API was tested after more than one year and subsequently used. Please justify this practice."	According to WHO TRS and ICH guidelines the API can be retested several times until the results are out of specifications. The retest periods is based on following conditions: Conditions for multiple retests 1. Scientific justification Stability data must support that the API remains stable over the cumulative storage period. * Each extension should not exceed the period supported by long-term stability studies 2. Packaging and storage · The container must remain intact and API stored under recommended conditions. · Any deviations (e.g., exposure to heat or humidity) disqualify the batch from further retest. 3. Analytical testing · At each retest, critical quality attributes (assay, impurities, appearance, water content, etc.) must meet specifications. · If a trend of degradation is observed (e.g., impurities rising toward limits), regulators may disallow further retests. For the API used in the trial batches the following justifications are considerable: · As for as stability studies are concerned the API manufacturer has performed the real time stability studies for a period of 60months (5 years). · At 60th month the all the results are within specifications meeting the WHO requirement. · The material was stored at controlled environmental conditions of humidity and temperature in raw material store. · At retesting, all the critical quality attributes were tested and found to be concordant with specifications. NOTE: The material after retesting is used only in the trial batches of Generic drug product. This retesting model is never practiced for the commercial batches.
Furthermore, evidence of purchase (procurement documents) of the impurities tested in the batch analysis of Olanzapine shall be submitted	The Olanzapine is a pharmacopoeal drug substance and its monograph is present in USP and BP. The material used in the trial batches are as per USP specifications.

The impurities were tested as per USP method. In the impurities results calculation no impurity standard is used except suitability standard. The impurities results are calculated using standard solution of olanzapine and sample solution of Olanzapine raw material. Standard solution: 2 µg/mL of USP Olanzapine RS in Diluent Sample solution: 0.4 mg/mL of Olanzapine in Diluent Although we have not performed the suitability, however the impurities were calculated as per USP method, using the relative retention time given in table in the olanzapine monograph. Analysis Samples: Standard solution and Sample solution Calculate the percentage of each impurity in the portion of Olanzapine taken: $\text{Result} = (r_U / r_S) \times (C_S / C_U) \times (1/F) \times 100$ r_U = peak response of each impurity from the Sample solution r_S = peak response of olanzapine from the Standard solution C_S = concentration of USP Olanzapine RS in the Standard solution (mg/mL) C_U = concentration of Olanzapine in the Sample solution (mg/mL) F = relative response factor for each impurity from Table 2 Table 2 Given in USP monograph We have not imported the impurities for the trial batches, as there is relaxation of impurity testing in the trial batches. However we commit to import and test the impurities in the commercial batches.

Decision

Rejected

The Board discussed that the shelf life / retest period of API can only be extended by API manufacturer supported by the stability data. In the instant case, May-2023 is the retest date for Olanzapine as per submitted COA of API manufacturer and the applicant i.e. finished product manufacturer has used the API after expiration of re-test period and manufactured the trial batches of finished product in June, 2024. Moreover, as per submitted COA of API from drug product manufacturer, the test results for quantification of impurities have been incorporated in the COA while the applicant has not imported the impurity standards. The applicant upon query, has stated that the impurities will be imported for testing of commercial batches.

The Board, in view of the above discussion, decided to Reject the application.

187	Case Category	Export Facilitation (Dr. Farhad Ullah)
	Name, address of Applicant.	Swiss Pharmaceuticals Pvt. Ltd. A/159, S.I.T.E.-II, Super Highway (000438)
	Application Form Dy. No / Tracking ID & date of submission	(A42-MVR-VE9W, 2024-10-09)
	Detail of Fee Submitted	37000.0, 2024-09-27,
	The proposed proprietary name / brand name	CO-OLANZA 6mg/25mg CAPSULE
	Label Claim	Each Capsule contains: Olanzapine.....6mg Fluoxetine as Hydrochloride.....25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's, 14's, 20's, 28-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Olanzagat Capsule by M/s Getz Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Atypical Antipsychotic

Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	M/s Palam Pharma PVT. LTD India,M/s. Vision Drugs Limited Hyderabad, India.
Detail of stability batches of drug product	3 batches having batch size of 1000 capsule each
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of loan letter from M/s Seraph Pharmaceutical for procurement of API along with intimation of borrowing of API letter to PE&R division DRAP. Firm has also submitted copy of clearance certificate for fluoxetine HCl issued dated 07-10-2022 specifying 25kg fluoxetine. Firm has also submitted copy of clearance certificate for Olanzapine issued dated 05-08-2020 specifying 05kg olanzapine.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Olanzaget 6mg/25mg Capsule by M/s Getz Pharma
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A
The status in reference regulatory authorities	Symbyax 6mg/25mg Capsule by Eli Lilly and Company Indianapolis, IN 46285, USA, USFDA Approved
GMP status of the firm	Firm has submitted copy of cGMP certificate issued based on inspection dated 26-10-2023.
Evidence of approval of manufacturing facility	Firm has submitted panel inspection report dated 31-07-2025 & 04-08-2025 for renewal of DML specifying Capsule (General) section

Evaluation Remarks

Shortcomings	Firm's Response
Stability study data of applied product at 6th month time point shall be submitted	Stability study data of applied product at 6th month time point is submitted
The retest date of olanzapine API as per submitted COA is May-2023 while manufacturing date of trial batches is 06-2024. Clarification shall be submitted as manufacturing of trial batches is subsequent to retest date of API.	The firm submitted that the date "May-2023" mentioned on the certificate of analysis of olanzapine is the "Retest date" not the date of expiry of raw material. According to ICH Q7 guidelines "Good Manufacturing Practice for API" under sub section 11.61 defines that: "An API expiry or retest date should be based on an evaluation of data derived from stability studies. Common practice is to use a retest date, not an expiration date". Based on above guidelines the material was analyzed at the retest date and the results were found within the specifications and then used for trial batches. Moreover the API manufacturer has performed and provided the real time stability study up to 60 months (5years). The results are satisfactory and concordant to the specifications, which indicate that the material is stable for up to 5 years.
Since reference has been made to ICH Q7 'Good Manufacturing Practice for API' under subsection 11.61 regarding retesting of APIs, it is noted that as per WHO guidelines (Annex 10: Stability testing of active pharmaceutical ingredients and finished pharmaceutical products, subsection 2.1.10), 'after this retest period a batch of API destined for use in the manufacture of FPP could be retested and then, if in compliance with the specification, could be used immediately (e.g. within 30 days). Complete testing of API should be done.' However, it is observed that the API was tested after	According to WHO TRS and ICH guidelines the API can be retested several times until the results are out of specifications. The retest periods is based on following conditions: Conditions for multiple retests 1. Scientific justification Stability data must support that the API remains stable over the cumulative storage period. * Each extension should not exceed the period supported by long-term stability studies 2. Packaging and storage The container must remain intact and API stored under recommended conditions. Any deviations (e.g., exposure to heat or humidity) disqualify the batch from further retest. 3. Analytical testing At each

more than one year and subsequently used. Please justify this practice.”	retest, critical quality attributes (assay, impurities, appearance, water content, etc.) must meet specifications. · If a trend of degradation is observed (e.g., impurities rising toward limits), regulators may disallow further retests. For the API used in the trial batches the following justifications are considerable: · As for as stability studies are concerned the API manufacturer has performed the real time stability studies for a period of 60months (5 years). · At 60th month the all the results are within specifications meeting the WHO requirement. · The material was stored at controlled environmental conditions of humidity and temperature in raw material store. · At retesting, all the critical quality attributes were tested and found to be concordant with specifications. NOTE: The material after retesting is used only in the trial batches of Generic drug product. This retesting model is never practiced for the commercial batches.
Furthermore, evidence of purchase (procurement documents) of the impurities tested in the batch analysis of Olanzapine shall be submitted	The Olanzapine is a pharmacopoeal drug substance and its monograph is present in USP and BP. The material used in the trial batches are as per USP specifications. The impurities were tested as per USP method. In the impurities results calculation no impurity standard is used except suitability standard. The impurities results are calculated using standard solution of olanzapine and sample solution of Olanzapine raw material. Standard solution: 2 µg/mL of USP Olanzapine RS in Diluent Sample solution: 0.4 mg/mL of Olanzapine in Diluent Although we have not performed the suitability, however the impurities were calculated as per USP method, using the relative retention time given in table in the olanzapine monograph. Analysis Samples: Standard solution and Sample solution Calculate the percentage of each impurity in the portion of Olanzapine taken: Result = (r U/r S) × (C S/C U) × (1/F) × 100 rU = peak response of each impurity from the Sample solution rS = peak response of olanzapine from the Standard solution CS = concentration of USP Olanzapine RS in the Standard solution (mg/mL) CU = concentration of Olanzapine in the Sample solution (mg/mL) F = relative response factor for each impurity from Table 2 Table 2 Given in USP monograph We have not imported the impurities for the trial batches, as there is relaxation of impurity testing in the trial batches. However we commit to import and test the impurities in the commercial batches

Decision

Rejected

The Board discussed that the shelf life / retest period of API can only be extended by API manufacturer supported by the stability data. In the instant case, May-2023 is the retest date for Olanzapine as per submitted COA of API manufacturer and the applicant i.e. finished product manufacturer has used the API after expiration of re-test period and manufactured the trial batches of finished product in June, 2024. Moreover, as per submitted COA of API from drug product manufacturer, the test results for quantification of impurities have been incorporated in the COA while

the applicant has not imported the impurity standards. The applicant upon query, has stated that the impurities will be imported for testing of commercial batches.

The Board, in view of the above discussion, decided to Reject the application.

188	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Bristol Mayer Biotech Pakistan 73 B Guldasht Town Zarrar Shaheed Lahore (05-352-0068)
	Application Form Dy. No / Tracking ID & date of submission	(GW3-YUB-HDZ2, 2024-04-29)
	Detail of Fee Submitted	150000.0, 150000.0 2023-12-18, 2024-04-22
	The proposed proprietary name / brand name	Northex 5
	Label Claim	Each tablet contains; Norethisterone BP.....5 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10x10 Tablets-As per SRO
	Shelf Life (Unit)	36 Month(s)Do not store above 30°C
	For generic drugs (me-too Status)	Primolut N Tablet by Bayer
	Pharmacotherapeutic Group of (API)	Synthetic second generation progestin
	Name, address of Manufacturing site:	Accent Pharmaceuticals & Diagnostics -Vill. Bhalon(Seri), P.O. Galanag Forest Road, Solan-173212, Himachal Pradesh, India-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference listed drug i.e. Primolut N by M/s Bayer-Weimar GmbH UND Co. KG. UK
	Name, address of Marketing Authorization Holder:	Accent Pharmaceuticals & Diagnostics , Vill. Bhalon(Seri), P.O. Galanag Forest Road, Solan-173212, Himachal Pradesh, India, India
	Details of Certificates (CoPP/FSC/cGMP):	GMP certificate valid till 09-02-2025.
	Details of Authorization Letter :	DSL: Copy o DSL valid till 18-10-2028 is submitted. LOA: Copy of legalized Letter of authorization (product specific) is submitted. FSC: Copy of legalized Free Sale certificate of multiple products including the applied product is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 48 months real time stability data (at 25oC & 60% RH) of 03 batches.
	The status in reference regulatory authorities	HSA(Signapore Approved)
	Evaluation Remarks	
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189	Decision	
	Approved	
	as per Import policy for inspection of manufacturer abroad.	
	Case Category	New Section (Farooq Aslam)
	Name, address of Applicant.	Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi (000333)
	Application Form Dy. No / Tracking ID & date of submission	(2WH-LER-15ZA, 2025-09-12)
	Detail of Fee Submitted	38700.0, 2025-08-06,
	The proposed proprietary name / brand name	ORNIPLEX 5g/10ml INJECTION

Label Claim	Each 10 ml ampoule contains: L-Ornithine L-Aspartate.....5g																				
Reference to Finished product specifications	As per Innovators Specification																				
Proposed Pack Size	(1x1's) 10ml-As per SRO																				
Shelf Life (Unit)	2 Year(s)Store at temperature 15°C to 30°C . Protect from light.																				
For generic drugs (me-too Status)	Hepa-Merz Infusion Concentration (5g /10mL) by M/s Brookes Pharma (Pvt.) Limited, Karachi – Pakistan																				
Pharmacotherapeutic Group of (API)	Amino Acid derivative																				
Name, address of Manufacturing site:	Self Manufacturing																				
Name & address of API manufacturer	Fuan Pharmaceutical Group Chongqing Bosen Pharmaceutical Co., Ltd																				
Detail of stability batches of drug product	Batches: 181NS02, 181NS03, 181NS04 (Batch size: 1000 ampoules) 06 months real time and 06 months accelerated stability data is submitted.																				
Documents for the procurement of API with approval from DRAP (in case of Import)	clearance certificate dated 27-11-2024 for 15.1 kg material is submitted.																				
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the innovator's product i.e. Hepa-Merz 5g/10ml injection (Merz Pharmaceuticals, Germany)																				
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	24 months real time and 06 month accelerated stability data according to the conditions of zone IV-A for 03 batches.																				
The status in reference regulatory authorities	Hepa-Merz 5g/10ml injection (Merz Pharmaceuticals, Germany)																				
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 16-02-2024.																				
Evidence of approval of manufacturing facility	Liquid injectable Ampoule-II (General) Section is approved. (New Section)																				
Evaluation Remarks																					
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Decision																					
Approved																					
190	<table> <tr> <td>Case Category</td><td>Routine (Farooq Aslam)</td></tr> <tr> <td>Name, address of Applicant.</td><td>Hospital supply Corporation 46-E/2, Block 6, P.E.C.H.S., Behind Fortune Centre, Shahrah-e- Faisal, Karachi -75350 (0395)</td></tr> <tr> <td>Application Form Dy. No / Tracking ID & date of submission</td><td>(3DE-XDN-DYV9, 2024-03-18)</td></tr> <tr> <td>Detail of Fee Submitted</td><td>150000.0, 150000.0 2023-09-20, 2024-03-14</td></tr> <tr> <td>The proposed proprietary name / brand name</td><td>Beracaine Spray (Lidocaine)</td></tr> <tr> <td>Label Claim</td><td>Each bottle (100ml solution) contains: Lidocaine.....10g Each delivered dose contains: Lidocaine.....10mg</td></tr> <tr> <td>Reference to Finished product specifications</td><td>United States Pharmacopeia</td></tr> <tr> <td>Proposed Pack Size</td><td>1s-Controlled</td></tr> <tr> <td>Shelf Life (Unit)</td><td>3 Year(s)Airtight Container, Stored at room temperature at 1°C to 30°C</td></tr> <tr> <td>For generic drugs (me-too Status)</td><td>could not be confirmed</td></tr> </table>	Case Category	Routine (Farooq Aslam)	Name, address of Applicant.	Hospital supply Corporation 46-E/2, Block 6, P.E.C.H.S., Behind Fortune Centre, Shahrah-e- Faisal, Karachi -75350 (0395)	Application Form Dy. No / Tracking ID & date of submission	(3DE-XDN-DYV9, 2024-03-18)	Detail of Fee Submitted	150000.0, 150000.0 2023-09-20, 2024-03-14	The proposed proprietary name / brand name	Beracaine Spray (Lidocaine)	Label Claim	Each bottle (100ml solution) contains: Lidocaine.....10g Each delivered dose contains: Lidocaine.....10mg	Reference to Finished product specifications	United States Pharmacopeia	Proposed Pack Size	1s-Controlled	Shelf Life (Unit)	3 Year(s)Airtight Container, Stored at room temperature at 1°C to 30°C	For generic drugs (me-too Status)	could not be confirmed
Case Category	Routine (Farooq Aslam)																				
Name, address of Applicant.	Hospital supply Corporation 46-E/2, Block 6, P.E.C.H.S., Behind Fortune Centre, Shahrah-e- Faisal, Karachi -75350 (0395)																				
Application Form Dy. No / Tracking ID & date of submission	(3DE-XDN-DYV9, 2024-03-18)																				
Detail of Fee Submitted	150000.0, 150000.0 2023-09-20, 2024-03-14																				
The proposed proprietary name / brand name	Beracaine Spray (Lidocaine)																				
Label Claim	Each bottle (100ml solution) contains: Lidocaine.....10g Each delivered dose contains: Lidocaine.....10mg																				
Reference to Finished product specifications	United States Pharmacopeia																				
Proposed Pack Size	1s-Controlled																				
Shelf Life (Unit)	3 Year(s)Airtight Container, Stored at room temperature at 1°C to 30°C																				
For generic drugs (me-too Status)	could not be confirmed																				

Pharmacotherapeutic Group of (API)	Local anesthetic
Name, address of Manufacturing site:	Firson Co., LTD.-47, Baekseokgongdan 1-ro, Seobuk-gu, Cheonan-si, Chungcheongnam-do, Republic of Korea-South
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against Angelcaine Spray (Lidocaine) by Ms Did Bio Co., Ltd., South Korea.
Name, address of Marketing Authorization Holder:	Firson Co., LTD., 47, Baekseokgongdan 1-ro, Seobuk-gu, Cheonan-si, Chungcheongnam-do, Republic of Korea, korea
Details of Certificates (CoPP/FSC/cGMP):	Pharmaceutical License dated 22-02-2023 is submitted. GMP certificate valid till 17-09-2023 is submitted.
Details of Authorization Letter :	CoPP: Copy of apostille CoPP No. 2023-G1-0308 dated 22-02-2023 is submitted. The applied product is available in free sale in exporting country, and the facilities & Operations conform to PIC/s/WHO-GMP as per submitted CoPP. DSL: DSL valid till 12-12-2028 is submitted. LOA: Product specific agency agreement is submitted.,
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 48 months real time (25oC & 60%RH) for 03 batches is submitted.
The status in reference regulatory authorities	Xylocaine 10mg/Delivered Dose Mucosal Spray-Aspen Pharma Trading HPRA Ireland Approved

Evaluation Remarks

in the initial application, the firm had submitted covering letter and module I for 100mL filled volume but module II and III contained the information regarding 50mL filled volume. Upon query, the applicant had revised module I for 50mL filled volume and stated that during filling of application form, 100mL filled volume was mentioned mistakenly. The firm has not submitted any fee.

Decision

Approved

as per import policy for inspection of manufacturer abroad. Moreover, the firm shall submit applicable as per SRO 1399(I)/2025 dated 01-08-2025 for revision of filled volume of the applied product from 100mL to 50mL.

191	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Helix Pharma (Pvt)., Ltd. Hakimsons House, A-56, S.I.T.E, Manghopir Road, Karachi-75700 (000030)
	Application Form Dy. No / Tracking ID & date of submission	(B5G-72M-DTR2, 2024-04-22)
	Detail of Fee Submitted	30000.0, 2024-04-02,
	The proposed proprietary name / brand name	APIX Tablets 2.5mg
	Label Claim	Each Film Coated Tablet Contains: Apixaban 2.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	24 Month(s)Store below 30C
	For generic drugs (me-too Status)	Apixaget by Getz Pharma, Afixba Tablets 2.5mg by Sami Pharma
	Pharmacotherapeutic Group of (API)	factor Xa inhibitor / anticoagulant
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Jiangxi Synergy Pharmaceutical Co.,Ltd.
	Detail of stability batches of drug product	Batches: TR223, TR224, TR225 (Batch Size: 1000 tablets) 06 months real time and o6 months accelerated

	Documents for the procurement of API with approval from DRAP (in case of Import)	stability data is submitted. Form 6 dated 27-07-2022 for 0.kg of Apixaban is submitted. Un attested invoice, packing list, receipt of DHL No. 5105058254 submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. Apixaget 2.5mg Tablet by M/s Getz Pharma.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 48 months real time stability studies according to the conditions of zone IV-A for 03 batches are submitted.
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 06-04-2023.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
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	Decision	
	Approved	
192	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(PLV-D28-Y898, 2024-04-23)
	Detail of Fee Submitted	30000.0, 2024-03-19,
	The proposed proprietary name / brand name	Eplic 400mg Tablet
	Label Claim	Each Tablet contains Carbamezapine.....400mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at cool &dry place below 30
	For generic drugs (me-too Status)	Tegral 400mg Tablet M/s Novartis Pharma (Pakistan) Limited Reg.# 079918
	Pharmacotherapeutic Group of (API)	Anti-convulsant
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CTX Lifesciences Pvt. Ltd. Address: Block No. 251-252, Sachin- Magdalla Road GIDC, Sachin, Surat – 394 230, Gujarat, INDIA
	Detail of stability batches of drug product	Batches: TEU001, TEU002, TEU003 (Batch size: 2500 tab) 06 months real time and 06 months accelerated stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 16-12-2022 is submitted for 25Kg material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Tegretol 400mg tablet by M/s Novartis Pharmaceuticals UK ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 12 month real time stability data is submitted.

	The status in reference regulatory authorities	Carbamazepine 400 mg Tablets M/s zure Pharmaceuticals Ltd, HPRA Ireealnd approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 03-04-2023.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	.	
	Decision	
	Approved	
193	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(SQX-Q72-89S2, 2024-04-18)
	Detail of Fee Submitted	30000.0, 2024-03-19,
	The proposed proprietary name / brand name	Eplic 400mg XR Tablet
	Label Claim	Each Extended Released tablet contains Carbamazepine.....400mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at cool &dry place below 30
	For generic drugs (me-too Status)	Epitab 400mg XR Tablet M/s Werrick Pharmaceuticals 216-217,I-10/3, industrial Area, Islamabad- Pakistan Reg.#031873
	Pharmacotherapeutic Group of (API)	Antacids or anti-reflux agent
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CTX Lifesciences Pvt. Ltd. Address: Block No. 251-252, Sachin- Magdalla Road GIDC, Sachin, Surat – 394 230, Gujarat, INDIA
	Detail of stability batches of drug product	Batches: TCY001, TCY002, TCY003 (Batch size: 2500 tab) 06 months real time and 06 month accelerated stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 16-12-2022 is submitted for 25Kg material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Tegretol 400mg prolonged release tablet by M/s Novartis pharmaceuticals UK Ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 12 month real time stability data is submitted.
	The status in reference regulatory authorities	Tegretol 400 mg Prolonged release Tablets M/s Novartis Pharmaceuticals UK Limited, HPRA Ireland approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 03-04-2023.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	.	
	Decision	

	Approved	
194	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	FAAS Pharmaceuticals (Pvt)Ltd F-748 L, S.I.T.E, Karachi (000767)
	Application Form Dy. No / Tracking ID & date of submission	(RUB-8A6-5PWA, 2024-03-13)
	Detail of Fee Submitted	30000.0, 2024-02-02,
	The proposed proprietary name / brand name	LEVOSUL
	Label Claim	EACH TABLET CONTAINS: LEVOSULPIRIDE.....25MG
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10s and 20s-As per SRO
	Shelf Life (Unit)	24 Month(s)At room temperature below 30 degree centigrade
	For generic drugs (me-too Status)	LEVOPRAID 25 mg tab by Pacific Pharma Registration Number 021649
	Pharmacotherapeutic Group of (API)	Antipsychotic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Alcon Biosciences Private Limited INDIA
	Detail of stability batches of drug product	Batches: T001, T002, T003 (Batch Size: 2000 tablets) 06 months real time and 06 months accelerated stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	DRAP Attested invoice No. AB/1/0119/21-22 dated 28-09-2021 vide Dy. No. 12231 dated 20-10-2021 for 1kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e Levopraid 25mg tablet by M/s Pacific Pharmaceuticals.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	48 months real time and 06 months accelerated stability data of 03 batches according to the conditions of zone IV-A is submitted.
	The status in reference regulatory authorities	LEVOPRAID 25mg tablet by EOFARMA SRL AIFA ITALY Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 04-05-2018.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
195	Evaluation Remarks	
	Last GMP inspection was conducted on 04-05-2018.	
	Decision	
	Approved	
	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	FAAS Pharmaceuticals (Pvt)Ltd F-748 L, S.I.T.E, Karachi (000767)
	Application Form Dy. No / Tracking ID & date of submission	(YQ4-2W4-4SJW, 2024-03-12)
	Detail of Fee Submitted	30000.0, 2024-02-02,
	The proposed proprietary name / brand name	LEVOSUL 50MG TAB

Label Claim	EACH TABLET CONTAINS LEVOSULPIRIDE 50MG (AS PER INNOVATORS SPECS)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	20-As per SRO
Shelf Life (Unit)	24 Month(s)At room temperature below 25 degree centigrade
For generic drugs (me-too Status)	LEVOPRAID 50 mg tab,Pacific Pharma Pvt Ltd, Registration Number 019755
Pharmacotherapeutic Group of (API)	Antipsychotic
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Alcon Biosciences Private Limited INDIA
Detail of stability batches of drug product	Batches: T001, T002, T003 (Batch Size: 2000 tablets) 06 months real time and 06 months accelerated stability data is submitted.
Documents for the procurement of API with approval from DRAP (in case of Import)	DRAP Attested invoice No. AB/1/0119/21-22 dated 28-09-2021 vide Dy. No. 12231 dated 20-10-2021 for 1kg material is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e Levopraid 50mg tablet by M/s Pacific Pharmaceuticals.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	48 months real time and 06 months accelerated stability data of 03 batches according to the conditions of zone IV-A is submitted.
The status in reference regulatory authorities	LEVOPRAID 50mg tablet, TEOFARMA SRL, Merck Sharp & Dohme Limited, AIFA ITALY Approved
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 04-05-2018.
Evidence of approval of manufacturing facility	Tablet General Section is approved.
Evaluation Remarks	
Last GMP inspection was conducted on 04-05-2018.	
Decision	
Approved	
196	Case Category
	Routine (Farooq Aslam)
	Name, address of Applicant.
	Macter International Limited F-216,S.I.T.E.,Karachi-Pakistan (000141)
	Application Form Dy. No / Tracking ID & date of submission
	(U7J-238-J2SH, 2024-03-19)
	Detail of Fee Submitted
	30000.0, 2024-01-18,
	The proposed proprietary name / brand name
	Esonap 375mg/20mg Tablets
	Label Claim
	Each delayed release film coated tablet contains: Naproxen....375mg (enteric coated) and an Immediate release (Esomeprazole part).....20mg (immediate release coating)
	Reference to Finished product specifications
	As per Innovators Specification
	Proposed Pack Size
	14's & 28's As per S-As per SRO
	Shelf Life (Unit)
	2 Year(s)Store below 30 degree centigrade
	For generic drugs (me-too Status)
	Glomov tablet (373/20) Reg No. 109339 by M/s Global Pharmaceuticals
	Pharmacotherapeutic Group of (API)
	NSAID/Anti-ulcer

Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Industrias Quimicas Falcon De Mexico S.A De C.V, Km 4.5 Carretera Federal Cuernavaca-Cuautla, CIVAC Jiutepec Morelos, Mexico, Jiangsu Zhongbang Pharmaceuticals Co., Ltd, 36 Shuanggao Road, Gaochun, Nanjing, China
Detail of stability batches of drug product	Batches: 22SB-110-001, 22SB-110-002 , 22SB-110-003 (Batch size: 3000 tablets) 06 months accelerated and 09 month real time stability data is provided.
Documents for the procurement of API with approval from DRAP (in case of Import)	Naproxen: Copy of Form 6 dated 01-01-2021 for 5kg material, copy of GD (KPAF-6018-30122020 Date: 30-12-2020) Esomeprazole: copy of Form 6 dated 26-10-2020 for 2 kg material, copy of GD (KPAF-4958-30102020 Date: 30-10-2020)
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e Vimovo 375/20mg tablet by M/s AstraZeneca group of companies.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Eomeprazole: 06 month real time and 24 months accelerated stability data according to the conditions of zone IV-A for 03 bathes is submitted. Naproxen: 06 month real time and 60 months accelerated stability data according to the conditions of zone IV-A for 03 bathes is submitted.
The status in reference regulatory authorities	USFDA Approved
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 04-08-2022.
Evidence of approval of manufacturing facility	Tablet General Section is approved.
Evaluation Remarks	
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Decision	
Approved	
197	Case Category
	New Section (Farooq Aslam)
	Name, address of Applicant.
	Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi (000333)
	Application Form Dy. No / Tracking ID & date of submission
	(TZ2-VSL-WPBX, 2024-08-23)
	Detail of Fee Submitted
	30000.0, 45030.0 2023-12-19, 2024-04-23
	The proposed proprietary name / brand name
	FIST Sachet
	Label Claim
	Each 1g sachet contains: Diclofenac sodium.....25mg
	Reference to Finished product specifications
	As per Innovators Specification
	Proposed Pack Size
	20's-As per SRO
	Shelf Life (Unit)
	2 Year(s)store in a cool and dry place below 30
	For generic drugs (me-too Status)
	could not be confirmed
	Pharmacotherapeutic Group of (API)
	NSAID
	Name, address of Manufacturing site:
	Self Manufacturing
	Name & address of API manufacturer
	Henan Dongtai Pharm Co,Ltd.
	Detail of stability batches of drug product
	Batches: 085NS06, 085NS06, 085NS06 (Batch size: 500 sachet) 06 months real time and 06 month accelerated stability data is submitted.

	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 21-07-2023 for 500kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against Voltadvance Sachet by M.s GSK, ITAly.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	36 months real time and 06 months accelerated stability data of 05 batches is submitted accorindg to the conditions of zone IV-A.
	The status in reference regulatory authorities	Voltadvance sachet by GSK, Aifa Italy Approved.
	GMP status of the firm	Additional Section (Sachet General) was granted vide letter No. F.1-18/92-Lic(Vol-III) dated 13th Jan, 2022.
	Evidence of approval of manufacturing facility	Additional Section (Sachet General) was granted vide letter No. F.1-18/92-Lic(Vol-III) dated 13th Jan, 2022.
	Evaluation Remarks	
	Decision	
	Approved	
198	Case Category	New Section (Farooq Aslam)
	Name, address of Applicant.	Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi (000333)
	Application Form Dy. No / Tracking ID & date of submission	(G3G-BER-P68T, 2024-04-29)
	Detail of Fee Submitted	30000.0, 2023-11-21,
	The proposed proprietary name / brand name	LINAMET 2.5/850mg tablet
	Label Claim	each film coated tablet contains: Linagliptin.....2.5mg Metformin HCl.....850mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	2 Year(s)store in a cool and dry place below 30
	For generic drugs (me-too Status)	could not be confirmed
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Exemed Pharmaceuticals ,Fuxin Long Rui Pharmaceuticals,India
	Detail of stability batches of drug product	Batces: T001, T002, T003 (Batch size: 750 tablets) 06 months real time and 06 months accelerated stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Linagliptin: Clearance certificate dated 01-08-2022 for 500 grams of Linagliptin. Metformin: Clearance certificate dated 15-08-2022 for Metformin HCl.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE ad CDP studies have been performed against the reference product i.e Jentaducto 2.5/850mg by M/s Boehringer Ingelheim Pharma, Germany.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Metformin HCl: o6 month accelerated and 72 months real time stability data of 03 baches according to the conditions of zone IV-A is submitted. Linagliptin: 06 months accelerated and 36 months real time stability data of 03 batches according to the conditions of zone IV-A is submitted.

	The status in reference regulatory authorities	Jentaducto 2.5/850mg tablets(Boehringer Ingelheim Pharma Germany
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 04-11-2021
	Evidence of approval of manufacturing facility	Tablet General Section is approved
	Evaluation Remarks	
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	Decision	
	Approved	
199	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Scilife Pharma Private Limited FD-57/58-A2, Korangi Creek Industrial Park (KCIP) (000837)
	Application Form Dy. No / Tracking ID & date of submission	(NL5-RTV-HQL1, 2025-02-07)
	Detail of Fee Submitted	37000.0, 2024-12-10,
	The proposed proprietary name / brand name	Toprol XR 50mg Tablet
	Label Claim	Each film-coated tablet contains: 47.5 metoprolol succinate equivalent to 50mg metoprolol tartrate.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO,15's-As per SRO,30's-As per SRO,50's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 25°C. Excursions permitted between 15°C and 30°C.
	For generic drugs (me-too Status)	Merol XL 50mg Tablet by M/s ATCO LABORATORIES LIMITED
	Pharmacotherapeutic Group of (API)	Beta adrenergic receptor antagonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Pellets Pharma Limited
	Detail of stability batches of drug product	Batches: 058B24, 075B24, 067B24 (Batch size: 2000 tablets) 06 months real time and 06 months accelerated stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 08-11-2023 is submitted for 2kg material and copy of GD (KPAF-11839-18122023) are submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Betaloc Zok 50mg ER tablet by M/s Astrazeneca AB, Sweden.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 24 months real time stability data according to the conditions of zone IV-B of 03 batches.
	The status in reference regulatory authorities	TOPROL XL 50MG TABLETS by M/S ASTRAZENECA GROUP OF COMPANIES, USA
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 22-02-2023
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
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	Decision	
	Approved	

200	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Scilife Pharma Private Limited FD-57/58-A2, Korangi Creek Industrial Park (KCIP) (000837)
	Application Form Dy. No / Tracking ID & date of submission	(PUR-9JW-94A2, 2025-02-07)
	Detail of Fee Submitted	37000.0, 2024-12-10,
	The proposed proprietary name / brand name	Toprol XR 100mg Tablet
	Label Claim	Each film-coated tablet contains 95mg metoprolol succinate equivalent to 100mg metoprolol tartrate.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO, 15's-As per SRO, 30's-As per SRO, 50's-As per SRO
	Shelf Life (Unit)	2 Year(s) Store at 25°C. Excursions permitted between 15°C and 30°C.
	For generic drugs (me-too Status)	Merol XL 100mg Tablet by M/s ATCO LABORATORIES LIMITED
	Pharmacotherapeutic Group of (API)	Beta adrenergic receptor antagonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Pellets Pharma Limited
	Detail of stability batches of drug product	Batches: 068B24, 076B24, 077B24 (Batch size: 2000 tablets) 06 months real time and 06 months accelerated stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 08-11-2023 is submitted for 2kg material and copy of GD (KPAF-11839-18122023) are submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Betaloc Zok 100mg ER tablet by M/s Astrazeneca AB, Sweden.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 24 months real time stability data according to the conditions of zone IV-B of 03 batches.
	The status in reference regulatory authorities	TOPROL XL 100MG TABLETS by M/S ASTRAZENECA GROUP OF COMPANIES, USA
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 22-02-2023
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
201	Evaluation Remarks	.
	Decision	
	Approved	
	Case Category	Priority As Per 257-M of RB (Farooq Aslam)
	Name, address of Applicant.	REVIVE HEALTH CARE 503, 5TH FLOOR EDEN HEIGHTS 6 MAIN GULBERG JAIL ROAD (05-352-0065)
	Application Form Dy. No / Tracking ID & date of submission	(S62-JRE-JR4D, 2025-09-04)
	Detail of Fee Submitted	313500.0, 2025-08-25,
	The proposed proprietary name / brand name	LENVIXA Capsule 4.0 mg

Label Claim	Each hard gelatin capsule contains: Lenvatinib mesilate equivalent to Lenvatinib.....4mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	30's HDPE Bottle Pack-As per SRO
Shelf Life (Unit)	48 Month(s)Store below 30 degree centigrade
For generic drugs (me-too Status)	Registration No: 106862, Lenvanix 4mg Capsule
Pharmacotherapeutic Group of (API)	Antineoplastic agent
Name, address of Manufacturing site:	Qilu Pharmaceutical Co., Ltd.-8888 Lvyou Road, High-tech Zone, Jinan, Shandong 250104-China
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against reference product (LENVIMA Capsule 4mg by M/s Eisai GmbH, Germany) against the applied product.
Name, address of Marketing Authorization Holder:	Qilu Pharmaceutical Co., Ltd., 8888 Lvyou Road, High-tech Zone, Jinan, Shandong 250104, China
Details of Certificates (CoPP/FSC/cGMP):	Eudra GMP Certificate No. ES/046HV/25 is submitted (inspection date 27-09-2024).
Details of Authorization Letter :	CoPP: Copy of legalized CoPP No. 20251220 valid till 11-08-2027 is submitted. The applied product is available in free sale in the market of exporting country and the facilities & operations conform to WHO-GMP. DSL: Copy of DSL valid till 21-05-2027 submitted. LOA: Letter of Authorization is submitted for the applied product.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	6 months of accelerated stability data (25 ± 2°C / 60% ± 5% RH) and 24 months of long- term stability data (2-8°C). Stability data of 03 batches is submitted.
The status in reference regulatory authorities	LENVIMA Capsule 4.0 mg, USFDA Approved
Evaluation Remarks	
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Decision	
Approved	
as per import policy for inspection of manufacturer abroad.	
202	Case Category
	Contract Manufacturing (Farooq Aslam)
	Name, address of Applicant.
	Surge Laboratories (Pvt.) Ltd. 10th KM, Faisalabad Road, Bikhi District, Sheikhpura. (000484)
	Application Form Dy. No / Tracking ID & date of submission
	(73D-NP2-Z3M3, 2025-08-18)
	Detail of Fee Submitted
	93000.0, 2025-06-25,
	The proposed proprietary name / brand name
	Cytig
	Label Claim
	Each vial contains: Tigecycline USP.....50mg (Lyophilized powder for injection) (Lyophilized powder for solution)
	Reference to Finished product specifications
	United States Pharmacopeia
	Proposed Pack Size
	1's -Controlled
	Shelf Life (Unit)
	2 Year(s)Store below at 30°C
	For generic drugs (me-too Status)
	Btig 50mg injection by M/s Bosch
	Pharmacotherapeutic Group of (API)
	Anti biotics Tetracycline

Name, address of Manufacturing site:	M/s. Nabiqasim Industries (Pvt.) Ltd.-17/24, Korangi Industrial Area, Karachi-
Name & address of API manufacturer	Fuan Pharmaceutical group chongqing bosen pharmaceutical co., Ltd
Detail of stability batches of drug product	Submitted stability study data of 2 batches at both accelerated as well as real time conditions. The stability data of first batch (TIH001) at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\% \text{ RH}$ for 6months and the real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\% \text{ RH}$ for 06 months The stability data of second batch (TIG002) at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\% \text{ RH}$ for 6 months and the real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\% \text{ RH}$ for 06 months. Batch size: 10,000 vials
Documents for the procurement of API with approval from DRAP (in case of Import)	1. Clearance Certificate dated 02-01-2025 issued by DRAP, Lahore Specifying quantity 1 Kg of Tigecycline 2. Clearance Certificate dated 26-09-2024 issued by DRAP, Lahore Specifying quantity 0.6 Kg of Tigecycline Clearance certificates have been issued to M/s NabiQasim.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been submitted against the comparator's product i.e. BTig50mg Lyophilized Powder for Injection by M/s Bosch Pharma Pvt Ltd
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted stability study data of 3 batches of Tigecycline (Drug substance) at both accelerated as well as real time conditions. The accelerated stability data is conducted at $25^{\circ}\text{C} \pm 2^{\circ}\text{C} / 60\% \pm 5\% \text{ RH}$ for 6 months. The real time stability data is conducted at $5^{\circ}\text{C} \pm 3^{\circ}\text{C} /$ for 24 months.
The status in reference regulatory authorities	MHRA Approved
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 27-05-2025 (NabiQasim)
Evidence of approval of manufacturing facility	Lyophilized vial section is approved (NabiQasim)
Evaluation Remarks	
The final market pack will include a 5mL 0.9% Sodium Chloride Injection as diluent.	
Decision	
Approved	
203	Case Category
	New Section (Farooq Aslam)
	Name, address of Applicant.
	Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi (000333)
	Application Form Dy. No / Tracking ID & date of submission
	(PN1-M4B-ZYLA, 2025-08-04)
	Detail of Fee Submitted
	37000.0, 2025-07-24,
	The proposed proprietary name / brand name
	T-DOL 100mg/2ml Injection
	Label Claim
	Each ampoule (2mL) contains: Tramadol HCl....100mg
	Reference to Finished product specifications
	British Pharmacopeia
	Proposed Pack Size
	1x5's-As per SRO
	Shelf Life (Unit)
	2 Year(s)store below 30

For generic drugs (me-too Status)	tramal inj 100mg/2mL by M/s The Searle Company Limited
Pharmacotherapeutic Group of (API)	opoid agonist
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Supariya lifesciences
Detail of stability batches of drug product	Batches: 207NS02, 207NS03, 207NS04 (Batch Size: 1500 Ampoules)
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 31-01-2025 for 50kg of material is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the comparator's product i.e. Tramal 100mg/2mL by M/s Searle.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 36 months real time stability data of 03 batches is submitted according to the conditions of zone IV-A.
The status in reference regulatory authorities	Tramadol injection 100mg/2mL by M/s Juno Pharma, TGA Australia
GMP status of the firm	GMP certificate issued on the basis o inspection conducted on 16-02-2024.
Evidence of approval of manufacturing facility	Liquid Injectable Ampoule -II (General) Section is approved (New Section)

Evaluation Remarks

New Section

Decision

Approved

204	Case Category	New Section (Farooq Aslam)
	Name, address of Applicant.	Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi (000333)
	Application Form Dy. No / Tracking ID & date of submission	(PL4-QBH-BZJ4, 2025-08-01)
	Detail of Fee Submitted	37000.0, 2025-07-15,
	The proposed proprietary name / brand name	CO-LIN 600mg/2ml Injection
	Label Claim	Each 2ml contains: Lincomycin as hydrochloride monohydrate USP....600mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x5's-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30
	For generic drugs (me-too Status)	lincocin 600mg/2ml by M/s Pfizer Pakistan ltd
	Pharmacotherapeutic Group of (API)	Lincosamide
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Topfond Pharmaceuticals Co.Ltd
	Detail of stability batches of drug product	Batches; 186NS02-186NS03-186NS04 (batch size: 1000 ampoules) 06 months real time and 06 months accelerate stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 29-11-2024 for 2.2kg of material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been submitted against the innovator's product i.e. Lincosin 600mg/2ml Injection by M/s Pfizer

		Pakistan Ltd..
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 36 months real time stability data of 03 batches conducted under the conditions of zone IV-A.
	The status in reference regulatory authorities	Lincosin 600mg/2ml injection by M/s pfizer, USFDA Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 16-02-2024 is submitted.
	Evidence of approval of manufacturing facility	Liquid Injectable Ampoule-II (General) section is approved (New Section)
	Evaluation Remarks	
	New Section	
	Decision	
	Approved	
205	Case Category	Export Facilitation (Farooq Aslam)
	Name, address of Applicant.	Scilife Pharma Private Limited FD-57/58-A2, Korangi Creek Industrial Park (KCIP) (000837)
	Application Form Dy. No / Tracking ID & date of submission	(B4J-G5U-WGGV, 2025-01-30)
	Detail of Fee Submitted	37000.0, 2024-11-11,
	The proposed proprietary name / brand name	Valid 40mg Tablet
	Label Claim	Each film coated tablet contains: Valsartan USP.....40mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14's-As per SRO,28's-As per SRO,75's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 25°C. Excursions permitted between 15°C and 30°C.
	For generic drugs (me-too Status)	Sevia 40mg Tablet by M/s Sami Pharmaceuticals Pvt.ltd
	Pharmacotherapeutic Group of (API)	Anti-hypertensive
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhejiang Huahai Pharmaceutical Co., Ltd.,
	Detail of stability batches of drug product	Batches: 006B24, 007B24, 008B24 (Batch size: 10,000 tablets) 06 months real time and 09 months accelerated stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 10-10-2023 for 800kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. Valtec 40mg tablet by M/s Tabros Pharma pvt ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	48 months real time and 06 months accelerated stability data is submitted for 03 batches according to the conditions of zone IV-B.
	The status in reference regulatory authorities	VALSARTAN 40MG TABLETS by M/S Ohm Labs Inc, USFDA
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 22-02-2023
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	

application is priority under exports facilitation as per letter No.F.1-6/2019-PR-I (EFD) dated 12.08.2025.

Decision

Approved

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Case Category	Export Facilitation (Farooq Aslam)
Name, address of Applicant.	Surge Laboratories (Pvt.) Ltd. 10th KM, Faisalabad Road, Bikhi District, Sheikhpura. (000484)
Application Form Dy. No / Tracking ID & date of submission	(SYD-PSP-P1SZ, 2024-10-09)
Detail of Fee Submitted	37000.0, 2024-09-25,
The proposed proprietary name / brand name	SALPRO
Label Claim	Each respule of 2.5mL contains: Ipratropium bromide 0.5mg Salbutamol sulfate eq to Salbutamol.....2.5mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	1's, 5's, 10's-As per SRO
Shelf Life (Unit)	2 Year(s)Store below 30 degree
For generic drugs (me-too Status)	Combihale Nebuliser solution 0.5mg/2.5mg by Hudson pharma
Pharmacotherapeutic Group of (API)	Drugs for obstructive airway diseases
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Aarti Industries Limited,Orex Pharma (Pvt.) Ltd.
Detail of stability batches of drug product	Batches: , ISN-2.5-011, ISN-2.5-010, ISN-2.5-011 (Batch size: 1000 respules) 06 months real time and 06 months accelerated stability data is submitted.
Documents for the procurement of API with approval from DRAP (in case of Import)	Ipratropium Bromide: DRAP attested invoice Dy.No. 2488/2020-DRAP dated 17-2-2020 for 0.25kg of material is submitted. Salbutamol Sulfate: DRAP attested invoice vide Dy.No. 12683/2021-DRAP dated 24-08-2021 is submitted for 1kg of material.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the reference product i.e. Combivent Nebuliser Solution by M/s Boehringer Ingelheim Limited, UK.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Ipratropium Bromide: 06 months accelerated and 12 months real time stability studies according to the conditions of zone IV-A of 03 batches is submitted. Salbutamol Sulfate: 06 months accelerated and 09-month real time stability studies according to the conditions of zone IV-B of 03 batches is submitted.
The status in reference regulatory authorities	MHRA Approved Combivent Nebuliser Solution (0.5mg+2.5mg)/2.5ml Boehringer Ingelheim Limited
GMP status of the firm	Last inspection report dated 27-09-2024 is submitted (Satisfactory level o GMP compliance)
Evidence of approval of manufacturing facility	Liquid injectable (including Blow Fill Seal area)

Evaluation Remarks

application is priority under exports facilitation as per letter No.F.1-6/2019-PR-I (EFD) dated 12.08.2025.

Decision

Approved

207

Case Category	Routine (Farooq Aslam)

Name, address of Applicant.	HIGHNOON LABORATORIES LIMITED 17.5 KM, MULTAN ROAD, LAHORE (05-352-0066)
Application Form Dy. No / Tracking ID & date of submission	(T87-RQW-N93D, 2024-04-30)
Detail of Fee Submitted	300000.0, 2024-04-18,
The proposed proprietary name / brand name	SYMBION 12/400 MAXHALER MULTIDOSE DRY POWDER INHALER
Label Claim	Each metered dose contains: Formoterol Fumarate dihydrate....12mcg Budesonide..... 400mcg Each delivered dose contains: Formoterol Fumarate dihydrate.... 9mcg Budesonide..... 320mcg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1 x 1's (60 doses)-As per SRO
Shelf Life (Unit)	2 Year(s)Do not store above 30°C
For generic drugs (me-too Status)	Combivair Forte 400/12mcg Rotacaps (107193)
Pharmacotherapeutic Group of (API)	Long acting beta agonist / Corticosteroid
Name, address of Manufacturing site:	Beximco Pharmaceuticals Ltd.-126 Kathaldia, Auchpara, Tongi, Gazipur, Bangladesh.-Bangladesh
Name & address of API manufacturer	FARMABIOS S.p.A.
Detail of stability batches of drug product	06 months accelerated and 24 months real time stability data according to zone IV-B for 03 batches is submitted.
Documents for the procurement of API with approval from DRAP (in case of Import)	CoPP: Copy of legalized CoPP No. DA/6-3/96/575 dated 14-01-2024 is submitted, The applied product is available in free sale in exporting country and the facilities and operations conform to WHO-GMP as per submitted CoPP. DSL: DSL valid till 12-09-2027 is submitted, LOA: Copy of legalized LOA is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the reference product i.e Symbicort 12/400 mcg by Astrazeneca, switzerland.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Formoterol: 06 months accelerated and 60 months Long term stability at 25°C (□ 2°C) and Relative Humidity of 60% (□ 5%) - for 03 batches. Budesonide: 06 months accelerated and 36 months real time stability data according to the conditions of zone IV-B for 03 batches is submitted.
The status in reference regulatory authorities	MHRA (Symbicort® Turbohaler® 400 micrograms/12 micrograms/inhalation, inhalation powder)
GMP status of the firm	GMP compliant as per submitted CoPP. GMP certificate dated 19-12-2023 is submitted.
Evidence of approval of manufacturing facility	N.A
Evaluation Remarks	
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Decision	
Approved	
as per policy for inspection of manufacturer abroad.	
208 Case Category	Routine (Farooq Aslam)
Name, address of Applicant.	SNB Pharma (Pvt) Ltd Plot # 142, Industrial Estate Hayatabad, Peshawar, KP, (000759)

Application Form Dy. No / Tracking ID & date of submission	(T2J-X1X-V8TR, 2024-03-06)
Detail of Fee Submitted	30000.0, 2023-12-15,
The proposed proprietary name / brand name	SN Dol Infant Drops
Label Claim	Each 0.8ml Contains: Paracetamol..... 80mg
Reference to Finished product specifications	Any Other
Proposed Pack Size	20ml, 30ml-As per SRO
Shelf Life (Unit)	2 Year(s)Room Temperature
For generic drugs (me-too Status)	Panadol Infants Drop Manufactured by GSK Phrama
Pharmacotherapeutic Group of (API)	Analgesic and antipyretic
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Citi Pharma Ltd
Detail of stability batches of drug product	Batches: 001, 002, 003 (Batch Size: 500 bottles:30mL) 06 months real time and 06 month accelerated stability data is submitted.
Documents for the procurement of API with approval from DRAP (in case of Import)	Invoice No. CP22-10410 dated 18-08-2022 from M/s Citi Pharma Limited for 200kg.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against Panadol Infants drops by M/s GSK Consumer Healthcare.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06months accelerated and 60 months real time stability data of 03 batches according tot he conditions fo zone IV-A is submitted.
The status in reference regulatory authorities	Panadol Infants Drop Approved by MHRA
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on03-07-2025.
Evidence of approval of manufacturing facility	Liquid syrup general section is approved

Evaluation Remarks

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Decision

Approved

209	Case Category	Export Facilitation (Farooq Aslam)
	Name, address of Applicant.	Scilife Pharma Private Limited FD-57/58-A2, Korangi Creek Industrial Park (KCIP) (000837)
	Application Form Dy. No / Tracking ID & date of submission	(BY7-5TW-229H, 2025-02-07)
	Detail of Fee Submitted	37000.0, 2024-12-10,
	The proposed proprietary name / brand name	Toprol XR 25mg Tablet
	Label Claim	Each film-coated tablet contains: 23.75 metoprolol succinate equivalent to 25mg metoprolol tartrate.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO,15's-As per SRO,30's-As per SRO,50's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 25°C. Excursions permitted between 15°C and 30°C.
	For generic drugs (me-too Status)	Merol XL 25mg Tablet by M/s ATCO LABORATORIES LIMITED
	Pharmacotherapeutic Group of (API)	Beta adrenergic receptor antagonist

	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Pellets Pharma Limited
	Detail of stability batches of drug product	Batches: 046B24, 056B24, 057B24 (Batch size: 2000 tablets) 06 months real time and 06 months accelerated stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 08-11-2023 is submitted for 2kg material and copy of GD (KPAF-11839-18122023) are submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Betaloc Zok25mg tablet by M/s Astrazeneca AB, Sweden.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 24 months real time stability data according to the conditions of zone IV-B of 03 batches.
	The status in reference regulatory authorities	TOPROL XL 25MG TABLETS by M/S ASTRAZENECA GROUP OF COMPANIES, USFDA Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 22-02-2023
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The instant application is priority under export facilitation as per letter dated 12.08.2025.	
	Decision	
	Approved	
210	Case Category	Export Facilitation (Farooq Aslam)
	Name, address of Applicant.	Scilife Pharma Private Limited FD-57/58-A2, Korangi Creek Industrial Park (KCIP) (000837)
	Application Form Dy. No / Tracking ID & date of submission	(N3R-Y2P-R8NE, 2024-10-09)
	Detail of Fee Submitted	75000.0, 2024-08-07,
	The proposed proprietary name / brand name	Sotag 400mg Tablet
	Label Claim	Each film-coated tablet contains: Sotagliflozin.....400mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x15s (15s)-As per SRO,2x15s (30s)-As per SRO,4x14s (56s)-As per SRO,5x10s (50s)-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 25°C. (Excursions permitted between 15°C to 30°C). Protect from Sunlight and moisture.
	For generic drugs (me-too Status)	could not be confirmed
	Pharmacotherapeutic Group of (API)	Sodium-Glucose co-transport inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Huanan Sunlong Pharmaceutical Co., Ltd.,
	Detail of stability batches of drug product	Batches: 129B24, 130B24, 131B24 (Batch size: 1000 tablets) 06 month accelerated and 06 months real time stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 29-03-2024 is submitted. Clearance certificate dated 50-04-2024 for 2kg material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Inpefa tablet 200mg by M/s

	Lexcom Pharmaceuticals INC, USA.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 36 months real time stability data according to the conditions of zone IV-A.
The status in reference regulatory authorities	INPEFA 400MG TABLET by Ms. Lexicon Pharmaceuticals, Inc, USA, USFDA Approved.
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 22-02-2023.
Evidence of approval of manufacturing facility	Tablet General Section is approved
Evaluation Remarks	
The instant application is priority under exports facilitation as per letter dated 12.08.2025.	
Decision	
Approved	
211	Case Category
	Export Facilitation (Farooq Aslam)
	Name, address of Applicant.
	Scilife Pharma Private Limited FD-57/58-A2, Korangi Creek Industrial Park (KCIP) (000837)
	Application Form Dy. No / Tracking ID & date of submission
	(2Y5-8TU-D7ZP, 2024-10-09)
	Detail of Fee Submitted
	75000.0, 2024-08-07,
	The proposed proprietary name / brand name
	SOTAG 200MG
	Label Claim
	Ech film-coated tablet contains: sotagliflozin.....200mg
	Reference to Finished product specifications
	As per Innovators Specification
	Proposed Pack Size
	1x15s (15s)-As per SRO,3x10s (30s)-As per SRO,4x14s (56s)-As per SRO,5x10s (50s)-As per SRO
	Shelf Life (Unit)
	2 Year(s)Store at 25°C. Excursions permitted between 15°C to 30°C
	For generic drugs (me-too Status)
	could not be confirmed
	Pharmacotherapeutic Group of (API)
	Sodium-Glucose co-transport inhibitor
	Name, address of Manufacturing site:
	Self Manufacturing
	Name & address of API manufacturer
	Huanan Sunlong Pharmaceutical Co., Ltd.,
	Detail of stability batches of drug product
	Batches: 132B24, 133B24, 134B24 (Batch size: 1500 tablets) 06 month accelerated and 06 months real time stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)
	Form 6 dated 29-03-2024 is submitted. Clearance certificate dated 05-04-2024 is submitted for 2kg material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile
	PE and CDP studies have been performed against the reference product i.e. Inpefa tablet 200mg by M/s Lexcom Pharmaceuticals INC, USA.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)
	06 months accelerated and 36 months real time stability data according to the conditions of zone IV-A.
	The status in reference regulatory authorities
	INPEFA TABLET 200MG BY M/S LEXICOM PHARMACEUTICALS INCS, USA (USFDA APPROVED)
	GMP status of the firm
	GMP certificate issued on the basis of inspection conducted on 22-02-2023.
	Evidence of approval of manufacturing facility
	Tablet General Section is approved
Evaluation Remarks	
The instant application is priority under exports facilitation as per letter dated 12.08.2025.	
Decision	

	Approved	
212	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan (01-374-0006)
	Application Form Dy. No / Tracking ID & date of submission	(ZHD-J85-E3UZ, 2024-04-23)
	Detail of Fee Submitted	300000.0, 2024-02-02,
	The proposed proprietary name / brand name	Ganaval® Tablet 450mg
	Label Claim	Each Film Coated Tablet contains: Valganciclovir as HCl.....450mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	One plastic Bottle (-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect from light and moisture.
	For generic drugs (me-too Status)	MAH: Roche (Pakistan) Brand Name: VALCYTE (Valganciclovir 450mg F.C Tablet)
	Pharmacotherapeutic Group of (API)	Antik-viral
	Name, address of Manufacturing site:	ALborz Zagros Pharmaceutical Company-No. 79, 4th Golestan Blv., Baharestan Industrial Zone, Karaj-Iran
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Valcyte tablet 450mg by Roche.
	Name, address of Marketing Authorization Holder:	Actoverco Pharmaceutical Company, 79, 4th Golestan Blv., Baharestan Industrial Zone. Karaj, Iran, Iran
	Details of Certificates (CoPP/FSC/cGMP):	GMP certificate 07-09-2021 is submitted. GMP compliant as per submitted CoPP.
	Details of Authorization Letter :	CoPP: Legalized copy of CoPP (No. 665/18884 dated 27-05-2023) is submitted. The applied product is available for free sale in the market of exporting country and the facilities & operations conform to WHO-GMP as per submitted CoPP. DSL: DSL valid till 15-08-2029 is submitted. LOA: Distribution certificate dated 09-01-2024 is submitted for the applied product issued in favor of the applicant,
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 60 months real time stability (at 25oC & 60%RH) for 03 batches is submitted.
	The status in reference regulatory authorities	VALCYTE (Valganciclovir 450mg) Manufactured By Roche , USFDA Approved
Evaluation Remarks		
Decision		
Approved		
as per the import policy for inspection of manufacturer abroad.		
213	Case Category	Export Facilitation (Farooq Aslam)
	Name, address of Applicant.	SAMI Pharmaceuticals Pvt. Ltd. F-95 Hub River Road S.I.T.E Karachi (000072)
	Application Form Dy. No / Tracking ID & date of submission	(365-BQ1-1TWS, 2024-11-05)
	Detail of Fee Submitted	75000.0, 2024-08-16,

The proposed proprietary name / brand name		MIROLIN 10mg Tablet
Label Claim		Each film coated tablet contains: Mirogabalin besylate equivalent to Mirogabalin.....10mg
Reference to Finished product specifications		As per Innovators Specification
Proposed Pack Size		De regulated-De-Controlled
Shelf Life (Unit)		2 Year(s)Do not store over 30°C
For generic drugs (me-too Status)		could not be confirmed
Pharmacotherapeutic Group of (API)		Gamma amino acids and derivatives / Gabapentinoid
Name, address of Manufacturing site:		Self Manufacturing
Name & address of API manufacturer		Shandong Kehui Pharamaceuticals Co., Ltd.
Detail of stability batches of drug product		Batches: Lab-1, Lab-2, Lab-3 (Batch size: 2000 tablets) 06 months real time and 06 month accelerated stability data is submitted.
Documents for the procurement of API with approval from DRAP (in case of Import)		Copy of form 6 dated 06-06-2023 for 0.6kg of material is submitted. copy of GD No. KPAF-4627-30052023 Date: 30-05-2023 is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile		PE and CDP studies have been performed against the reference product i.e. Tarlige tablet 10mg by M/s Daichi Sankyo, Japan.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		06 months accelerated and 18 months real time stability studies according to the conditions of zone Iv-A for 03 batches.
The status in reference regulatory authorities		Tarlige 10mg Tablet (PMDA approved)
GMP status of the firm		GMP certificate issued on the basis of inspection conducted on 01-07-2024.
Evidence of approval of manufacturing facility		Tablet General Section is approved.
Evaluation Remarks		
The instant application is priority under exports facilitation as per letter No.F.1-6/2019-PR-I (EFD) dated 12.08.2025.		
Decision		
Approved		
214	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Cell Health Sciences , Plot No 217, Industrial Triangle, Kahuta Road, Islamabad (000711)
	Application Form Dy. No / Tracking ID & date of submission	(WJU-9LL-A9D9, 2024-03-12)
	Detail of Fee Submitted	30000.0, 2023-12-29,
	The proposed proprietary name / brand name	CellCar 400mg tablets
	Label Claim	Each Film coated Tablets contains: Carbamazepine 400mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	5x10's-As per SRO
	Shelf Life (Unit)	2 Year(s)25
	For generic drugs (me-too Status)	Tegretol 400mg tablet(Novartis Pharma (Pakistan) Ltd.)021529
	Pharmacotherapeutic Group of (API)	Anticonvulsant
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CTX LifeScience Pvt. Ltd

	Detail of stability batches of drug product	Batches: T1CJ23, T2CJ23, T3CJ23 (Batch Size: 1500 tablets) 06 months real time and 06 months accelerated stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 16-12-2022 issued to M/s Wimits Pharmaceuticals for 25kg material is submitted. Loan letter dated 19-09-2023 for 5kg material from M/s Wimits Pharmaceuticals is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Tegretol 400mg by Novartis Pharma.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	72 months real time and 06 month accelerated stability data is submitted according to the conditions of zone IV-A for 03 batches.
	The status in reference regulatory authorities	MHRA Approved.
	GMP status of the firm	Inspection report dated 06-12-2021 & 26-01-2022 is submitted.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	.
	Decision	
	Approved	
	subject to verification of loan letter.	
215	Case Category	New Section (Farooq Aslam)
	Name, address of Applicant.	Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi (000333)
	Application Form Dy. No / Tracking ID & date of submission	(T1Q-5JU-69Q5, 2025-08-19)
	Detail of Fee Submitted	37000.0, 2025-06-27,
	The proposed proprietary name / brand name	NISALE 0.9% 10ml Injection
	Label Claim	Each 10ml ampoule contains: sodium chloride..... 0.9% w/v
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1x100's-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30
	For generic drugs (me-too Status)	Celine 0.9% injection 10mL ampoule by M/s Surge Laboraotries
	Pharmacotherapeutic Group of (API)	normal saline
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Resino Herbs Pvt Ltd
	Detail of stability batches of drug product	Batches: 189NS02-189NS03-189NS04 (Batch Size: 1000 ampoules) 06 months real time and 06 months accelerated data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan letter form M/s Evolution Pharmaceuticals pvt. ltd., Islamabad for 2kg of Sodium Chloride is submitted. Clearance certificate dated 02-08-2024 issued to M/s Evolution Pharmaceuticals is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the comparator's product i.e. Celine 0.9% 10mL ampoule by M/s Surge Laboratories.

Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 60 months real time stability study data according to the conditions of zone IV-A for 03 batches is submitted.
The status in reference regulatory authorities	sodium chloride 0.95 10ml Ampoule injection Hikma Pharma USFDA Approved
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 16-02-2024.
Evidence of approval of manufacturing facility	Liquid Injectable Ampoule-II (General) section is approved (New Section)

Evaluation Remarks

New Section.

Decision

Approved

subject to verification of loan letter.

216	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Bristol Mayer Biotech Pakistan 73 B Guldasht Town Zarrar Shaheed Lahore (05-352-0068)
	Application Form Dy. No / Tracking ID & date of submission	(6PU-246-79Q2, 2024-03-08)
	Detail of Fee Submitted	150000.0, 150000.0 2023-12-04, 2024-02-15
	The proposed proprietary name / brand name	Testoki 1000mg/4ml
	Label Claim	Each vial (4ml) contains: Testosterone Undecanoate.....1000 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Pack size 1 x 4 ml s-As per SRO
	Shelf Life (Unit)	24 Month(s)Store at a temperature not exceeding 25 °C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Nebido 1000 mg/4 ml, solution for injection
	Name, address of Manufacturing site:	Sanzyme Pvt Ltd-Unit-II, Survey No:35 Dhandha, Idar road, Himatnagar-383 001 Gujarat, India-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been submitted against the reference product i.e Nibido 1000mg/4ml inj (HPRA Approved).
	Name, address of Marketing Authorization Holder:	Sanzyme Pvt Ltd, Unit-II, Survey No:35 Dhandha, Idar road, Himatnagar-383 001 Gujarat, India, India
	Details of Certificates (CoPP/FSC/cGMP):	The facilities and operations conform to WHO-GMP as per submitted CoPP.
	Details of Authorization Letter :	CoPP: Copy of legalized CoPP MFG/WHO GMP/COPP/2024/0156247406 valid till 16-10-2025 is submitted. The applied product is available in free sale in exporting country and the facilities & operations conform to WHO-GMP. DSL: DSL is valid till 18-10-2028 LOA: Product specific letter of authorization is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	48 months real time (2 to 8oC) and accelerated stability at 25oC & 60%RH for 03 batches is submitted.
	The status in reference regulatory authorities	Nebido 1000 mg/4 ml, solution for injection (vial and Ampoule), HPRA Ireland Approved
	Evaluation Remarks	
	Decision	
	Approved	

as per import policy for inspection of manufacturer abroad.

217	Case Category	Export Facilitation (Farooq Aslam)
	Name, address of Applicant.	Getz Pharma (Pvt) Limited 29-30/27,Korangi Industrial Area karachi (000284)
	Application Form Dy. No / Tracking ID & date of submission	(YYY-WXV-A1E2, 2024-11-20)
	Detail of Fee Submitted	75000.0, 2024-09-05,
	The proposed proprietary name / brand name	Elaget Tablets 150mg
	Label Claim	Each film-coated tablet contains: Elagolix Sodium equivalent to Elagolix.....150mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	10's, 20's, 14's, 28-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store above 30°C. Protect from sunlight and moisture..
	For generic drugs (me-too Status)	Not Applicable
	Pharmaceutical Group of (API)	Gonadotropin releasing hormone receptor antagonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Halolife (Xiamen) Technology Co., Ltd.,
	Detail of stability batches of drug product	Batches: 694DS01, 694DS02, 694DS03 (Batch size: 1250 tablets) 06 months real time and 06 months accelerated stability data is submitted according to zone IV-B.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 (for 5kg material) and unattested invoice are submitted. Copy of GD No. KPAF-9962-29102023 Date: 29-10-2023 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been submitted against the reference product i.e. Orilissa tablet 150mg by M/s Abbvie corporation, Canada.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	GMP certificate issued on the basis of inspection conducted on 10-11-2023 is submitted.
	The status in reference regulatory authorities	ORILISSA Tablets 150mg manufactured by M/s AbbVie Inc., USA.
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 10-11-2023 is submitted.
	Evidence of approval of manufacturing facility	Tablet General Section is approved
	Evaluation Remarks	
	The instant application is priority under export facilitation as per letter No. No.F.1-6/2019-PR-II (EFD)/Pt dated 03.03.2025.	
	Decision	
	Approved	
218	Case Category	Export Facilitation (Farooq Aslam)
	Name, address of Applicant.	Getz Pharma (Pvt) Limited 29-30/27,Korangi Industrial Area karachi (000284)
	Application Form Dy. No / Tracking ID & date of submission	(NDE-GH3-3915, 2024-11-21)
	Detail of Fee Submitted	75000.0, 2024-09-05,
	The proposed proprietary name / brand name	Elaget Tablets 200mg

Label Claim	Each film-coated tablet contains: Elagolix Sodium equivalent to Elagolix.....200mg
Reference to Finished product specifications	Manufacturer Specification
Proposed Pack Size	10's, 20's, 14's, 28-As per SRO
Shelf Life (Unit)	2 Year(s)Do not store above 30°C. Protect from sunlight and moisture.
For generic drugs (me-too Status)	Not applicable
Pharmacotherapeutic Group of (API)	Gonadotropin releasing hormone receptor antagonist
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Halolife (Xiamen) Technology Co., Ltd.,
Detail of stability batches of drug product	Batches: 698DS01, 698DS02, 698DS03 (Batch size: 1250 tablets) 06 months real time and 06 months accelerated stability data is submitted according to zone IV-B.
Documents for the procurement of API with approval from DRAP (in case of Import)	.Form 6 (for 5kg material) and unattested invoice are submitted. Copy of GD No. KPAF-9962-29102023 Date: 29-10-2023 is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been submitted against the reference product i.e. Orilissa tablet 200mg by M/s Abbvie corporation, Canada.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated (at 25°C±2°C with relative humidity 60%±5%) and 24 months real time stability data (5°C±3°C) of 03 batches is submitted.
The status in reference regulatory authorities	ORILISSA Tablets 200mg by M/s AbbVie Inc., USFDA Approved
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 10-11-2023 is submitted.
Evidence of approval of manufacturing facility	Tablet General Section is approved.
Evaluation Remarks	
The instant application is priority under export facilitation as per letter No. No.F.1-6/2019-PR-II (EFD)/Pt dated 03.03.2025.	
Decision	
Approved	
219	
Case Category	Any Other (Farooq Aslam)
Name, address of Applicant.	Hilton Pharma (Pvt) Limited. Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area (000136)
Application Form Dy. No / Tracking ID & date of submission	(SWM-9SA-YPM5, 2025-09-11)
Detail of Fee Submitted	75000.0, 2024-12-16,
The proposed proprietary name / brand name	Tadalafil tablets 5mg
Label Claim	Each film-coated tablet contains: Tadalafil, USP..... 5mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	10's-De-Controlled,12's-De-Controlled,15's-De-Controlled,16's-De-Controlled,2's-De-Controlled,20's-De-Controlled,30's-De-Controlled,4's-De-Controlled,5's-De-Controlled,6's-De-Controlled,8's-De-Controlled
Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect from sunlight . keep out of the reach of Children .

	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Phosphodiesterase (PDE) Inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	century Pharmaceuticals ltd.
	Detail of stability batches of drug product	Batches: TAD-1536-01/25, TAD-1541-01/25, TAD-1542-01/25 (Batch Size: 14,285 tablets) Accelerated & Long term Stability data of 06 months is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	1. Form 6 dated 11-11-2024 for 1.24 Kg material is submitted. 2. Copy of invoice dated 18-01-2024 3. Copy of Airway bill
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence report & CDP studies have been performed against reference product Cialis Tablets 5mgby Eli Lilly and Company, Canada is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated (6 months) & Long term (60 months) Stability data according to zone IV-A for 03 batches is submitted.
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	GMP Certificate no. 13/2025-DRAP(K) dated 20th January 2025 issued on the basis of inspection conducted on 9-10th Dec, 2024.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	Out of queue consideration as per the decision of DRAP Authority.	
	Decision	
	Approved	
220	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	Hilton Pharma (Pvt) Limited. Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area (000136)
	Application Form Dy. No / Tracking ID & date of submission	(639-U1G-V7SP, 2025-09-11)
	Detail of Fee Submitted	75000.0, 2024-12-16,
	The proposed proprietary name / brand name	Tadalafil Tablets 2.5mg
	Label Claim	Each film-coated tablet contains: Tadalafil, USP..... 2.5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-De-Controlled,12's-De-Controlled,15's-De-Controlled,16's-De-Controlled,2's-De-Controlled,20's-De-Controlled,30's-De-Controlled,4's-De-Controlled,5's-De-Controlled,6's-De-Controlled,8's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect from sunlight . keep out of the reach of Children .
	For generic drugs (me-too Status)	could not be confirmed
	Pharmacotherapeutic Group of (API)	Phosphodiesterase (PDE) Inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	century Pharmaceuticals ltd.
	Detail of stability batches of drug product	Batches: TAD-1539-01/25, TAD-1543-01/25, TAD-1544-01/25 (Batch Size: 14,285 tablets) Accelerated & Long term Stability data of 06 months is submitted.

Documents for the procurement of API with approval from DRAP (in case of Import)	1. Form 6 dated 11-11-2024 for 1.24 Kg material is submitted. 2. Copy of invoice dated 18-01-2024 3. Copy of Airway bill
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence report & CDP studies have been performed against reference product Cialis Tablets 2.5mgby Eli Lilly and Company, Canada is submitted.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated (6 months) & Long term (60 months) Stability data according to zone IV-A for 03 batches is submitted.
The status in reference regulatory authorities	USFDA Approved
GMP status of the firm	GMP Certificate no. 13/2025-DRAP(K) dated 20th January 2025 issued on the basis of inspection conducted on 9-10th Dec, 2024.
Evidence of approval of manufacturing facility	Tablet General Section is approved.
Evaluation Remarks	
Out of queue consideration as per the decision of DRAP Authority.	
Decision	
Approved	
Case Category	Export Facilitation (Farooq Aslam)
Name, address of Applicant.	SAMI Pharmaceuticals Pvt. Ltd. F-95 Hub River Road S.I.T.E Karachi (000072)
Application Form Dy. No / Tracking ID & date of submission	(88M-1YU-Q5T7, 2024-09-09)
Detail of Fee Submitted	75000.0, 2024-08-16,
The proposed proprietary name / brand name	MIROLIN 5mg Tablet
Label Claim	Each film coated tablet contains: Mirogabalin besylate equivalent to Mirogabalin.....5mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	De regulated-De-Controlled
Shelf Life (Unit)	2 Year(s)Do not store over 30°C
For generic drugs (me-too Status)	could not be confirmed
Pharmacotherapeutic Group of (API)	Gamma amino acids and derivatives / Gabapentinoid
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Shandong Kehui Pharamaceuticals Co., Ltd.
Detail of stability batches of drug product	Batches: Lab-1, Lab-2, Lab-3 (Batch size: 2000 tablets) 06 months real time and 06 month accelerated stability data is submitted.
Documents for the procurement of API with approval from DRAP (in case of Import)	Copy of form 6 dated 06-06-2023 for 0.6kg of material is submitted. copy of GD No. KPAF-4627-30052023 Date: 30-05-2023 is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Tarlige tablet 5mg by M/s Daichi Sankyo, Japan.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 18 months real time stability studies according to the conditions of zone Iv-A for 03 batches.
The status in reference regulatory authorities	Tarlige 5mg Tablet (PMDA approved)
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 01-07-2024.

	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The instant application is priority under exports facilitation as per letter No.F.1-6/2019-PR-I (EFD) dated 12.08.2025.	
	Decision	
	Approved	
222	Case Category	Export Facilitation (Farooq Aslam)
	Name, address of Applicant.	SAMI Pharmaceuticals Pvt. Ltd. F-95 Hub River Road S.I.T.E Karachi (000072)
	Application Form Dy. No / Tracking ID & date of submission	(ARR-E84-Q8BL, 2024-06-14)
	Detail of Fee Submitted	75000.0, 2024-06-03,
	The proposed proprietary name / brand name	MIROLIN
	Label Claim	Each film coated tablet contains : Mirogabalin besylate equivalent to Mirogabalin.....2.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store over 30°C
	For generic drugs (me-too Status)	could not be confirmed
	Pharmacotherapeutic Group of (API)	Gamma amino acids and derivatives / Gabapentinoid
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Kehui Pharamaceuticals Co., Ltd.
	Detail of stability batches of drug product	Batches: Lab-1, Lab-2, Lab-3 (Batch size: 2000 tablets) 06 months real time and 06 month accelerated stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Copy of form 6 dated 06-06-2023 for 0.6kg of material is submitted. copy of GD No. KPAF-4627-30052023 Date: 30-05-2023 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Tarlige tablet 2.5mg by M/s Daichi Sankyo, Japan.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 18 months real time stability studies according to the conditions of zone Iv-A for 03 batches.
	The status in reference regulatory authorities	Tarlige
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 01-07-2024.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The instant application is priority under exports facilitation as per letter No.F.1-6/2019-PR-I (EFD) dated 12.08.2025.	
	Decision	
	Approved	
223	Case Category	Export Facilitation (Farooq Aslam)
	Name, address of Applicant.	SAMI Pharmaceuticals Pvt. Ltd. F-95 Hub River Road S.I.T.E Karachi (000072)
	Application Form Dy. No / Tracking ID & date of submission	(S46-RL9-MM2L, 2024-09-18)

	Detail of Fee Submitted	75000.0, 2024-08-16,
	The proposed proprietary name / brand name	MIROLIN 15mg Tablet
	Label Claim	Each film coated tablet contains Mirogabalin Besylate equivalent to Mirogabalin 15mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	De regulated-De-Controlled
	Shelf Life (Unit)	2 Year(s)Do not store over 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Gamma amino acids and derivatives / Gabapentinoid
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Kehui Pharamaceuticals Co., Ltd.
	Detail of stability batches of drug product	Batches: Lab-1, Lab-2, Lab-3 (Batch size: 2000 tablets) 06 months real time and 06 month accelerated stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Copy of form 6 dated 06-06-2023 for 0.6kg of material is submitted. copy of GD No. KPAF-4627-30052023 Date: 30-05-2023 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Tarlige tablet 15mg by M/s Daichi Sankyo, Japan.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 18 months real time stability studies according to the conditions of zone Iv-A for 03 batches.
	The status in reference regulatory authorities	Tarlige 15mg Tablet (PMDA approved)
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 01-07-2024.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The instant application is priority under exports facilitation as per letter No.F.1-6/2019-PR-I (EFD) dated 12.08.2025.	
	Decision	
	Approved	
224	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	HIGHNOON LABORATORIES LIMITED 17.5 KM, MULTAN ROAD, LAHORE (05-352-0066)
	Application Form Dy. No / Tracking ID & date of submission	(8RE-4LA-XHT4, 2024-05-16)
	Detail of Fee Submitted	300000.0, 2024-03-20,
	The proposed proprietary name / brand name	SYMBION 6/200 MAXHALER MULTIDOSE DRY POWDER INHALER
	Label Claim	Each metered dose contains: Formoterol Fumarate dihydrate.... 6mcg Budesonide..... 200mcg Each delivered dose contains: Formoterol Fumarate dihydrate. 4.5mcg Budesonide..... 160mcg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 x 1's (60 doses)-As per SRO
	Shelf Life (Unit)	2 Year(s)Do Not Store Above 30°C.
	For generic drugs (me-too Status)	Combivair 200 Rotacaps. (054316)

Pharmacotherapeutic Group of (API)	Long acting beta agonist / Corticosteroid
Name, address of Manufacturing site:	Beximco Pharmaceuticals Ltd.-126 Kathaldia, Auchpara, Tongi, Gazipur, Bangladesh.-Bangladesh
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the reference product i.e Symbicort 6/200 mcg by Astrazeneca, switzerland.
Name, address of Marketing Authorization Holder:	Beximco Pharmaceuticals Ltd., 19 Dhanmondi R/A, Road No. 7, Dhaka 1205, Bangladesh., Bangladesh
Details of Certificates (CoPP/FSC/cGMP):	GMP compliant as per submitted CoPP. GMP certificate dated 19-12-2023 is submitted. CoPP: Copy of legalized CoPP No. DA/6-3/96/574 dated 14-01-2024 is submitted, The applied product is available in free sale in exporting country, and the facilities an
Details of Authorization Letter :	DSL: DSL valid till 12-09-2027 is submitted, LOA: Copy of legalized LOA is submitted.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	25°C (□ 2°C) and Relative Humidity of 60% (□ 5%) - for 03 batches. Budesonide: 06 months accelerated and 36 months real time stability data according to the conditions of zone IV-B for 03 batches is submitted.
The status in reference regulatory authorities	MHRA Approved (Symbicort Turbohaler)
Evaluation Remarks	
Import	
Decision	
Approved	
as per import policy for inspection of manufacturer abroad.	
225	Case Category
	Routine (Farooq Aslam)
	Name, address of Applicant.
	HIGHNOON LABORATORIES LIMITED 17.5 KM, MULTAN ROAD, LAHORE (05-352-0066)
	Application Form Dy. No / Tracking ID & date of submission
	(VN8-SRY-Y4HR, 2024-05-10)
	Detail of Fee Submitted
	300000.0, 2024-03-20,
	The proposed proprietary name / brand name
	SYMBION 6/100 MAXHALER MULTIDOSE DRY POWDER INHALER
	Label Claim
	Each metered dose contains: Formoterol Fumarate dihydrate.... 6mcg Budesonide..... 100mcg Each delivered dose contains: Formoterol Fumarate dihydrate. 4.5mcg Budesonide..... 80mcg
	Reference to Finished product specifications
	As per Innovators Specification
	Proposed Pack Size
	1 x 1's (60 doses)-As per SRO
	Shelf Life (Unit)
	2 Year(s)Do Not Store Above 30°C.
	For generic drugs (me-too Status)
	Combivair 100 Rotacaps (054311)
	Pharmacotherapeutic Group of (API)
	Long acting beta agonist / Corticosteroid
	Name, address of Manufacturing site:
	Beximco Pharmaceuticals Ltd.-126 Kathaldia, Auchpara, Tongi, Gazipur, Bangladesh.-Bangladesh
	Pharmaceutical Equivalence and Comparative Dissolution Profile
	PE studies have been performed against the reference product i.e Symbicort 12/400 mcg by Astrazeneca, switzerland.
	Name, address of Marketing Authorization Holder:
	Beximco Pharmaceuticals Ltd., 19 Dhanmondi R/A, Road No. 7, Dhaka 1205, Bangladesh., Bangladesh

Details of Certificates (CoPP/FSC/cGMP):	GMP compliant as per submitted CoPP. GMP certificate dated 19-12-2023 is submitted. CoPP: Copy of legalized CoPP No. DA/6-3/96/573 dated 14-01-2024 is submitted, The applied product is available in free sale in exporting country and the facilities and
Details of Authorization Letter :	DSL: DSL valid till 12-09-2027 is submitted, LOA: Copy of legalized LOA is submitted.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Formoterol: 06 months accelerated and 60 months Long term stability at 25°C (□ 2°C) and Relative Humidity of 60% (□ 5%) - for 03 batches. Budesonide: 06 months accelerated and 36 months real time stability data according to the conditions of zone IV-B for 03 batches is submitted.
The status in reference regulatory authorities	MHRA approved (Symbicort Turbohaler)
Evaluation Remarks	
Import	
Decision	
Approved	
as per import policy for inspection of manufacturer abroad.	
226	Case Category
	Any Other (Farooq Aslam)
	Name, address of Applicant.
	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission
	(1PP-LM1-MN33, 2025-07-28)
	Detail of Fee Submitted
	37000.0, 2025-07-25,
	The proposed proprietary name / brand name
	Procial 2.5mg Tablet
	Label Claim
	Each Film coated Tablet contains: Tadalafil.....2.5mg
	Reference to Finished product specifications
	United States Pharmacopeia
	Proposed Pack Size
	1 x 4's, 1x5's, 1 x 10's, 2 x 10's, 4x7's, 3 x 10'-As per SRO
	Shelf Life (Unit)
	2 Year(s)Store at room temperature below 30
	For generic drugs (me-too Status)
	fildil 2.5mg Tablet Hingnoon Laboratories (Approved in 345th Meeting)
	Pharmacotherapeutic Group of (API)
	phosphodiesterase (PDE) inhibitors.
	Name, address of Manufacturing site:
	Self Manufacturing
	Name & address of API manufacturer
	Ultra Tech India Ltd. Add: Plot Nos. 24, 25 & 26, New Chemical Zone, M.I.D.C. Taloja, Tal. Panvel, Dist. Raigad-410208, Maharashtra, India
	Detail of stability batches of drug product
	Batches: TIW001, TIW002, TIW003 (Batch size: 2000 tablets) 06 months real time and 06 months accelerated stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)
	Loan from M/s AsianContinental Pvt. Ltd. is submitted for 500 grams. Clearance certificate dated 06-06-2024 for 1Kg of Tadalafil issued to M/s Asian Continental.
	Pharmaceutical Equivalence and Comparative Dissolution Profile
	PE and CDP studies have been performed against reference product i.e. Cialis 2.5mg FilmTabletten of M/s Eli Lilly Nederland B.V., Papendorpseweg 83, 3528BJ Utrecht, Niederlande (USFDA Approved)

Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated at Temp:40±2°C, Humidity:75±5% RH & Real Time at Temp:30±2°C, Humidity:65±5% RH (36 months)
The status in reference regulatory authorities	Cialis 2.5mg Tablet of M/s Eli Lilly and Co..(ireland)Ltd. (EMA Approved)
GMP status of the firm	GMP certificate No. 188/2023-DRAP(AD-3489860170 Dated 14-11-2023 is submitted
Evidence of approval of manufacturing facility	Tablet General Section is approved.

Evaluation Remarks

The application has been entertained as per the decision of DRAP Authority.

Decision

Approved

The Board further decided that registration letter will be issued after verification of authenticity of submitted stability data by the panel constituted by the Chairman Registration Board.

227	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(9LG-5U5-JQ74, 2025-07-28)
	Detail of Fee Submitted	37000.0, 2025-07-25,
	The proposed proprietary name / brand name	Procial 5mg Tablet
	Label Claim	Each Film coated Tablet contains: Tadalafil.....5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 x 4's, 1x5's, 1 x 10's, 2 x 10's, 4x7's, 3 x 10'-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature below 30
	For generic drugs (me-too Status)	Fildil 5mg Tablet Hingnoon Laboratories
	Pharmacotherapeutic Group of (API)	phosphodiesterase (PDE) inhibitors.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Ultra Tech India Ltd. Add: Plot Nos. 24, 25 & 26, New Chemical Zone, M.I.D.C. Taloja, Tal. Panvel, Dist. Raigad-410208, Maharashtra, India
	Detail of stability batches of drug product	Batches: TIX001, TIX002, TIX003 (Batch size: 2000 tablets) 06 months real time and 06 months accelerated stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan from M/s AsianContinental Pvt. Ltd. is submitted for 500 grams. Clearance certificate dated 06-06-2024 for 1Kg of Tadalafil issued to M/s Asian Continental.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against reference product i.e. Cialis 5mg FilmTabletten of M/s Eli Lilly Nederland B.V., Papendorpseweg 83, 3528BJ Utrecht, Niederlande (USFDA Approved)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated at Temp:40±2°C, Humidity:75±5% RH & Real Time at Temp:30±2°C, Humidity:65±5% RH (36 months)
	The status in reference regulatory authorities	Cialis 5mg FilmTabletten of M/s Eli Lilly Nederland B.V., Papendorpseweg 83, 3528BJ Utrecht, Niederlande (USFDA Approved)
	GMP status of the firm	GMP certificate No. 188/2023-DRAP(AD-3489860170 Dated 14-11-2023 is submitted

	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been entertained as per the decision of DRAP Authority.	
	Decision	
	Approved	
	The registration letter will be issued after verification of submitted stability data through Product specific Inspection.	
228	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(BZ9-4WS-NGWY, 2025-07-28)
	Detail of Fee Submitted	37000.0, 2025-07-25,
	The proposed proprietary name / brand name	Procial 20mg Tablet
	Label Claim	Each Film coated Tablet contains: Tadalafil.....20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 x 4's, 1x5's, 1 x 10's, 2 x 10's, 4x7's, 3 x 10'-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature below 30
	For generic drugs (me-too Status)	fildil 20mg Tablet Hingnoon Laboratories
	Pharmacotherapeutic Group of (API)	phosphodiesterase (PDE) inhibitors.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Ultra Tech India Ltd. Add: Plot Nos. 24, 25 & 26, New Chemical Zone, M.I.D.C. Taloja, Tal. Panvel, Dist. Raigad-410208, Maharashtra, India
	Detail of stability batches of drug product	Batches: TIZ001, TIZ002, TIZ003 (Batch size: 2000 tablets) 06 months real time and 06 months accelerated stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan from M/s AsianContinental Pvt. Ltd. is submitted for 500 grams. Clearance certificate dated 06-06-2024 for 1Kg of Tadalafil issued to M/s Asian Continental.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	E and CDP studies have been performed against reference product i.e. Cialis 20mg FilmTabletten of M/s Eli Lilly Nederland B.V., Papendorpseweg 83, 3528BJ Utrecht, Niederlande (USFDA Approved)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated at Temp:40±2°C, Humidity:75±5% RH & Real Time at Temp:30±2°C, Humidity:65±5% RH (36 months)
	The status in reference regulatory authorities	Cialis 20mg FilmTabletten of M/s Eli Lilly Nederland B.V., Papendorpseweg 83, 3528BJ Utrecht, Niederlande (EMA Approved)
	GMP status of the firm	GMP certificate No. 188/2023-DRAP(AD-3489860170 Dated 14-11-2023 is submitted
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been entertained as per the decision of DRAP Authority.	
	Decision	

Not Applicable

The registration letter will be issued after verification of submitted stability data through Product specific Inspection.

229	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(PZ8-W7R-8BZU, 2025-07-28)
	Detail of Fee Submitted	37000.0, 2025-07-25,
	The proposed proprietary name / brand name	Procial 10mg Tablet
	Label Claim	Each Film coated Tablet contains: Tadalafil.....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 x 4's, 1x5's, 1 x 10's, 2 x 10's, 4x7's, 3 x 10'-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature below 30
	For generic drugs (me-too Status)	fildil 10mg Tablet Hingnoon Laboratories
	Pharmacotherapeutic Group of (API)	Tadalafil is in a class of medications called phosphodiesterase (PDE) inhibitors.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Ultra Tech India Ltd. Add: Plot Nos. 24, 25 & 26, New Chemical Zone, M.I.D.C. Taloja, Tal. Panvel, Dist. Raigad-410208, Maharashtra, India
	Detail of stability batches of drug product	Batches: TIY001, TIY002, TIY003 (Batch size: 2000 tablets) 06 months real time and 06 months accelerated stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan from M/s AsianContinental Pvt. Ltd. is submitted for 500 grams. Clearance certificate dated 06-06-2024 for 1Kg of Tadalafil issued to M/s Asian Continental.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against reference product i.e. Cialis 10mg FilmTabletten of M/s Eli Lilly Nederland B.V., Papendorpseweg 83, 3528BJ Utrecht, Niederlande (USFDA Approved)(EMA Approved)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated at Temp:40±2°C, Humidity:75±5% RH & Real Time at Temp:30±2°C, Humidity:65±5% RH (36 months)
	The status in reference regulatory authorities	Cialis 10mg FilmTabletten of M/s Eli Lilly Nederland B.V., Papendorpseweg 83, 3528BJ Utrecht, Niederlande (EMA Approved)
	GMP status of the firm	GMP certificate No. 188/2023-DRAP(AD-3489860170 Dated 14-11-2023 is submitted
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been entertained as per the decision of DRAP Authority.	
	Decision	
	Not Applicable	

The registration letter will be issued after verification of submitted stability data through Product specific Inspection.

230	Case Category	New Section (Farooq Aslam)
	Name, address of Applicant.	Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi (000333)
	Application Form Dy. No / Tracking ID & date of submission	(3LM-B5Y-JEZE, 2025-08-19)
	Detail of Fee Submitted	37000.0, 2025-06-27,
	The proposed proprietary name / brand name	NISALE 0.9% 100ml Infusion
	Label Claim	Each 100ml contains: sodium chloride.....0.9g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x1's 100ml-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30
	For generic drugs (me-too Status)	medisol NS Intravenous infusion by M/s Medipak
	Pharmacotherapeutic Group of (API)	parental fluid & electrolyte replinisher
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Resino Herbs Pvt Ltd
	Detail of stability batches of drug product	Batches: 190NS02-190NS03-190NS04 (Batch size: 200 vials) 06 months real time and 06 months accelerated stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan letter form M/s Evolution Pharmaceuticals pvt. ltd., Islamabad for 2kg of Sodium Chloride is submitted. Clearance certificate dated 02-08-2024 issued to M/s Evolution Pharmaceuticals is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the reference product i.e. Sodium Chloride 0.9% 100ml infusion by M/s Siegfried Germany.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 60 months real time stability study data according to the conditions of zone IV-A for 03 batches is submitted.
	The status in reference regulatory authorities	sodium chloride 0.9% 100ml injection Siegfried Hamelin Germany
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 16-02-2024.
	Evidence of approval of manufacturing facility	Liquid injectable vial SVP-III (General) section is approved (New Section)
	Evaluation Remarks	
	New Section	
	Decision	
	Approved	
	subject to verification of loan letter.	
231	Case Category	New Section (Farooq Aslam)
	Name, address of Applicant.	Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi (000333)
	Application Form Dy. No / Tracking ID & date of submission	(7MJ-BX2-P9VG, 2025-07-30)
	Detail of Fee Submitted	37000.0, 2025-07-23,

The proposed proprietary name / brand name	EPRENOR 4mg/4ml Injection
Label Claim	Each 4ml ampoule contains: Noradrenaline Bitartrate eq. to noradrenaline.....4mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	2x5's-As per SRO
Shelf Life (Unit)	2 Year(s)store below 30
For generic drugs (me-too Status)	Epinor injection 4mg/4mL by M/s Allmed Pvt. Ltd.
Pharmacotherapeutic Group of (API)	Sympathomimetic drug
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Synnatt Pharma India
Detail of stability batches of drug product	Batches: 185NS02-185NS03-185NS04 (Batch Size: 1500 Ampoules) 06 months real time and 06 months accelerated stability data is submitted.
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 27-11-2024 for 0.025Kg of material is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the comparator's product i.e. Epinor 4mg/4mL injection by M/s Allmed Pvt. Ltd.,.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 36 months real time stability study data of 03 batches conducted under the conditions of zone IV-A is submitted.
The status in reference regulatory authorities	Levophed injection 4mg/4mL by Hospira Inc, USFDA Approved
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 16-02-2024.
Evidence of approval of manufacturing facility	Liquid Injectable Ampoule-II (General) Section is approved (New Section).

Evaluation Remarks

New Section

Decision

Approved

232	Case Category	Export Facilitation (Farooq Aslam)
	Name, address of Applicant.	Vision Pharmaceuticals Pvt Ltd Plot#22-23, Industrial Triangle, Kahuta Road, Islamabad. (000517)
	Application Form Dy. No / Tracking ID & date of submission	(B4P-QXG-676L, 2025-01-28)
	Detail of Fee Submitted	37000.0, 2025-01-15,
	The proposed proprietary name / brand name	GLOTAVIS 600MG INJECTION
	Label Claim	Each vial contains: Glutathione as Sodium.....600mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in a cool dry place, below 30oC.
	For generic drugs (me-too Status)	could not be confirmed
	Pharmacotherapeutic Group of (API)	Antioxidant used for prophylaxis of neuropathy following chemotherapy treatment with cisplatin or analogues.
	Name, address of Manufacturing site:	Self Manufacturing

Name & address of API manufacturer	MAC CHEM PRODUCTS (INDIA) PVT. LTD ADDRESS: N-211/2/10. M.I.D.C.,BOISAR,DISTRICT THANE,PIN-401 506,MAHARASHTRA,INDIA.
Detail of stability batches of drug product	Batches: T001, T002, T003 (Batch size: 750 vials) 06 months real time and 06 month accelerated stability data is submitted.
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 09-09-2024 for 1.5kg material is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against Thione 600mg for injection by M/s Friends Pharma (pvt) ltd.,
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 24 months real time stability study data according to the conditions of zone IV-A for 03 batches is submitted.
The status in reference regulatory authorities	AIFA ITALY Approved.
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 13-01-2023.
Evidence of approval of manufacturing facility	Sterile dry powder injectable vial (General) section is approved.

Evaluation Remarks

The instant application is priority under export facilitation as per letter No.F.1-6/2019-PR-II (EFD)/Pt dated 03.03.2025.Solvent: WFI

Decision

Approved

233	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	Scotmann Pharmaceuticals Plot #5D , Industrial Area, I-10/3 Islamabad (000498)
	Application Form Dy. No / Tracking ID & date of submission	(7AV-PDU-LMMV, 2025-09-19)
	Detail of Fee Submitted	37000.0, 1700 2025-05-02, 2025-09-16
	The proposed proprietary name / brand name	Tadalafil Tablets 5mg
	Label Claim	Each film coated tablet contains: Tadalafil 5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO,12's-As per SRO,14's-As per SRO,15's-As per SRO,16's-As per SRO,2's-As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO,4's-As per SRO,5's-As per SRO,6's -As per SRO,7's-As per SRO,8's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C.
	For generic drugs (me-too Status)	Fildil Tablets 5mg (Highnoon Laboratories Ltd.)
	Pharmacotherapeutic Group of (API)	Phosphodiesterase (PDE) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Ami Lifesciences Private Limited.
	Detail of stability batches of drug product	Accelerated & Real Time Stability Studies Performed on B. No. T-01, T-02 & T-03, B. Size: 1000 Tablets on Initial, 3, 6 Months testing intervals.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance Certificate No. RO-5C4CA1 Dated 05/02/2025 for 0.5kg material is submitted.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence has been performed with Reference Product (Cialis Tablet 5mg) B. No. D634366 and Dissolution Profile of both products (Cialis Tablet 5mg and Tadalafil Tablets 5mg) was compared at 3 pH (1.2, 4.5 & 6.8).
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months Accelerated & 24 months Real Time Stability Studies Performed on B. No. TDL/50040321, TDL/50050321, TDL/50060421 according to the conditions of zone IV-B.
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	last inspection report dated 22-02-2024. Renewal recommended.
	Evidence of approval of manufacturing facility	General Tablet Section Approved and Renewed by CLB Dated: 26-02-2024
	Evaluation Remarks	
	The application has been entertained in compliance to the decision of DRAP Authority.	
	Decision	
	Approved	
234	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Bristol Mayer Biotech Pakistan 73 B Guldast Town Zarrar Shaheed Lahore (05-352-0068)
	Application Form Dy. No / Tracking ID & date of submission	(2HX-BAT-4GQ5, 2024-03-13)
	Detail of Fee Submitted	150000.0, 150000.0 2023-12-04, 2024-03-05
	The proposed proprietary name / brand name	Sugest 100mg/mL
	Label Claim	Each 1mL ampoule contains: Progesterone BP.....100mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	5 x 1ml Ampoules-As per SRO
	Shelf Life (Unit)	24 Month(s)Store below 30°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Progesterons / steroidal hormone
	Name, address of Manufacturing site:	Sanzyme Pvt Ltd-Unit-II, Survey No:35 Dhandha, Idar road, Himatnagar-383 001 Gujarat, India-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against Susten (Progesterone Injection 100 mg/mL) by M/s Sun Pharmaceuticals India.
	Name, address of Marketing Authorization Holder:	Sanzyme Pvt Ltd, Unit-II, Survey No:35 Dhandha, Idar road, Himatnagar-383 001 Gujarat, India, India
	Details of Certificates (CoPP/FSC/cGMP):	Drug manufacturing license of M/s Montage Laboratories Pvt. Ltd, India is submitted valid till 28-May, 2024. CoPP: Copy of legalized CoPP No. Mfg/WHO-GMP/COPP/2023/176522875 valid till 16-10-2025 is submitted. The applied product is available in free sa
	Details of Authorization Letter :	Authorization letter: Copy of product specific letter of authorization is submitted for the applied product.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	60 months real time and 06 months accelerated stability data is submitted for 03 batches according to the conditions of zone IV-A.

	The status in reference regulatory authorities	MHRA Approved
	Evaluation Remarks	
	.	
	Decision	
	Approved as per import policy for inspection of manufacturer abroad.	
235	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Biogen Life Sciences 8-KM, Chak Beli Road, Rawat, (000911)
	Application Form Dy. No / Tracking ID & date of submission	(DQJ-RA9-GQ3Z, 2024-10-08)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-21, 2024-09-23
	The proposed proprietary name / brand name	KETOCONIZ 2% Lotion
	Label Claim	Each ml contains: Ketoconazole.....20 mg (w/v)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Room Condition
	For generic drugs (me-too Status)	Cleanazol shampoo 20mg by M/s Caraway.
	Pharmacotherapeutic Group of (API)	Imidazole antifungal class of medications
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CUREWORTH DRUGS & INTERMEDIATES PVT. LTD. Plot No. N- 49, Additional Ambernath M.I.D.C, Ambernath (E), Dist. Thane, Pin 421506, Maharashtra, India.
	Detail of stability batches of drug product	Batches: K001, K002, K003 (Batch size: 2000 bottles) 06 months real time and 06 motnhs accelerated stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 10-03-2023 for 25kg material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against comparator's product Ketagen lotion by M/s Biogen Pharma, Rawat.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 60 months real time stability data according to the conditions of zone IV-B is submitted.
	The status in reference regulatory authorities	Ketoconazole shampoo 2% by M/s Cosette, USFDA Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 01-06-2023.
	Evidence of approval of manufacturing facility	Lotion Section (General) is approved.
	Evaluation Remarks	
	.	
	Decision	
	Approved	
236	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Bosch Pharmaceuticals (Pvt) Ltd. Plot No. 221-223, Sector-23, Korangi Industrial Area (000350)
	Application Form Dy. No / Tracking ID & date of submission	(U2Q-MJD-XH4R, 2024-04-30)

Detail of Fee Submitted	30000.0, 2024-01-09,
The proposed proprietary name / brand name	Napzol Tablets 500mg + 20mg
Label Claim	Each modified release tablet contains: Naproxen as enteric coated core.....500mg Esomeprazole (as magnesium trihydrate) as IR.....20mg
Reference to Finished product specifications	Manufacturer Specification
Proposed Pack Size	28's, 14's, 10's-As per SRO
Shelf Life (Unit)	2 Year(s)Do not store above 30°C
For generic drugs (me-too Status)	Glomov Tablets 500mg + 20mg by M/s Global Pharma
Pharmacotherapeutic Group of (API)	NSAID/anti-ulcer
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Divis Laboratories Limited (Unit-2), Chippada Village, Annavaram Post - 531 162, Bheemunipatnam Mandal, Visakhapatnam District, Andhra Pradesh, India,Metrochem API Private Limited, Unit-1, Plot No. 62/C/6, Pipeline Road, Phase - I, IDA, Jeedimetla, Quthbullapur (M), Medchal - Malkajgiri (Dist) - 500 055, Telangana State, India.
Detail of stability batches of drug product	Batches: TR-NAPZOL-03, TR-NAPZOL-04, TR-NAPZOL-05 (Batch size: 1500 tablets) 6 months accelerated and 6 months real time stability data is submitted.
Documents for the procurement of API with approval from DRAP (in case of Import)	Esomeprazole: Form 6 dated 10-10-2022 for 1kg material, unattested invoice dated 29-0-2022, packing list and airway bill are submitted. Naproxen: Form 6 dated 30-12-2022 for 5kg material, unattested invoice dated 26-12-2022,
Pharmaceutical Equivalence and Comparative Dissolution Profile	P.E and CDP studies have been performed against the reference product i.e Vimovo 500/20 tablet, Ireland Approved.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Naproxen: 6 months accelerated and 60 months real time stability data according the the conditions of zone IV-Á for 03 batches is submitted. Esomeprazole Magnesium: 6 months accelerated and 60 months real time stability data according the the conditions of zone IV-Á for 03 batches is submitted.
The status in reference regulatory authorities	USFDA Approved
GMP status of the firm	Inspection report dated 13-02-2023 is submitted.
Evidence of approval of manufacturing facility	Tablet General Section is approved.
Evaluation Remarks	
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Decision	
Approved	
237	
Case Category	Routine (Farooq Aslam)
Name, address of Applicant.	Bosch Pharmaceuticals (Pvt) Ltd. Plot No. 221-223, Sector-23, Korangi Industrial Area (000350)
Application Form Dy. No / Tracking ID & date of submission	(L4L-YXJ-8JEQ, 2024-03-25)

Detail of Fee Submitted	30000.0, 2024-01-09,
The proposed proprietary name / brand name	Napzol Tablets 375mg + 20mg
Label Claim	Each modified-release tablet contains: Naproxen as enteric coated core..... 375mg Esomeprazole (as magnesium trihydrate) as IR..... 20mg
Reference to Finished product specifications	Manufacturer Specification
Proposed Pack Size	28's, 14's, 10's-As per SRO
Shelf Life (Unit)	2 Year(s)Do not store above 30°C
For generic drugs (me-too Status)	Glomov Tablets 375mg + 20mg
Pharmacotherapeutic Group of (API)	NSAID/anti-ulcer
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Divis Laboratories Limited (Unit-2), Chippada Village, Annavaram Post - 531 162, Bheemunipatnam Mandal, Visakhapatnam District, Andhra Pradesh, India,Metrochem API Private Limited, Unit - I, Plot No 62/C/6, Pipeline Road, Phase -I, IDA, Jeedimetla, Quthbullapur (M), Medchal - Malkajgiri (Dist) - 500 055, Telangana State, India
Detail of stability batches of drug product	Batches: TR-NAPZOL-06, TR-NAPZOL-07, TR-NAPZOL-08 (Batch size: 1500 tablets) 06 months real time and 6 months accelerated stability is submitted.
Documents for the procurement of API with approval from DRAP (in case of Import)	Esomeprazole: Form 6 dated 10-10-2022 for 1kg material, unattested invoice dated 29-0-2022, packing list and airway bill are submitted. Naproxen: Form 6 dated 30-12-2022 for 5kg material, unattested invoice dated 26-12-2022,
Pharmaceutical Equivalence and Comparative Dissolution Profile	P.E and CDP studies have been performed against the reference product i.e Vimovo 375/20 tablet, Ireland Approved.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Naproxen: 6 months accelerated and 60 months real time stability data according the the conditions of zone IV-Á for 03 batches is submitted. Esomeprazole Magnesium: 6 months accelerated and 60 months real time stability data according the the conditions of zone IV-Á for 03 batches is submitted.
The status in reference regulatory authorities	USFDA Approved
GMP status of the firm	Inspection report dated 13-02-2023 is submitted.
Evidence of approval of manufacturing facility	Tablet General Section is approved.
Evaluation Remarks	
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Decision	
Approved	
238	Case Category
	New Section (Farooq Aslam)
	Name, address of Applicant.
	Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi (000333)
	Application Form Dy. No / Tracking ID & date of submission
	(AUA-3YG-AQXG, 2024-11-21)
	Detail of Fee Submitted
	75000.0, 2024-02-13,

The proposed proprietary name / brand name	URO-C Effervescent sachet
Label Claim	Each 4g sachet contains: sodium bicarbonate.....1760mg Tartaric acid.....890mg citric acid anhydrous....720mg sodium citrate anhydrous.....630mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1x8-As per SRO
Shelf Life (Unit)	2 Year(s)store in a cool and dry place below 30
For generic drugs (me-too Status)	-
Pharmacotherapeutic Group of (API)	Urinary alkaliniser
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Qingdao ICD Biochemistry Co. Ltd,RZBC (Juxian) Co. Ltd.,RZBC(Juxian) Co. Ltd.,Tata chemicals Europe Ltd.
Detail of stability batches of drug product	Batches: 087NS02, 087NS03, 087NS04 (Batch size: 500 Sachet)
Documents for the procurement of API with approval from DRAP (in case of Import)	not submitted
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against reference product i.e Ural effervescent Sachet by Aspen Pharma Pty ltd, Australia.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	not submitted
The status in reference regulatory authorities	URAL Effervescent Sachet (aspen Pharma Pty Ltd. TGA Australia
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 04-11-2021.
Evidence of approval of manufacturing facility	Sachet General Section is approved (New Section)
Evaluation Remarks	
Following are the observations:1. The firm has not submitted data of drug substance in section 3.2.S.2.2, 3.2.S.3, 3.2.S.3.2, 3.2.S.4, 3.2.S.4.5, 3.2.S.5 , 3.2.S.6, 3.2.S.7 (stability).2. The firm could not provide documents confirming import of drug substances and has stated that: {our formulation contains all the materials which are used as inactive as well so at the time of registration when we chose this product than materials used in this formulation are same as the one already use in different formulations which were purchased locally but in current practice we import all API's as per standard procedure. For your reference we already enclosed all the invoices of materials purchased locally}3. The firm has provided invoices from local vendors. 4. The firm could not provide the GMP / drug manufacuirng license of th emanufactruers.	
Decision	
Rejected	
The Board was apprised that the materials used in the applied formulation are used as excipient as well as APIs in pharmaceutical drug products. The Board discussed that the excipients can be procured/purchased from the local vendors and in case of import, the APIs can only be imported by DML holders from Pharmaceutical Manufacturing facility. However, in either case materials shall be of pharmaceutical grade and be procured from a GMP compliant unit. In the instant case, the applicant had procured the APIs used in the formulation from a local unauthorized vendor without any supportive data. Therefore, the Board decided to reject case.	
239	Case Category
	Any Other (Farooq Aslam)
	Name, address of Applicant.
	Getz Pharma (Pvt) Limited 29-30/27,Korangi Industrial Area karachi (000284)
	Application Form Dy. No / Tracking ID & date of submission
	(P3T-EBM-N4S4, 2025-09-11)

	Detail of Fee Submitted	38700.0, 2025-08-25,
	The proposed proprietary name / brand name	TADAFIL Tablets 5mg
	Label Claim	Each film-coated tablet contains: Tadalafil.....5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO,12's-As per SRO,20's-As per SRO,4's-As per SRO,8's-As per SRO
	Shelf Life (Unit)	24 Month(s)Do not store above 30°C.
	For generic drugs (me-too Status)	Fildil Tablets 5mg by M/s Highnoon Laboratories Ltd., Lahore.
	Pharmacotherapeutic Group of (API)	phosphodiesterase 5 (PDE5) inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Batches: 735DS01, 735DS01 (Batch Size: 5000 Tablets) Firm has submitted stability data of 02 batches placed at accelerated and real time conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 20-12-2024 for 1kg material is submitted. Copy of unattested invoice dated 09-07-2024 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted PE & CDP performed against reference product 'Cialis Tablets 5mg'
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted 03 batches of stability studies of drug substance placed at accelerated and real time (24 months) according to the conditons of zone IV-A.
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 10-11-2023.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The case has been entertained in compliance to the decision of DRAP Authority.	
	Decision	
	Approved	
240	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	Getz Pharma (Pvt) Limited 29-30/27,Korangi Industrial Area karachi (000284)
	Application Form Dy. No / Tracking ID & date of submission	(W3T-M9Y-QBNA, 2025-09-11)
	Detail of Fee Submitted	38700.0, 2025-08-25,
	The proposed proprietary name / brand name	TADAFIL Tablets 10mg
	Label Claim	Each film-coated tablet contains: Tadalafil.....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO,12's-As per SRO,20's-As per SRO,4's-As per SRO,8's-As per SRO
	Shelf Life (Unit)	24 Month(s)Do not store above 30°C.
	For generic drugs (me-too Status)	Tadalis Tablets 10mg (Reg. No.: 128042) by M/s Hilton Pharma (Pvt.) Ltd., Karachi.
	Pharmacotherapeutic Group of (API)	phosphodiesterase 5 (PDE5) inhibitor
	Name, address of Manufacturing site:	Self Manufacturing

	Name & address of API manufacturer	
	Detail of stability batches of drug product	Batches: 736DS01, 736DS01 (Batch Size: 5000 Tablets) Firm has submitted stability data of 02 batches placed at accelerated and real time conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 20-12-2024 for 1kg material is submitted. Copy of unattested invoice dated 09-07-2024 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted PE & CDP performed against reference product 'Cialis Tablets 10mg'
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted 03 batches of stability studies of drug substance placed at accelerated and real time (24 months) according to the conditions of zone IV-A.
	The status in reference regulatory authorities	Cialis Tablets 10mg from USFDA
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 10-11-2023.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The case has been entertained in compliance to the decision of DRAP Authority.	
	Decision	
	Approved	
241	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	Getz Pharma (Pvt) Limited 29-30/27,Korangi Industrial Area karachi (000284)
	Application Form Dy. No / Tracking ID & date of submission	(98S-HDR-7EL9, 2025-09-11)
	Detail of Fee Submitted	38700.0, 2025-08-25,
	The proposed proprietary name / brand name	TADAFIL Tablets 20mg
	Label Claim	Each film-coated tablet contains: Tadalafil.....20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO,12's-As per SRO,20's-As per SRO,4's-As per SRO,8's-As per SRO
	Shelf Life (Unit)	24 Month(s)Do not store above 30°C.
	For generic drugs (me-too Status)	Tadalafil Tablets 20mg (Reg. No.: 128041) by M/s Hilton Pharma (Pvt.) Ltd., Karachi.
	Pharmacotherapeutic Group of (API)	phosphodiesterase 5 (PDE5) inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Yangtai Jitai Pharmaceutical Co. Ltd.,
	Detail of stability batches of drug product	Batches: 737DS01, 738DS02 (Batch Size: 1200 Tablets) 06 months real time and 06 months accelerated stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 20-12-2024 for 1kg material is submitted. Copy of unattested invoice dated 24-05-2024 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted PE & CDP performed against reference product 'Cialis Tablets 20mg'
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted 03 batches of stability studies of drug substance placed at accelerated (06 months and real time (60 months) according to the conditions of zone IV-A.
	The status in reference regulatory authorities	USFDA Approved

	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 10-11-2023.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The case has been entertained in compliance to the decision of DRAP Authority.	
	Decision	
	Approved	
242	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(W5J-LAR-Q79N, 2024-03-27)
	Detail of Fee Submitted	75000.0, 2024-02-28,
	The proposed proprietary name / brand name	DEXTRAM 75MG/25MG TABLET
	Label Claim	Each Film Coated tablet contains: Tramadol HCl 75mg Dexketoprofen trometamol Equivalent to Dexketoprofen 25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x7's, 1x10's, 2x10'-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at cool &dry place below 30
	For generic drugs (me-too Status)	N.A
	Pharmacotherapeutic Group of (API)	Analgesic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Metrochem API Private Limited, Address: Unit-IV, Plot No. 34B, 40B & 60B, J.N. Pharma City, Thanam Village, Parawada Mandal, Vishakhapatnam District, Andhra Pradesh -531021, India.,Proto Chemicals Address: AG Tschachen 2 8756 Mitlödi (Glarus Süd) Switzerland
	Detail of stability batches of drug product	Provided as conditions of zone IV A
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted Form 5 for tramadol hydrochloride and Form 6 for Dexketoprofen trometamol
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided as conditions of zone IV A
	The status in reference regulatory authorities	Approved in MHRA, Skudexa 75 mg/25 mg film-coated tablets M/s Menarini – Von Heyden GmbH Leipziger Strasse 7-13 01097
	GMP status of the firm	GMP certificate is issued to the firm based on evaluation conducted on 03.04.2023.
	Evidence of approval of manufacturing facility	GMP certificate dated 14.11.2023 & section approval letter No. 1-51/2004-Lic dated 07th February 2014 indicate Tablet general section of firm.
	Evaluation Remarks	
	The queries of PEC and response of firm is summarized in table below:	
	Queries	Response

Import documents like Form 5 /Form 6 for tramadol hydrochloride also any document so to verify that M/s. Chemo is trader of M/s. Protochemicals. Import documents like clearance certificate from DRAP I&E for Dexketoprofen trometamol.

Firm has submitted Form 5 for tramadol hydrochloride & Form 6 for Dexketoprofen trometamol. (License to Import) for Dexketoprofen trometamol. Manufacturer of API 'tramadol hydrochloride' is M/s. Protochemicals. However on invoice M/s. Chemo is mentioned. Upon clarification firm has submitted that M/s. Chemo is trader of M/s. Protochemicals but there is no any supporting document of it.

Decision

Approved

Approved.

Registration letter shall be issued after verification of authenticity of submitted stability data by panel constituted by Chairman Registration Board

243	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	Aulton Pharmaceuticals Plot # 84/1,Block A, Phase 5 , Industrial Estate Hattar, KPK, (000828)
	Application Form Dy. No / Tracking ID & date of submission	(JM1-1BL-U34S, 2024-03-12)
	Detail of Fee Submitted	30000.0, 2024-02-13,
	The proposed proprietary name / brand name	Empazin M XR 12.5mg/1000mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Empagliflozin (as Immediate Release Coating) 12.5mg Metformin HCl (as Extended Release Core) 1000mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	28's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Erli Plus XR Tablet 12.5/1000mg by PharmEvo
	Pharmacotherapeutic Group of (API)	Anti- Diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. Fuxin Long Rui Pharmaceutical Address: Fluoride Industrial Park, Fumeng County, Fuxin City, Liaoning Province-123000, China. M/s. Aarti Drugs Limited Add: Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat India.396155. India
	Detail of stability batches of drug product	Provided as per conditions of zone IVA
	Documents for the procurement of API with approval from DRAP (in case of Import)	For Metformin Form 6 and DRAP attested commercial invoice is provided. For Empagliflozin Form 6 is provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided as per conditions of zone IVA
	The status in reference regulatory authorities	SYNJARDY XR Tablet by M/s. Boehringer Ingelheim International GmbH, Ingelheim, Germany
	GMP status of the firm	ok
	Evidence of approval of manufacturing facility	Licensing Division's Letter No. 1-17/2013-Lic(Vol_I) dated 3rd November 2015 confirm tablet general section of the firm.
	Evaluation Remarks	
	-	

Decision																																																					
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244	<table> <tr> <td>Case Category</td><td>New Section (Haleema Sharif)</td></tr> <tr> <td>Name, address of Applicant.</td><td>Caraway Pharmaceuticals PLOT NO.12, STREET NO.3 NATIONAL INDUSTRIAL ZONE RAWAT, PAKISTAN (000629)</td></tr> <tr> <td>Application Form Dy. No / Tracking ID & date of submission</td><td>(BSY-UL9-7UHH, 2025-07-18)</td></tr> <tr> <td>Detail of Fee Submitted</td><td>37000.0, 2025-04-29,</td></tr> <tr> <td>The proposed proprietary name / brand name</td><td>Zolpid 5mg Tablet</td></tr> <tr> <td>Label Claim</td><td>Each Film Coated Tablet Contains: Zolpidem Tartrate.....5mg (USP Specs)</td></tr> <tr> <td>Reference to Finished product specifications</td><td>United States Pharmacopeia</td></tr> <tr> <td>Proposed Pack Size</td><td>7's, 10's, 14's, 20'-As per SRO</td></tr> <tr> <td>Shelf Life (Unit)</td><td>2 Year(s)Store Between 15° to 30°C.</td></tr> <tr> <td>For generic drugs (me-too Status)</td><td>Demtrat 5mg Tablet (Reg# 061072) By M/s Bosch Pharma.</td></tr> <tr> <td>Pharmacotherapeutic Group of (API)</td><td>Benzodiazepine related agents. Used as hypnotics and sedatives</td></tr> <tr> <td>Name, address of Manufacturing site:</td><td>Self Manufacturing</td></tr> <tr> <td>Name & address of API manufacturer</td><td>Cambrex Profarmaco Milano S.r.l. Via Curiel, 34 20067 Paullo, Milano</td></tr> <tr> <td>Detail of stability batches of drug product</td><td>Stability Studies of Drug Substance as per conditions of zone IV A submitted by firm.</td></tr> <tr> <td>Documents for the procurement of API with approval from DRAP (in case of Import)</td><td>Document for Procurement of API clearance certificate is provided by firm.</td></tr> <tr> <td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical Equivalence studies and Comparative Dissolution Profile are Provided.</td></tr> <tr> <td>Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)</td><td>Stability Studies of Drug Substance as per conditions of zone IV A submitted by firm</td></tr> <tr> <td>The status in reference regulatory authorities</td><td>Zolpidem Tartrate 5mg Tablets By Zentiva Pharma UK Limited 12 New Fetter Lane London EC4A 1JP United Kingdom. (MHRA Approved Drug)</td></tr> <tr> <td>GMP status of the firm</td><td>GMP Certificate dated 7th August 2024 is issued to the firm based upon inspection conducted on 31.07.2024.</td></tr> <tr> <td>Evidence of approval of manufacturing facility</td><td>Section Approval Letter No. 1-9/2004_Lic(vol-II) dated 4th July 2022 confirming Tablet Psychotropic Section is submitted by firm.</td></tr> <tr> <td colspan="2">Evaluation Remarks</td></tr> <tr> <td colspan="2">The queries of PEC and response of firm is summarized in table below:</td></tr> <tr> <td colspan="2"> <table> <tr> <th>Queries</th><th>Response</th></tr> <tr> <td>Readable batch analysis/COA of imported lots of drug substance by drug substance manufacturer.</td><td>Provided</td></tr> <tr> <td>Readable valid GMP certificate of drug substance manufacturer as GMP certificate was issued to the firm based on inspection conducted in year 2021 and it is not valid now.</td><td>GMP certificate of drug substance manufacturer valid till 12.10.2026 is provided by firm.</td></tr> </table> </td></tr> </table>	Case Category	New Section (Haleema Sharif)	Name, address of Applicant.	Caraway Pharmaceuticals PLOT NO.12, STREET NO.3 NATIONAL INDUSTRIAL ZONE RAWAT, PAKISTAN (000629)	Application Form Dy. No / Tracking ID & date of submission	(BSY-UL9-7UHH, 2025-07-18)	Detail of Fee Submitted	37000.0, 2025-04-29,	The proposed proprietary name / brand name	Zolpid 5mg Tablet	Label Claim	Each Film Coated Tablet Contains: Zolpidem Tartrate.....5mg (USP Specs)	Reference to Finished product specifications	United States Pharmacopeia	Proposed Pack Size	7's, 10's, 14's, 20'-As per SRO	Shelf Life (Unit)	2 Year(s)Store Between 15° to 30°C.	For generic drugs (me-too Status)	Demtrat 5mg Tablet (Reg# 061072) By M/s Bosch Pharma.	Pharmacotherapeutic Group of (API)	Benzodiazepine related agents. Used as hypnotics and sedatives	Name, address of Manufacturing site:	Self Manufacturing	Name & address of API manufacturer	Cambrex Profarmaco Milano S.r.l. Via Curiel, 34 20067 Paullo, Milano	Detail of stability batches of drug product	Stability Studies of Drug Substance as per conditions of zone IV A submitted by firm.	Documents for the procurement of API with approval from DRAP (in case of Import)	Document for Procurement of API clearance certificate is provided by firm.	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence studies and Comparative Dissolution Profile are Provided.	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Studies of Drug Substance as per conditions of zone IV A submitted by firm	The status in reference regulatory authorities	Zolpidem Tartrate 5mg Tablets By Zentiva Pharma UK Limited 12 New Fetter Lane London EC4A 1JP United Kingdom. (MHRA Approved Drug)	GMP status of the firm	GMP Certificate dated 7th August 2024 is issued to the firm based upon inspection conducted on 31.07.2024.	Evidence of approval of manufacturing facility	Section Approval Letter No. 1-9/2004_Lic(vol-II) dated 4th July 2022 confirming Tablet Psychotropic Section is submitted by firm.	Evaluation Remarks		The queries of PEC and response of firm is summarized in table below:		<table> <tr> <th>Queries</th><th>Response</th></tr> <tr> <td>Readable batch analysis/COA of imported lots of drug substance by drug substance manufacturer.</td><td>Provided</td></tr> <tr> <td>Readable valid GMP certificate of drug substance manufacturer as GMP certificate was issued to the firm based on inspection conducted in year 2021 and it is not valid now.</td><td>GMP certificate of drug substance manufacturer valid till 12.10.2026 is provided by firm.</td></tr> </table>		Queries	Response	Readable batch analysis/COA of imported lots of drug substance by drug substance manufacturer.	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Case Category	New Section (Haleema Sharif)																																																				
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Application Form Dy. No / Tracking ID & date of submission	(BSY-UL9-7UHH, 2025-07-18)																																																				
Detail of Fee Submitted	37000.0, 2025-04-29,																																																				
The proposed proprietary name / brand name	Zolpid 5mg Tablet																																																				
Label Claim	Each Film Coated Tablet Contains: Zolpidem Tartrate.....5mg (USP Specs)																																																				
Reference to Finished product specifications	United States Pharmacopeia																																																				
Proposed Pack Size	7's, 10's, 14's, 20'-As per SRO																																																				
Shelf Life (Unit)	2 Year(s)Store Between 15° to 30°C.																																																				
For generic drugs (me-too Status)	Demtrat 5mg Tablet (Reg# 061072) By M/s Bosch Pharma.																																																				
Pharmacotherapeutic Group of (API)	Benzodiazepine related agents. Used as hypnotics and sedatives																																																				
Name, address of Manufacturing site:	Self Manufacturing																																																				
Name & address of API manufacturer	Cambrex Profarmaco Milano S.r.l. Via Curiel, 34 20067 Paullo, Milano																																																				
Detail of stability batches of drug product	Stability Studies of Drug Substance as per conditions of zone IV A submitted by firm.																																																				
Documents for the procurement of API with approval from DRAP (in case of Import)	Document for Procurement of API clearance certificate is provided by firm.																																																				
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence studies and Comparative Dissolution Profile are Provided.																																																				
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Studies of Drug Substance as per conditions of zone IV A submitted by firm																																																				
The status in reference regulatory authorities	Zolpidem Tartrate 5mg Tablets By Zentiva Pharma UK Limited 12 New Fetter Lane London EC4A 1JP United Kingdom. (MHRA Approved Drug)																																																				
GMP status of the firm	GMP Certificate dated 7th August 2024 is issued to the firm based upon inspection conducted on 31.07.2024.																																																				
Evidence of approval of manufacturing facility	Section Approval Letter No. 1-9/2004_Lic(vol-II) dated 4th July 2022 confirming Tablet Psychotropic Section is submitted by firm.																																																				
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The queries of PEC and response of firm is summarized in table below:																																																					
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	Import documents of drug substance like clearance certificates from DRAP I&E section.	Provided
	In 3.2.P.2.1.2 (Excipients) this statement is written what does it mean?? (It was therefore concluded that amino acids were for the most part compatible with commonly used excipients, including all excipients selected in the final formulation)	Firm explained that it was a typo error
Decision		
Approved		
Approved		
245	Case Category	New Section (Haleema Sharif)
	Name, address of Applicant.	Caraway Pharmaceuticals PLOT NO.12, STREET NO.3 NATIONAL INDUSTRIAL ZONE RAWAT, PAKISTAN (000629)
	Application Form Dy. No / Tracking ID & date of submission	(3PL-Q13-BR6T, 2025-05-05)
	Detail of Fee Submitted	37000.0, 2025-02-03,
	The proposed proprietary name / brand name	Clonaz 0.5mg Tablet
	Label Claim	Each Tablet Contains: Clonazepam.....0.5mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's, 20's, 30's, 40-As per SRO
	Shelf Life (Unit)	2 Year(s)Store Between 15° to 30°C.
	For generic drugs (me-too Status)	Magura 0.5mg Tablet (Registration No. 061630) By Sami Pharmaceuticals Pvt Ltd.
	Pharmacotherapeutic Group of (API)	Benzodiazepine derivatives
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Cambrex Profarmaco Milano S.r.l. Via Curiel, 34 20067 Paullo, Milano
	Detail of stability batches of drug product	Stability Studies of applied formulation as per conditions of zone IV A submitted by firm.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Document for Procurement of API clearance certificate is provided by firm. Computerized No. E9880812768367 date of issue 03. July.2024
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence studies and Comparative Dissolution Profile are Provided.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Studies of Drug Substance as per conditions of zone IV A submitted by firm
	The status in reference regulatory authorities	Clonazepam Neuraxpharm 0.5 mg Tablets, approved in MHRA
	GMP status of the firm	GMP Certificate dated 7th August 2024 is issued to the firm based upon inspection conducted on 31.07.2024.
	Evidence of approval of manufacturing facility	Section Approval Letter No. 1-9/2004_Lic(vol-II) dated 4th July 2022 confirming Tablet Psychotropic Section is submitted by firm.
Evaluation Remarks		
The queries of PEC and response of firm is summarized in table below:		
	Queries	Response
	Evidence of guideline supporting three sampling points 15, 30, and 45 minutes in comparative dissolution Minutes of 351st Meeting of Registration Board (23rd – 24th September, 2025)	Provided, Reference of CDP guideline by TGA, Australia stating following: The percentage of 237

profile/otherwise submit CDP at sampling points as recommended by WHO/ICH/USFDA guideline.	nominal content released are measured at a minimum of three (3) suitably spaced time point (excluding zero time point) to provide a profile for each batch (e.g. at 5, 15, 30 and 45 minutes, or as appropriate to achieve virtually complete dissolution).
Readable batch analysis/COA of imported lots of drug substance by drug substance manufacturer.	Provided
Import documents of drug substance like clearance certificates from DRAP I&E section.	Provided
Readable valid GMP certificate of drug substance manufacturer.	GMP certificate of drug substance manufacturer valid till 12.10.2026 is provided by firm.
In 3.2.P.2.1.2 (Excipients) this statement is written what does it mean?? (It was therefore concluded that amino acids were for the most part compatible with commonly used excipients, including all excipients selected in the final formulation)	It is a Typographical mistake/Unintentional copy of the statement.so kindly do not consider the specific statement as mentioned.
In section 3.2.S.4.3 please submit analytical method verification studies by drug product manufacturer.	Provided
Clarify the role of PRC Ticinum Lab mentioned in method validation protocol for hydrazine etc determination.	The testing of hydrazine as per USP not mandated however it was performed by drug substance manufacturer as Hydrazine is class 1 Carcinogenic compound (ICH M9). The PRC Ticinum Lab is an outsource lab from which the drug substance manufacturer performed the tests for hydrazine etc. determination.
In section 3.2.S.4.1 justify this limit; NMT 10% any unspecified impurity.	It's a typographic mistake. It is NMT 0.1%: any unspecified impurity. Amended document is attached in Attached in Annexure-H

Decision

Approved

Approved

246	Case Category	New License (Haleema Sharif)
	Name, address of Applicant.	Caraway Pharmaceuticals PLOT NO.12, STREET NO.3 NATIONAL INDUSTRIAL ZONE RAWAT, PAKISTAN (000629)
	Application Form Dy. No / Tracking ID & date of submission	(7GZ-96M-L391, 2025-05-05)
	Detail of Fee Submitted	37000.0, 2025-04-29,
	The proposed proprietary name / brand name	Clonaz 1mg Tablet
	Label Claim	Each Tablet Contains: Clonazepam.....1mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's, 20's, 30's, 40-As per SRO
	Shelf Life (Unit)	2 Year(s)Store Between 15° to 30°C.
	For generic drugs (me-too Status)	Nazepam Tablet 1mg (Registration No. 94164) By Glitz Pharma.
	Pharmacotherapeutic Group of (API)	Benzodiazepine derivatives
	Name, address of Manufacturing site:	Self Manufacturing

Name & address of API manufacturer	Cambrex Profarmaco Milano S.r.l. Via Curiel, 34 20067 Paullo, Milano
Detail of stability batches of drug product	Stability Studies of applied formulation as per conditions of zone IV A submitted by firm.
Documents for the procurement of API with approval from DRAP (in case of Import)	Document for Procurement of API clearance certificate is provided by firm. Computerized No. E9880812768367 date of issue 03. July.2024
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence studies and Comparative Dissolution Profile are Provided.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Studies of Drug Substance as per conditions of zone IV A submitted by firm
The status in reference regulatory authorities	Clonazepam Neuraxpharm 1mg Tablet By Neuraxpharm UK Ltd, Approved in MHRA
GMP status of the firm	GMP Certificate dated 7th August 2024 is issued to the firm based upon inspection conducted on 31.07.2024.
Evidence of approval of manufacturing facility	Section Approval Letter No. 1-9/2004_Lic(vol-II) dated 4th July 2022 confirming Tablet Psychotropic Section is submitted by firm.

Evaluation Remarks

The queries of PEC and response of firm is summarized in table below:

Queries	Response
Evidence of guideline supporting three sampling points 15, 30, and 45 minutes in comparative dissolution profile/otherwise submit CDP at sampling points as recommended by WHO/ICH/USFDA guideline.	Provided, Reference of CDP guideline by TGA, Australia stating following: The percentage of nominal content released are measured at a minimum of three (3) suitably spaced time point (excluding zero time point) to provide a profile for each batch (e.g. at 5, 15, 30 and 45 minutes, or at appropriate to achieve virtually complete dissolution).
Readable batch analysis/COA of imported lots of drug substance by drug substance manufacturer.	Provided
Import documents of drug substance like clearance certificates from DRAP I&E section.	Provided
Readable valid GMP certificate of drug substance manufacturer.	GMP certificate of drug substance manufacturer valid till 12.10.2026 is provided by firm.
In 3.2.P.2.1.2 (Excipients) this statement is written what does it mean?? (It was therefore concluded that amino acids were for the most part compatible with commonly used excipients, including all excipients selected in the final formulation)	It is a Typographical mistake/Unintentional copy of the statement.so kindly do not consider the specific statement as mentioned.
In section 3.2.S.4.3 please submit analytical method verification studies by drug product manufacturer.	Provided
Clarify the role of PRC Ticinum Lab mentioned in method validation protocol for hydrazine etc determination.	The testing of hydrazine as per USP not mandated however it was performed by drug substance manufacturer as Hydrazine is class 1 Carcinogenic compound (ICH M9). The PRC Ticinum Lab is an outsource lab from which the drug substance manufacturer performed the tests for hydrazine etc. determination.
In section 3.2.S.4.1 justify this limit; NMT 10% any unspecified impurity.	It's a typographic mistake. It is NMT 0.1%: any unspecified impurity. Amended document is attached in Attached in Annexure-H

Decision

Approved

Approved

247	Case Category	New Section (Haleema Sharif)
	Name, address of Applicant.	Caraway Pharmaceuticals PLOT NO.12, STREET NO.3 NATIONAL INDUSTRIAL ZONE RAWAT, PAKISTAN (000629)
	Application Form Dy. No / Tracking ID & date of submission	(M8A-M42-9YN2, 2025-07-18)
	Detail of Fee Submitted	37000.0, 2025-02-03,
	The proposed proprietary name / brand name	Loraz 1mg Tablet
	Label Claim	Each Tablet Contains: Lorazepam.....1mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's, 20's, 28's, 30-As per SRO
	Shelf Life (Unit)	2 Year(s)Store Between 15° to 30°C.
	For generic drugs (me-too Status)	Zativan 1mg Tablet (Reg# 58629) By Zanclok Pharmaceutical Laboratories, F/5 SITE Hyderabad., Hyderabad
	Pharmacotherapeutic Group of (API)	Benzodiazepine derivatives
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Cambrex Profarmaco Milano S.r.l. Via Curiel, 34 20067 Paullo, Milano
	Detail of stability batches of drug product	Stability Studies of applied formulation as per conditions of zone IV A submitted by firm.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Document for Procurement of API clearance certificate is provided by firm. Computerized No. E9880812768367 date of issue 03. July.2024
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence studies and Comparative Dissolution Profile are Provided.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Studies of Drug Substance as per conditions of zone IV A submitted by firm
	The status in reference regulatory authorities	Lorazepam 1mg Tablets Approved in MHRA
	GMP status of the firm	GMP Certificate dated 7th August 2024 is issued to the firm based upon inspection conducted on 31.07.2024.
	Evidence of approval of manufacturing facility	Section Approval Letter No. 1-9/2004 Lic(vol-II) dated 4th July 2022 confirming Tablet Psychotropic Section is submitted by firm.

Evaluation Remarks

The queries of PEC and response of firm is summarized in table below:

Queries	Response
Readable batch analysis/COA of imported lots of drug substance by drug substance manufacturer.	Provided/uploaded by firm
Import documents of drug substance like clearance certificates from DRAP I&E section.	Clearance certificate is uploaded by firm.
Readable valid GMP certificate of drug substance manufacturer as GMP certificate was issued to the firm based on inspection conducted in year 2021 and it is not valid now.	Valid GMP certificate of drug substance manufacturer is uploaded by firm.
In 3.2.P.2.1.2 (Excipients) this statement is written what does it mean?? (It was therefore concluded that amino acids were for the	It was a typographical mistake /Unintentional copying of the statement.

most part compatible with commonly used excipients, including all excipients selected in the final formulation).	
Accelerated stability studies of drug substance by drug substance manufacturer.	Accelerated stability studies of drug substance by drug substance manufacturer are uploaded by firm
Evidence of innovator product excipients so to compare with excipients of applied formulation.	Firm has stated that the excipients used in the drug product formulation were taken from the MHRA Approved product & also submitted link for verification.

Decision

Approved

Approved

248	Case Category	New Section (Haleema Sharif)
	Name, address of Applicant.	Caraway Pharmaceuticals PLOT NO.12, STREET NO.3 NATIONAL INDUSTRIAL ZONE RAWAT, PAKISTAN (000629)
	Application Form Dy. No / Tracking ID & date of submission	(U6X-M6D-129P, 2025-05-05)
	Detail of Fee Submitted	37000.0, 2025-01-07,
	The proposed proprietary name / brand name	Prolam 0.5mg Tablet
	Label Claim	Each Tablet contains: Alprazolam 0.5mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's, 20's 30's, 40'-As per SRO
	Shelf Life (Unit)	2 Year(s)Store Between 15° to 30°C.
	For generic drugs (me-too Status)	Azolam 0.5mg Tablet (Registration No. 017577) By Martin Dow Pharmaceutical Limited.
	Pharmacotherapeutic Group of (API)	Benzodiazepine related agents. Used as hypnotics and sedatives
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Cambrex Profarmaco Milano S.r.l. Via Curiel, 34 20067 Paullo, Milano
	Detail of stability batches of drug product	Stability Studies of applied formulation as per conditions of zone IV A submitted by firm.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Document for Procurement of API clearance certificate is provided by firm. Computerized No. E9880812768367 date of issue 03. July.2024
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence studies and Comparative Dissolution Profile are Provided.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Studies of Drug Substance as per conditions of zone IV A submitted by firm
	The status in reference regulatory authorities	Xanax 0.5mg Tablets (MHRA Approved / FDA Approved/ HPRA Approved Drug)
	GMP status of the firm	GMP Certificate dated 7th August 2024 is issued to the firm based upon inspection conducted on 31.07.2024.
	Evidence of approval of manufacturing facility	Section Approval Letter No. 1-9/2004_Lic(vol-II) dated 4th July 2022 confirming Tablet Psychotropic Section is submitted by firm.
	Evaluation Remarks	

The queries of PEC and response of firm is summarized in table below:

Queries	Response
Evidence of guideline supporting these sampling points 10, 20, and 30 minutes in comparative dissolution profile/otherwise submit CDP at sampling points as recommended by WHO/ICH/USFDA guideline.	Firm has provided reference of CDP guideline by TGA, Australia stating following: The percentage of nominal content released are measured at a minimum of three (3) suitably spaced time points (excluding zero time point) to provide a profile for each batch (e.g. at 5, 15, 30 and 45 minutes, or as appropriate to achieve virtually complete dissolution).
Batch analysis of imported lots of drug substance by drug substance manufacturer.	Provided/Uploaded
Import documents of drug substance like clearance certificates from DRAP I&E section.	Uploaded
Following statement is mentioned in submitted dossier, please clarify: It was therefore concluded that amino acids were for the most part compatible with commonly used excipients, including all excipients selected in the final formulation.	It is a Typographical mistake/Unintentional copying of the statement.so kindly do not consider the specific statement as mentioned.
Readable valid GMP certificate of drug substance manufacturer.	GMP certificate of drug substance manufacturer valid till 12.10.2026 is provided by firm with one of its application.
Analytical method of drug substance by drug substance manufacturer.	Uploaded

Decision

Approved

Approved

249	Case Category	New Section (Haleema Sharif)
	Name, address of Applicant.	Caraway Pharmaceuticals PLOT NO.12, STREET NO.3 NATIONAL INDUSTRIAL ZONE RAWAT, PAKISTAN (000629)
	Application Form Dy. No / Tracking ID & date of submission	(U7S-R9R-J282, 2025-05-05)
	Detail of Fee Submitted	37000.0, 2025-01-09,
	The proposed proprietary name / brand name	Prolam 1mg Tablet
	Label Claim	Each Tablet contains: Alprazolam.....1mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's, 20's, 30's 40'-As per SRO
	Shelf Life (Unit)	2 Year(s)Store Between 15° to 30°C.
	For generic drugs (me-too Status)	Azolam 1mg Tablet (Registration No. 0.17578) By Maetin Dow Pharmaceutical Limited.
	Pharmacotherapeutic Group of (API)	Benzodiazepine related agents. Used as hypnotics and sedatives
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Cambrex Profarmaco Milano S.r.l. Via Curiel, 34 20067 Paullo, Milano
	Detail of stability batches of drug product	Stability Studies of applied formulation as per conditions of zone IV A submitted by firm.

Documents for the procurement of API with approval from DRAP (in case of Import)	Document for Procurement of API clearance certificate is provided by firm. Computerized No. E9880812768367 date of issue 03. July.2024
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence studies and Comparative Dissolution Profile are Provided.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Studies of Drug Substance as per conditions of zone IV A submitted by firm
The status in reference regulatory authorities	Xanax 1mg Tablets . (HPRA/FDA approved Drug)
GMP status of the firm	GMP Certificate dated 7th August 2024 is issued to the firm based upon inspection conducted on 31.07.2024.
Evidence of approval of manufacturing facility	Section Approval Letter No. 1-9/2004_Lic(vol-II) dated 4th July 2022 confirming Tablet Psychotropic Section is submitted by firm.

Evaluation Remarks

The queries of PEC and response of firm is summarized in table below:

Queries	Response
Evidence of guideline supporting these sampling points 10, 20, and 30 minutes in comparative dissolution profile/otherwise submit CDP at sampling points as recommended by WHO/ICH/USFDA guideline.	Firm has provided reference of CDP guideline by TGA, Australia stating following: The percentage of nominal content released are measured at a minimum of three (3) suitably spaced time points (excluding zero time point) to provide a profile for each batch (e.g. at 5, 15, 30 and 45 minutes, or as appropriate to achieve virtually complete dissolution).
Batch analysis of imported lots of drug substance by drug substance manufacturer.	Provided/Uploaded
Import documents of drug substance like clearance certificates from DRAP I&E section.	Uploaded
Following statement is mentioned in submitted dossier, please clarify: It was therefore concluded that amino acids were for the most part compatible with commonly used excipients, including all excipients selected in the final formulation.	It is a Typographical mistake/Unintentional copying of the statement.so kindly do not consider the specific statement as mentioned.
Readable valid GMP certificate of drug substance manufacturer.	GMP certificate of drug substance manufacturer valid till 12.10.2026 is provided by firm with one of its application.
Analytical method of drug substance by drug substance manufacturer.	Uploaded

Decision

Approved
Approved.

250	Case Category	New Section (Haleema Sharif)
	Name, address of Applicant.	Caraway Pharmaceuticals PLOT NO.12, STREET NO.3 NATIONAL INDUSTRIAL ZONE RAWAT, PAKISTAN (000629)
	Application Form Dy. No / Tracking ID & date of submission	(2AR-SVA-6X3W, 2025-07-18)
	Detail of Fee Submitted	37000.0, 2025-04-29,
	The proposed proprietary name / brand name	Zolpid 10mg Tablet
	Label Claim	Each Film coated Tablet contains: Zolpidem Tartrate.....10mg (USP Specs)

Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	7's, 10's, 14's, 20'-As per SRO
Shelf Life (Unit)	2 Year(s)Store Between 15° to 30°C.
For generic drugs (me-too Status)	Zorelax 10mg Tablet (Reg# 057725) By Brookes Pharma (Pvt) Ltd.
Pharmacotherapeutic Group of (API)	Benzodiazepine related agents. Used as hypnotics and sedatives
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Cambrex Profarmaco Milano S.r.l. Via Curiel, 34 20067 Paullo, Milano
Detail of stability batches of drug product	Stability Studies of applied formulation as per conditions of zone IV A submitted by firm.
Documents for the procurement of API with approval from DRAP (in case of Import)	Document for Procurement of API clearance certificate is provided by firm. Computerized No. E9880812768367 date of issue 03. July.2024
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence studies and Comparative Dissolution Profile are Provided.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Studies of Drug Substance as per conditions of zone IV A submitted by firm
The status in reference regulatory authorities	Zolpidem Tartrate 10mg Tablets Approved in MHRA
GMP status of the firm	GMP Certificate dated 7th August 2024 is issued to the firm based upon inspection conducted on 31.07.2024.
Evidence of approval of manufacturing facility	Section Approval Letter No. 1-9/2004_Lic(vol-II) dated 4th July 2022 confirming Tablet Psychotropic Section is submitted by firm.

Evaluation Remarks

The queries of PEC and response of firm is summarized in table below:

Queries	Response
Readable batch analysis/COA of imported lots of drug substance by drug substance manufacturer.	Provided
Readable valid GMP certificate of drug substance manufacturer as GMP certificate was issued to the firm based on inspection conducted in year 2021 and it is not valid now.	GMP certificate of drug substance manufacturer valid till 12.10.2026 is provided by firm.
Import documents of drug substance like clearance certificates from DRAP I&E section.	Provided
In 3.2.P.2.1.2 (Excipients) this statement is written what does it mean?? (It was therefore concluded that amino acids were for the most part compatible with commonly used excipients, including all excipients selected in the final formulation)	Firm explained that it was a typo error

Decision

Approved

Approved.

251	Case Category	New Section (Haleema Sharif)
	Name, address of Applicant.	Caraway Pharmaceuticals PLOT NO.12, STREET NO.3 NATIONAL INDUSTRIAL ZONE RAWAT, PAKISTAN (000629)
	Application Form Dy. No / Tracking ID & date of submission	(QGL-TVM-6MV2, 2025-07-18)
	Detail of Fee Submitted	37000.0, 2025-02-03,

The proposed proprietary name / brand name	Loraz 2mg Tablet
Label Claim	Each Tablet Contains: Lorazepam.....2mg (USP Specs)
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	10's, 20's, 30's, 40-As per SRO
Shelf Life (Unit)	2 Year(s)Store Between 15° to 30°C.
For generic drugs (me-too Status)	Magura 2mg Tablet (Registration No. 061631) By SAMI Pharmaceuticals Pvt. Ltd. F-95 Hub River Road S.I.T.E Karachi.
Pharmacotherapeutic Group of (API)	Benzodiazepine derivatives
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Cambrex Profarmaco Milano S.r.l. Via Curiel, 34 20067 Paullo, Milano
Detail of stability batches of drug product	Stability Studies of applied formulation as per conditions of zone IV A submitted by firm.
Documents for the procurement of API with approval from DRAP (in case of Import)	Document for Procurement of API clearance certificate is provided by firm. Computerized No. E9880812768367 date of issue 03. July.2024
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence studies and Comparative Dissolution Profile are Provided.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Studies of Drug Substance as per conditions of zone IV A submitted by firm
The status in reference regulatory authorities	Clonazepam Neuraxpharm 2mg Tablets Approved in MHRA.
GMP status of the firm	GMP Certificate dated 7th August 2024 is issued to the firm based upon inspection conducted on 31.07.2024.
Evidence of approval of manufacturing facility	Section Approval Letter No. 1-9/2004_Lic(vol-II) dated 4th July 2022 confirming Tablet Psychotropic Section is submitted by firm.

Evaluation Remarks

The queries of PEC and response of firm is summarized in table below:

Queries	Response
Readable batch analysis/COA of imported lots of drug substance by drug substance manufacturer.	Provided/uploaded by firm
Import documents of drug substance like clearance certificates from DRAP I&E section.	Clearance certificate is uploaded by firm.
Readable valid GMP certificate of drug substance manufacturer as GMP certificate was issued to the firm based on inspection conducted in year 2021 and it is not valid now.	Valid GMP certificate of drug substance manufacturer is uploaded by firm.
In 3.2.P.2.1.2 (Excipients) this statement is written what does it mean?? (It was therefore concluded that amino acids were for the most part compatible with commonly used excipients, including all excipients selected in the final formulation).	It was a typographical mistake /Unintentional copying of the statement.
Accelerated stability studies of drug substance by drug substance manufacturer.	Accelerated stability studies of drug substance by drug substance manufacturer are uploaded by firm
Evidence of innovator product excipients so to compare with excipients of applied formulation.	Firm has submitted USFDA SMPC attached indicating that excipients of applied product are similar to reference product.

Decision

Approved

252	Approved	
	Case Category	Priority As Per 257-M of RB (Haleema Sharif)
	Name, address of Applicant.	ATCO LIFE SCIENCES (PRIVATE) LIMITED B-18 S.I.T.E. Karachi (051)
	Application Form Dy. No / Tracking ID & date of submission	(1E2-XPV-7ME7, 2025-03-27)
	Detail of Fee Submitted	300000.0, 2024-11-18,
	The proposed proprietary name / brand name	GEMTOR 200mg for IV Injection
	Label Claim	Each vial contains: Gemcitabine Hydrochloride equivalent to Gemcitabine 200 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1×1's -Controlled
	Shelf Life (Unit)	2 Year(s)Don't store & transport above 30degree centigrade
	For generic drugs (me-too Status)	Zefei 200mg powder for injection Reg No. 95876
	Pharmacotherapeutic Group of (API)	Anti- cancer
	Name, address of Manufacturing site:	Eskayef Pharmaceuticals Limited-Rupganj Plant: Murapara, Rupganj, Narayanganj 1464, Bangladesh-Bangladesh
	Name & address of API manufacturer	Laurus Labs Limited, Plot No. 21, Jawaharlal Nehru Pharma City, Visakhapatnam, Andhra Pradesh
	Detail of stability batches of drug product	Provided as per conditions of zone IV a
	Documents for the procurement of API with approval from DRAP (in case of Import)	N/A, as Finished productImport.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP, Not applicable, PE; Provided.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	As per conditions of Zone II
	The status in reference regulatory authorities	Approved in MHRA
	GMP status of the firm	Attested CoPP is submitted by firm
	Evidence of approval of manufacturing facility	Attested CoPP is submitted by firm
Evaluation Remarks		
	Queries	Response
	Either legalized or Apostille CoPP (If Bangladesh is member of Apostille convention), as submitted is notarized only.	CoPP is attested by Ministry of Commerce of Bangladesh.
	Stability data of drug substance is generated at R&D facility, is it GMP/GLP compliant facility?	Kindly informed that stability studies of the drug substance were conducted at Laurus Labs Limited, Plot No. DS-1 & 2, IKP Knowledge Park, Genome Valley, Telangana, which is a R&D and quality testing site of Laurus Labs. The licensed manufacturing site for the drug substance is Plot No. 21, Jawaharlal Nehru Pharma City, Visakhapatnam, Andhra Pradesh, which is the approved site for commercial production. Both sites belong to Laurus Labs Limited, and the stability data generated at the R&D site is valid and acceptable to support the quality of the drug substance manufactured at the licensed site.
	There is difference in limits of impurities and assay between Eur. Pharmacopoeia & USP monograph, can	Kindly be informed that, Eskayef follows Ph. Eur. Pharmacopoeia specifications for drug substances
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	drug product comply with USP monograph. please justify.	qualification. But there is no monograph in the Ph. Eur. Pharmacopoeia for the drug product. But USP compendia method is available of this drug product and Eskayef adopts this USP method to release the product. As per comparison of below, it is confirmed that USP specification complies with the SK+F Specification. Hence, Product reference is USP.
	long term stability data of drug substance as per conditions of zone IV a.	As per recent communication with API manufacturer, Laurus Labs, they have confirmed the availability of stability data under Zone II ($25 \pm 2^{\circ}\text{C}$ / $60 \pm 5\%$ RH) conditions for up to 60 months, along with accelerated condition data for up to 6 months. While Zone IV A-specific data yet to available, we would like to highlight that Eskayef, as the finished product manufacturer, has generated extensive stability data under the required climatic zones for the final drug product:
	Decision	
	Approved	
	Approved subject to submission of Legalized/Apostille CoPP and as per import policy.	
253	Case Category	Priority As Per 257-M of RB (Haleema Sharif)
	Name, address of Applicant.	ATCO LIFE SCIENCES (PRIVATE) LIMITED B-18 S.I.T.E. Karachi (051)
	Application Form Dy. No / Tracking ID & date of submission	(TEZ-6SG-2MAG, 2025-03-23)
	Detail of Fee Submitted	300000.0, 2024-11-18,
	The proposed proprietary name / brand name	GEMTOR 1 g for IV Injection
	Label Claim	Each vial contains: Gemcitabine 1 g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1×1's -Controlled
	Shelf Life (Unit)	2 Year(s)Don't store & transport above 30degree centigrade
	For generic drugs (me-too Status)	Gemcitabel Lyophilized Powder For Solution For Infusion Reg. No. 88401
	Pharmacotherapeutic Group of (API)	Anti-Cancer
	Name, address of Manufacturing site:	Eskayef Pharmaceuticals Limited-Murapara, Rupganj, Narayanganj 1464, Bangladesh-Bangladesh
	Name & address of API manufacturer	Laurus Labs Limited
	Detail of stability batches of drug product	Stability studies submitted as per conditions of Zone IVa
	Documents for the procurement of API with approval from DRAP (in case of Import)	Finished Pharmaceutical Product Import.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP; Not applicable, PE; Provided
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided as condition of Zone II
	The status in reference regulatory authorities	Approved in MHRA

	GMP status of the firm	Attested CoPP is submitted by Firm
	Evidence of approval of manufacturing facility	Attested CoPP is submitted by firm
Evaluation Remarks		
	Queries	Response
	Either legalized or Apostille CoPP (If Bangladesh is member of Apostille convention), as submitted is notarized only.	CoPP is attested by Ministry of Commerce of Bangladesh.
	Stability data of drug substance is generated at R&D facility, is it GMP/GLP compliant facility?	Kindly informed that stability studies of the drug substance were conducted at Laurus Labs Limited, Plot No. DS-1 & 2, IKP Knowledge Park, Genome Valley, Telangana, which is a R&D and quality testing site of Laurus Labs. The licensed manufacturing site for the drug substance is Plot No. 21, Jawaharlal Nehru Pharma City, Visakhapatnam, Andhra Pradesh, which is the approved site for commercial production. Both sites belong to Laurus Labs Limited, and the stability data generated at the R&D site is valid and acceptable to support the quality of the drug substance manufactured at the licensed site.
	There is difference in limits of impurities and assay between Eur. Pharmacopoeia & USP monograph, can drug product comply with USP monograph. please justify.	Kindly be informed that, Eskayef follows Ph. Eur. Pharmacopoeia specifications for drug substances qualification. But there is no monograph in the Ph. Eur. Pharmacopoeia for the drug product. But USP compendia method is available of this drug product and Eskayef adopts this USP method to release the product. As per comparison of below, it is confirmed that USP specification complies with the SK+F Specification. Hence, Product reference is USP.
	long term stability data of drug substance as per conditions of zone IV a.	As per recent communication with API manufacturer, Laurus Labs, they have confirmed the availability of stability data under Zone II ($25 \pm 2^{\circ}\text{C}$ / $60 \pm 5\%$ RH) conditions for up to 60 months, along with accelerated condition data for up to 6 months. While Zone IV A-specific data yet to available, we would like to highlight that Eskayef, as the finished product manufacturer, has generated extensive stability data under the required climatic zones for the final drug product:
Decision		
Approved		
Approved subject to submission of Legalized/Apostille CoPP and as per import policy.		
254	Case Category	New Section (Haleema Sharif)
	Name, address of Applicant.	Caraway Pharmaceuticals PLOT NO.12, STREET NO.3 NATIONAL INDUSTRIAL ZONE RAWAT, PAKISTAN (000629)
	Application Form Dy. No / Tracking ID & date of submission	(B2Z-PAN-494N, 2025-05-05)

Detail of Fee Submitted	37000.0, 2025-01-07,
The proposed proprietary name / brand name	Bromaz 3mg Tablet
Label Claim	Each Tablet Contains: Bromazepam.....3mg (Innovator' Specs)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	10's, 20' 30's, 40's-As per SRO
Shelf Life (Unit)	2 Year(s)Store Between 15° to 30°C.
For generic drugs (me-too Status)	Lexotanil 3mg Tablet (Registration No. 001043) By Martin Dow Pharmaceutical Limited Plot No. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan.
Pharmacotherapeutic Group of (API)	Benzodiazepine related agents. Used as hypnotics and sedatives
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Cambrex Profarmaco Milano S.r.l. Via Curiel, 34 20067 Paullo, Milano
Detail of stability batches of drug product	Six-month stability studies of applied formulation as per conditions of zone IV A submitted by firm.
Documents for the procurement of API with approval from DRAP (in case of Import)	Document for Procurement of API clearance certificate is provided by firm. Computerized No. E9880812768367 date of issue 03. July.2024
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence studies and Comparative Dissolution Profile are Provided.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Studies of Drug Substance as per conditions of zone IV A submitted by firm
The status in reference regulatory authorities	Approved in TGA; Lexotan 3mg Tablet By Pharmaco (Australia) Ltd. Level 13, 465 Victoria Avenue Chatswood Australia
GMP status of the firm	GMP Certificate dated 7th August 2024 is issued to the firm based upon inspection conducted on 31.07.2024.
Evidence of approval of manufacturing facility	Section Approval Letter No. 1-9/2004_Lic(vol-II) dated 4th July 2022 confirming Tablet Psychotropic Section is submitted by firm.

Evaluation Remarks

The queries of PEC and response of firm is summarized in table below:

Queries	Response
Evidence of guideline supporting three sampling points 15, 30, and 45 minutes in comparative dissolution profile/otherwise submit CDP at sampling points as recommended by WHO/ICH/USFDA guideline.	Firm has provided reference of CDP guideline by TGA, Australia stating following: The percentage of nominal content released are measured at a minimum of three (3) suitably spaced time points (excluding zero time point) to provide a profile for each batch (e.g. at 5, 15, 30 and 45 minutes, or as appropriate to achieve virtually complete dissolution).
Readable batch analysis/COA of imported lots of drug substance by drug substance manufacturer.	Uploaded
Import documents of drug substance like clearance certificates from DRAP I&E section.	Uploaded
Readable valid GMP certificate of drug substance manufacturer.	Uploaded
Analytical method of drug substance by drug substance manufacturer.	Uploaded

Reference for this acceptance limit in dissolution test NLT 80% (Q) in 45 min.	Firm has referred to Guidance document approved by RB in its 293rd meeting stating following: General recommendations of European Directorate for the Quality of Medicines (EDQM) In most cases, when tested under reasonable and justified test conditions, the acceptance criterion at level S1 is that at least 80 per cent of the active substance is released within a specified time, typically 45 min or less. This corresponds to a Q=75%, since, for level S1 the individual value of each of the 6 units tested is not less than Q + 5 per cent, i.e. not less than 80 per cent.

Decision

Approved

Approved.

255	Case Category	New Section (Haleema Sharif)
	Name, address of Applicant.	Caraway Pharmaceuticals PLOT NO.12, STREET NO.3 NATIONAL INDUSTRIAL ZONE RAWAT, PAKISTAN (000629)
	Application Form Dy. No / Tracking ID & date of submission	(5TZ-GS6-5Q33, 2025-05-05)
	Detail of Fee Submitted	37000.0, 2025-01-07,
	The proposed proprietary name / brand name	Bromaz 6mg Tablet
	Label Claim	Each Tablet Contains: Bromazepam.....6mg (Innovator's specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 20' 30's, 40's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store Between 15° to 30°C.
	For generic drugs (me-too Status)	Penzee Tablet 6mg Reg No. 67762.
	Pharmacotherapeutic Group of (API)	Benzodiazepine related agents. Used as hypnotics and sedatives
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Cambrex Profarmaco Milano S.r.l. Via Curiel, 34 20067 Paullo, Milano
	Detail of stability batches of drug product	Six-month stability studies of applied formulation as per conditions of zone IV A submitted by firm.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Document for Procurement of API clearance certificate is provided by firm. Computerized No. E9880812768367 date of issue 03. July.2024
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence studies and Comparative Dissolution Profile are Provided.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Studies of Drug Substance as per conditions of zone IV A submitted by firm
	The status in reference regulatory authorities	Lexotan 6mg Tablet By Pharmaco (Australia) Ltd Level 13, 465 Victoria Avenue Chatswood AUSTRALIA, (TGA Approved Drug)
	GMP status of the firm	GMP Certificate dated 7th August 2024 is issued to the firm based upon inspection conducted on 31.07.2024.
	Evidence of approval of manufacturing facility	Section Approval Letter No. 1-9/2004_Lic(vol-II) dated 4th July 2022 confirming Tablet Psychotropic Section is

submitted by firm.

Evaluation Remarks

The queries of PEC and response of firm is summarized in table below:

Queries	Response
Evidence of guideline supporting three sampling points 15, 30, and 45 minutes in comparative dissolution profile/otherwise submit CDP at sampling points as recommended by WHO/ICH/USFDA guideline.	Firm has provided reference of CDP guideline by TGA, Australia stating following: The percentage of nominal content released are measured at a minimum of three (3) suitably spaced time points (excluding zero time point) to provide a profile for each batch (e.g. at 5, 15, 30 and 45 minutes, or as appropriate to achieve virtually complete dissolution).
Readable batch analysis/COA of imported lots of drug substance by drug substance manufacturer.	Uploaded
Import documents of drug substance like clearance certificates from DRAP I&E section.	Uploaded
Readable valid GMP certificate of drug substance manufacturer.	Uploaded
Analytical method of drug substance by drug substance manufacturer.	Uploaded
Reference for this acceptance limit in dissolution test NLT 80% (Q) in 45 min.	Firm has referred to Guidance document approved by RB in its 293rd meeting stating following: General recommendations of European Directorate for the Quality of Medicines (EDQM) In most cases, when tested under reasonable and justified test conditions, the acceptance criterion at level S1 is that at least 80 per cent of the active substance is released within a specified time, typically 45 min or less. This corresponds to a Q=75%, since, for level S1 the individual value of each of the 6 units tested is not less than Q + 5 per cent, i.e. not less than 80 per cent.

Decision

Approved

Approved

256	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	Kaizen Pharmaceuticals (Pvt) Ltd Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi (000755)
	Application Form Dy. No / Tracking ID & date of submission	(32V-REZ-JVME, 2024-03-13)
	Detail of Fee Submitted	75000.0, 2024-03-04,
	The proposed proprietary name / brand name	Revofen
	Label Claim	Each gram contains: Diclofenac Diethyl Ammonium.....23.2mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100g-As per SRO,20g-As per SRO,30g-As per SRO,50g-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C in a cool and dry place.
	For generic drugs (me-too Status)	Nil
	Pharmacotherapeutic Group of (API)	Analgesic

Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Aarti Drugs Limited
Detail of stability batches of drug product	Submitted for six months as per conditions of zone IVa
Documents for the procurement of API with approval from DRAP (in case of Import)	Loan documents from Platinum Pharma uploaded
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE; Submitted. CDP; Not Applicable
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	submitted as per conditions of zone IV A
The status in reference regulatory authorities	Medicine and Healthcare Products Regulatory Agency (MHRA)
GMP status of the firm	GMP certificate is issued to the firm based upon inspection conducted on 03.01.2023.
Evidence of approval of manufacturing facility	CLB letter No. 2-5/2009-Lic (Vol-II) dated 3rd March 2023 indicate Oral Hygiene (Mouth wash) Semi Solid & Toothpaste

Evaluation Remarks

Some queries of PEC and response of firm is summarized in table below for consideration of Board:

Queries	Response
Submit analytical method validation studies on all parameters excluding LOQ & LOD for drug product as you have submitted only method verification studies (required for pharmacopoeial product) and your product is not pharmacopoeial.	This is in reference to your query regarding the requirement for analytical method validation of Diclofenac Diethylammonium Gel, based on the observation that the product is not listed in any official pharmacopoeia and that only method verification data were submitted. We would like to clarify that Diclofenac Diethylammonium, also referred to as Diclofenac Diethylamine, is in fact listed in the British Pharmacopoeia (BP). The BP includes monographs for both the active pharmaceutical ingredient (API) as well as the topical gel formulation under the name Diclofenac Diethylamine. As confirmed by authoritative references such as PubChem (National Center for Biotechnology Information, NCBI), Diclofenac Diethylammonium and Diclofenac Diethylamine are recognized synonyms and chemically equivalent. In light of this, we respectfully submit that the product should be considered pharmacopoeial. Therefore, method verification is applicable and in line with the guidelines for pharmacopoeial products.
Invoice is not DRAP attested, please submit DRAP attested invoice.	Firm has submitted clearance certificate along with loan documents from platinum Pharma.

Decision

Approved

Approved

257	Case Category	New Section (Haleema Sharif)
	Name, address of Applicant.	Caraway Pharmaceuticals PLOT NO.12, STREET NO.3 NATIONAL INDUSTRIAL ZONE RAWAT, PAKISTAN (000629)
	Application Form Dy. No / Tracking ID & date of submission	(HZZ-796-WDV5, 2025-07-18)
	Detail of Fee Submitted	37000.0, 2025-03-18,
	The proposed proprietary name / brand name	Clonaz 2mg Tablet

Label Claim	Each Tablet Contains: Clonazepam.....2mg (USP Specs)
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	10's, 20's, 30's, 40-As per SRO
Shelf Life (Unit)	2 Year(s)Store Between 15° to 30°C.
For generic drugs (me-too Status)	Magura 2mg Tablet (Registration No. 061631) By SAMI Pharmaceuticals Pvt. Ltd. F-95 Hub River Road S.I.T.E Karachi.
Pharmacotherapeutic Group of (API)	Anxiolytics, Benzodiazepine derivatives
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Cambrex Profarmaco Milano S.r.l. Via Curiel, 34 20067 Paullo, Milano
Detail of stability batches of drug product	Stability Studies of applied formulation as per conditions of zone IV A submitted by firm.
Documents for the procurement of API with approval from DRAP (in case of Import)	Document for Procurement of API clearance certificate is provided by firm. Computerized No. E9880812768367 date of issue 03. July.2024
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence studies and Comparative Dissolution Profile are Provided.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Studies of Drug Substance as per conditions of zone IV A submitted by firm
The status in reference regulatory authorities	Clonazepam Neuraxpharm 2mg Tablets Approved in MHRA
GMP status of the firm	GMP Certificate dated 7th August 2024 is issued to the firm based upon inspection conducted on 31.07.2024.
Evidence of approval of manufacturing facility	Section Approval Letter No. 1-9/2004_Lic(vol-II) dated 4th July 2022 confirming Tablet Psychotropic Section is submitted by firm.

Evaluation Remarks

Some queries of PEC and response of firm is summarized in table below for consideration of Board:

Query	Response
Clarify the matter regarding fee challan (it is for post registration variation not for new product approval) & adjustment of fee challan of Rupee 15000/- Submit Fresh fee OR Fee adjustment approval.	The fee 15000 pkr submitted as fee adjustment fee. The payment 37000 were submitted for some other purpose, so as per DRAP policy we adjusted the fee as registration fee of the drug product registration. Firm has further submitted that their request for fee adjustment is approved vide tracking ID: U52- UQ5- LJLD. However, I cannot verify the request as I cannot open it.

Decision

Approved

Approved

258	Case Category	New Section (Haleema Sharif)
	Name, address of Applicant.	Caraway Pharmaceuticals PLOT NO.12, STREET NO.3 NATIONAL INDUSTRIAL ZONE RAWAT, PAKISTAN (000629)
	Application Form Dy. No / Tracking ID & date of submission	(MZ5-SRE-NSWG, 2025-05-05)

Detail of Fee Submitted	37000.0, 2025-01-09,
The proposed proprietary name / brand name	Prolam 2mg Tablet
Label Claim	Each Tablet contains: Alprazolam.....2mg (USP Specs)
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	10's, 20's, 30's, 40-As per SRO
Shelf Life (Unit)	2 Year(s)Store Between 15° to 30°C.
For generic drugs (me-too Status)	Aloram 2mg Tablet (Registration No. 065309) By Global Pharmaceutical Pvt. Ltd
Pharmacotherapeutic Group of (API)	Benzodiazepine related agents. Used as hypnotics and sedatives
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Cambrex Profarmaco Milano S.r.l. Via Curiel, 34 20067 Paullo, Milano
Detail of stability batches of drug product	Stability Studies of applied formulation as per conditions of zone IV A submitted by firm.
Documents for the procurement of API with approval from DRAP (in case of Import)	Document for Procurement of API clearance certificate is provided by firm. Computerized No. E9880812768367 date of issue 03. July.2024
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence studies and Comparative Dissolution Profile are Provided.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Studies of Drug Substance as per conditions of zone IV A submitted by firm
The status in reference regulatory authorities	Alprazolam 2mg Tablets By M/s JAMP Pharma Corporation Date of Revision: July 24, 2018 1310 rue Nobel Boucherville, Québec J4B 5H3 (Health Canada Approved)
GMP status of the firm	GMP Certificate dated 7th August 2024 is issued to the firm based upon inspection conducted on 31.07.2024.
Evidence of approval of manufacturing facility	GMP Certificate dated 7th August 2024 is issued to the firm based upon inspection conducted on 31.07.2024.
Evaluation Remarks	
Some queries of PEC and response of firm is summarized in table below for consideration of Board:	
Query	Response
In previously submitted CDP study Repot the sampling time points were 10, 20, 30 minutes and now you have submitted a revised report with sampling time points 10,15,20,30 minutes.	Firm has submitted revised report with following time points with four time points 10, 15, 30 and 45 minutes
Decision	
Approved	
Approved	
259 Case Category	Routine (Haleema Sharif)
Name, address of Applicant.	Nabiqasim Industries (Pvt) Ltd., 17/24, Korangi Industrial Area, Karachi. (000105)
Application Form Dy. No / Tracking ID & date of submission	(8ZL-8L5-7U6D, 2024-04-18)
Detail of Fee Submitted	30000.0, 2024-02-19,
The proposed proprietary name / brand name	Valtab 450mg Tablet

Label Claim	Each film coated tablet contains: Valganciclovir Hydrochloride USP eq. to Valganciclovir.....450mg (USP Specifications)
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	7's, 10's, 14's, 20'-As per SRO
Shelf Life (Unit)	2 Year(s)Below 30° C
For generic drugs (me-too Status)	Yes (Valcyte Tablets 450mg by Roche Pakistan Ltd)
Pharmacotherapeutic Group of (API)	Antivirals for systemic use
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	ANHUI HAIKANG PHARMACEUTICAL CO. LTD
Detail of stability batches of drug product	Provided as per conditions of Zone IVA for six months
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has uploaded in Module I DRAP attested invoice
Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided as per conditions of Zone IVA
The status in reference regulatory authorities	Approved in USFDA, Valcyte tablets by Roche Pharmaceuticals New Jersey.
GMP status of the firm	GMP certificate issued to the firm based on inspection conducted on 22.05.2022.
Evidence of approval of manufacturing facility	CLB letter No. 2-20/85-Lic Vol-5 dated 27th April 2020 confirms Capsule General section.

Evaluation Remarks

Queries of PEC and response of firm is summarized in table below for consideration of Board:

Queries	Response
GMP certificate of drug substance manufacturer is by Anqing Biomedical Industry Association not by Anhui Provincial Drug Administration.	Firm has submitted Drug Manufacturing License of drug substance manufacturer issuing authority Anhui Provincial Drug Administration.
In COA residual solvents have not been mentioned or tested.	Firm has submitted new COA of batch No. C005025091401 indicating test for residual solvents with limits/specifications and results shows compliance to specifications.

Decision

Approved

Approved

260	Case Category	Export Facilitation (Haleema Sharif)
	Name, address of Applicant.	Bosch Pharmaceuticals (Pvt) Ltd. Plot No. 221-223, Sector-23, Korangi Industrial Area (000350)
	Application Form Dy. No / Tracking ID & date of submission	(9LW-1G8-HZGD, 2024-09-02)
	Detail of Fee Submitted	30000.0, 2024-08-02,
	The proposed proprietary name / brand name	Entron Injection 8 mg / 4 ml
	Label Claim	Each 4ml ampoule contains: Ondansetron Hydrochloride (as Dihydrate) USP equivalent to Ondansetron.....8mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's -As per SRO

Shelf Life (Unit)	2 Year(s)Store below 30°C
For generic drugs (me-too Status)	Onseget Injection 8mg/4ml , M/s Getz Pharma Pakistan (Pvt.) Ltd.
Pharmacotherapeutic Group of (API)	Anti-Emetic
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	CTX LIFESCIENCES (Pvt) Ltd. Block No. 251-252 Sachin-Magdalla Road GIDC, Sachin, Surat-394 230, Gujarat, INDIA.
Detail of stability batches of drug product	Provide as per conditions of zone IV b for six months
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted import license
Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided as per conditions of Zone IVB
The status in reference regulatory authorities	Approved in Health Products Regulatory Authority (HPRA) & MHRA
GMP status of the firm	Compliant
Evidence of approval of manufacturing facility	available

Evaluation Remarks

Queries of PEC and Response of firm is summarized in the table below:

Queries	Response
Commercial invoice is not DRAP attested.	The material was cleared from the customs on the basis of the Drug Import License (DIL).
Stability studies of drug substance as per conditions of zone IVA if not available comply following instructions as mentioned in guideline: · In case where the real time stability data of drug substance is conducted at 25°C ± 2°C/60% RH ±5% RH, the firm shall submit the record of data logger for the storage conditions throughout the transportation. · Moreover, in case of use of ingredients whose stability testing has not been done as per Zone IVA, then the manufacturer of finished pharmaceutical product, shall submit real term stability studies data of the product for at least 1 year along with degradation studies in the finished pharmaceutical product.	Firm has submitted stability studies of drug substance as per conditions of Zone IVb.
Clarification from drug substance manufacturer regarding difference in address on GMP certificate and submitted dossier along with supportive document from concerned regulatory Authority (if any) please. Address on technical documents: M/s. CTX Lifesciences Pvt. Ltd. Block No. 251-252 Sachin-Magdalla Road GIDC, Sachin, Surat – 394 230 Gujarat, INDIA Address on GMP certificate: M/s. CTX Lifesciences Pvt. Ltd. Block No. 251 / P, 252/ P,253 TO 255, 256 / P,258 / P,276 / P,277, 278 / P,279 TO 282, 283 / P, 284 / P GIDC. City-Sachin-DIST. - Surat – 394 230 Gujarat State, INDIA.	We have been informed by M/s. CTX LIFESCIENCES Pvt. Ltd. through letter No. dated 03 June 2025 that the short address “Block No. 251-252 Sachin-Magdalla Road GIDC, Sachin, Surat-394 230, Gujarat, INDIA” which represents their company’s factory main entrance as a general practice for the ease of understanding and convenience of correspondence/contact purpose. As there is no addition or deletion of plots/blocks, therefore it will not impact on the quality of the drug substance. M/s. CTX LIFESCIENCES Pvt. Ltd is in the process of harmonization of the address on all technical documents in line with the Manufacturing License and WHO-GMP certificate

document. This harmonization shall be completed by next 6 months.

Decision

Approved

Approved

261	Case Category	Export Facilitation (Haleema Sharif)
	Name, address of Applicant.	Bosch Pharmaceuticals (Pvt) Ltd. Plot No. 221-223, Sector-23, Korangi Industrial Area (000350)
	Application Form Dy. No / Tracking ID & date of submission	(RX3-QTM-4HLM, 2025-02-10)
	Detail of Fee Submitted	37000.0, 2024-11-12,
	The proposed proprietary name / brand name	Entron Tablet 8mg
	Label Claim	Each film coated tablet contains Ondansetron HCl Dihydrate equivalent to Ondansetron 8mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's, 20's 30's, 40'-As per SRO
	Shelf Life (Unit)	36 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Onseget (Ondansetron) Tablet 8mg by M/s Getz Pharma (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Anti-Emetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CTX Lifesciences Pvt.Ltd. situated at Block no. 251-252 Sachin- Magdalla Road, GIDC, Sachin, Surat-394 230, Gujrat, India
	Detail of stability batches of drug product	provided
	Documents for the procurement of API with approval from DRAP (in case of Import)	The material was cleared on the basis of Import License as per firm's claim.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	provided
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
	The status in reference regulatory authorities	Approved in MHRA
	GMP status of the firm	GMP Certification is issued to the firm based on inspection conducted on 25.04.2024.
	Evidence of approval of manufacturing facility	CLB letter No. 2-4/2010-Lic (Vol-I) dated 30th June 2020 indicate tablet General Section I & II.

Evaluation Remarks

Queries of PEC and Response of firm is summarized in the table below:

Queries	Response
Commercial invoice is not DRAP attested.	The material was cleared from the customs on the basis of the Drug Import License (DIL).
Stability studies of drug substance as per conditions of zone IVA if not available comply following instructions as mentioned in guideline: · In case where the real time stability data of drug substance is conducted at 25°C ± 2°C/60% RH ±5% RH, the firm shall submit the record of data logger for the storage conditions throughout the transportation. · Moreover, in	Firm has submitted stability studies of drug substance as per conditions of Zone IVb.

	case of use of ingredients whose stability testing has not been done as per Zone IVA, then the manufacturer of finished pharmaceutical product, shall submit real term stability studies data of the product for at least 1 year along with degradation studies in the finished pharmaceutical product.	
	Address on dossier is CTX Lifesciences Pvt. Ltd. Block No. 251-252 Sachin- Magdalla Road GIDC, Sachin, Surat – 394 230 Gujarat, INDIA & while address on GMP certificate is CTX Lifesciences Pvt. Ltd. Block No. 251 / P, 252/ P, 253 TO 255, 256 / P, 258 / P, 276 / P, 277, 278 / P, 279 TO 282, 283 / P, 284 / P GIDC. City-Sachin- DIST. - Surat – 394 230 Gujarat State, INDIA. Please clarify that Block No 251-252 on dossier and Block No. 251/P, 252/P on GMP Certificate are similar along with documented evidence if any OR a statement from concerned regulatory authority of country of origin.	We have been informed by M/s. CTX LIFESCIENCES Pvt. Ltd. through letter No. dated 03 June 2025 that the short address “Block No. 251-252 Sachin-Magdalla Road GIDC, Sachin, Surat-394 230, Gujarat, INDIA” which represents their company’s factory main entrance as a general practice for the ease of understanding and convenience of correspondence/contact purpose. As there is no addition or deletion of plots/blocks, therefore it will not impact on the quality of the drug substance. M/s. CTX LIFESCIENCES Pvt. Ltd is in the process of harmonization of the address on all technical documents in line with the Manufacturing License and WHO-GMP certificate document. This harmonization shall be completed by next 6 months.
Decision		
Approved		
Approved		
262	Case Category	New Section (Haleema Sharif)
	Name, address of Applicant.	Hi-Med Pharmaceuticals 208C Sundar industrial estate Raiwind Road Lahore (000884)
	Application Form Dy. No / Tracking ID & date of submission	(96G-R9M-WYGE, 2025-07-17)
	Detail of Fee Submitted	37000.0, 2025-05-14,
	The proposed proprietary name / brand name	Painzol Injection 30mg/ml
	Label Claim	Each 1ml Ampule contains: Ketorolac Tromethamine.....30mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1ml x 5Ampule-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at below 25 degree celcius
	For generic drugs (me-too Status)	TORADOL INJECTION 30MG/ML (MARTIN DOW)
	Pharmacotherapeutic Group of (API)	Non-steroidal anti-inflammatory drug (NSAID)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Satyadivis Pharmaceuticals Pvt. Ltd.
	Detail of stability batches of drug product	Attached
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted loan letter by MedPharm
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached

Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached
The status in reference regulatory authorities	TORADOL INJECTION 30MG/ML (ATNAHS PHARMA UK Ltd)
GMP status of the firm	GMP Certificate attached (Valid till 22-09-2027)
Evidence of approval of manufacturing facility	Drug Manufacturing Liscence attached (000884)

Evaluation Remarks

Queries of PEC and Response of firm is summarized in the table below for consideration of the Board:

Queries	Response
In analytical method of drug substance injection volume is 10µl while on chromatograms of analytical method validation studies injection volume is 100µl. please make it clear.	Firm has submitted revised chromatograms with 10µl Injection volume as mentioned in analytical method.
Drug excipient compatibility studies by drug product manufacturer .	In assay of drug excipient compatibility studies Injection volume both in method and chromatograms still 100µl
Uploaded stability studies as per conditions of Zone IV A seems fake/ copy of previously uploaded studies. if FPP don't have stability studies of drug substance as per conditions of zone IVA please comply following instruction mentioned in CTD guidance document available on DRAP site: In case where the real time stability data of drug substance is conducted at 25°C ± 2°C/60% RH ±5% RH, the firm shall submit the record of data logger for the storage conditions throughout the transportation. Moreover, in case of use of ingredients whose stability testing has not been done as per Zone IVA, then the manufacturer of finished pharmaceutical product, shall submit real term stability studies data of the product for at least 1 year along with degradation studies in the finished pharmaceutical product.	Firm has stability studies of three batches as per conditions of Zone IVa

Decision

Deferred

Registration Board deferred the case for Product Specific Inspection by panel constituted by Chairman Registration Board.

263	Case Category	New Section (Haleema Sharif)
	Name, address of Applicant.	Hi-Med Pharmaceuticals 208C Sundar industrial estate Raiwind Road Lahore (000884)
	Application Form Dy. No / Tracking ID & date of submission	(DVG-8EL-9GVR, 2025-07-17)
	Detail of Fee Submitted	37000.0, 2025-05-14,
	The proposed proprietary name / brand name	Painzol Injection 10mg/ml
	Label Claim	Each 1ml Ampoule contains: Ketorolac Tromethamine.....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 x 5's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at below 25 degree celcius
	For generic drugs (me-too Status)	Monak Injection 10mg/ml (English Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	Non-steroidal anti-inflammatory drug (NSAID)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Satyadivis Pharmaceuticals Pvt. Ltd.
	Detail of stability batches of drug product	Attached

Documents for the procurement of API with approval from DRAP (in case of Import)	Loan documents by Med Pharma Are submitted by firm
Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached
The status in reference regulatory authorities	TORADOL INJECTION 10MG/ML (ATNAHS PHARMA UK Ltd)
GMP status of the firm	GMP Certificate attached (Valid till 22-09-2027)
Evidence of approval of manufacturing facility	Drug Manufacturing Liscence attached (000884)

Evaluation Remarks

Some of queries of PEC and Response of firm is summarized in the table below for consideration of the Board:

Queries	Response
In analytical method of drug substance injection volume is 10µl while on chromatograms of analytical method validation studies injection volume is 100µl. please make it clear.	Firm has submitted revised chromatograms with 10µl Injection volume as mentioned in analytical method.
Drug excipient compatibility studies by drug product manufacturer .	In assay of drug excipient compatibility studies Injection volume both in method and chromatograms still 100µl
Uploaded stability studies as per conditions of Zone IV A seems fake/ copy of previously uploaded studies. if FPP don't have stability studies of drug substance as per conditions of zone IVA please comply following instruction mentioned in CTD guidance document available on DRAP site: In case where the real time stability data of drug substance is conducted at 25°C ± 2°C/60% RH ±5% RH, the firm shall submit the record of data logger for the storage conditions throughout the transportation. Moreover, in case of use of ingredients whose stability testing has not been done as per Zone IVA, then the manufacturer of finished pharmaceutical product, shall submit real term stability studies data of the product for at least 1 year along with degradation studies in the finished pharmaceutical product.	Firm has stability studies of three batches as per conditions of Zone IVa

Decision

Deferred

Registration Board deferred the case for Product Specific Inspection by panel constituted by Chairman Registration Board.

264	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Biogen PHarma 8-KM, Chak Beli Road, Rawat, (000639)
	Application Form Dy. No / Tracking ID & date of submission	(8R8-ZJW-2UVQ, 2025-01-08)
	Detail of Fee Submitted	75000.0, 300000.0 2024-04-04, 2024-12-20
	The proposed proprietary name / brand name	Tamstone-D Capsule
	Label Claim	Each hard gelatin capsule contains: Dutasteride (as soft gelatin capsule) 0.5 mg Tamsulosin hydrochloride (as modified release pellets) 0.4 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x10's-As per SRO

	Shelf Life (Unit)	3 YearRoom Condition
	For generic drugs (me-too Status)	Maxflow-D Capsule by CCL Pharmaceuticals (Pvt.) Ltd
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Biogen Life Science -8-km, Chakbeli Road, Rawat, Rawalpindi -
	The status in reference regulatory authorities	Dutasteride/Tamsulosin hydrochloride 0.5 mg / 0.4 mg hard capsules Milpharm Limited Medicines and H
	Detail of previous approval	335th RB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
265	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Steris Pharmaceuticals Plot No 9 Near Synpac Hattar Private Industrial Estate Haripur Road Hattar (000995)
	Application Form Dy. No / Tracking ID & date of submission	(U19-9VU-3263, 2025-02-12)
	Detail of Fee Submitted	75000.0, 18000.0 2024-09-02, 2024-10-17
	The proposed proprietary name / brand name	Isotin
	Label Claim	Each Soft Gel Capsule Contain: Isotretinoin 10mg (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Yes
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Biogen Life Sciences- 8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	https://www.medicines.org.uk/emc/product/12130/smpc#g
	Detail of previous approval	Biotin Softgel Capsules /312th Registration Board Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
266	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)

	Application Form Dy. No / Tracking ID & date of submission	(9VP-3WJ-5AN8, 2025-03-12)
	Detail of Fee Submitted	93000.0, 2024-11-19,
	The proposed proprietary name / brand name	DUTAFLOW SOFTGEL CAPSULE
	Label Claim	Each hard gelatin capsule contains: Dutasteride (as soft gelatin capsule) 0.5 mg Tamsulosin hydrochloride (as modified release pellets) 0.4 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO -As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Maxflow-D Capsule(CCL Pharmaceuticals (Pvt.) Ltd.)091571
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Dutasteride/Tamsulosin hydrochloride 0.5 mg / 0.4 mg hard capsules(Milpharm Limited)(Medicines and Healthcare products Regulatory Agency (MHRA))
	Detail of previous approval	335th meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
267	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Amarant Pharmaceuticals Private Limited 158 D. Tore, Gadap Road, Super Highway, Karachi (000584)
	Application Form Dy. No / Tracking ID & date of submission	(2SL-Q9B-Y6HA, 2025-03-20)
	Detail of Fee Submitted	93000.0, 2024-11-07,
	The proposed proprietary name / brand name	Biodronic
	Label Claim	Each 100ml vial contains: Zoledronic acid as monohydrate.....5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1-As per SRO
	Shelf Life (Unit)	2 Year15 - 30 degree celsius
	For generic drugs (me-too Status)	Zometa infusion
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Biogen Life Sciences-8-Km, Chakbeli Road, Rawat-
	The status in reference regulatory authorities	ZOLEDRONIC ACID 5MG/100ML SOLUTION FOR INFUSION MHRA Approved
	Detail of previous approval	Gen-Zole 5mg/100ml infusion,333
	Evaluation Remarks	

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

268	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Amarant Pharmaceuticals Private Limited 158 D. Tore, Gadap Road, Super Highway, Karachi (000584)
	Application Form Dy. No / Tracking ID & date of submission	(48Y-YJP-XN5L, 2025-03-20)
	Detail of Fee Submitted	93000.0, 2024-11-07,
	The proposed proprietary name / brand name	Merop 2g injection
	Label Claim	Each vial contains: Meropenem trihydrate eq. to meropenem.....2g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1-As per SRO
	Shelf Life (Unit)	2 Year15 - 30 degree celsius
	For generic drugs (me-too Status)	Memem Injection of Global Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Biogen Life Sciences-8Km, Chakbeli Road Rawat, Rawalpindi-
	The status in reference regulatory authorities	Merrem Injection (USFDA Approved)
	Detail of previous approval	Mi-Penem injection 2g, 335
269	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Solaris Life Sciences Private Limited , Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992)
	Application Form Dy. No / Tracking ID & date of submission	(RUL-S9R-UH5Q, 2025-03-20)
	Detail of Fee Submitted	93000.0, 2024-11-28,
	The proposed proprietary name / brand name	TAGLINE-50MG INJECTION IV
	Label Claim	Each Vial Contains: Tigecycline.....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C

	For generic drugs (me-too Status)	M/s Pfizer Pharma, Tygacil-50mg Injection, Reg. No. 045642
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Biogen Life Sciences-8-KM, Chakbeli Road, Rawat, Rawalpindi-PAKISTAN.-
	The status in reference regulatory authorities	Tygacil 50mg powder for solution for Infusion of M/s Pfizer Limited, UK (MHRA Approved)
	Detail of previous approval	Tygagen 50mg Injection (DRB M-339)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
270	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Amarant Pharmaceuticals Private Limited 158 D. Tore, Gadap Road, Super Highway, Karachi (000584)
	Application Form Dy. No / Tracking ID & date of submission	(PPA-GTR-TB2V, 2025-01-31)
	Detail of Fee Submitted	93000.0, 2024-11-07,
	The proposed proprietary name / brand name	Carfer 50mg injection
	Label Claim	Each 10ml vial contains: Ferric carboxymaltose equivalent to elemental iron 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5-As per SRO
	Shelf Life (Unit)	2 Year15 - 30 degree celsius
	For generic drugs (me-too Status)	Frotox 50mg/ml Injection
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Biogen Life Sciences-8Km, Chakbeli Road Rawat, Rawalpindi-
	The status in reference regulatory authorities	Ferinject Dispersion for Injection/Infusion is Approved in MHRA
	Detail of previous approval	IROGEN 50MG/ML INJECTION,339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
271	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Amarant Pharmaceuticals Private Limited 158 D. Tore, Gadap Road, Super Highway, Karachi (000584)

Application Form Dy. No / Tracking ID & date of submission	(B1R-RT9-W13Q, 2025-01-31)
Detail of Fee Submitted	93000.0, 2024-11-07,
The proposed proprietary name / brand name	Emess 40mg injection
Label Claim	Each vial contains: Esomeprazole.....40mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1-As per SRO
Shelf Life (Unit)	2 Year15 - 30 degree celsius
For generic drugs (me-too Status)	Nexum injection by Getz
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Biogen Life Sciences-8Km, Chakbeli Road Rawat, Rawalpindi-
The status in reference regulatory authorities	Nexium injection by AstraZeneca
Detail of previous approval	Esogen injection,312

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

272	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Amarant Pharmaceuticals Private Limited 158 D. Tore, Gadap Road, Super Highway, Karachi (000584)
	Application Form Dy. No / Tracking ID & date of submission	(77H-P6E-9AN9, 2025-01-31)
	Detail of Fee Submitted	93000.0, 2024-11-07,
	The proposed proprietary name / brand name	G-cal 7.5mg injection
	Label Claim	Each 1ml ampoule Contains: Cholecalciferol.....7.5mg (300000IU)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1-As per SRO
	Shelf Life (Unit)	2 Year15 - 30 degree celsius
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Biogen Life Sciences-8Km, Chakbeli Road Rawat, Rawalpindi-
	The status in reference regulatory authorities	AIFA Italy Approved
	Detail of previous approval	3D Injection 7.5mg/mL (Oral / IM),335

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

	Decision	
	Approved	
273	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Amarant Pharmaceuticals Private Limited 158 D. Tore, Gadap Road, Super Highway, Karachi (000584)
	Application Form Dy. No / Tracking ID & date of submission	(1JQ-ZR6-REUN, 2025-03-20)
	Detail of Fee Submitted	93000.0, 2024-11-07,
	The proposed proprietary name / brand name	Merop 500mg injection
	Label Claim	Each vial contains: Meropenem trihydrate eq to meropenem 500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1-As per SRO
	Shelf Life (Unit)	2 Year15 - 30 degree celsius
	For generic drugs (me-too Status)	Memem Injection of Global Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Biogen Pharmaceuticals-8-Km, Chakbeli Road, Rawat-
	The status in reference regulatory authorities	Merrem Injection (USFDA Approved)
	Detail of previous approval	MEROGEN Injection 500mg,312
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
274	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Amarant Pharmaceuticals Private Limited 158 D. Tore, Gadap Road, Super Highway, Karachi (000584)
	Application Form Dy. No / Tracking ID & date of submission	(UQ3-6EV-457S, 2025-03-20)
	Detail of Fee Submitted	93000.0, 2024-11-07,
	The proposed proprietary name / brand name	Merop 1g injection
	Label Claim	Each vial contains: Meropenem trihydrate eq. to meropenem.....1g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1-As per SRO
	Shelf Life (Unit)	2 Year15 - 30 degree celsius
	For generic drugs (me-too Status)	Memem Injection of Global Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Biogen Pharmaceuticals-8-Km, Chakbeli Road, Rawat-
	The status in reference regulatory authorities	Merrem Injection (USFDA Approved)
	Detail of previous approval	MEROGEN Injection 1g,312
	Evaluation Remarks	

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

275	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welwrd Pharmaceuticals Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar (000574)
	Application Form Dy. No / Tracking ID & date of submission	(UL3-G53-X8AD, 2025-03-10)
	Detail of Fee Submitted	75000.0, 18000.0 2024-06-24, 2025-02-21
	The proposed proprietary name / brand name	HY-KOR 250mg Injection
	Label Claim	Each Vial Contains: Hydrocortisone equivalent Hydrocortisone Sodium Succinate (USP).....250mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year20-25C
	For generic drugs (me-too Status)	CORTISONE 250MG INJECTION by VISION PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wenovo Pharmaceuticals-PLOT No. 31-32, PUNJAB SMALL INDUSTRIAL ESTATE, TAXILA, Rawalpindi.-
	The status in reference regulatory authorities	USFDA approved
	Detail of previous approval	HY?KOR 250MG sterile powder for injection approved in 339 DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
276	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winbrains Research Laboratories Plot No. 69/1 Block B, Phase I-II Industrial Estate, Hattar, Pakistan (000725)
	Application Form Dy. No / Tracking ID & date of submission	(887-PLT-2936, 2025-04-05)
	Detail of Fee Submitted	75000.0, 18000.0 2024-06-26, 2025-02-21
	The proposed proprietary name / brand name	Methyll 500mg Injection

	Label Claim	Each Vial Contains: Methylprednisolone as Sodium Succinate (USP).....500Mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C.
	For generic drugs (me-too Status)	Solu Medrol injection by Pfizer
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wenovo Pharmaceuticals-Plot No. 31 & 32, Punjab Small Industrial Estate, Taxila, Rawalpindi-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Methyll 500mg Injection approved in M-339 DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
277	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Athan Pharmaceuticals Plot # 84/2,Block A, Phase 5 , Industrial Estate Hattar, KPK, (000900)
	Application Form Dy. No / Tracking ID & date of submission	(16B-77P-G3Y6, 2025-07-29)
	Detail of Fee Submitted	93000.0, 2025-07-23,
	The proposed proprietary name / brand name	Silden 100 mg Tabs
	Label Claim	Each Film Coated Tablet Contains: Sildenafil as Citrate (USP).....100mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Siltrate 100 mg Tablet by Weather Fold pharmaceuticals
	Pharmacotherapeutic Group of (API)	Drug used in erectile dysfunction
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK.-
	The status in reference regulatory authorities	Approved by UK MHRA https://www.medicines.org.uk/emc/product/13880/smpc#g
	Detail of previous approval	Siltrate 100 mg Tablet, DRB 345
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

Approved

278	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winlet Pharmaceuticals (Pvt) Ltd. 30-Km, Lahore Sargodha Raod, Sargodha (000874)
	Application Form Dy. No / Tracking ID & date of submission	(1NH-PUW-ZBWW, 2025-04-08)
	Detail of Fee Submitted	93000.0, 2024-10-21,
	The proposed proprietary name / brand name	Betalet
	Label Claim	Each gm contains: Terbinafine HCl.....10.0mg
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	1,s-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 °C
	For generic drugs (me-too Status)	Lamisil Cream
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Biogen life sciences -8-km chakbeli road rawat Rawalpindi-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	M-313
Evaluation Remarks		
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.		
Decision		
Approved		
279	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Steris Pharmaceuticals Plot No 9 Near Synpac Hattar Private Industrial Estate Haripur Road Hattar (000995)
	Application Form Dy. No / Tracking ID & date of submission	(1PA-AYP-RDBY, 2025-07-18)
	Detail of Fee Submitted	93000.0, 2025-03-13,
	The proposed proprietary name / brand name	Famoris Dry Suspension
	Label Claim	Each 5ml contains: Femotidine.....40mg (USP Spec's)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 25
	For generic drugs (me-too Status)	Yes
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd-Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, Rawalpindi-Pakistan-
	The status in reference regulatory authorities	Registered in USA.

Detail of previous approval	Famodin 40mg/5ml Dry Suspension, Minutes of 344th meeting of Registration Board

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

280	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	UniMark Pharmaceuticals Pvt. Ltd. Plot No. 7-A, Street No. S-7, National Industrial Zone, Rawat (000557)
	Application Form Dy. No / Tracking ID & date of submission	(1S5-H6T-MXAH, 2025-07-22)
	Detail of Fee Submitted	93000.0, 2025-04-11,
	The proposed proprietary name / brand name	Azil 40mg Tablet
	Label Claim	Each uncoated tablet contains Azilsartan Medoxomil Potassium eq. to Azilsartan Medoxomil 40mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30s-As per SRO
	Shelf Life (Unit)	2 Year 15° to 30°C
	For generic drugs (me-too Status)	Azilazon Tablets of M/S Horizon Pharma
	Pharmacotherapeutic Group of (API)	Angiotensin Receptor Blocker (ARB)
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot #122, Block A, Phase V, Industrial Estate, Hattar, Haripur, KPK -
	The status in reference regulatory authorities	Edarbi tablet of M/S Takeda pharma FDA Approved
	Detail of previous approval	DRAP Meeting No M-326
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
281	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Steris Pharmaceuticals Plot No 9 Near Synpac Hattar Private Industrial Estate Haripur Road Hattar (000995)
	Application Form Dy. No / Tracking ID & date of submission	(1X9-ZP8-1J1E, 2025-07-18)
	Detail of Fee Submitted	93000.0, 2025-03-13,
	The proposed proprietary name / brand name	PROSEC-S
	Label Claim	Each Sachet contains: Omeprazole 20mg Sodium bicarbonate 1680mg (Innovator Spec's)

Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 YearBelow 25
For generic drugs (me-too Status)	Yes
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd-Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, Rawalpindi-Pakistan-
The status in reference regulatory authorities	SRA , https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=021636
Detail of previous approval	OME 20mg+1680mg Sachet, Minutes of 344th meeting of Registration Board

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

282	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Effort Pharmaceuticals (Pvt.) Ltd., 28-Km, Ferozepur Road (000879)
	Application Form Dy. No / Tracking ID & date of submission	(218-SLM-64AS, 2025-07-25)
	Detail of Fee Submitted	93000.0, 2025-06-20,
	The proposed proprietary name / brand name	Efitrax 250mg IM Injection
	Label Claim	Each vial contains: Ceftriaxone Sodium equivalent to Ceftriaxone 250 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C and dry place.
	For generic drugs (me-too Status)	Brand Name: Rocephin. Manufacturer: M/s Martin Dow
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Name, address of Manufacturing site:	High-Cure Research Laboratories. -19 KM Tayyaba Industrial Zone Sheikhpura Road Lahore, Punjab, Pakistan.-
	The status in reference regulatory authorities	USFDA approved Rocephin
	Detail of previous approval	Minutes of 331st Meeting of Registration Board held on 31st Oct – 2nd Nov, 2023 Page 3391
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	

	Decision	
	Approved	
283	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	linear pharma plot # 18 street # s-4 national industrial zone (rcci) rawat islamabad (000670)
	Application Form Dy. No / Tracking ID & date of submission	(22G-9B9-JQ7M, 2025-07-30)
	Detail of Fee Submitted	75000.0, 18000.0 2024-08-26, 2025-05-20
	The proposed proprietary name / brand name	PERISET 4mg/5ml Syrup
	Label Claim	Each 5ml contains: Ondansetron (as hydrochloride dihydrate).....4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50ml-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature.
	For generic drugs (me-too Status)	Zofran syrup by GSK
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-
	The status in reference regulatory authorities	Zofran oral solution by GSK
	Detail of previous approval	Apron 4mg/5ml syrup (Meeting # 316th)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
284	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Swiss Pharmaceuticals Pvt. Ltd. A/159, S.I.T.E.-II, Super Highway (000438)
	Application Form Dy. No / Tracking ID & date of submission	(2PT-HTE-DAWQ, 2025-07-29)
	Detail of Fee Submitted	93000.0, 2025-07-28,
	The proposed proprietary name / brand name	Silda 100mg Tablet
	Label Claim	Each film coated tablet contains: Sildenafil Citrate 140.45 mg eq. to sildenafil.....100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Brand name: Ripple 100mg Tablet, Manufacturer/Registration holder: Solaris Life Sciences, Approved in 345th DRB meeting
	Pharmacotherapeutic Group of (API)	Selective inhibitor of cyclic GMP-specific phosphodiesterase (Type V) with vasodilator action; Urologicals; Drugs used in erectile dysfunction.

	Name, address of Manufacturing site:	M/s SOLARIS LIFE SCIENCES (PVT.) LTD,-Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, Rawalpindi-PAKISTAN.-
	The status in reference regulatory authorities	Brand Name: Viagra 100mg Tablet MAH: VIATRIS I Thawra st.Almaza Cairo Egypt Approved by: US FDA Approved
	Detail of previous approval	RIPPLE 100MG TABLETS, 345th meeting of Registration Board (19th – 21st February, 2025)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
285	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Panacea Pharmaceuticals plot No 04,Street S-6 National industrial Zone RCCI rawat islamabad (000600)
	Application Form Dy. No / Tracking ID & date of submission	(2YM-A6S-D339, 2025-07-28)
	Detail of Fee Submitted	93000.0, 2025-07-22,
	The proposed proprietary name / brand name	Tegson 50mg Injection
	Label Claim	Each vial contains: Tigecycline (Lyophilized Powder) 50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Tygacil 50mg Injection, Wyeth Pakistan Limited
	Pharmacotherapeutic Group of (API)	Antibacterial Agent
	Name, address of Manufacturing site:	Bio-Labs (Pvt.) Ltd.-Plot No. 145,Industrial Triangle Kahuta Road Islamabad- Pakistan-
	The status in reference regulatory authorities	FDA approve drug.
	Detail of previous approval	Bactecil 50mg Injection IV, 330th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
286	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	UniMark Pharmaceuticals Pvt. Ltd. Plot No. 7-A, Street No. S-7, National Industrial Zone, Rawat (000557)

Application Form Dy. No / Tracking ID & date of submission	(31D-VLN-136R, 2025-07-22)
Detail of Fee Submitted	93000.0, 2025-04-11,
The proposed proprietary name / brand name	Azil 80mg Tablet
Label Claim	Each uncoated tablet contains: Azilsartan medoxomil Potassium eq. to Azilsartan Medoxomil 80mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	30s-As per SRO
Shelf Life (Unit)	2 Year15° to 30°C
For generic drugs (me-too Status)	Azilazon tablet by M/S Horizon Pharma
Pharmacotherapeutic Group of (API)	Angiotensin Receptor Blocker (ARB)
Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot #122, Block A, Phase V, Industrial Estate, Hattar, Haripur, KPK-
The status in reference regulatory authorities	Edarbi tablet of M/S Takeda pharma FDA Approved
Detail of previous approval	DRAP Meeting No M-326

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

287	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Nicholas Pharmaceuticals Plot 34, Street SS-2, National Industrial Zone, Rawat (000886)
	Application Form Dy. No / Tracking ID & date of submission	(365-2GA-LXLW, 2025-07-29)
	Detail of Fee Submitted	93000.0, 2025-07-25,
	The proposed proprietary name / brand name	VIGA 25mg Tablets
	Label Claim	Each Film coated tablet contains: Sildenafil as citrate 25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year25°C
	For generic drugs (me-too Status)	Ripple 25mg Tablets
	Pharmacotherapeutic Group of (API)	Rakshit Drugs PVT LTD
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd.-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	Viagra 25mg Tablet
	Detail of previous approval	Ripple 25mg Tablets, M345

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other

conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

288	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Pine Pharmaceuticals Plot No, 40, S-4, Rawat Industrial Estate, Islamabad (000955)
	Application Form Dy. No / Tracking ID & date of submission	(3H5-62B-HQDY, 2025-07-29)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	Sildicell 50mg Tablets
	Label Claim	Each film coated Tablet contains: Sildenafil Citrate 70.225 mg eq. to sildenafil 50mg (USP Spec's.)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	New Molecule
	Pharmacotherapeutic Group of (API)	Selective inhibitor of cyclic GMP-specific phosphodiesterase (Type V) with vasodilator action; Urologicals; Drugs used in erectile dysfunction.
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd.-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	Viagra 50mg Tablet of VIATRIS US FDA Approved
	Detail of previous approval	345th Meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
289	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Dyson Research Laboratories (Pvt.) Ltd 28-Km Ferozpur Road Lahore (000559)
	Application Form Dy. No / Tracking ID & date of submission	(427-A8N-RZSD, 2025-06-27)
	Detail of Fee Submitted	93000.0, 2025-02-14,
	The proposed proprietary name / brand name	Clinso
	Label Claim	Each ml contains: Clindamycin Phosphate eq. to Clindamycin 10mg.
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	30mL-As per SRO
	Shelf Life (Unit)	2 YearStore below 25C.
	For generic drugs (me-too Status)	Kleocin Topical Lotion by Himont Pharmaceutical (Pvt.) Ltd.

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Labs (Pvt.) Ltd.-Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad.-
	The status in reference regulatory authorities	Clindamycin Phosphate by FOUGERA PHARMS, approved in United States agency for Food and Drug Administration (USFDA).
	Detail of previous approval	C-Mycin Lotion 1% (Clindamycin as Phosphate), approved in Minutes of 335th meeting of Registration
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
290	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Effort Pharmaceuticals (Pvt.) Ltd., 28-Km, Ferozepur Road (000879)
	Application Form Dy. No / Tracking ID & date of submission	(45Q-LL8-QGZW, 2025-07-25)
	Detail of Fee Submitted	93000.0, 2025-06-20,
	The proposed proprietary name / brand name	Efitrax Injection 500mg IM
	Label Claim	Each vial contains: Ceftriaxone Sodium equivalent to Ceftriaxone 500 mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C and dry place.
	For generic drugs (me-too Status)	Brand Name: Rocephin. Manufacturer: M/s Martin Dow
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Name, address of Manufacturing site:	High-Cure Research Laboratories. -19 KM Tayyaba Industrial Zone Sheikhpura Road Lahore, Punjab, Pakistan.-
	The status in reference regulatory authorities	USFDA approved Rocephin
	Detail of previous approval	Minutes of 331st Meeting of Registration Board held on 31st Oct – 2nd Nov, 2023 page no:3388
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
291	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

Name, address of Applicant.	GT Pharma Pvt. Ltd 713- Sundar Industrial Estate, Sundar Raiwind Road, (000829)
Application Form Dy. No / Tracking ID & date of submission	(45V-XDR-W1V2, 2025-05-26)
Detail of Fee Submitted	93000.0, 2025-01-27,
The proposed proprietary name / brand name	Silagra 50mg Tablet
Label Claim	Each film coated tablet contains: Sildenafil (as citrate) 50mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	4's-As per SRO
Shelf Life (Unit)	2 YearControlled Room
For generic drugs (me-too Status)	Viagra 50mg Tablet
Pharmacotherapeutic Group of (API)	phosphodiesterase-5 (PDE-5) inhibitors
Name, address of Manufacturing site:	Gray's Pharmaceuticals-Plot No. 2, Street No. N-3, National Industrial Zone Rawat-
The status in reference regulatory authorities	US-FDA
Detail of previous approval	Seldem 50mg Tablet approved in 345th Registration Board Meeting

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

292	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	MEDPHARM RESEARCH LAB 28 KM FEROPUR ROAD LAHORE (000878)
	Application Form Dy. No / Tracking ID & date of submission	(4DB-WY9-YL2X, 2025-07-09)
	Detail of Fee Submitted	75000.0, 18000.0 2024-05-08, 2024-11-25
	The proposed proprietary name / brand name	Citomed 1g
	Label Claim	Each 4ml Contains: CITICOLINE AS SODIUM.= 1g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per DPC-As per SRO
	Shelf Life (Unit)	2 Yearbelow 24 degree
	For generic drugs (me-too Status)	Citolin 1g
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	May & Baker Pvt Ltd-HOUSE NO 23, STREET NO 5 SECTOR B, GHORI BLOCK BAHRIA TOWN, Pakistan-
	The status in reference regulatory authorities	AIFA approved
	Detail of previous approval	Maykoline 1gm/4ml 323rd Meeting

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for Minutes of 351st Meeting of Registration Board (23rd – 24th September, 2025)

cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

293	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Seraph Pharmaceutical Plot No 210, Industrial Triangle Kahuta Road, Islamabad. (000860)
	Application Form Dy. No / Tracking ID & date of submission	(4HA-N9N-LXNY, 2025-07-29)
	Detail of Fee Submitted	93000.0, 2025-07-16,
	The proposed proprietary name / brand name	Seagra 100mg Tablet
	Label Claim	Each film coated Tablet contains: Sildenafil Citrate eq. to sildenafil 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Brand Name: Ripple 100mg Tablet Manufacturer: Solaris Pharma Rawat
	Pharmacotherapeutic Group of (API)	Selective inhibitor of cyclic GMP-specific phosphodiesterase
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd.-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	FDA approved
	Detail of previous approval	Ripple 100mg Tablet, 345th
Evaluation Remarks		
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.		
Decision		
Approved		
294	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	AKHSAH PHARMACEUTICALS (PVT) LTD. Plot No. 47, Street No. S-10, RCCI INDUSTRIAL ESTATE RAWAT ISLAMABAD (000943)
	Application Form Dy. No / Tracking ID & date of submission	(4JH-28M-T4GY, 2025-07-24)
	Detail of Fee Submitted	93000.0, 2025-07-14,
	The proposed proprietary name / brand name	Axachole Injection 5mg/1ml
	Label Claim	Each 1ml ampoule contains: Cholecalciferol.....5 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1ml-As per SRO
	Shelf Life (Unit)	24 Year(s)15 Degree Celsius - 25 Degree Celsius

	For generic drugs (me-too Status)	D DROP Inj by Ipram Pharmaceuticals Reg No 052799
	Pharmacotherapeutic Group of (API)	Vitamin D analog
	Name, address of Manufacturing site:	M/s Carer pharmaceuticals Industries, -Plot # 27, Main Road, Rawat Industrial Estate, Rawat -
	The status in reference regulatory authorities	VITAMIN D3 GOOD INJECTION Doucharl-Recodrati-ANSM (France) approved.
	Detail of previous approval	Cara-D3, 326th DRB Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
295	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winthrox Laboratories Pvt. Ltd K-219-A, SITE, Super Highway Phase II, Karachi (000807)
	Application Form Dy. No / Tracking ID & date of submission	(4QY-HZA-EGZG, 2025-06-16)
	Detail of Fee Submitted	75000.0, 2024-02-13,
	The proposed proprietary name / brand name	Mipro Tablet 50mg/200mcg
	Label Claim	Each film coated modified release tablet contains: Diclofenac Sodium.....50mg (Enteric coated core) Misoprostol....200mcg (Immediate Release Coat) (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Rotec Tablet 50mg/200mcg by Searle Pakistan
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals Pvt. Ltd.-Plot. No. 129, Sundar Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Arthrotec 50mg/200mcg Tablet
	Detail of previous approval	Artec 50mg/200mcgTablet in 343 Meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
296	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

Name, address of Applicant.	Welmed Pharmaceutical Industries (Pvt) Ltd. Plot No. 108/1 Road No. R-2 I.E. Gadoon. (000546)
Application Form Dy. No / Tracking ID & date of submission	(4WA-8TT-GVG5, 2025-07-09)
Detail of Fee Submitted	75000.0, 2024-09-03,
The proposed proprietary name / brand name	TAZOWEL 4.5GM INJECTION
Label Claim	Each Vail contains: Piperacillin (as piperacillin sodium) : 4.0 g + Tazobactam (as Tazobactam Sodium) : 0.5gm
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	1 's-As per SRO
Shelf Life (Unit)	2 YearStore at controlled room temperature.
For generic drugs (me-too Status)	Tanzo Injection
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhpura Road, Lahore-Pakistan-
The status in reference regulatory authorities	USFDA Approved
Detail of previous approval	Tazopip 4.5gm Injection, Meeting No. 335th

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

297	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Fredmann Pharmaceuticals Pvt. Ltd Plot No. 82-83B, Old Industrial Area, Mirpur Azad Kashmir (000760)
	Application Form Dy. No / Tracking ID & date of submission	(54G-93Y-ZN4J, 2025-07-29)
	Detail of Fee Submitted	93000.0, 2025-01-29,
	The proposed proprietary name / brand name	Negra 100mg Tablets
	Label Claim	Each film coated tablets contains: Sildenafil (as Citrate) - ----- 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's-De-Controlled
	Shelf Life (Unit)	2 Yearat room temperature
	For generic drugs (me-too Status)	Silagro Tablet by Nabi Qasim
	Pharmacotherapeutic Group of (API)	Rakshit Drugs Private Limited, India
	Name, address of Manufacturing site:	Gray's Pharmaceuticals-Plot No: 2, Street No: N-3, National Industrial Zone, Rawat, Islamabad-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Visilda 100mg Tablet, M-345

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt

the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

298	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Panacea Pharmaceuticals plot No 04, Street S-6 National industrial Zone RCCI rawat islamabad (000600)
	Application Form Dy. No / Tracking ID & date of submission	(564-1Z4-8N74, 2025-07-28)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	Efficient 5mg/5mL Syrup
	Label Claim	Each 5ml contains: Ebastine 5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Simstine 5mg/5ml Syrup, Simz Pharmaceuticals (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	Second-generation Antihistamine
	Name, address of Manufacturing site:	Seraph Pharmaceutical-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
	The status in reference regulatory authorities	EBASTEL 1mg/1ml oral solution, Spain Approved.
	Detail of previous approval	EBESTOL 5mg/5ml Syrup, 336th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
299	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Steris Pharmaceuticals Plot No 9 Near Synpac Hattar Private Industrial Estate Haripur Road Hattar (000995)
	Application Form Dy. No / Tracking ID & date of submission	(5BS-LAA-6VYH, 2025-06-16)
	Detail of Fee Submitted	93000.0, 2025-02-25,
	The proposed proprietary name / brand name	Cinodrom-L
	Label Claim	Each ml contains: Fluocinolone Acetonide..... (0.01%w/v) (USP Spec's)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 25
	For generic drugs (me-too Status)	Yes
	Pharmacotherapeutic Group of (API)	

Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd-Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, Rawalpindi-Pakistan.-
The status in reference regulatory authorities	SRA Registered in UNited State
Detail of previous approval	Minutes of 339th meeting of Registration Board, with brand name of FLOCINOL 0.01% Lotion

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

300	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	PERFECT PHARMA (PVT) LTD 5Km, Manga Road, Raiwind, Lahore (000469)
	Application Form Dy. No / Tracking ID & date of submission	(5PP-872-3H4G, 2025-06-17)
	Detail of Fee Submitted	93000.0, 2025-04-23,
	The proposed proprietary name / brand name	Perchol-D 5mg/ml Injection
	Label Claim	Each ml Contains Vitamin D3 = 5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's Ampoule-As per SRO
	Shelf Life (Unit)	2 Year25
	For generic drugs (me-too Status)	D Trees Injection
	Pharmacotherapeutic Group of (API)	Analogue of Vitamin D
	Name, address of Manufacturing site:	May & Baker (Pvt) Ltd-45 Km Dina Nath Multan Road Lahore-
	The status in reference regulatory authorities	Approved by ANSM of FRANCE
	Detail of previous approval	May-D3 5mg/ml Injection , Meeting No 327
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
301	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medwell Pharmaceuticals 1 km, terbella road, lawrencepur, faqirabad Attock (000699)
	Application Form Dy. No / Tracking ID & date of submission	(5X4-QGZ-QQDL, 2025-06-05)
	Detail of Fee Submitted	75000.0, 2024-05-23,

	The proposed proprietary name / brand name	Ondo 8mg/4ml Injection
	Label Claim	Each ml of ampoule contains: Ondansetron as Hydrochloride Dihydrate.... 2 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 X 5's, 1x1'-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Onset 8mg/4ml Injection by M/s Pharmedic (Pvt) Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals Pvt. -Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Zofran 8mg /4ml injection by M/S Novartis Pharmaceuticals UK Ltd.
	Detail of previous approval	Stawia 8mg/4ml Injection (Ondansetron Hcl Dihydrate) by M/s Wimits Pharmaceuticals Pvt. Ltd. approv
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
302	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Kohinoor Industries 159-160/B Small Industrial Estate, Sahiwal (000197)
	Application Form Dy. No / Tracking ID & date of submission	(64A-DQA-MRGR, 2025-06-26)
	Detail of Fee Submitted	93000.0, 2025-01-28,
	The proposed proprietary name / brand name	Zonova
	Label Claim	Each film coated tablet contain Vonoprazan Fumarate eq. to Vonoprazan 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 CG
	For generic drugs (me-too Status)	Venozan 10mg
	Pharmacotherapeutic Group of (API)	Jiangxi Synergy Pharmaceuticals Co. Ltd China
	Name, address of Manufacturing site:	M/s Jaskan Pharmaceuticals Pvt, LTD-Plot # 50, Sunder Industrial Estate Lahore-
	The status in reference regulatory authorities	Vocinti Tablet 10mg
	Detail of previous approval	Vona 10mg, 340
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

Approved

303	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welcome Pakistan Trading Pharma (Pvt) Ltd Chakri Interchange, Gangawala (000987)
	Application Form Dy. No / Tracking ID & date of submission	(67H-9PL-YGDP, 2025-08-01)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	ONDANZ 4mg/2ml Injection
	Label Claim	Each Ampoule (2mL) Contains: Ondansetron as Hydrochloride Dihydrate.....4mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25c
	For generic drugs (me-too Status)	Doston Injection by Vision Pharma
	Pharmacotherapeutic Group of (API)	Serotonin 5-Ht3 Receptor Antagonists
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Area, Hattar.-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Ondanz, DRB 343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
304	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welmed Pharmaceutical Industries (Pvt) Ltd. Plot No. 108/1 Road No. R-2 I.E. Gadoon. (000546)
	Application Form Dy. No / Tracking ID & date of submission	(6A4-GLE-PMJG, 2025-06-17)
	Detail of Fee Submitted	75000.0, 18000.0 2024-09-03, 2025-03-25
	The proposed proprietary name / brand name	Pregawel 82.5mg CR Tablet
	Label Claim	each Film Coated Extended Release tablet contains: Pregabalin.....82.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3 x 10's-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Lyrica CR 82.5mg tablet
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Limited.-Plot # 129, Sunder Industrial Estate Lahore.-
	The status in reference regulatory authorities	US
	Detail of previous approval	Gabal 82.5mg CR Tablet, Meeting No. 324

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision**Approved**

305	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wallace Pharma Evolutions Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (000951)
	Application Form Dy. No / Tracking ID & date of submission	(6E2-222-24AE, 2025-06-17)
	Detail of Fee Submitted	93000.0, 2025-01-22,
	The proposed proprietary name / brand name	Emzaa-ML Tablet
	Label Claim	Each Film Coated Extended Release Tablet contains: Empagliflozin.....12.5mg Linagliptin.....2.5MG (As immediate release core) Metformin Hydrochloride*.....1000MG (As extended release core) (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	DIAMPA LXR Tablet by Getz Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Welmark Pharmaceuticals-Plot No. 122, Phase-V, Block-B, Industrial Estate, Hattar.-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Empeg-ML XR Tablet, DRB 340
306	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Panacea Pharmaceuticals plot No 04, Street S-6 National industrial Zone RCCI rawat islamabad (000600)
	Application Form Dy. No / Tracking ID & date of submission	(6GX-U22-QUS9, 2025-07-28)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	• Sulbapar 2g Injection

Label Claim	Each vial contains: Cefoperazone (as Sodium) 1000mg Sulbactam (as Sodium) 1000mg
Reference to Finished product specifications	Any Other
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 YearStore below 30C
For generic drugs (me-too Status)	Cefbac Injection 2g Seraph Pharmaceutical, Islamabad
Pharmacotherapeutic Group of (API)	Cephalosporins Antibiotics
Name, address of Manufacturing site:	Seraph Pharmaceutical-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
The status in reference regulatory authorities	FDA Approved drug
Detail of previous approval	CEBACTUM 2gm Injection, 326th

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

307	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Effort Pharmaceuticals (Pvt.) Ltd., 28-Km, Ferozepur Road (000879)
	Application Form Dy. No / Tracking ID & date of submission	(6JE-PDT-16UR, 2025-07-25)
	Detail of Fee Submitted	93000.0, 2025-06-20,
	The proposed proprietary name / brand name	Fizone 1gm Injection IV
	Label Claim	Each vial contains: Cefoperazone Sodium equivalent to Cefoperazone... 500 mg Salbactam Sodium equivalent to Salbactam 500 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C and dry place.
	For generic drugs (me-too Status)	Brand Name: Xorbact. Manufacturer: M/s Highnoon
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Name, address of Manufacturing site:	High-Cure Research Laboratories. -19 KM Tayyaba Industrial Zone Shekhupura Road Lahore, Punjab, Pakistan.-
	The status in reference regulatory authorities	Sulperazon ® by Pfizer , Italy.
	Detail of previous approval	Minutes of 333rd meeting of Registration Board (19th To 20th December, 2023) Page NO.211

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

	Decision	
	Approved	
308	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	High-Q Pharmaceuticals Plot# 224 and 225/1, sector 23, Korangi Industrial area, Karachi (000597)
	Application Form Dy. No / Tracking ID & date of submission	(6L1-VEV-T4XA, 2025-07-29)
	Detail of Fee Submitted	93000.0, 2025-07-28,
	The proposed proprietary name / brand name	Stallagra
	Label Claim	Each Film Coated Tablet Contains: Sildenafil as Citrate (USP).....50mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Yearstore below 30°C
	For generic drugs (me-too Status)	Hilsil Tablets 50mg- HILTON PHARMA (Approved in 345th DRB minutes)
	Pharmacotherapeutic Group of (API)	phosphodiesterase 5 (PDE5) inhibitors
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Estate, Hattar.-
	The status in reference regulatory authorities	Lekap 50 mg film-coated tablets Approved in MHRA-UK
	Detail of previous approval	Siltrate 50mg Tablet- 345 DRB meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
309	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Effort Pharmaceuticals (Pvt.) Ltd., 28-Km, Ferozepur Road (000879)
	Application Form Dy. No / Tracking ID & date of submission	(6N9-X13-E75T, 2025-07-25)
	Detail of Fee Submitted	93000.0, 2025-06-20,
	The proposed proprietary name / brand name	Fixim DS 200mg Oral Suspension
	Label Claim	Each 5 ml contains: (after reconstitution) Cefixime (as tri-hydrate)..... 200 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C and dry place.
	For generic drugs (me-too Status)	Brand Name: Icef. Manufacturer: M/s ICI
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Name, address of Manufacturing site:	High-Cure Research Laboratories. -19 KM Tayyaba Industrial Zone Sheikhpura Road Lahore, Punjab,
	(23rd – 24th September, 2025)	

		Pakistan.-
	The status in reference regulatory authorities	USFDA approved SUPRAX® by Lupin.
	Detail of previous approval	Minutes of 331st Meeting of Registration Board held on 31st Oct – 2nd Nov, 2023 page no:3401
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
310	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Air Pharmaceuticals(Pvt.)Ltd Plot No's 74, 75-A, Small Industrial Estate, Kasur (000977)
	Application Form Dy. No / Tracking ID & date of submission	(6TV-98U-1P6X, 2025-06-27)
	Detail of Fee Submitted	75000.0, 2024-08-19,
	The proposed proprietary name / brand name	Cefiair Dry Suspension
	Label Claim	Each 5mlcontains: Cefixime (as trihydrate).....100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's (30ml)-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30°C in dry cool environment
	For generic drugs (me-too Status)	TYSEN Dry Suspension Himont Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Novamed Pharmaceuticals(Pvt.)Ltd-28-KM, FEROZEPUR ROAD, NEAR GRAND AVENUE, Lahore Nishter Town-
	The status in reference regulatory authorities	Cefixime Capsule 100mg/5ml, approved in FDA USA BELCHER
	Detail of previous approval	Product Name, Meeting No Icef (M-308nd DRB Approved)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
311	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Magns Pharmaceuticals Plot # 7B Value Addition City Sahianwala Road Khurrianwala (000849)
	Application Form Dy. No / Tracking ID & date of submission	(72U-PU5-D5WT, 2025-06-27)

Detail of Fee Submitted	93000.0, 2025-03-25,
The proposed proprietary name / brand name	Ketomag
Label Claim	Each ml Contains: Ketorolac Tromethamine= 30mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	10,s-As per SRO,30,s-As per SRO,5,s-As per SRO
Shelf Life (Unit)	2 Yearstore below 30 oC
For generic drugs (me-too Status)	Toradol injection by M/s Martin Dow
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	M/s May & Baker (Pvt) Ltd., -45 Km, Dina Nath, Multan Road, Lahore.-
The status in reference regulatory authorities	MHRA approved
Detail of previous approval	Ketorol 30 mg injection 323 rd meeting

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

312

Case Category	Contract Manufacturing (Incharge Evaluation Cell)
Name, address of Applicant.	Saffron Pharmaceuticals 19-Km Sheikhpura Road (000616)
Application Form Dy. No / Tracking ID & date of submission	(784-RJ7-BBB5, 2025-08-19)
Detail of Fee Submitted	93000.0, 2025-06-17,
The proposed proprietary name / brand name	SANEM 1g Injection
Label Claim	Each vial contains: Meropenem (as Trihydrate) 1gm (Blended with Sodium Carbonate) (As per USP Specifications)
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	1 x 1's-As per SRO
Shelf Life (Unit)	24 MonthStore below 30°C
For generic drugs (me-too Status)	Meronem 1g Injection IV
Pharmacotherapeutic Group of (API)	Written in Module-1
Name, address of Manufacturing site:	Stallion Pharmaceuticals PVT, LTD.-581 - Sundar Industrial Estate, Lahore, Lahore. Tel: + 92 42 35297647 - 48-
The status in reference regulatory authorities	UKMHRA
Detail of previous approval	Mopen Injection 1gm - 312th Meeting of Registration Board

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other

conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

313	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welcome Pakistan Trading Pharma (Pvt) Ltd Chakri Interchange, Gangawala (000987)
	Application Form Dy. No / Tracking ID & date of submission	(7MM-LXZ-7EXU, 2025-08-01)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	Restom 80mg Tablet
	Label Claim	Each film coated tablets contains: Resmetirom 80mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25c
	For generic drugs (me-too Status)	Resmirom Tablet by Getz Pharma
	Pharmacotherapeutic Group of (API)	Thyroid hormone receptor-beta (THR-beta) agonist
	Name, address of Manufacturing site:	Jenner Pharmaceuticals Pvt Ltd-Plot No. 3, M-2, Pharmazone, 26-KM, Lahore Sharaqpur Road, District Sheikhpura.-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Diffra Tablet, DRB 347
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
314	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Effort Pharmaceuticals (Pvt.) Ltd., 28-Km, Ferozepur Road (000879)
	Application Form Dy. No / Tracking ID & date of submission	(7QP-313-H6WU, 2025-07-25)
	Detail of Fee Submitted	93000.0, 2025-06-20,
	The proposed proprietary name / brand name	Efitrax Injection 1gm IV
	Label Claim	Each vial contains: Ceftriaxone Sodium equivalent to Ceftriaxone 1G
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C and dry place.
	For generic drugs (me-too Status)	Brand Name: Rocephin. Manufacturer: M/s Martin Dow
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics

Name, address of Manufacturing site:	High-Cure Research Laboratories. -19 KM Tayyaba Industrial Zone Sheikhupura Road Lahore, Punjab, Pakistan.-
The status in reference regulatory authorities	USFDA approved Rocephin
Detail of previous approval	Minutes of 331st Meeting of Registration Board held on 31st Oct – 2nd Nov, 2023 page no:3380
Evaluation Remarks	
In light of Registration Board’s decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
Decision	
Approved	
Case Category	Contract Manufacturing (Incharge Evaluation Cell)
Name, address of Applicant.	Kohinoor Industries 159-160/B Small Industrial Estate, Sahiwal (000197)
Application Form Dy. No / Tracking ID & date of submission	(7SD-4QU-UB4N, 2025-06-16)
Detail of Fee Submitted	93000.0, 2025-01-28,
The proposed proprietary name / brand name	Fayric
Label Claim	Each 10ml Vial Contains: Iron as Ferric Carboxymaltose.....500mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per SRO-De-Controlled
Shelf Life (Unit)	2 YearBelow 30 CG
For generic drugs (me-too Status)	Ferinject 500ml / 10ml
Pharmacotherapeutic Group of (API)	West Bengal Chemical Industries Limited India
Name, address of Manufacturing site:	MS Wnsfeild Pharmaceuticals-Plot No. 122, Block-A, Phase-V, Industrial Estate Hattar-
The status in reference regulatory authorities	Ferinject 50 mg iron/mL dispersion for injection/infusion.
Detail of previous approval	Ferinject, M-343
Evaluation Remarks	
In light of Registration Board’s decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
Decision	
Approved	
Case Category	Contract Manufacturing (Incharge Evaluation Cell)
Name, address of Applicant.	Jenner Pharmceuticals Pvt. Ltd Plot No. 03, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhupura (000823)

Application Form Dy. No / Tracking ID & date of submission	(7SY-GY9-W5S2, 2025-06-19)
Detail of Fee Submitted	93000.0, 2025-02-17,
The proposed proprietary name / brand name	Jenvoq 15mg SR Tablets
Label Claim	Each sustained release tablet contains: Upadacitinib as Hemihydrate 15mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	10s, 20s, 30s & 7s, -As per SRO
Shelf Life (Unit)	24 MonthStore below 30C
For generic drugs (me-too Status)	Jaksa SR 15mg Tablets (124892) by McOlson Research Laboratories
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	McOlson Research Laboratories (Pvt) Ltd.-Plot No. 2, M2 Pharma Zone 26-Km, Lahore Sharaqpur Road, Disst Sheikupura-Pakistan-
The status in reference regulatory authorities	US-FDA (https://www.accessdata.fda.gov/drugsatfda_docs/label/20
Detail of previous approval	Upadacitinib 15mg SR Tablets M-343

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

317	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(7VE-15H-NRBQ, 2025-06-16)
	Detail of Fee Submitted	93000.0, 2024-11-27,
	The proposed proprietary name / brand name	COXNEC 90MG TABLETS
	Label Claim	Each Film Coated Tablet Contains: Etoricoxib.....90mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO -As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	ETOXIB 90mg TABLET(HIRANI'S PHARMA)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	WNSFEILD Pharmaceuticals, -PLOT NO.122, PHASE-V, BLOCK-A, INDUSTRIAL ESTATE, HATTAR, KPK, PAKISTAN-
	The status in reference regulatory authorities	Product Name = ETORICOXIB 90mg TABLET UK MHRA Reference: https://www.medicines.org.uk/emc/product/733/smpc

	Detail of previous approval	336th meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
318	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Swiss Pharmaceuticals Pvt. Ltd. A/159, S.I.T.E.-II, Super Highway (000438)
	Application Form Dy. No / Tracking ID & date of submission	(7ZA-RW2-PD6T, 2025-07-23)
	Detail of Fee Submitted	93000.0, 2025-02-14,
	The proposed proprietary name / brand name	Ceftar Powder For Injection 600mg
	Label Claim	Each Vial contains: Ceftaroline Fosamil as Ceftaroline Fosamil Monoacetate Monohydrate with L-arginine.....600mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x1's, 1x10's, As per-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Manufacturer Name: M/S Pfizer Ireland Pharmaceuticals, Brand Name & Strength: Zinforo Powder for Concentrate for Solution for Injection, Composition: Each vial Contains: Ceftaroline Fosamil Monoacetat
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt.) Ltd. -Plot No. 129, Sundar Industrial Estate Raiwind Road Lahore Pakistan-
	The status in reference regulatory authorities	Manufacturer Name: M/S Allergan USA, Inc.Madison, NJ 07940, Brand Name & Strength: Teflaro (ceftaroline Fosamil) for Injection 600mg/vial, Composition: Each vial Contains: Ceftaroline Fosamil Monoacetate Monohydrate with L-arginine eq. to Ceftaroline Fosamil.....600mg NDC 0456-0600-10 Packing: 10single-use vial Dosage Form: Powder for Injection Reference Regulatory Authority: USFDA approved.
	Detail of previous approval	Teflor 600mg Injection, M-339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
319	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

Name, address of Applicant.	Synchro Pharmaceuticals 77-Industrial Estate, Kot Lakhpat (000575)
Application Form Dy. No / Tracking ID & date of submission	(877-ATR-P97S, 2025-05-19)
Detail of Fee Submitted	93000.0, 2025-01-28,
The proposed proprietary name / brand name	Synagra
Label Claim	Each film coated tablet contains: Sildenafil (as Citrate) 100mg
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	4's-De-Controlled
Shelf Life (Unit)	2 Yearstore at room temperature
For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	Rakshit Drugs Pvt. Ltd. - India
Name, address of Manufacturing site:	Gray's Pharmaceuticals-Plot # 2, Street No # N-3, National Industrial Zone Rawat, Islamabad-Pakistan.-
The status in reference regulatory authorities	MHRA
Detail of previous approval	Selden, M-345

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

320	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Panacea Pharmaceuticals plot No 04, Street S-6 National industrial Zone RCCI rawat islamabad (000600)
	Application Form Dy. No / Tracking ID & date of submission	(8GV-P6Z-6ZXQ, 2025-07-28)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	Dewtrazon 250mg Injection IM
	Label Claim	Each vial contains: Ceftriaxone sodium equivalent to Ceftriaxone 250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Droncef Injection 250mg IM (Seraph Pharmaceutical, Islamabad)
	Pharmacotherapeutic Group of (API)	Third-generation Cephalosporins
	Name, address of Manufacturing site:	Seraph Pharmaceutical-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	SIXONE 250mg Injection (IM), 307th

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for

cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

321	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winlet Pharmaceuticals (Pvt) Ltd. 30-Km, Lahore Sargodha Raod, Sargodha (000874)
	Application Form Dy. No / Tracking ID & date of submission	(8VL-3TJ-T2XJ, 2024-06-13)
	Detail of Fee Submitted	75000.0, 2023-04-06,
	The proposed proprietary name / brand name	Nelbulet 10mg injection
	Label Claim	10mg /ml
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10,s-As per SRO
	Shelf Life (Unit)	2 Year20 to 25 °C
	For generic drugs (me-too Status)	Nalfoline Injection
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/S BIO LAB-PLOT NO 145 KAHUTA INDUSTRIAL TRIANGLE ISLAMABAD-
	The status in reference regulatory authorities	FDA APPORVED
	Detail of previous approval	---
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
322	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Effort Pharmaceuticals (Pvt.) Ltd., 28-Km, Ferozepur Road (000879)
	Application Form Dy. No / Tracking ID & date of submission	(8VZ-J1R-EP4A, 2025-07-25)
	Detail of Fee Submitted	93000.0, 2025-06-20,
	The proposed proprietary name / brand name	Efidrox DS 250mg Suspension
	Label Claim	Each 5ml contains: (after reconstitution) Cefadroxil as monohydrate 250 mg.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C and dry place.
	For generic drugs (me-too Status)	Brand Name: Duricef 250mg/5ml Manufacturer: M/s GSK Reg. # 010057
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics

Name, address of Manufacturing site:	High-Cure Research Laboratories. -19 KM Tayyaba Industrial Zone Sheikhpura Road Lahore, Punjab, Pakistan.-
The status in reference regulatory authorities	Duracef 250mg/5ml by JUTE DARMA, Spain. Listed in European Medicine Agency (EMA)
Detail of previous approval	Minutes of 333rd meeting of Registration Board (19th To 20th December, 2023) Page NO.219

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

323	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Magns Pharmaceuticals Plot # 7B Value Addition City Sahianwala Road Khurrianwala (000849)
	Application Form Dy. No / Tracking ID & date of submission	(9NA-B89-6V48, 2025-06-16)
	Detail of Fee Submitted	93000.0, 2025-03-25,
	The proposed proprietary name / brand name	Magset
	Label Claim	Each 4ml Contains: Ondansetron as Hydrochloride dihydrate = 8MG
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4 ml x 1,s-As per SRO
	Shelf Life (Unit)	2 Yearstore below 30 oC
	For generic drugs (me-too Status)	Onset injection by Pharmedic
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s May & Baker (Pvt) Ltd., -45 Km, Dina Nath, Multan Road, Lahore.-
	The status in reference regulatory authorities	MHRA & USFDA approved
	Detail of previous approval	Incet injection 8mg/4ml 321 st meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
324	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	jupiter Pharma Plot No 25 Street S-6 RCCI Rawat Rawalpindi (000838)
	Application Form Dy. No / Tracking ID & date of submission	(9P2-GZV-UETH, 2025-07-24)

Detail of Fee Submitted	75000.0, 18000.0 2024-02-02, 2025-07-15
The proposed proprietary name / brand name	Winpa Tablet 12.5mg 1000mg
Label Claim	Each Film Coated Tablet contains: Empagliflozin.....12.5mg Metformin Hydrochloride.....1000mg (Product Complies Innovator's Specs)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As Per SRO-As per SRO
Shelf Life (Unit)	2 YearStore below 25°C
For generic drugs (me-too Status)	DiAmpa Tablet by Getz pharma
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	winbrains Research Laboratories-Plot No. 69/1, Phase I-II, Industrial Estate, Hattar.-
The status in reference regulatory authorities	Usfda Approved
Detail of previous approval	Winpa Tablet, DRB 343

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

325	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Onyx Pharmaceuticals 30-A small Industrial Estate mansehra (000440)
	Application Form Dy. No / Tracking ID & date of submission	(9V4-4V4-LWUS, 2025-07-29)
	Detail of Fee Submitted	93000.0, 2025-02-04,
	The proposed proprietary name / brand name	Dynox 100mg Tablets
	Label Claim	Each film coated tablet contains: Sildenafil (as Citrate) -- ----- 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's-De-Controlled
	Shelf Life (Unit)	2 Yearat room temperature
	For generic drugs (me-too Status)	Silagro Tablet by Nabi Qasim
	Pharmacotherapeutic Group of (API)	Rakshit Drugs Private Limited, India
	Name, address of Manufacturing site:	Gray's Pharmaceuticals-Plot No: 2, Street No: N-3, National Industrial Zone, Rawat, Islamabad-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Visilda 100mg Tablet, M-345

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other

conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

326	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winthrox Laboratories Pvt. Ltd K-219-A, SITE, Super Highway Phase II, Karachi (000807)
	Application Form Dy. No / Tracking ID & date of submission	(A2R-UZZ-2SZW, 2025-06-16)
	Detail of Fee Submitted	75000.0, 2024-02-13,
	The proposed proprietary name / brand name	Mipro Tablet 75mg/200mcg
	Label Claim	Each film coated modified release tablet contains: Diclofenac Sodium.....75mg (Enteric coated core) Misoprostol....200mcg (Immediate Release Coat) (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Rotec Tablet 75mg/200mcg by Searle Pakistan
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals Pvt. -Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Arthrotec 75mg/200mcg Tablet
	Detail of previous approval	Artec 75mg/200mcg Tablet Approved in 343rd Meeting of Registration Board
Evaluation Remarks		
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.		
Decision		
Approved		
327	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welcome Pakistan Trading Pharma (Pvt) Ltd Chakri Interchange, Gangawala (000987)
	Application Form Dy. No / Tracking ID & date of submission	(AAB-QL2-W4TT, 2025-08-01)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	EMPEG-ML 5mg, 2.5mg, 1000mg
	Label Claim	Each Film Coated Extended Release Tablet contains: Empagliflozin.....5MG Linagliptin.....2.5MG (As immediate release core) Metformin Hydrochloride*.....1000MG (As extended release core) (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25c
	For generic drugs (me-too Status)	Ezliz XR Tablet by Welmark
	Pharmacotherapeutic Group of (API)	Sodium-glucose co-transporter 2 (SGLT2) inhibitors Dipeptidyl peptidase-4 (DPP-4) inhibitors Biguanide
	Name, address of Manufacturing site:	Welmark Pharmaceuticals-Plot NO. 122, Block-B, Phase-V, Industrial Estate, Hattar, KPK. -
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	EMPEG Tablet, DRB 340
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
328	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(ABH-NPG-UT44, 2025-06-19)
	Detail of Fee Submitted	93000.0, 2024-11-27,
	The proposed proprietary name / brand name	TOFIX 5MG TABLETS
	Label Claim	Each Film Coated Tablet contains: Tofacitinib Citrate eq, to Tofacitinib.....5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO -As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Tofajak 5mg Tablets (Hirani's Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	WNSFEILD Pharmaceuticals, -PLOT NO.122, PHASE- V, BLOCK-A, INDUSTRIAL ESTATE, HATTAR, KPK, -
	The status in reference regulatory authorities	Registered by UK MHRA(Pfizer Europe MA EEIG Boulevard de la Plaine 17 1050 Bruxelles Belgium)
	Detail of previous approval	343rd
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	

329	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Akson Pharmaceuticals (Pvt) Ltd Plot No. 9-B/1&2, street No.D-1, Old Industrial estate, Mirpur, Azad Kashmir (000486)
	Application Form Dy. No / Tracking ID & date of submission	(ABY-U53-BD3T, 2025-08-01)
	Detail of Fee Submitted	93000.0, 2025-07-07,
	The proposed proprietary name / brand name	Sonafil Suspension 10mg
	Label Claim	Each ml contains: Sildenafil as citrate..... 10mg (USP Spec's)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearPlace below 30 centigrade
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	phosphodiesterase 5 (PDE5) inhibitors
	Name, address of Manufacturing site:	Solaris Life Sciences-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	Revatio 10mg/ml Oral Suspension (Upjohn UK Limited)
	Detail of previous approval	Ripple 10mg/ml Powder for Oral Suspension - 344th Meeting
Evaluation Remarks		
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.		
Decision		
Approved		
330	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Fassgen Pharmaceuticals PLOT # 67-1A- PHASE III. INDUSTRIAL EASTATE (000646)
	Application Form Dy. No / Tracking ID & date of submission	(ADE-M5L-J2VY, 2025-05-19)
	Detail of Fee Submitted	93000.0, 2025-01-23,
	The proposed proprietary name / brand name	Fasdenafil 100mg
	Label Claim	Each Film Coated Tablet Contains: Sildenafil (as Citrate) 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	4's-As per SRO
	Shelf Life (Unit)	2 Year30
	For generic drugs (me-too Status)	Selden 100 mg
	Pharmacotherapeutic Group of (API)	Rakshit Drugs Private Limited, India
	Name, address of Manufacturing site:	Grays Pharmaceuticals-Grays Pharmaceuticals, Plot No-2, Street No- N-3, National Industrial Zone, Rawat., Islamabad.-
	The status in reference regulatory authorities	MH RA
	Detail of previous approval	Selden 100 mg, 345th meeting of Registration Board

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision**Approved**

331	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winthrox Laboratories Pvt. Ltd K-219-A, SITE, Super Highway Phase II, Karachi (000807)
	Application Form Dy. No / Tracking ID & date of submission	(ASA-BYA-EHWU, 2025-06-16)
	Detail of Fee Submitted	93000.0, 2025-01-15,
	The proposed proprietary name / brand name	Wonoprin Tablet
	Label Claim	Each film coated tablet contains: Vonoprazan as Fumarate (outer immediate release layer).....10mg Aspirin (as enteric coated inner core).....100mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Asvon Tablet By Swiss Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s WnsFeild Pharmaceuticals-Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	Registration Status = Registered by JAPAN - PMDA Product Name = Cabpirin 10mg + 100mg Tablets Japan - PMDA Reference: www.pmda.go.jp/files/000239466.pdf
	Detail of previous approval	Venospa Tablet approved in Meeting of 324 Drug Registration Board for Wnsfeild Pharmaceuticals
332	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
332	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Panacea Pharmaceuticals plot No 04,Street S-6 National industrial Zone RCCI rawat islamabad (000600)
	Application Form Dy. No / Tracking ID & date of submission	(B19-A7D-DTYL, 2025-05-05)
	Detail of Fee Submitted	93000.0, 2025-01-23,

The proposed proprietary name / brand name	Jinagra
Label Claim	Each film coated tablet contains: Sildenafil (as Citrate).....100mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	As per SRO-De-Controlled
Shelf Life (Unit)	2 YearBelow 30%
For generic drugs (me-too Status)	Pfizer Pharmaceuticals
Pharmacotherapeutic Group of (API)	General
Name, address of Manufacturing site:	Gray's Pharmceuticals-Plot#2, Street N# N-3, National Industrial Zone Rawat, Islamabad-Pakistan-
The status in reference regulatory authorities	USFDA
Detail of previous approval	DRB,M-345

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

333	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Max Pharmaceuticals Plot #12, Street # N-7, National Industrial Zone, Rawat, Islamabad. 44000 (000671)
	Application Form Dy. No / Tracking ID & date of submission	(B8A-STJ-9G7H, 2025-05-15)
	Detail of Fee Submitted	93000.0, 2025-04-22,
	The proposed proprietary name / brand name	Hoze 40mg Injection
	Label Claim	Each vial contains: Pantoprazole sodium sesquihydrate equivalent to Pantoprazole 40mg (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1 Injection in 1 Uni-De-Controlled
	Shelf Life (Unit)	2 YearStore below 25 degree centigrade. Protect from heat, light and moisture.
	For generic drugs (me-too Status)	Product: Zopent 40mg Injection Manufacturer: Hilton Pharma Karachi Pack size:1's Registration No.: 070681
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor (PPI)
	Name, address of Manufacturing site:	Swera Pharmaceuticals-Address: Plot No. 27, Street No. S-4 National Industrial Zone, Rawat, Islamabad, Pakistan.-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	Pantoera 40mg injection, 344th meeting

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other

conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

334	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Panacea Pharmaceuticals plot No 04, Street S-6 National industrial Zone RCCI rawat islamabad (000600)
	Application Form Dy. No / Tracking ID & date of submission	(B94-4DA-L2A5, 2025-07-28)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	Sulbapar 1g Injection
	Label Claim	Each vial contains: Cefoperazone (as Sodium) 500mg Sulbactam (as Sodium) 500mg
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Cefbac Injection 1g Seraph Pharmaceutical, Islamabad
	Pharmacotherapeutic Group of (API)	Cephalosporins Antibiotics
	Name, address of Manufacturing site:	Seraph Pharmaceutical-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
	The status in reference regulatory authorities	FDA Approved drug
	Detail of previous approval	CEBACTUM 1gm Injection, 326th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
335	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Genetics Pharmaceuticals Pvt. Ltd 539-A Sundar Industrial Estate Raiwind Road Lahore (000845)
	Application Form Dy. No / Tracking ID & date of submission	(BA1-TRE-7H87, 2025-06-17)
	Detail of Fee Submitted	93000.0, 2025-04-30,
	The proposed proprietary name / brand name	Gentof 5mg Tablet
	Label Claim	Each Film Coated Tablet contains: Tofacitinib Citrate eq. to Tofacitinib 5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearProtect from heat light and moisture
	For generic drugs (me-too Status)	Manufacturer Name: Hiranis Pharmaceuticals Pvt. Ltd. Reg. No.: (110057) Brand Name & Strength: Tofajak 5mg Tablets

	Pharmacotherapeutic Group of (API)	Immunosuppressants, Janus-associated kinase (JAK) inhibitors; ATC code: L04AF01
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-Name: Wimits Pharmaceuticals (Pvt.) Ltd. Address: Plot # 129, Sunder Industrial Estate Lahore-
	The status in reference regulatory authorities	Reference Regulatory Authority: U.S. FDA Manufactured by Pfizer Labs Division, NY Brand name: Xeljanz 5mg Composition: Each tablet contains: Tofacitinib.....5mg NDC: 0069-1001-01
	Detail of previous approval	343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
336	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Panacea Pharmaceuticals plot No 04, Street S-6 National industrial Zone RCCI rawat islamabad (000600)
	Application Form Dy. No / Tracking ID & date of submission	(BAP-HME-1ZSW, 2025-07-28)
	Detail of Fee Submitted	93000.0, 2025-07-22,
	The proposed proprietary name / brand name	Esopan 40mg Injection
	Label Claim	Each vial contains: Esomeprazole Sodium equivalent to Esomeprazole 40mg.
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Esso 40mg IV Injection, Shaigan Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitors (PPI)
	Name, address of Manufacturing site:	Bio-Labs (Pvt.) Ltd. -Plot No. 145, Industrial Triangle Kahuta Road Islamabad- Pakistan -
	The status in reference regulatory authorities	FDA approve drug.
	Detail of previous approval	Esorok 40mg Injection, 331st
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
337	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

Name, address of Applicant.	Alliance Pharmaceuticals (pvt) Ltd 112-A Hayatabad Industrial Estate (000594)
Application Form Dy. No / Tracking ID & date of submission	(BD1-NT5-A89H, 2025-07-28)
Detail of Fee Submitted	93000.0, 2025-07-16,
The proposed proprietary name / brand name	Silvanta 100mg Tab
Label Claim	Each Film Coated Tablet Contains: Sildenafil Citrate eq-to Sildenafil.....25mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	1x4 and 1x 10-De-Controlled
Shelf Life (Unit)	2 Year(s)30C
For generic drugs (me-too Status)	Ripple
Pharmacotherapeutic Group of (API)	M/S: Rakshit Drugs PVT LTD. INDIA
Name, address of Manufacturing site:	M/s Solaris Life Sciences-Plot#08, Street.S-1, RCCI, Industrial Estate Rawat-
The status in reference regulatory authorities	USFDA Approved
Detail of previous approval	RIPPLE 25MG TABLETS - 345th Meeting

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

338	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welwrd Pharmaceuticals Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar (000574)
	Application Form Dy. No / Tracking ID & date of submission	(BNA-479-WGV6, 2025-07-29)
	Detail of Fee Submitted	93000.0, 2025-07-19,
	The proposed proprietary name / brand name	SILTRATE 100MG TABLET
	Label Claim	Each Film Coated Tablet contains: Sildenafil as Citrate 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year20-25C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Phosphodiesterase 5 (PDE5) inhibitors. ATC code: G04BE03
	Name, address of Manufacturing site:	M/s Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Area, Hattar.-
	The status in reference regulatory authorities	Viagra 50mg & 100mg (sildenafil) tablets, USFDA approved.
	Detail of previous approval	Siltrate 100mg Tablet Minutes of 345th meeting of Registration Board

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

339	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	High-Q Pharmaceuticals Plot# 224 and 225/1, sector 23, Korangi Industrial area, Karachi (000597)
	Application Form Dy. No / Tracking ID & date of submission	(BRL-LL5-MU2R, 2025-07-29)
	Detail of Fee Submitted	93000.0, 2025-07-28,
	The proposed proprietary name / brand name	Stallagra
	Label Claim	Each Film Coated Tablet Contains: Sildenafil as Citrate (USP).....100mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Yearstore below 30°C
	For generic drugs (me-too Status)	Hilsil Tablets 100mg- HILTON PHARMA (Approved in 345th DRB minutes)
	Pharmacotherapeutic Group of (API)	phosphodiesterase 5 (PDE5) inhibitors
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Estate, Hattar.-
	The status in reference regulatory authorities	Lekap 100 mg film-coated tablets Approved in MHRA-UK
	Detail of previous approval	Siltrate 100mg Tablet- 345 DRB meeting
340	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Seraph Pharmaceutical Plot No 210, Industrial Triangle Kahuta Road, Islamabad. (000860)
	Application Form Dy. No / Tracking ID & date of submission	(BUP-7DL-5AN4, 2025-07-29)
	Detail of Fee Submitted	93000.0, 2025-07-16,
	The proposed proprietary name / brand name	Seagra 50mg Tablet
	Label Claim	Each film coated Tablet contains: Sildenafil Citrate eq. to sildenafil 50mg
	Reference to Finished product specifications	United States Pharmacopeia

	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Brand Name: Ripple 50mg Tablet Manufacturer: Solaris Pharma Rawat
	Pharmacotherapeutic Group of (API)	Selective inhibitor of cyclic GMP-specific phosphodiesterase
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd.-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	FDA approved
	Detail of previous approval	Ripple 50mg Tablet, 345th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
341	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Acumen Healthcare (Pvt.) Ltd plot#, 39, 40 Street S2, Rawat Industrial Estate, Islamabad (000932)
	Application Form Dy. No / Tracking ID & date of submission	(BX9-YT6-W1JX, 2025-06-20)
	Detail of Fee Submitted	93000.0, 2024-12-19,
	The proposed proprietary name / brand name	Acumep 40mg Capsule
	Label Claim	Each Capsule contains: Esomeprazole magnesium trihydrate 22.5% enteric coated pellets eq. to Esomeprazole..... 40MG (Product Complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°c
	For generic drugs (me-too Status)	Sold Capsule by Regal Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Welcome Pakistan Trading Pharma (Pvt) Ltd-Chakri Interchange, Gangawala, Rawalpindi-
	The status in reference regulatory authorities	Usfda Approved
	Detail of previous approval	Ezimep Capsule, DRB 339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
342	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

Name, address of Applicant.	Panacea Pharmaceuticals plot No 04, Street S-6 National industrial Zone RCCI rawat islamabad (000600)
Application Form Dy. No / Tracking ID & date of submission	(BXZ-75X-L9UZ, 2025-07-28)
Detail of Fee Submitted	93000.0, 2025-07-18,
The proposed proprietary name / brand name	Restop 1mg/1mL Oral Solution
Label Claim	Each 1ml contains; Risperidone 1mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 YearStore below 30C
For generic drugs (me-too Status)	PERSCH Oral Solution Barrett Hodgson Pakistan (Pvt) Ltd. F/423 SITE Karachi.
Pharmacotherapeutic Group of (API)	Atypical antipsychotics
Name, address of Manufacturing site:	Seraph Pharmaceutical-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
The status in reference regulatory authorities	FDA Approved drug
Detail of previous approval	ORIS 1mg/ml Oral Solution, 336th

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

343	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Bio-Next Pharmaceuticals plot no 50 street no S-10 RCCI Rawat (000910)
	Application Form Dy. No / Tracking ID & date of submission	(BYZ-LS6-Q4MB, 2024-10-21)
	Detail of Fee Submitted	75000.0, 18000.0 2024-08-23, 2024-10-15
	The proposed proprietary name / brand name	Ketonext Scalp Lotion (Shampoo based)
	Label Claim	Each gram contains:
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	30 ml ,60ml, 100ml &-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30
	For generic drugs (me-too Status)	Ketowin Lotion by M/s Shaigan
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Labs (Pvt) Ltd.,-Plot No. 145, Industrial triangle Kahuta road Islamabad.-
	The status in reference regulatory authorities	Nizoral Shampoo; MHRA approved
	Detail of previous approval	

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other

conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

344	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Aulton Pharmaceuticals Plot # 84/1,Block A, Phase 5 , Industrial Estate Hattar, KPK, (000828)
	Application Form Dy. No / Tracking ID & date of submission	(D3D-96D-18R2, 2025-07-29)
	Detail of Fee Submitted	93000.0, 2025-07-23,
	The proposed proprietary name / brand name	Aultafile 100mg Tablets
	Label Claim	Each Film Coated Tablet Contains: Sildenafil as Citrate (USP).....100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO / DPC-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Siltrate 100mg Tablet by Weather folds Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Drugs used in erectile dysfunction
	Name, address of Manufacturing site:	WEATHER FOLDS Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar-
	The status in reference regulatory authorities	SILDENAFIL CITRATE 100MG TABLET approved by MHRA (https://www.medicines.org.uk/emc/product/13880/smpc#)
	Detail of previous approval	Siltrate 100mg Tablet (345th Meeting), Application tracking ID: (EBM-YMA-SNRT, 2024-12-17)
Evaluation Remarks		
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.		
Decision		
Approved		
345	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Swiss Pharmaceuticals Pvt. Ltd. A/159, S.I.T.E.-II, Super Highway (000438)
	Application Form Dy. No / Tracking ID & date of submission	(D5E-PG1-2JA6, 2025-07-29)
	Detail of Fee Submitted	93000.0, 2025-07-28,
	The proposed proprietary name / brand name	Silda 25mg Tablet
	Label Claim	Each Film coated tablet contains: Sildenafil citrate 35.1125mg equivalent to Sildenafil.....25mg.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C

For generic drugs (me-too Status)	Brand name: Ripple 25mg Tablet, Manufacturer/Registration holder: Solaris Life Sciences, Approved in 345th DRB meeting
Pharmacotherapeutic Group of (API)	elective inhibitor of cyclic GMP-specific phosphodiesterase (Type V) with vasodilator action; Urologicals; Drugs used in erectile dysfunction.
Name, address of Manufacturing site:	M/s SOLARIS LIFE SCIENCES (PVT.) LTD,-Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, Rawalpindi-PAKISTAN.-
The status in reference regulatory authorities	Brand Name: Viagra 25mg Tablet MAH: VIATRIS I Thawra st.Almaza Cairo Egypt Approved by: US FDA Approved
Detail of previous approval	RIPPLE 25MG TABLETS, 345th meeting of Registration Board (19th – 21st February, 2025)

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

346	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welcome Pakistan Trading Pharma (Pvt) Ltd Chakri Interchange, Gangawala (000987)
	Application Form Dy. No / Tracking ID & date of submission	(D7M-27B-2T5A, 2025-08-01)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	Biltex 20mg Tablet
	Label Claim	Each Uncoated Tablet contains: Bilastine.....20MG (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25c
	For generic drugs (me-too Status)	Biltino Tablet by Wezen Pharma
	Pharmacotherapeutic Group of (API)	Benzimidazoles
	Name, address of Manufacturing site:	Wezen Pharmaceuticals-Plot No. 23 & 24, S-1, RCCI, Industrial Estate, Rawat-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Biltex Tablet, DRB 335

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

347	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (000790)
	Application Form Dy. No / Tracking ID & date of submission	(DA5-7QM-5VTD, 2025-08-04)
	Detail of Fee Submitted	75000.0, 18000.0 2024-07-24, 2024-10-21
	The proposed proprietary name / brand name	FINRO 20mg Tablet
	Label Claim	Each Film Coated Tablet contains: Finerenone.....20mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year20-25C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Area, Hattar.-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	M-348
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
348	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medwell Pharmaceuticals 1 km, terbella road, lawrencepur, faqirabad Attock (000699)
	Application Form Dy. No / Tracking ID & date of submission	(DLJ-5RR-9EWE, 2025-06-11)
	Detail of Fee Submitted	93000.0, 2024-12-31,
	The proposed proprietary name / brand name	SALBO-MED 200mcg Rota Capsule
	Label Claim	Each Rotacapsule contains: Salbutamol as Sulphate.....200mcg (Product Complies BP Specs)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Aerotec 200mcg Capsule Highnoon Laboratories (Reg# 044593)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	winbrains Research Laboratories-Plot No. 69/1, Phase I-II, Industrial Estate, Hattar.-
	The status in reference regulatory authorities	Usfda Approved
	Detail of previous approval	SBT, DRB 336

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision**Approved**

349	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Panacea Pharmaceuticals plot No 04, Street S-6 National industrial Zone RCCI rawat islamabad (000600)
	Application Form Dy. No / Tracking ID & date of submission	(DUV-B2L-S99T, 2025-07-28)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	• Tiram 100mg/mL Oral Solution
	Label Claim	Each ml contains: Levetiracetam 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Epian 100mg/ml Oral Solution Pharmasol (Pvt) Ltd Plot No. 549, Sundar Industrial Estate, Lahore, Pakistan
	Pharmacotherapeutic Group of (API)	Antiepileptics
	Name, address of Manufacturing site:	Seraph Pharmaceutical-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
	The status in reference regulatory authorities	FDA Approved drug
	Detail of previous approval	Levace 100mg/ml Oral Solution, 339th
350	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Magns Pharmaceuticals Plot # 7B Value Addition City Sahianwala Road Khurrianwala (000849)
	Application Form Dy. No / Tracking ID & date of submission	(DUW-5M7-NLJ6, 2025-06-05)
	Detail of Fee Submitted	93000.0, 2025-03-25,
	The proposed proprietary name / brand name	Magsum
	Label Claim	Each Vial Contains: Cefoperazone as Sodium...500mg Sulbactam as Sodium...500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 x1,s -As per SRO

	Shelf Life (Unit)	2 Yearstore below 30 oC
	For generic drugs (me-too Status)	Cebac Injection by Bosch pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Nicholas Pharmaceuticals-Plot # 34, Street No. SS-2, National Industrial Zone, Rawat, Islamabad.-
	The status in reference regulatory authorities	Sulperazone Intravenous Injection 1g by Pfizer PMDA JAPAN
	Detail of previous approval	Wincef 1 gm injection 333rd meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
351	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wallace Pharma Evolutions Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (000951)
	Application Form Dy. No / Tracking ID & date of submission	(DX9-2PT-LVYG, 2025-06-13)
	Detail of Fee Submitted	75000.0, 18000.0 2024-06-23, 2025-04-22
	The proposed proprietary name / brand name	Winpa 5mg + 1000mg XR Tablet
	Label Claim	Each Film Coated Tablet contains: Empagliflozin (as Immediate release coating).....5mg Metformin Hydrochloride (As Extended Release Core).....1000mg (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Erli Plus XR TABLET by PharmEvo
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Winbrains Research Laboratories-Plot No. 69/1, Phase I-II, Industrial Estate, Hattar, KPK.-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Winpa 5/1000 mg Tablet approved in M-343 DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
352	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

Name, address of Applicant.	Panacea Pharmaceuticals plot No 04, Street S-6 National industrial Zone RCCI rawat islamabad (000600)
Application Form Dy. No / Tracking ID & date of submission	(DXP-7JE-J133, 2025-07-28)
Detail of Fee Submitted	93000.0, 2025-07-18,
The proposed proprietary name / brand name	Muscolax 4mg/2mL Injection
Label Claim	Each 2ml ampoule contains: Thiocolchicoside 4mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 YearStore below 30C
For generic drugs (me-too Status)	Muscoril Injection 4mg/2ml, Searle Pharmaceuticals
Pharmacotherapeutic Group of (API)	MYORELEXANT
Name, address of Manufacturing site:	Seraph Pharmaceutical-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
The status in reference regulatory authorities	ANSM FRANCE
Detail of previous approval	Tiofrel 4mg/2ml Injection, 335th

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

353	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Akson Pharmaceuticals (Pvt) Ltd Plot No. 9-B/1&2, street No.D-1, Old Industrial estate, Mirpur, Azad Kashmir (000486)
	Application Form Dy. No / Tracking ID & date of submission	(DXX-MM2-SP2S, 2025-06-26)
	Detail of Fee Submitted	75000.0, 18000.0 2024-07-25, 2025-06-23
	The proposed proprietary name / brand name	F-Zole 150mg Capsule
	Label Claim	Each capsule contains: Fluconazole.....150mg (BP Spec's)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year15-30 °C
	For generic drugs (me-too Status)	Diflucan 150mg Capsule
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Solaris Life Sciences-Solaris Life Sciences (Pvt.) Ltd.Plot No. 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	Registered in United Kingdom Diflucan 150mg Capsule
	Detail of previous approval	Fluzole 150mg Capsule,M-336

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for
Minutes of 351st Meeting of Registration Board (23rd – 24th September, 2025)

cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

354	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Panacea Pharmaceuticals plot No 04, Street S-6 National industrial Zone RCCI rawat islamabad (000600)
	Application Form Dy. No / Tracking ID & date of submission	(E3P-TGZ-Q92H, 2025-07-28)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	Onitron 4mg/5mL Oral Solution
	Label Claim	Each 5ml contains: Ondansetron hydrochloride dihydrate eq. to ondansetron.....4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Onderaph 4mg/5ml Oral Solution Seraph Pharmaceutical
	Pharmacotherapeutic Group of (API)	Anti-emeticsand Anti-nauseants, (Serotonin (5HT3) antagonist)
	Name, address of Manufacturing site:	Seraph Pharmaceutical-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	RESTON 4mg/5ml Oral Solution, 336th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
355	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welwrd Pharmaceuticals Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar (000574)
	Application Form Dy. No / Tracking ID & date of submission	(E3X-MND-QGE5, 2025-07-29)
	Detail of Fee Submitted	93000.0, 2025-07-19,
	The proposed proprietary name / brand name	SILTRATE 50MG TABLET
	Label Claim	Each Film Coated Tablet contains: Sildenafil as Citrate 50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year20-25C
	For generic drugs (me-too Status)	NA

Pharmacotherapeutic Group of (API)	Phosphodiesterase 5 (PDE5) inhibitors. ATC code: G04BE03
Name, address of Manufacturing site:	M/s Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Area, Hattar.-
The status in reference regulatory authorities	Viagra 50mg & 100mg (sildenafil) tablets, USFDA approved.
Detail of previous approval	Siltrate 50mg Tablet Minutes of 345th meeting of Registration Board

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

356	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winbrains Research Laboratories Plot No. 69/1 Block B, Phase I-II Industrial Estate, Hattar, Pakistan (000725)
	Application Form Dy. No / Tracking ID & date of submission	(EW9-P5Y-7AB2, 2025-08-01)
	Detail of Fee Submitted	93000.0, 2025-07-21,
	The proposed proprietary name / brand name	Empeg-ML 25mg, 5mg, 1000mg Tablet
	Label Claim	Each Film Coated Extended Release Tablet contains: Empagliflozin.....25mg Linagliptin.....5MG (As immediate release core) Metformin Hydrochloride*.....1000MG (As extended release core) (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C.
	For generic drugs (me-too Status)	Ezliz XR Tablet by Welmark Pharma
	Pharmacotherapeutic Group of (API)	Sodium-glucose co-transporter 2 (SGLT2) inhibitors Dipeptidyl peptidase-4 (DPP-4) inhibitors Biguanide
	Name, address of Manufacturing site:	Welmark Pharmaceuticals-Plot No. 122, Phase-V, Block-B, Industrial Estate, Hattar, KPK. -
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Empeg, DRB 340
357	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
357	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

Name, address of Applicant.	Acumen Healthcare (Pvt.) Ltd plot#, 39, 40 Street S2, Rawat Industrial Estate, Islamabad (000932)
Application Form Dy. No / Tracking ID & date of submission	(EZ7-J7L-9N7Y, 2025-06-20)
Detail of Fee Submitted	93000.0, 2024-12-19,
The proposed proprietary name / brand name	Cefopara 1gm Injection
Label Claim	Each vial contains; Cefoperazone as sodium.....500mg Sulbactam as sodium.....500mg (Product Complied JP Specs)
Reference to Finished product specifications	Any Other
Proposed Pack Size	As Per SRO-As per SRO
Shelf Life (Unit)	2 YearStore below 25°C
For generic drugs (me-too Status)	Uszone Inj by Usawa Pharma
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Estate, Hattar.-
The status in reference regulatory authorities	Usfda Approved
Detail of previous approval	Prazon Injection, DRB 331

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

358	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Nicholas Pharmaceuticals Plot 34, Street SS-2, National Industrial Zone, Rawat (000886)
	Application Form Dy. No / Tracking ID & date of submission	(EZA-ZUB-GYBM, 2025-07-29)
	Detail of Fee Submitted	93000.0, 2025-07-25,
	The proposed proprietary name / brand name	VIGA 50mg Tablets
	Label Claim	Each film coated Tablet contains: Sildenafil as Citrate 50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year25°C
	For generic drugs (me-too Status)	Ripple 50mg Tablets
	Pharmacotherapeutic Group of (API)	Rakshit Drugs PVT LTD
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd.-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	Viagra 50mg Tablet
	Detail of previous approval	Ripple 50mg Tablets, M345

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for

cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

359	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Well Care Pharmaceuticals A/7 PSIE (000465)
	Application Form Dy. No / Tracking ID & date of submission	(GYT-XUM-QS15, 2025-04-30)
	Detail of Fee Submitted	93000.0, 2025-01-22,
	The proposed proprietary name / brand name	sildiwel
	Label Claim	each film coated tablet contains: Sildenafil as citrate.....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 °C
	For generic drugs (me-too Status)	Gray,s pharma
	Pharmacotherapeutic Group of (API)	phosphodiesterase (PDE) inhibitors
	Name, address of Manufacturing site:	M/S Gray,s pharma-plot no 2, street no N-3 RCCI rawat-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	M-345
Evaluation Remarks		
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.		
Decision		
Approved		
360	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Onyx Pharmaceuticals 30-A small Industrial Estate mansehra (000440)
	Application Form Dy. No / Tracking ID & date of submission	(H5E-AU3-9EBE, 2025-08-12)
	Detail of Fee Submitted	75000.0, 18000.0 2024-06-25, 2025-07-09
	The proposed proprietary name / brand name	Vonobact Injection 2gm
	Label Claim	Each Vial Contains: Cefoperazone as Sodium.....1 gm Salbactam as Sodium.....1 gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Yearstore below 25°C
	For generic drugs (me-too Status)	Cebac Injection by Bosch Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Nicholas Pharmaceuticals-plot no 34, Street no SS-2, National Industrial zone, Rawat ,Islamabad-

	The status in reference regulatory authorities	Sulperazone Intravenous Injection 2g by Pfizer
	Detail of previous approval	Wincef 2g Injection (Meeting 333rd)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
361	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medwell Pharmaceuticals 1 km, terbella road, lawrencepur, faqirabad Attock (000699)
	Application Form Dy. No / Tracking ID & date of submission	(H6B-VBT-4U6W, 2025-06-13)
	Detail of Fee Submitted	75000.0, 18000.0 2024-05-24, 2025-05-23
	The proposed proprietary name / brand name	Weldrox 500mg Capsules
	Label Claim	Each Capsule contains Cefadroxil (as Monohydrate) 500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	12's-De-Controlled
	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	Evacef 500mg Capsule Highnoon Lahore
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Gray's Pharmaceuticals-Plot No 2, Street No N-3, National Industrial Zone, Rawat, Islamabad Islamabad Urban-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Jaycil 500mg Capsule 316th DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
362	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Air Pharmaceuticals(Pvt.)Ltd Plot No's 74, 75-A, Small Industrial Estate, Kasur (000977)
	Application Form Dy. No / Tracking ID & date of submission	(H6G-ZZ1-J8DS, 2025-04-06)
	Detail of Fee Submitted	30000.0, 63000.0 2024-01-30, 2025-02-14
	The proposed proprietary name / brand name	MoxiAir

	Label Claim	Each 250ml vial contains: Moxifloxacin as HCL.....400mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30°C in dry cool environment
	For generic drugs (me-too Status)	Moxiget 400mg/250 ml by Getz
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Novamed Pharmaceuticals(Pvt.)Ltd-28KM Ferozepur Road Lahore-
	The status in reference regulatory authorities	MOXIFALON 400 mg / 250 mL Solution for infusion MHRA approved
	Detail of previous approval	AspiMox Infusion 400mg/250ml , M-333 DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
363	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Swiss Pharmaceuticals Pvt. Ltd. A/159, S.I.T.E.-II, Super Highway (000438)
	Application Form Dy. No / Tracking ID & date of submission	(HHX-WR8-S57Q, 2025-07-29)
	Detail of Fee Submitted	93000.0, 2025-07-28,
	The proposed proprietary name / brand name	Silda 50mg Tablet
	Label Claim	Each film coated tablet contains: Sildenafil Citrate 70.225 mg eq. to sildenafil.....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Brand name: Ripple 50mg Tablet, Manufacturer/Registration holder: Solaris Life Sciences, Approved in 345th DRB meeting
	Pharmacotherapeutic Group of (API)	Selective inhibitor of cyclic GMP-specific phosphodiesterase (Type V) with vasodilator action; Urologicals; Drugs used in erectile dysfunction.
	Name, address of Manufacturing site:	M/s SOLARIS LIFE SCIENCES (PVT.) LTD,-Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, Rawalpindi-PAKISTAN.-
	The status in reference regulatory authorities	Brand Name: Viagra 50mg Tablet MAH: VIATRIS I Thawra st.Almaza Cairo Egypt Approved by: US FDA Approved
	Detail of previous approval	RIPPLE 50MG TABLETS, 345th meeting of Registration Board (19th – 21st February, 2025)
	Evaluation Remarks	

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

364	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Athan Pharmaceuticals Plot # 84/2,Block A, Phase 5 , Industrial Estate Hattar, KPK, (000900)
	Application Form Dy. No / Tracking ID & date of submission	(HW4-ARN-BVAH, 2025-07-29)
	Detail of Fee Submitted	93000.0, 2025-07-23,
	The proposed proprietary name / brand name	Silden 50 mg Tabs
	Label Claim	Each Film Coated Tablet Contains: Sildenafil as Citrate (USP).....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Siltrate 100 mg Tablet by Weather Fold pharmaceuticals
	Pharmacotherapeutic Group of (API)	Drug used in erectile dysfunction
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK.-
	The status in reference regulatory authorities	MHRA https://www.medicines.org.uk/emc/product/13880/smpc#g
	Detail of previous approval	Siltrate 50 mg Tablet, DRB 345
365	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medwell Pharmaceuticals 1 km, terbella road, lawrencepur, faqirabad Attock (000699)
	Application Form Dy. No / Tracking ID & date of submission	(HWV-18V-JU16, 2025-06-13)
	Detail of Fee Submitted	75000.0, 18000.0 2024-05-23, 2025-05-19
	The proposed proprietary name / brand name	Ondo 4mg/2ml Injection
	Label Claim	Each ml of ampoule contains; Ondansetron as Hydrochloride Dihydrate 2mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 X 5's, 1x1's-As per SRO

Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
For generic drugs (me-too Status)	Onset 4mg/2ml Injection by M/s Pharmedic (Pvt) Ltd.
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals Pvt. -Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore-
The status in reference regulatory authorities	Zofran 4mg /2ml injection by M/S Novartis Pharmaceuticals UK Ltd.
Detail of previous approval	Stawia 4mg/2ml Injection (Ondansetron HCl Dihydrate)M/s Wimits Pharmaceuticals Pvt. Ltd. is already

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

366	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	De-Mont Research Laboratories (Pvt.) Ltd. 20 Km, Lahore-Sheikhupura Road, Sheikhupura, Pakistan (000844)
	Application Form Dy. No / Tracking ID & date of submission	(HWV-YP1-2ULA, 2025-07-29)
	Detail of Fee Submitted	93000.0, 2025-07-04,
	The proposed proprietary name / brand name	P-FORCE 100MG TABLET
	Label Claim	Each Film Coated Tablet Contains: Sildenafil as Citrate (USP).....100mg (Product complies USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	AS PER SRO-As per SRO
	Shelf Life (Unit)	2 Yearstore below 30 degree centigrade
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 inhibitor (PDE5-I)
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals -Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK PAKISTAN -
	The status in reference regulatory authorities	Viagra 100mg (sildenafil) tablets, USFDA approved.
	Detail of previous approval	Siltrate 100mg Tablet (M # 345)

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

367	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Alliance Pharmaceuticals (pvt) Ltd 112-A Hayatabad Industrial Estate (000594)
	Application Form Dy. No / Tracking ID & date of submission	(JEW-W3J-15T9, 2025-07-28)
	Detail of Fee Submitted	93000.0, 2025-07-16,
	The proposed proprietary name / brand name	Silvanta 50mg
	Label Claim	Each Film Coated Tablet Contains: Sildenafil Citrate eq-to Sildenafil.....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4 and 1x 10-As per SRO
	Shelf Life (Unit)	2 Year(s)30C
	For generic drugs (me-too Status)	Ripple 50 mg
	Pharmacotherapeutic Group of (API)	M/S: Rakshit Drugs PVT LTD. INDIA
	Name, address of Manufacturing site:	M/s Solaris Life Sciences-Plot#08, Street.S-1, RCCI, Industrial Estate Rawat-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	RIPPLE 50MG TABLETS - 345th Meeting
Evaluation Remarks		
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.		
Decision		
Approved		
368	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welwink Pharmaceuticals G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751)
	Application Form Dy. No / Tracking ID & date of submission	(JND-N28-Q21S, 2025-08-01)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	Mirolin 5mg Tablet
	Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to Mirogabalin.....5mg (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25c
	For generic drugs (me-too Status)	Miro Tablet by Nabiqasim
	Pharmacotherapeutic Group of (API)	Anti convulsants
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Limited-Plot # 129, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan-
	The status in reference regulatory authorities	PMDA Japan
	Detail of previous approval	Mirogab Tablet, DRB 344
Evaluation Remarks		

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

369	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Effort Pharmaceuticals (Pvt.) Ltd., 28-Km, Ferozepur Road (000879)
	Application Form Dy. No / Tracking ID & date of submission	(JPY-BTS-XZZM, 2025-07-25)
	Detail of Fee Submitted	93000.0, 2025-06-20,
	The proposed proprietary name / brand name	Fizone Dry Powder for Injection 2g
	Label Claim	Each vial contains: Cefoperazone Sodium equivalent to Cefoperazone... 1000 mg Salbactam Sodium equivalent to Salbactam 1000 mg
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C and dry place.
	For generic drugs (me-too Status)	Brand Name: Xorbact. Manufacturer: M/s Highnoon
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Name, address of Manufacturing site:	High-Cure Research Laboratories. -19 KM Tayyaba Industrial Zone Sheikhpura Road Lahore, Punjab, Pakistan.-
	The status in reference regulatory authorities	Sulperazon ® by Pfizer , Italy.
	Detail of previous approval	Minutes of 333rd meeting of Registration Board (19th To 20th December, 2023) Page NO.214
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	

Decision

Approved

370	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Trigon Pharmaceuticals (Private) Ltd 8-k.m thokar raiwind road Lahore (000342)
	Application Form Dy. No / Tracking ID & date of submission	(JQY-S6L-ZT1S, 2025-05-19)
	Detail of Fee Submitted	93000.0, 2025-01-23,
	The proposed proprietary name / brand name	DUM
	Label Claim	Each Tablet Contains: Sildenafil (as Citrate) ----- ----- 100mg

Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	1* 4's-As per SRO
Shelf Life (Unit)	2 YearBelow 25
For generic drugs (me-too Status)	Viagra 100mg Tablet (Pfizer Pharmaceuticals)
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Gray's Pharmaceuticals -Plot No: 2, Street No: N-3, National Industrial Zone Rawat, Islamabad -
The status in reference regulatory authorities	SILDENAFIL CITRATE (AJANTA PHARMA LTD)
Detail of previous approval	M-345

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

371	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Biogen PHarma 8-KM, Chak Beli Road, Rawat, (000639)
	Application Form Dy. No / Tracking ID & date of submission	(JTM-Y25-GMSG, 2025-06-05)
	Detail of Fee Submitted	75000.0, 2024-07-02,
	The proposed proprietary name / brand name	Terbizam 1% w/w LOTION
	Label Claim	Each gm contains: Terbinafine hydrochloride 10.0mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	20ml 30ml 60ml-As per SRO
	Shelf Life (Unit)	3 YearRoom Condition
	For generic drugs (me-too Status)	Manufacturer Name M/s Tabros Pharma Brand Name Cutis Lotion Registration Number: 067109
	Pharmacotherapeutic Group of (API)	Antifungal Agents
	Name, address of Manufacturing site:	Biogen Life Science -8-km, Chakbeli Road, Rawat Rawalpindi-
	The status in reference regulatory authorities	Netherland (RRA)Lamisil Lotion 1%
	Detail of previous approval	TERBIGEN 1% Lotion, Minutes of 335th meeting of Registration Board (25th April, 2024)

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

372	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

Name, address of Applicant.	wellbornpharmachem&biologicals Plot No.51/1,52/2 Phase I & II Industrial Estate, Hattar-Pakistan (000657)
Application Form Dy. No / Tracking ID & date of submission	(JWW-DY8-DBX4, 2025-04-25)
Detail of Fee Submitted	93000.0, 2025-01-24,
The proposed proprietary name / brand name	Seldiborn
Label Claim	Each film coated tablet contains: Sildenafil 100mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	4,S-As per SRO
Shelf Life (Unit)	2 YearBelow 30 C
For generic drugs (me-too Status)	viagra 100mg tablet
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	M/S Grays Pharmaceuticals-plot No 2, street no N-3, National industrial zone Rawat-
The status in reference regulatory authorities	VIAGRA100mg tablet
Detail of previous approval	Selden 100mg Tablet, 345
Evaluation Remarks	
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
Decision	
Approved	
373	
Case Category	Contract Manufacturing (Incharge Evaluation Cell)
Name, address of Applicant.	AKHSAH PHARMACEUTICALS (PVT) LTD. Plot No. 47, Street No. S-10, RCCI INDUSTRIAL ESTATE RAWAT ISLAMABAD (000943)
Application Form Dy. No / Tracking ID & date of submission	(JXX-Q49-SSEJ, 2025-07-24)
Detail of Fee Submitted	93000.0, 2025-07-16,
The proposed proprietary name / brand name	Axafer Injection 500mg/10ml
Label Claim	Each Ampoule contains: Iron as Ferric Carboxymaltose 500mg/10ml (As per Innovator's Specifications)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	10ml-As per SRO
Shelf Life (Unit)	24 Year(s)15 Degree Celsius - 25 Degree Celsius
For generic drugs (me-too Status)	Ferinject Injection (Each 10ml vial contains: Iron as Ferric carboxymaltose 500mg) of M/s. RG Pharmaceutical Reg.no. 072548.
Pharmacotherapeutic Group of (API)	Anti-Anemic
Name, address of Manufacturing site:	M/s Carer pharmaceuticals Industries,-Plot # 27, Main Road, Rawat Industrial Estate, Rawat-
The status in reference regulatory authorities	Injectafer Injection 500mg Iron /10ml (USFDA Approved)

Detail of previous approval	Meeting No. 333, CareInject Injection 50 mg Iron/ml; 10 ml.(New Approved Name: Feronyl)

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

374	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Panacea Pharmaceuticals plot No 04, Street S-6 National industrial Zone RCCI rawat islamabad (000600)
	Application Form Dy. No / Tracking ID & date of submission	(L3W-XZS-P9J7, 2025-07-28)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	Dewtrazon 500mg Injection IM
	Label Claim	Each vial contains: Ceftriaxone sodium equivalent to Ceftriaxone 500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Droncef Injection 500mg IM (Seraph Pharmaceutical, Islamabad)
	Pharmacotherapeutic Group of (API)	Third-generation Cephalosporins
	Name, address of Manufacturing site:	Seraph Pharmaceutical-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	SIXONE 500mg Injection (IM), 307th
375	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Crown Pharmaceuticals Plot 286, Kahuta industrial Triangle, Kahota Road, Islamabad (000456)
	Application Form Dy. No / Tracking ID & date of submission	(LAG-PG8-W96M, 2025-08-12)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	Vonoc 20mg Tablet

Label Claim	Each film coated tablet contains: Vonoprazan Fumarate equivalent to Vonoprazan.....20mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	14's, 20's, 30's -De-Controlled
Shelf Life (Unit)	2 YearStore below 30 centi grade
For generic drugs (me-too Status)	Vonozan 20mg tablet by Getz Pharma
Pharmacotherapeutic Group of (API)	Potassium-competitive acid blocker
Name, address of Manufacturing site:	LINTA PHARMACEUTICALS -Plot# 03, street # S-5, National Industrial Zone, Rawat, Islamabad, Pakistan.-
The status in reference regulatory authorities	TAKECAB by Takeda Pharmaceutical Company Limited Japan
Detail of previous approval	Vonopraz 20mg Tablet, Minutes of 336th meeting of Registration Board (04th-06th June, 2024).

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

376	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Panacea Pharmaceuticals plot No 04,Street S-6 National industrial Zone RCCI rawat islamabad (000600)
	Application Form Dy. No / Tracking ID & date of submission	(LG2-7PZ-B8TG, 2025-07-28)
	Detail of Fee Submitted	93000.0, 2025-07-22,
	The proposed proprietary name / brand name	Magfast Injection 40mg
	Label Claim	Each vial contains: Omeprazole Sodium equivalent to Omeprazole 40mg.
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Vyber Injection , Shaigan Pharmaceuticals (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitors (PPI)
	Name, address of Manufacturing site:	Bio-Labs (Pvt.) Ltd.-Plot No. 145,Industrial Triangle Kahuta Road Islamabad- Pakistan-
	The status in reference regulatory authorities	Omeprazole 40mg powder for solution for infusion, Zentiva Pharma Uk Limited
	Detail of previous approval	Omepranext Injection 40mg IV, 324th

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

	Approved	
377	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Nutrabiobiotics Pharmaceuticals PLOT NO 89- K/3 INDUSTRIAL ESTATE , HAYATABAD, PESHAWAR (001008)
	Application Form Dy. No / Tracking ID & date of submission	(LJ4-H1B-HJTD, 2025-07-29)
	Detail of Fee Submitted	93000.0, 2025-07-22,
	The proposed proprietary name / brand name	Semax Tablet 50mg
	Label Claim	Each film coated Tablet contains: Sildenafil Citrate 70.225 mg eq. to sildenafil 50mg (USP Spec's.)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4's , 1x10's-As per SRO
	Shelf Life (Unit)	2 YearBelow 30
	For generic drugs (me-too Status)	Silagro by Nabi Qasim Pharma
	Pharmacotherapeutic Group of (API)	phosphodiesterase (PDE) inhibitors
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd,-Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, Rawalpindi-PAKISTAN.-
	The status in reference regulatory authorities	Viagra 50mg tablet
	Detail of previous approval	Ripple 50mg tablet , 345 Meeting of Registration Board
Evaluation Remarks		
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.		
Decision		
Approved		
378	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winbrains Research Laboratories Plot No. 69/1 Block B, Phase I-II Industrial Estate, Hattar, Pakistan (000725)
	Application Form Dy. No / Tracking ID & date of submission	(LJX-ESJ-ZHDY, 2025-08-01)
	Detail of Fee Submitted	93000.0, 2025-07-21,
	The proposed proprietary name / brand name	Siltrate 100mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Sildenafil as Citrate (USP).....100mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C.
	For generic drugs (me-too Status)	Sylano Tablet by Wnsfeild Pharma
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 inhibitor (PDE5-I)
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK. -
	The status in reference regulatory authorities	USFDA Approved
Minutes of 351st Meeting of Registration Board (23rd – 24th September, 2025)		

	Detail of previous approval	Siltrate, DRB 345
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
379	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Synchro Pharmaceuticals 77-Industrial Estate, Kot Lakhpat (000575)
	Application Form Dy. No / Tracking ID & date of submission	(LQH-QJP-6Z94, 2025-05-05)
	Detail of Fee Submitted	93000.0, 2025-01-28,
	The proposed proprietary name / brand name	Synagra
	Label Claim	Each film coated tablet contains: Sildenafil (as Citrate)..... 50mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	4's-De-Controlled
	Shelf Life (Unit)	2 Yearstore at room temperature
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Rakshit Drugs Pvt. Ltd. - India
	Name, address of Manufacturing site:	Gray's Pharmaceuticals-Plot # 2, Street No # N-3, National Industrial Zone Rawat, Islamabad-Pakistan.-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
380	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	jupiter Pharma Plot No 25 Street S-6 RCCI Rawat Rawalpindi (000838)
	Application Form Dy. No / Tracking ID & date of submission	(LSU-Q27-7LZ7, 2025-05-02)
	Detail of Fee Submitted	93000.0, 2025-03-12,
	The proposed proprietary name / brand name	Siltrate 50mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Sildenafil as Citrate (USP).....50mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia

	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Estate, Hattar.-
	The status in reference regulatory authorities	Usfda Approved
	Detail of previous approval	Siltrate Tablet, DRB 345
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
381	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medwell Pharmaceuticals 1 km, terbella road, lawrencepur, faqirabad Attock (000699)
	Application Form Dy. No / Tracking ID & date of submission	(M6Y-DSX-TDTE, 2025-06-13)
	Detail of Fee Submitted	93000.0, 2024-12-31,
	The proposed proprietary name / brand name	BUDECORT FORTE 400/12 MCG DPI CAPSULE
	Label Claim	Each Rotacap Rota Capsule contains: Budesonide (USP).....400Mcg Formoterol Fumarate (USP) 12Mcg (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Venticort Rotacaps 400mg + 12mcg Highnoon Labs (Reg#089365)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	winbrains Research Laboratories-Plot No. 69/1, Phase I-II, Industrial Estate, Hattar.-
	The status in reference regulatory authorities	Usfda Approved
	Detail of previous approval	Combrain, DRB 339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
382	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

Name, address of Applicant.	Kohinoor Industries 159-160/B Small Industrial Estate, Sahiwal (000197)
Application Form Dy. No / Tracking ID & date of submission	(MG7-YZX-N981, 2025-07-03)
Detail of Fee Submitted	93000.0, 2025-01-28,
The proposed proprietary name / brand name	Zonova 20mg
Label Claim	Each film coated tablet contain Vonoprazon Fumarate eq. to Vonoprazon ...20mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 YearBelow 30 CG
For generic drugs (me-too Status)	Vonozan 20mg
Pharmacotherapeutic Group of (API)	Jiangxi Synergy Pharmaceuticals Co. Ltd China
Name, address of Manufacturing site:	Jaskan Pharmaceuticals Pvt, LTD-Plot # 50, Sunder Industrial Estate Lahore-
The status in reference regulatory authorities	Vocinti Tablet 20mg
Detail of previous approval	Zonova 20mg, 340

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

383	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wezen Pharmaceuticals Industrial Estate Rawat (000882)
	Application Form Dy. No / Tracking ID & date of submission	(MJU-9HW-X1G6, 2025-07-29)
	Detail of Fee Submitted	93000.0, 2025-07-21,
	The proposed proprietary name / brand name	Siltrate 50mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Sildenafil as Citrate (USP).....50mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Sylano Tablet by Wnsfeild Pharma
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 inhibitor (PDE5-I)
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Siltrate, DRB 345

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt

the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

384	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Acumen Healthcare (Pvt.) Ltd plot#, 39, 40 Street S2, Rawat Industrial Estate, Islamabad (000932)
	Application Form Dy. No / Tracking ID & date of submission	(MS1-21L-1HBT, 2025-06-20)
	Detail of Fee Submitted	93000.0, 2024-12-19,
	The proposed proprietary name / brand name	Acumep 20mg Capsule
	Label Claim	Each Capsule contains: Esomeprazole magnesium trihydrate 22.5% enteric coated pellets eq. to Esomeprazole..... 20mg (Product Complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Sold Capsule by Regal Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Welcome Pakistan Trading Pharma (Pvt) Ltd-Chakri Interchange, Gangawala, Rawalpindi-
	The status in reference regulatory authorities	Usfda Approved
	Detail of previous approval	Ezimep Capsule, DRB 339
385	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welmed Pharmaceutical Industries (Pvt) Ltd. Plot No. 108/1 Road No. R-2 I.E. Gadoon. (000546)
	Application Form Dy. No / Tracking ID & date of submission	(MSW-4T8-3MA2, 2025-07-09)
	Detail of Fee Submitted	75000.0, 2024-09-03,
	The proposed proprietary name / brand name	Odinzeo 8mg/4ml Injection
	Label Claim	Each ml of Ampoule contains: Ondansetron as hydrochloride Dihydrate.....2mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 x 1's-As per SRO,1 x 5's-As per SRO
	Shelf Life (Unit)	2 Year Between 2° and 30°
	For generic drugs (me-too Status)	Zofran 8mg/4ml Injection
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Limited.-Plot # 129, Sunder Industrial Estate Lahore-
	The status in reference regulatory authorities	HPRA Approved
	Detail of previous approval	Stawia 8mg/4ml Injection Approved in Meeting No. 326th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
386	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Acumen Healthcare (Pvt.) Ltd plot#, 39, 40 Street S2, Rawat Industrial Estate, Islamabad (000932)
	Application Form Dy. No / Tracking ID & date of submission	(MWU-JRA-A6T4, 2025-06-17)
	Detail of Fee Submitted	93000.0, 2024-12-10,
	The proposed proprietary name / brand name	Dexlan 30mg Capsule
	Label Claim	Each Capsule Contains: Dexlansoprazole as Dual Delayed Release Pellets.....30MG (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Dexxo Capsule by Weather Folds Pharma.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wezen Pharmaceuticals-Plot #23 & 24, S-1, RCCI Industrial Estate, Rawat-
	The status in reference regulatory authorities	Usfda Approved
	Detail of previous approval	Dexzen Capsule, DRB 330
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
387	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Effort Pharmaceuticals (Pvt.) Ltd., 28-Km, Ferozepur Road (000879)
	Application Form Dy. No / Tracking ID & date of submission	(MYG-8BM-JS54, 2025-07-25)

Detail of Fee Submitted	93000.0, 2025-06-20,
The proposed proprietary name / brand name	Efidrox 125mg Suspension
Label Claim	Each 5ml contains: (after reconstitution) Cefadroxil as monohydrate 125 mg (USP Specs.)
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	as per SRO-As per SRO
Shelf Life (Unit)	2 YearStore below 30°C and dry place.
For generic drugs (me-too Status)	Brand Name: Duricef 125mg/5ml. Manufacturer: M/s GSK
Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
Name, address of Manufacturing site:	High-Cure Research Laboratories. -19 KM Tayyaba Industrial Zone Sheikhpura Road Lahore, Punjab, Pakistan.-
The status in reference regulatory authorities	Biodroxil 125mg/5ml by Sandoz GMBH, Austria Listed in European Medicine Agency (EMA)
Detail of previous approval	Minutes of 333rd meeting of Registration Board (19th To 20th December, 2023) Page NO.217

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

388	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(N3N-ZSY-5QJ4, 2025-06-13)
	Detail of Fee Submitted	93000.0, 2024-11-27,
	The proposed proprietary name / brand name	CINACET 30MG TABLETS
	Label Claim	Each Film Coated Tablet contains: Cinacalcet Hcl eq. to Cinacalcet.....30mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO -As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Censipar Tablet 30 mg(CCL Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	WNSFEILD Pharmaceuticals, -PLOT NO.122, PHASE-V, BLOCK-A, INDUSTRIAL ESTATE, HATTAR, KPK, PAKISTAN-
	The status in reference regulatory authorities	Product Name = CINACALCET HCL 30mg TABLET UK MHRA Reference: https://www.medicines.org.uk/emc/product/11483/smpc#g
	Detail of previous approval	343rd

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision**Approved**

389	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Panacea Pharmaceuticals plot No 04, Street S-6 National industrial Zone RCCI rawat islamabad (000600)
	Application Form Dy. No / Tracking ID & date of submission	(N65-W4W-T9W8, 2025-07-28)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	Dewtrazon 1g Injection IV
	Label Claim	Each vial contains: Ceftriaxone sodium equivalent to Ceftriaxone 1000mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStove below 30C
	For generic drugs (me-too Status)	Droncef Injection 1g IV (Seraph Pharmaceutical, Islamabad)
	Pharmacotherapeutic Group of (API)	Third-generation Cephalosporins
	Name, address of Manufacturing site:	Seraph Pharmaceutical-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	SNARE Injection 1g IV, 307th
390	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winlet Pharmaceuticals (Pvt) Ltd. 30-Km, Lahore Sargodha Raod, Sargodha (000874)
	Application Form Dy. No / Tracking ID & date of submission	(N6M-GRW-8H3U, 2025-04-28)
	Detail of Fee Submitted	93000.0, 2025-01-22,
	The proposed proprietary name / brand name	sildenafil
	Label Claim	Each film coated tablet contains: Sildenafil (as Citrate).....100mg
	Reference to Finished product specifications	United States Pharmacopeia

Proposed Pack Size	4,S-As per SRO
Shelf Life (Unit)	2 YearBelow 30 °C
For generic drugs (me-too Status)	viagra
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	M/S Gray,s pharma-plot no 2, street no N-3 RCCI rawat-
The status in reference regulatory authorities	FDA APPORVED
Detail of previous approval	M-345

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

391	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	McOlson Research Laboratories Pvt. Ltd Plot No. 02, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhupura Pakistan (000664)
	Application Form Dy. No / Tracking ID & date of submission	(NTD-GAQ-V63A, 2025-07-29)
	Detail of Fee Submitted	93000.0, 2025-07-04,
	The proposed proprietary name / brand name	Vigorex 50 mg Tablets
	Label Claim	Each Film Coated Tablet Contains: Sildenafil as Citrate (USP): 50mg (Product Complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's, 20's' 30's, 100's-As per SRO
	Shelf Life (Unit)	2 YearBelow 30C
	For generic drugs (me-too Status)	Siltrate 50 mg Tablets (Weather Folds Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	Phosphodiesterase 5 (PDE5) inhibitors
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, Haripur, KPK-
	The status in reference regulatory authorities	Approved by UK MHRA https://www.medicines.org.uk/emc/product/13880/smpc#g
	Detail of previous approval	Siltrate 50 mg Tablets approved in DRB meeting no. 345
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
392	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (000790)

Application Form Dy. No / Tracking ID & date of submission	(NX2-SQL-BN1G, 2025-07-25)
Detail of Fee Submitted	93000.0, 2025-07-21,
The proposed proprietary name / brand name	Ondanz 4mg/5ml Syrup
Label Claim	Each 5ml Contains: Ondansetron as Ondansetron Hydrochloride Dihydrate (USP).....4mg (Product complies USP Specs)
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 YearStore below 25c
For generic drugs (me-too Status)	Ondan syrup 4mg/5ml by Bio Mark Pharmaceuticals
Pharmacotherapeutic Group of (API)	Serotonin 5-Ht3 Receptor Antagonists
Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-
The status in reference regulatory authorities	USFDA Approved
Detail of previous approval	Ondanz Syrup, DRB 339

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

393	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wnsfeild Pharmaceuticals Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK (000610)
	Application Form Dy. No / Tracking ID & date of submission	(PL3-59P-67R3, 2025-08-01)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	Mirolin 5mg Tablet
	Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to Mirogabalin.....5mg (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°c
	For generic drugs (me-too Status)	Miro Tablet by Nabiqasim
	Pharmacotherapeutic Group of (API)	Anti convulsants
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt Ltd-Plot # 129, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan-
	The status in reference regulatory authorities	PMDA Japan
	Detail of previous approval	Mirogab, DRB 344

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt

the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

394	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Onyx Pharmaceuticals 30-A small Industrial Estate mansehra (000440)
	Application Form Dy. No / Tracking ID & date of submission	(PM7-LMM-2DV6, 2025-07-29)
	Detail of Fee Submitted	93000.0, 2025-02-04,
	The proposed proprietary name / brand name	Dynox 50mg Tablets
	Label Claim	Each film coated tablet contains: Sildenafil (as Citrate) -- ----- 50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's-De-Controlled
	Shelf Life (Unit)	2 Yearat room temperature
	For generic drugs (me-too Status)	Silagro Tablet by Nabi Qasim
	Pharmacotherapeutic Group of (API)	Rakshit Drugs Private Limited, India
	Name, address of Manufacturing site:	Gray's Pharmaceuticals-Plot No: 2, Street No: N-3, National Industrial Zone, Rawat, Islamabad-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Visilda 50mg Tablet, M-345
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
395	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welmed Pharmaceutical Industries (Pvt) Ltd. Plot No. 108/1 Road No. R-2 I.E. Gadoon. (000546)
	Application Form Dy. No / Tracking ID & date of submission	(PN9-Z3X-JDJU, 2025-07-09)
	Detail of Fee Submitted	75000.0, 2024-09-03,
	The proposed proprietary name / brand name	Cefwel 500mg Capsule
	Label Claim	Each Capsule Contains: Cefadroxil Monohydrate eq. to Cefadroxil.....500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2 x 6-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Duricef 500mg Capsule
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Limited-Plot # 129, Sunder Industrial Estate Lahore.-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	Cefaxil 500mg Capsule, Meeting no. 335th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
396	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	McOlson Research Laboratories Pvt. Ltd Plot No. 02, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhpura Pakistan (000664)
	Application Form Dy. No / Tracking ID & date of submission	(PXD-Q4U-JRTJ, 2025-07-29)
	Detail of Fee Submitted	93000.0, 2025-07-04,
	The proposed proprietary name / brand name	Vigorex 100 mg Tablets
	Label Claim	Each Film Coated Tablet Contains: Sildenafil as Citrate (USP): 100mg (Product Complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's, 20's 30's, 100's-As per SRO
	Shelf Life (Unit)	2 YearBelow 30C
	For generic drugs (me-too Status)	Siltrate 100 mg Tablets (Weather Folds Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	Phosphodiesterase 5 (PDE5) inhibitors
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot # 69/2. Phase-II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	Approved by UK MHRA https://www.medicines.org.uk/emc/product/13880/smpc#g
	Detail of previous approval	Siltrate 100 mg Tablets approved in DRB meeting no. 345
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
397	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medwell Pharmaceuticals 1 km, terbella road, lawrencepur, faqirabad Attock (000699)
	Application Form Dy. No / Tracking ID & date of submission	(QPJ-JYZ-SPLT, 2025-06-13)

Detail of Fee Submitted	75000.0, 18000.0 2024-05-24, 2025-05-23
The proposed proprietary name / brand name	Weldrox 125mg Suspension
Label Claim	Each 5ml o reconstituted suspension contains Cefadroxil (as Monohydrate) 125mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	60ml-De-Controlled
Shelf Life (Unit)	2 YearRoom Temperature
For generic drugs (me-too Status)	Evacef 125mg Suspension Highnoon Lahore
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Gray's Pharmaceuticals-Plot No 2, Street No N-3, National Industrial Zone, Rawat, Islamabad Islamabad Urban-
The status in reference regulatory authorities	MHRA
Detail of previous approval	Jaycil 125mg/5ml Suspension 316th DRB
Evaluation Remarks	
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
Decision	
Approved	

398	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Saffron Pharmaceuticals 19-Km Sheikhpura Road (000616)
	Application Form Dy. No / Tracking ID & date of submission	(QPU-2UY-JTQQ, 2025-08-19)
	Detail of Fee Submitted	93000.0, 2025-06-17,
	The proposed proprietary name / brand name	SANEM 500mg Injection
	Label Claim	Each vial contains: Meropenem (as Trihydrate) 500mg (Blended with Sodium Carbonate) (As per USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 x 1's-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30°C
	For generic drugs (me-too Status)	Meronem 500mg Injection IV
	Pharmacotherapeutic Group of (API)	Written in Module-1
	Name, address of Manufacturing site:	Stallion Pharmaceuticals PVT, LTD.-581 - Sundar Industrial Estate, Lahore, Lahore. Tel: + 92 42 35297647 - 48-
	The status in reference regulatory authorities	UKMHRA
	Detail of previous approval	Mopen Injection 500mg - 312th Meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt	

the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

399	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Seraph Pharmaceutical Plot No 210, Industrial Triangle Kahuta Road, Islamabad. (000860)
	Application Form Dy. No / Tracking ID & date of submission	(R43-U56-L793, 2025-07-29)
	Detail of Fee Submitted	93000.0, 2025-07-16,
	The proposed proprietary name / brand name	Seagra 25mg Tablet
	Label Claim	Each Film coated tablet contains: Sildenafil citrate equivalent to Sildenafil.... 25mg.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Brand Name: Ripple 25mg Tablet Manufacturer: Solaris Pharma Rawat
	Pharmacotherapeutic Group of (API)	Selective inhibitor of cyclic GMP-specific phosphodiesterase
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd.-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	FDA approved
	Detail of previous approval	Ripple 25mg Tablet, 345th
400	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Panacea Pharmaceuticals plot No 04,Street S-6 National industrial Zone RCCI rawat islamabad (000600)
	Application Form Dy. No / Tracking ID & date of submission	(RA3-72V-HX7G, 2025-07-28)
	Detail of Fee Submitted	93000.0, 2025-07-22,
	The proposed proprietary name / brand name	Pois Injection 40mg
	Label Claim	Each vial contains: Pantoprazole sodium equivalent to Pantoprazole 40mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C

	For generic drugs (me-too Status)	Toprazole 40mg Injection, Morgan Technologies Services Karachi.
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitors (PPI)
	Name, address of Manufacturing site:	Bio-Labs (Pvt.) Ltd.-Plot No. 145,Industrial Triangle Kahuta Road Islamabad- Pakistan-
	The status in reference regulatory authorities	FDA approve drug.
	Detail of previous approval	PantoNext 40mg Injection, 343rd
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
401	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winbrains Research Laboratories Plot No. 69/1 Block B, Phase I-II Industrial Estate, Hattar, Pakistan (000725)
	Application Form Dy. No / Tracking ID & date of submission	(RJP-35G-GZSX, 2025-08-01)
	Detail of Fee Submitted	93000.0, 2025-07-21,
	The proposed proprietary name / brand name	Empeg-ML 10mg, 5mg, 1000mg Tablet
	Label Claim	Each Film Coated Extended Release Tablet contains: Empagliflozin.....10MG Linagliptin.....5MG (As immediate release core) Metformin Hydrochloride*.....1000MG (As extended release core) (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C.
	For generic drugs (me-too Status)	Ezliz XR Tablet by Welmark Pharma
	Pharmacotherapeutic Group of (API)	Sodium-glucose co-transporter 2 (SGLT2) inhibitors Dipeptidyl peptidase-4 (DPP-4) inhibitors Biguanide
	Name, address of Manufacturing site:	Welmark Pharmaceuticals-Plot No. 122, Phase-V, Block-B, Industrial Estate, Hattar, KPK. -
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Empeg, DRB 340
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
402	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

Name, address of Applicant.		Wezen Pharmaceuticals Industrial Estate Rawat (000882)
Application Form Dy. No / Tracking ID & date of submission		(RS1-VE8-G733, 2025-07-29)
Detail of Fee Submitted		93000.0, 2025-07-21,
The proposed proprietary name / brand name		Siltrate 100mg Tablet
Label Claim		Each Film Coated Tablet Contains: Sildenafil as Citrate (USP).....100mg (Product complies USP Specs)
Reference to Finished product specifications		As per Innovators Specification
Proposed Pack Size		As per SRO-As per SRO
Shelf Life (Unit)		2 YearStore below 25°C
For generic drugs (me-too Status)		Sylano Tablet by Wnsfeild Pharma
Pharmacotherapeutic Group of (API)		Phosphodiesterase-5 inhibitor (PDE5-I)
Name, address of Manufacturing site:		Weather Folds Pharmaceuticals-Plot No. 129, Sunder Industrial Estate, Raiwind Road, Lahore-
The status in reference regulatory authorities		USFDA Approved
Detail of previous approval		Siltrate, DRB 345
Evaluation Remarks		
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.		
Decision		
Approved		
403	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	De-Mont Research Laboratories (Pvt.) Ltd. 20 Km, Lahore-Sheikhupura Road, Sheikhupura, Pakistan (000844)
	Application Form Dy. No / Tracking ID & date of submission	(SDU-X6E-UE49, 2025-07-29)
	Detail of Fee Submitted	93000.0, 2025-07-04,
	The proposed proprietary name / brand name	P-FORCE 50MG TABLET
	Label Claim	Each Film Coated Tablet Contains: Sildenafil as Citrate (USP).....50mg (Product complies USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	AS PER SRO-As per SRO
	Shelf Life (Unit)	2 Yearstore below 30 degree centigrade
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 inhibitor (PDE5-I)
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals -Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK PAKISTAN -
	The status in reference regulatory authorities	Viagra 50mg (sildenafil) tablets, USFDA approved.
	Detail of previous approval	Siltrate 50mg Tablet (M # 345)
	Evaluation Remarks	

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

404	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	M/s Daneen Pharma (Pvt) Ltd Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, (000688)
	Application Form Dy. No / Tracking ID & date of submission	(SM1-PDE-9BDE, 2025-07-03)
	Detail of Fee Submitted	75000.0, 18000.0 2024-08-01, 2025-06-24
	The proposed proprietary name / brand name	Zuvaroz Plus
	Label Claim	Each film coated tablet contains: Rosuvastatin calcium eq. to Rosuvastatin 40mg Ezetimibe 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's, 9's, 10's, 14's-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30°C. Protect from heat, light and moisture.
	For generic drugs (me-too Status)	Rosca-EZ (Reg. # 120396) mfg. by Genix Pharma Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Genix Pharma (Pvt.) Ltd.-44, 45-B, Korangi Creek Road, Karachi-75190, Pakistan-
	The status in reference regulatory authorities	Zenon 40/10mg film coated tablets (Sanofi), MHRA approved.
	Detail of previous approval	Rosca Plus Tablet, DRB 336
Evaluation Remarks		
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.		
Decision		
Approved		
405	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Panacea Pharmaceuticals plot No 04, Street S-6 National industrial Zone RCCI rawat islamabad (000600)
	Application Form Dy. No / Tracking ID & date of submission	(SRW-57B-DQX8, 2025-07-28)
	Detail of Fee Submitted	93000.0, 2025-07-22,
	The proposed proprietary name / brand name	Memtocin 10mg/5mL Oral Solution
	Label Claim	Each 5ml contains: Memantine Hydrochloride 10mg

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearstore below 30C
	For generic drugs (me-too Status)	Afdol 10mg/5ml oral solution, AGP Pharma (PVT) LTD.
	Pharmacotherapeutic Group of (API)	Other Anti-dementia drugs
	Name, address of Manufacturing site:	Seraph Pharmaceutical-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
	The status in reference regulatory authorities	FDA Approved Drug
	Detail of previous approval	MEMXIO 10mg/5ml oral solution, 336th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
406	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medwell Pharmaceuticals 1 km, terbella road, lawrencepur, faqirabad Attock (000699)
	Application Form Dy. No / Tracking ID & date of submission	(T9Y-NLV-58BW, 2025-07-29)
	Detail of Fee Submitted	93000.0, 2025-01-28,
	The proposed proprietary name / brand name	Silawel 50mg Tablet
	Label Claim	Each film coated tablet contains: Sildenafil (as Citrate) 50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's-De-Controlled
	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	Viagra 50mg Tablet
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Gray's Pharmaceuticals-PLOT NO 2, STREET NO, N-3, NATIONAL INDUSTRIAL ZONE RAWAT-
	The status in reference regulatory authorities	Attached
	Detail of previous approval	VISILDA 50mg Tablet Registration No. (127637) 345th DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
407	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

Name, address of Applicant.	M/s Daneen Pharma (Pvt) Ltd Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, (000688)
Application Form Dy. No / Tracking ID & date of submission	(TDS-39G-YVWW, 2025-06-12)
Detail of Fee Submitted	75000.0, 75000.0 2024-08-01, 2024-08-01
The proposed proprietary name / brand name	Zuvaroz Plus Tablet 20mg+10mg
Label Claim	Each film coated tablet contains: Rosuvastatin calcium equivalent to Rosuvastatin 20mg Ezetimibe 10mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	7's, 9's, 10's, 14'-As per SRO
Shelf Life (Unit)	24 MonthStore below 30°C. Protect from heat, light and moisture.
For generic drugs (me-too Status)	Rolip EZE 20mg/10mg Mfg. by Hilton Pharma Pvt. Ltd.
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Genix Pharma (Pvt.) Ltd.-44, 45-B, Korangi Creek Road, Karachi-75190, Pakistan-
The status in reference regulatory authorities	Roszet 20mg/10mg Film coated tablet mfg. Merck Sharp & Dohme by
Detail of previous approval	Rosca Plus 20mg/10mg, DRB 336

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

408	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	jupiter Pharma Plot No 25 Street S-6 RCCI Rawat Rawalpindi (000838)
	Application Form Dy. No / Tracking ID & date of submission	(TG6-6PS-HYRD, 2025-05-02)
	Detail of Fee Submitted	93000.0, 2025-03-12,
	The proposed proprietary name / brand name	Siltrate 100mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Sildenafil as Citrate (USP).....100mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Estate, Hattar.-
	The status in reference regulatory authorities	Usfda Approved
	Detail of previous approval	Siltrate Tablet, DRB 345
	Evaluation Remarks	

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

409	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Effort Pharmaceuticals (Pvt.) Ltd., 28-Km, Ferozepur Road (000879)
	Application Form Dy. No / Tracking ID & date of submission	(TGN-L5M-DP9N, 2025-07-25)
	Detail of Fee Submitted	93000.0, 2025-06-20,
	The proposed proprietary name / brand name	Fixim 200mg Capsule
	Label Claim	Each capsule contains: Cefixime (as tri-hydrate)..... 200 mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C and dry place.
	For generic drugs (me-too Status)	Brand Name: Icef. Manufacturer: M/s ICI
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Name, address of Manufacturing site:	High-Cure Research Laboratories. -19 KM Tayyaba Industrial Zone Sheikhpura Road Lahore, Punjab, Pakistan.-
	The status in reference regulatory authorities	Cefixima Normon 200 Mg Hard Capsules EFG (Spain Approved)
	Detail of previous approval	Minutes of 331st Meeting of Registration Board held on 31st Oct – 2nd Nov, 2023 Page 3404
	Evaluation Remarks	
410	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Jinnah Pharmaceuticals Pvt Ltd 13 Km Lahore Road Multan (000578)
	Application Form Dy. No / Tracking ID & date of submission	(TX7-QL7-L66D, 2025-05-05)
	Detail of Fee Submitted	93000.0, 2025-01-25,
	The proposed proprietary name / brand name	J.Agra
	Label Claim	Each film coated tablet contains: Sildenafil (as Citrate).....100mg

	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 YearBelow 30%
	For generic drugs (me-too Status)	Pfizer Pharmaceuticals
	Pharmacotherapeutic Group of (API)	General
	Name, address of Manufacturing site:	M/S Grays Pharmaceuticals-t Plot#2, Street N# N-3, National Industrial Zone Rawat, Islamabad-Pakistan-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	DRB,M-345
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
411	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Onyx Pharmaceuticals 30-A small Industrial Estate mansehra (000440)
	Application Form Dy. No / Tracking ID & date of submission	(U21-8JD-2Z5X, 2025-08-12)
	Detail of Fee Submitted	75000.0, 18000.0 2024-06-27, 2025-07-09
	The proposed proprietary name / brand name	Carbamol Injection 50mg/ml
	Label Claim	Each ml contains: Iron as Ferric Carboxymaltose..... 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Yearstore below 25°C
	For generic drugs (me-too Status)	FCM Injection by Genix Pharma, Karachi
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio Labs (Pvt) Ltd-Plot No. 145,Industrial Triangle Kahuta Road Islamabad- Pakistan-
	The status in reference regulatory authorities	Ferric Carboxymaltose Injection by AM REGENT, USFDA approved
	Detail of previous approval	MaltEvo 50mg/ml Solution for Injection (Meeting # 331st)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
412	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

Name, address of Applicant.	Effort Pharmaceuticals (Pvt.) Ltd., 28-Km, Ferozepur Road (000879)
Application Form Dy. No / Tracking ID & date of submission	(U5E-T27-QXGA, 2025-07-25)
Detail of Fee Submitted	93000.0, 2025-06-20,
The proposed proprietary name / brand name	Efidrox 500mg Capsule
Label Claim	Each capsule contains Cefadroxil monohydrate equivalent to Cefadroxil 500 mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	as per SRO-As per SRO
Shelf Life (Unit)	2 YearStore below 30°C and dry place.
For generic drugs (me-too Status)	Brand Name: Duricef 500 mg Capsule Manufacturer: M/s GSK
Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
Name, address of Manufacturing site:	High-Cure Research Laboratories. -19 KM Tayyaba Industrial Zone Sheikhpura Road Lahore, Punjab, Pakistan.-
The status in reference regulatory authorities	USFDA approved Duricef® 500mg Capsule.
Detail of previous approval	Minutes of 333rd meeting of Registration Board (19th To 20th December, 2023) Page NO.224

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

413	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Acumen Healthcare (Pvt.) Ltd plot#, 39, 40 Street S2, Rawat Industrial Estate, Islamabad (000932)
	Application Form Dy. No / Tracking ID & date of submission	(UUQ-855-XH8U, 2025-06-20)
	Detail of Fee Submitted	93000.0, 2024-12-19,
	The proposed proprietary name / brand name	Cefopara 2gm Injection
	Label Claim	Each vial contains; Cefoperazone as sodium.....1000mg Sulbactam as sodium.....1000mg (Product Complied JP Specs)
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Uszone Inj by Usawa Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Estate, Hattar.-
	The status in reference regulatory authorities	Usfda Approved

	Detail of previous approval	Prazon Injection, DRB 331
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
414	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welcome Pakistan Trading Pharma (Pvt) Ltd Chakri Interchange, Gangawala (000987)
	Application Form Dy. No / Tracking ID & date of submission	(VH1-M9B-U3BM, 2025-08-01)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	Azchlo 12.5mg/40mg Tablet
	Label Claim	Each Film Coated Tablet contains: Azilsartan Medoxomil Potassium eq. to Azilsartan Medoxomil 40MG Chlorthalidone 12.5MG (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25c
	For generic drugs (me-too Status)	Azchlo Tablet by Weather Folds
	Pharmacotherapeutic Group of (API)	Thiazide-Like Diuretics & Anti-Hypertensive
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Area, Hattar.-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Azchlo Tablet, DRB 343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
415	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medwell Pharmaceuticals 1 km, terbella road, lawrencepur, faqirabad Attock (000699)
	Application Form Dy. No / Tracking ID & date of submission	(VTV-9GD-6X7M, 2025-07-29)
	Detail of Fee Submitted	93000.0, 2025-01-28,
	The proposed proprietary name / brand name	Silawel 100mg Tablet

Label Claim	Each film coated tablet contains: Sildenafil (as Citrate) 100mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	4's-De-Controlled
Shelf Life (Unit)	2 YearRoom Temperature
For generic drugs (me-too Status)	Viagra 100mg Tablet
Pharmacotherapeutic Group of (API)	Attached
Name, address of Manufacturing site:	Gray's Pharmaceuticals-PLOT NO 2, STREET NO, N-3, NATIONAL INDUSTRIAL ZONE RAWAT-
The status in reference regulatory authorities	MHRA
Detail of previous approval	VISILDA 100mg Tablet Registration No. (127638) in 345th DRB

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

416	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Effort Pharmaceuticals (Pvt.) Ltd., 28-Km, Ferozepur Road (000879)
	Application Form Dy. No / Tracking ID & date of submission	(W8T-E6M-RSR5, 2025-07-25)
	Detail of Fee Submitted	93000.0, 2025-06-20,
	The proposed proprietary name / brand name	Fixim 100mg Oral Suspension
	Label Claim	Each 5 ml contains: (after reconstitution) Cefixime (as tri-hydrate)..... 100 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C and dry place.
	For generic drugs (me-too Status)	Brand Name: Icef. Manufacturer: M/s ICI
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Name, address of Manufacturing site:	High-Cure Research Laboratories. -19 KM Tayyaba Industrial Zone Sheikhpura Road Lahore, Punjab, Pakistan.-
	The status in reference regulatory authorities	USFDA approved SUPRAX® by Lupin.
	Detail of previous approval	Minutes of 331st Meeting of Registration Board held on 31st Oct – 2nd Nov, 2023 Page 3397

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

417	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Aulton Pharmaceuticals Plot # 84/1,Block A, Phase 5 , Industrial Estate Hattar, KPK, (000828)
	Application Form Dy. No / Tracking ID & date of submission	(WD5-YW7-SX7Z, 2025-07-29)
	Detail of Fee Submitted	93000.0, 2025-07-23,
	The proposed proprietary name / brand name	Aultafile 50mg Tablets
	Label Claim	Each film coated tablet contains: Sildenafil as Citrate.....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO / DPC-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Siltrate 50mg Tablet by Weather folds Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Drugs used in erectile dysfunction
	Name, address of Manufacturing site:	WEATHER FOLDS Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar-
	The status in reference regulatory authorities	SILDENAFIL CITRATE 50MG TABLET approved by MHRA (https://www.medicines.org.uk/emc/product/13880/smcp#
	Detail of previous approval	Siltrate 50mg Tablet (345th Meeting), Application tracking ID: (Z4V-L39-RJ93, 2024-12-17)
Evaluation Remarks		
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.		
Decision		
Approved		
418	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Invictus Pharmaceuticals Plot No. 21, 26 Street No. NS.2, National Industrial Zone Rawat, Islamabad (000892)
	Application Form Dy. No / Tracking ID & date of submission	(WJR-5A7-ABMW, 2025-06-13)
	Detail of Fee Submitted	93000.0, 2024-12-31,
	The proposed proprietary name / brand name	Koldar 100mg Infusion
	Label Claim	Each ml contains: Paracetamol 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's Vail-As per SRO
	Shelf Life (Unit)	24 Month25°C
	For generic drugs (me-too Status)	Provas infusion by sami Pharma.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Labs(Pvt).Ltd-Plot No. 145,Industrial Triangle Kahuta Road Islamabad- Pakistan -

	The status in reference regulatory authorities	US FDA
	Detail of previous approval	Cetol100ml Infusion. Minutes of 322nd meeting of Registration Board (8th &10th November,2022)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
419	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Effort Pharmaceuticals (Pvt.) Ltd., 28-Km, Ferozepur Road (000879)
	Application Form Dy. No / Tracking ID & date of submission	(WW2-1W3-LQEU, 2025-07-25)
	Detail of Fee Submitted	93000.0, 2025-06-20,
	The proposed proprietary name / brand name	Fixim 400mg Capsule
	Label Claim	Each capsule contains: Cefixime (as tri-hydrate)..... 400 mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C and dry place.
	For generic drugs (me-too Status)	Brand Name: Icef. Manufacturer: M/s ICI
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Name, address of Manufacturing site:	High-Cure Research Laboratories. -19 KM Tayyaba Industrial Zone Sheikhpura Road Lahore, Punjab, Pakistan.-
	The status in reference regulatory authorities	Cefixima Normon 400 Mg Hard Capsules EFG (Spain Approved)
	Detail of previous approval	Minutes of 331st Meeting of Registration Board held on 31st Oct – 2nd Nov, 2023 page no:3407
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
420	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Panacea Pharmaceuticals plot No 04,Street S-6 National industrial Zone RCCI rawat islamabad (000600)
	Application Form Dy. No / Tracking ID & date of submission	(WXB-Z6B-ML5Q, 2025-05-05)

Detail of Fee Submitted	93000.0, 2025-01-23,
The proposed proprietary name / brand name	Jinagra
Label Claim	Each film coated tablet contains: Sildenafil (as Citrate).....50mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	As per SRO-De-Controlled
Shelf Life (Unit)	2 YearBelow 30%
For generic drugs (me-too Status)	Pfizer Pharmaceuticals
Pharmacotherapeutic Group of (API)	Genral
Name, address of Manufacturing site:	Gray's Pharmaceuticsa-Plot#2, Street N# N-3, National Industrial Zone Rawat, Islamabad-Pakistan,-
The status in reference regulatory authorities	USFDA
Detail of previous approval	DRB,M-345

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

421	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Crown Pharmaceuticals Plot 286, Kahuta industrial Triangle, Kahota Road, Islamabad (000456)
	Application Form Dy. No / Tracking ID & date of submission	(X94-B6Q-8E5Q, 2025-08-12)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	Vonoc 10mg Tablet
	Label Claim	Each film coated tablet contains: Vonoprazan Fumarate equivalent to Vonoprazan.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's, 20's, 30's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30 centi grade
	For generic drugs (me-too Status)	Vonozan 10mg tablet by Getz Pharma
	Pharmacotherapeutic Group of (API)	Potassium-competitive acid blocker
	Name, address of Manufacturing site:	LINTA PHARMACEUTICALS-Plot# 03, street # S-5, National Industrial Zone, Rawat, Islamabad, Pakistan.-
	The status in reference regulatory authorities	TAKECAB by Takeda Pharmaceutical Company Limited Japan
	Detail of previous approval	Vonopraz 10mg Tablet, Minutes of 336th meeting of Registration Board (04th-06th June, 2024).

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other

conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

422	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welcome Pakistan Trading Pharma (Pvt) Ltd Chakri Interchange, Gangawala (000987)
	Application Form Dy. No / Tracking ID & date of submission	(X9A-N42-9U7S, 2025-08-01)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	EMPEG-ML 12.5mg, 2.5mg, 1000mg XR Tablet
	Label Claim	Each Film Coated Extended Release Tablet contains: Empagliflozin.....12.5mg Linagliptin.....2.5MG (As immediate release core) Metformin Hydrochloride*.....1000MG (As extended release core) (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25c
	For generic drugs (me-too Status)	Ezliz XR Tablet by Welmark Pharma
	Pharmacotherapeutic Group of (API)	Sodium-glucose co-transporter 2 (SGLT2) inhibitors Dipeptidyl peptidase-4 (DPP-4) inhibitors Biguanide
	Name, address of Manufacturing site:	Welmark Pharmaceuticals-Plot NO. 122, Block-B, Phase-V, Industrial Estate, Hattar, KPK. -
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	EMPEG-ML XR Tablet , DRB 340
Evaluation Remarks		
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.		
Decision		
Approved		
423	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welcome Pakistan Trading Pharma (Pvt) Ltd Chakri Interchange, Gangawala (000987)
	Application Form Dy. No / Tracking ID & date of submission	(XHS-G8Y-39UL, 2025-08-01)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	Ondanz 8mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Ondansetron as Hydrochloride Dihydrate (USP).....8mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia

	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25c
	For generic drugs (me-too Status)	Oniron 8mg Tablet by Genome Pharma
	Pharmacotherapeutic Group of (API)	Serotonin 5-Ht3 Receptor Antagonists
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Area, Hattar.-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Ondanz, DRB 343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
424	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	GT Pharma Pvt. Ltd 713- Sundar Industrial Estate, Sundar Raiwind Road, (000829)
	Application Form Dy. No / Tracking ID & date of submission	(Y13-LXE-SD9Z, 2025-05-19)
	Detail of Fee Submitted	93000.0, 2025-01-27,
	The proposed proprietary name / brand name	Silagra 100mg Tablet
	Label Claim	Each film coated tablet contains: Sildenafil (as citrate) 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's-As per SRO
	Shelf Life (Unit)	2 YearControlled Room
	For generic drugs (me-too Status)	Viagra 100mg Tablet
	Pharmacotherapeutic Group of (API)	phosphodiesterase-5 (PDE-5) inhibitors
	Name, address of Manufacturing site:	Gray's Pharmaceuticals-Plot No. 2, Street No. N-3, National Industrial Zone Rawat-
	The status in reference regulatory authorities	US-FDA
	Detail of previous approval	Seldem 100mg Tablet approved in 345th Registration Board Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
425	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	SHAWAN PHARMACEUTICALS PLOT # 37, NS-1. NATIONAL INDUSTRIAL ZONE. RAWAT (000627)

Application Form Dy. No / Tracking ID & date of submission	(Y5H-7QB-NQ7D, 2025-03-17)
Detail of Fee Submitted	93000.0, 2024-11-22,
The proposed proprietary name / brand name	TAZOCILIN
Label Claim	Each Tazocilin 4.5 g vial provides piperacillin sodium equivalent to 4 grams of piperacillin and tazobactam sodium equivalent to 0.5 g of tazobactam.
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 YearRoom Temperature
For generic drugs (me-too Status)	Piptaz 4.5g IV Injection
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Evolution Pharmaceuticals-Plot #: 25 & 26, Street #: S-3, RCCI, National Industrial Zone, Rawat, Islamabad - Pakistan-
The status in reference regulatory authorities	USFDA, ZOSYN 4.5g inj
Detail of previous approval	Piptaz 4.5g IV Injection

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

426	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Acumen Healthcare (Pvt.) Ltd plot#, 39, 40 Street S2, Rawat Industrial Estate, Islamabad (000932)
	Application Form Dy. No / Tracking ID & date of submission	(YPN-TEA-EMW6, 2025-06-17)
	Detail of Fee Submitted	93000.0, 2024-12-10,
	The proposed proprietary name / brand name	Dexlan 60mg Capsule
	Label Claim	Each Capsule Contains: Dexlansoprazole as Dual Delayed Release Pellets.....60mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Dexxo Capsule by Weather Folds Pharma.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wezen Pharmaceuticals-Plot #23 & 24, S-1, RCCI Industrial Estate, Rawat-
	The status in reference regulatory authorities	Usfda Approved
	Detail of previous approval	Dexzen Capsule, DRB 330

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for

cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

427	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Alliance Pharmaceuticals (pvt) Ltd 112-A Hayatabad Industrial Estate (000594)
	Application Form Dy. No / Tracking ID & date of submission	(YRQ-NBH-Z2MP, 2025-07-24)
	Detail of Fee Submitted	93000.0, 2025-07-16,
	The proposed proprietary name / brand name	Silvanta 100mg Tab
	Label Claim	Each Film Coated Tablet Contains: Sildenafil Citrate eq-to Sildenafil...100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4 and 1x 10-As per SRO
	Shelf Life (Unit)	2 Year(s)30C
	For generic drugs (me-too Status)	Ripple 100mg
	Pharmacotherapeutic Group of (API)	M/S: Rakshit Drugs PVT LTD. INDIA
	Name, address of Manufacturing site:	M/s Solaris Life Sciences-Plot#08, Street.S-1, RCCI, Industrial Estate Rawat-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Ripple 100mg (M345)

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

428	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winlet Pharmaceuticals (Pvt) Ltd. 30-Km, Lahore Sargodha Raod, Sargodha (000874)
	Application Form Dy. No / Tracking ID & date of submission	(YTA-TTJ-QDG1, 2025-05-02)
	Detail of Fee Submitted	93000.0, 2025-01-22,
	The proposed proprietary name / brand name	sildenawin
	Label Claim	Each film coated tablet contains: Sildenafil (as Citrate).....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 °C
	For generic drugs (me-too Status)	Gray,s pharma
	Pharmacotherapeutic Group of (API)	phosphodiesterase (PDE) inhibitors

	Name, address of Manufacturing site:	M/S Gray,s pharma-plot no 2, street no N-3 RCCI rawat-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	M-343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
429	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Onyx Pharmaceuticals 30-A small Industrial Estate mansehra (000440)
	Application Form Dy. No / Tracking ID & date of submission	(ZBX-YDA-5WVS, 2025-08-12)
	Detail of Fee Submitted	75000.0, 18000.0 2024-06-25, 2025-07-09
	The proposed proprietary name / brand name	Vonobact Injection 1gm
	Label Claim	Each vial contains: Cefoperazone as Sodium.....500mg Salbactam as Sodium.....500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Yearstore below 25°C
	For generic drugs (me-too Status)	Cebac Injection by Bosch Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Nicholas Pharmaceuticals-plot no 34, Street no SS-2, National Industrial zone, Rawat ,Islamabad-
	The status in reference regulatory authorities	Sulperazone Intravenous Injection 1g by Pfizer
	Detail of previous approval	Wincef 1g Injection (Meeting 333rd)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
430	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Nutrabiocotics Pharmaceuticals PLOT NO 89- K/3 INDUSTRIAL ESTATE , HAYATABAD, PESHAWAR (001008)
	Application Form Dy. No / Tracking ID & date of submission	(ZTS-PDP-UY3M, 2025-07-29)
	Detail of Fee Submitted	93000.0, 2025-07-22,
	The proposed proprietary name / brand name	Semax Tablet 100mg

Label Claim	Each film coated Tablet contains: Sildenafil Citrate 140.45 mg eq. to sildenafil 100mg (USP Spec's.)
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	1x4's , 1x10's-As per SRO
Shelf Life (Unit)	2 YearBelow 30
For generic drugs (me-too Status)	Silagro by Nabi Qasim Pharma
Pharmacotherapeutic Group of (API)	phosphodiesterase (PDE) inhibitors
Name, address of Manufacturing site:	Solaris Life Sciences Private Limited, -Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, Rawalpindi-PAKISTAN.-
The status in reference regulatory authorities	Viagra 100mg tablet
Detail of previous approval	Ripple 100mg tablet , 345 Meeting of Registartion Board

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

431	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Dyson Research Laboratories (Pvt.) Ltd 28-Km Ferozpur Road Lahore (000559)
	Application Form Dy. No / Tracking ID & date of submission	(3EE-RJR-DRG7, 2025-08-29)
	Detail of Fee Submitted	93000.0, 2025-02-14,
	The proposed proprietary name / brand name	Tekas
	Label Claim	Each 1ml Ampoule Contains: Ketorolac Tromethamine.....30mg.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5's-As per SRO
	Shelf Life (Unit)	2 YearStore below 25C.
	For generic drugs (me-too Status)	Ketorolac Injection 30mg by Winsfelid Pharmaceutical (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Labs (Pvt.) Ltd.-Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad.-
	The status in reference regulatory authorities	Ketorolac Tromethamine Injection by HOSPIRA., registered in United States agency for Food and Drug Administration (USFDA).
	Detail of previous approval	Katwari Injection 30mg/ml (Ketorolac Tromethamine), approved in 343 meeting of registration board he

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other

conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

432	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Swiss Pharmaceuticals Pvt. Ltd. A/159, S.I.T.E.-II, Super Highway (000438)
	Application Form Dy. No / Tracking ID & date of submission	(77R-P8U-QTQX, 2025-08-29)
	Detail of Fee Submitted	93000.0, 2025-02-17,
	The proposed proprietary name / brand name	ELLA Tablet 150mg
	Label Claim	Each Film coated tablet contains: Elagolix sodium Equivalent to Elagolix 150mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x10's, 2x7'-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Brand name: Elagolixin 150mg Tablet, Manufacturer/Registration holder: Kaizan Pharmaceuticals Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt) Ltd. -Plot No. 129, Sundar Industrial Estate Raiwind Road Lahore Pakistan. Phone: 042-111 116 366 -
	The status in reference regulatory authorities	Manufacturer Name: AbbVie Inc. North Chicago, IL 60064 03-B517, Brand Name & Strength: Orilissa(Elagolix) 150mg tablet, NDC0074-0038-28, Reference Regulatory Authority: USFDA approved.
	Detail of previous approval	Orlix 150mg Tablet, M-343
Evaluation Remarks		
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.		
Decision		
Approved		
433	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Kanel Pharma Plot No. 6, Street No. SS-3, National Industrial Zone, Rawat (000758)
	Application Form Dy. No / Tracking ID & date of submission	(93P-DU8-ZV2L, 2025-08-29)
	Detail of Fee Submitted	93000.0, 2025-06-18,
	The proposed proprietary name / brand name	HYDROTRIM
	Label Claim	Each vial contains:- Hydrocortisone sodium succinate as ready to fill powder equivalent to Hydrocortisone 100MG
	Reference to Finished product specifications	United States Pharmacopeia
Minutes of 351st Meeting of Registration Board		(23rd – 24th September, 2025)

	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearControlled Room Temprature
	For generic drugs (me-too Status)	Cortisone 100mg Injection by Vision Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Name, address of Manufacturing site:	M/S Wenovo Pharmaceuticals-Plot # 31,32, Punjab Small Industrial Estate, Taxila, Rawalpindi -
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	HY-KOR 100mg Injection, 339th Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
434	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Swiss Pharmaceuticals Pvt. Ltd. A/159, S.I.T.E.-II, Super Highway (000438)
	Application Form Dy. No / Tracking ID & date of submission	(9HV-XJT-UNSY, 2025-08-29)
	Detail of Fee Submitted	93000.0, 2025-02-17,
	The proposed proprietary name / brand name	TAPENT Tablet 50mg
	Label Claim	Each Film Coated Tablet contains: Tapentadol HCl eq. To Tapentadol.....50mg.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x10's, 2x7'-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Brand Name & Strength: Tapento IR 50mg Tablet., Manufacturer Name: M/s Sami Pakistan.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt) Ltd. -Plot No. 129, Sundar Industrial Estate Raiwind Road Lahore Pakistan. Phone: 042-111 116 366 -
	The status in reference regulatory authorities	Manufacturer Name: M/s Grünenthal GmbH, Germany., Brand Name & Strength: Palexia IR 50mg Tablet., Reference Regulatory Authority: MHRA approved.
	Detail of previous approval	Tydol 50mg IR Tablet, M-343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	

The Registration Board approved the grant of registration of the applied product with the condition that manufacturer shall ensure the following directions for use on the labelling of the drug product in a clear manner:

"To be used by patients 18 years of age or older for the management of moderate to severe chronic pain."

435	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	UniMark Pharmaceuticals Pvt. Ltd. Plot No. 7-A, Street No. S-7, National Industrial Zone, Rawat (000557)
	Application Form Dy. No / Tracking ID & date of submission	(9LY-EVT-25R4, 2025-08-29)
	Detail of Fee Submitted	93000.0, 2025-02-10,
	The proposed proprietary name / brand name	Elvis Injection 2gm
	Label Claim	Each vial contains ceftriaxone sodium eq. to ceftriaxone 2000mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1*1s-As per SRO
	Shelf Life (Unit)	2 Year 15° to 30°C
	For generic drugs (me-too Status)	Oxidil Injection of M/S Sami Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/S Seraph Pharmaceuticals-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
	The status in reference regulatory authorities	Rocephin Injection MHRA approved
	Detail of previous approval	Sixone 2gm Injection, 331 DRAP Registration Board Meeting
Evaluation Remarks		
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.		
Decision		
Approved		
436	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Swiss Pharmaceuticals Pvt. Ltd. A/159, S.I.T.E.-II, Super Highway (000438)
	Application Form Dy. No / Tracking ID & date of submission	(9M3-4L3-TDVY, 2025-08-29)
	Detail of Fee Submitted	93000.0, 2025-02-17,
	The proposed proprietary name / brand name	MIROGAB Tablet 5mg
	Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to Mirogabalin.....5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
	Shelf Life (Unit)	2 Year Store below 30°C
	For generic drugs (me-too Status)	Brand Name: Mirogab 5mg Tablet, Manufacturer/ Brand Holder: M/s Wimits Pharmaceuticals (Pvt) Ltd.
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt.) Ltd. -Plot No. 129, Sundar Industrial Estate Raiwind Road Lahore Pakistan-
	The status in reference regulatory authorities	Manufacturer Name: Daiichi Sankyo Co., Ltd, Brand Name & Strength: Tarlige Tablets 5mg.
	Detail of previous approval	Mirogab 5mg Tablet, M-344.
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
437	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	INVENTOR PHARMA PVT LTD Plot No. K-196 S.I.T.E, Super Highway Phase-II (000866)
	Application Form Dy. No / Tracking ID & date of submission	(AV8-R9V-U2E7, 2025-08-29)
	Detail of Fee Submitted	93000.0, 2025-02-12,
	The proposed proprietary name / brand name	Invenzo 2.25 g Injection
	Label Claim	Each Vial Contains: Piperacillin Sodium USP eq. to 2.0 gm Piperacillin Tazobactam Sodium MS eq. to 250 mg Tazobactam
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1,s-As per SRO
	Shelf Life (Unit)	2 Year15C-25 C
	For generic drugs (me-too Status)	Tanzo 2.25 g injection
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Fleming Pharmaceuticals-23- Km Lahore- Sheikhpura Road, Lahore.-
	The status in reference regulatory authorities	Zosyn injection
	Detail of previous approval	Fletazo Injection 2.25 g , 323rd meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
438	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Air Pharmaceuticals(Pvt.)Ltd Plot No's 74, 75-A, Small Industrial Estate, Kasur (000977)
	Application Form Dy. No / Tracking ID & date of submission	(DML-ZQJ-LDN2, 2025-08-29)

Detail of Fee Submitted	93000.0, 2025-02-14,
The proposed proprietary name / brand name	Air -D3
Label Claim	Each ml contains: Cholecalciferol.....300,000IU
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	1's-As per SRO,100's-As per SRO,5's-As per SRO
Shelf Life (Unit)	2 Yearbelow 30°C in dry cool environment
For generic drugs (me-too Status)	Invid -3 by Novamed
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Novamed Pharmaceuticals(Pvt.)Ltd-28-KM, FEROZEPUR ROAD, NEAR GRAND AVENUE, Lahore Nishter Town-
The status in reference regulatory authorities	DI BASE 300,000 IU Solution by Abiogen Pharma Italy
Detail of previous approval	Invid-3 Injection (M-322nd DRB Approved)

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

439	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Kanel Pharma Plot No. 6, Street No. SS-3, National Industrial Zone, Rawat (000758)
	Application Form Dy. No / Tracking ID & date of submission	(XAX-53U-G3D3, 2025-08-29)
	Detail of Fee Submitted	93000.0, 2025-06-18,
	The proposed proprietary name / brand name	HYDROTRIM
	Label Claim	Each vial contains:- Hydrocortisone sodium succinate as ready to fill powder equivalent to Hydrocortisone 250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearControlled Room Temperature
	For generic drugs (me-too Status)	Cortisone 250mg Injection by Vision Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Name, address of Manufacturing site:	M/S Wenovo Pharmaceuticals-Plot # 31,32, Punjab Small Industrial Estate, Taxila, Rawalpindi -
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	HY?KOR 250mg Injection, 339th Meeting

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

440	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Panacea Pharmaceuticals plot No 04, Street S-6 National industrial Zone RCCI rawat islamabad (000600)
	Application Form Dy. No / Tracking ID & date of submission	(151-GAW-UMR1, 2025-08-28)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	Dewtrazon 500mg Injection IV
	Label Claim	Each vial contains: Ceftriaxone sodium equivalent to Ceftriaxone 500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Droncef Injection 500mg IV (Seraph Pharmaceutical, Islamabad)
	Pharmacotherapeutic Group of (API)	Third-generation Cephalosporins
	Name, address of Manufacturing site:	Seraph Pharmaceutical-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	ACRUX 500mg Injection IV, 317th
Evaluation Remarks		
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.		
Decision		
Approved		
441	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(3EQ-PN8-VL5N, 2025-08-28)
	Detail of Fee Submitted	93000.0, 2025-06-04,
	The proposed proprietary name / brand name	Tacor 0.5mg Capsules
	Label Claim	Each Capsule contains: Tacrolimus Monohydrate equivalent to Tacrolimus 0.5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Me To Registration Status: Registered in Pakistan Brand Name: Tacgraf 0.5mg Capsules Manufacturer: CCL Pharmaceuticals Address: 65, Quaid-e-Azam Industrial Estate Kot Lakhpat, Lahore
	Pharmacotherapeutic Group of (API)	Immunosuppressants

Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd.-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
The status in reference regulatory authorities	SRA Registration Status: Registered in USFDA Abbreviated New Drug Application (ANDA): 090596 Brand Name: Tacrolimus Capsules 0.5mg, USP Manufacturer: Mylan Pharmaceuticals Inc.
Detail of previous approval	344th

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

442	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(6JU-HLW-4DLZ, 2025-08-28)
	Detail of Fee Submitted	93000.0, 2025-06-04,
	The proposed proprietary name / brand name	Fosfo-3g Sachet
	Label Claim	Each Sachet Contains; Fosmomycin Trometamol Eq. to Fosfomycin 3g (Innovator Spec's)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Me too Status: Registered in Pakistan Brand Name: Focin Ultra sachet Manufacturer: Tabros Pharma (Pvt.) Ltd Address: Essa House, 32-1-C, Block-6, P.E.C.H.S., Karachi-Pakistan
	Pharmacotherapeutic Group of (API)	antibiotics
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd.-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - -
	The status in reference regulatory authorities	SRA Registration Status: Registered in switzerland Brand Name: Monurol 3g Sachet Manufacturer: Zambon Switzerland Ltd., Address: 6814 Cadempino, Switzerland
	Detail of previous approval	347th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	

443	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(8H5-YM6-E92G, 2025-08-28)
	Detail of Fee Submitted	93000.0, 2025-06-04,
	The proposed proprietary name / brand name	Tacor 0.1% Ointment
	Label Claim	Each gram contains: Tacrolimus (as monohydrate).....1mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Me To Registration Status: Registered in Pakistan Brand Name: Eczemus Ointment 0.1% Manufacturer: Brookes Pharma (Private) Limited Address: 58 & 59, Sector- 15 Main Korangi Industrial Local Rd, Secto
	Pharmacotherapeutic Group of (API)	Tacrolimus Monohydrate
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd.-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	RA Registration Status: US FDA Approved Brand Name: Tacrolimus Ointment 0.1% Manufacturer: Accord Healthcare Address: Sage House, 319 Pinner Road North Harrow, Middlesex HA1 4HF - London UK https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=211688
444	Detail of previous approval	345th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
444	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(9PN-9EY-R9LN, 2025-08-28)
	Detail of Fee Submitted	93000.0, 2025-06-04,
	The proposed proprietary name / brand name	FLOCINOL 0.01% LOTION
	Label Claim	Each ml Contains; Fluocinolone Acetonide.....0.1mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Synalar lotion (Pharma Health pakistran (pvt). ltd)
	Pharmacotherapeutic Group of (API)	Corticosteroid WHO ATC Code: D07AC04

	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan-
	The status in reference regulatory authorities	Registered in United state.(SYNALAR®) IGI Laboratories, Inc.
	Detail of previous approval	339th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
445	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(BSW-Z1Q-JYRS, 2025-08-28)
	Detail of Fee Submitted	93000.0, 2025-06-04,
	The proposed proprietary name / brand name	Fultose 50mg/ml Injection
	Label Claim	Each ml contains: Iron as Ferric Carboxymaltose...50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10ml x 1's -As per SRO,10ml x 5's-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	108583 FCM Injection 500mg/10ml(Genix Pharma Limited, Karachi.)
	Pharmacotherapeutic Group of (API)	Haematinics
	Name, address of Manufacturing site:	Bio-Labs(Pvt).Ltd-Plot No. 145,Industrial Triangle Kahuta Road Islamabad- Pakistan-
	The status in reference regulatory authorities	Drugs@FDA: FDA-Approved Drugs
	Detail of previous approval	331st
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
446	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(M9P-5BG-DH9M, 2025-08-28)
	Detail of Fee Submitted	93000.0, 2025-06-04,

The proposed proprietary name / brand name	Tacor 5mg Capsules
Label Claim	Each Capsule contains: Tacrolimus Monohydrate equivalent to Tacrolimus.....5mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 Year30C
For generic drugs (me-too Status)	Me To Registration Status: Registered in Pakistan Brand Name: Inograp 5mg Capsules Manufacturer: Platinum Pharmaceuticalm (Pvt.) Ltd. Address: H2X7+2Q5, Shalley Valley, Rawalpindi, Punjab 46000
Pharmacotherapeutic Group of (API)	Immunosuppressants
Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd.-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
The status in reference regulatory authorities	SRA Registration Status: Registered in USA Brand Name: Tacrolimus Capsules 5mg, USP Manufacturer: Mylan Pharmaceuticals Inc. Address: 781 Chestnut Ridge Road Morgantown, WV 26505 United States. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=090596
Detail of previous approval	344th

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

447	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(S99-JDB-QGRH, 2025-08-28)
	Detail of Fee Submitted	93000.0, 2025-06-04,
	The proposed proprietary name / brand name	Tacor 1mg Capsules
	Label Claim	Each Capsule contains: Tacrolimus Monohydrate equivalent to Tacrolimus.....1mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Me To Registration Status: Registered in Pakistan Brand Name: Tacgraf 1mg Capsules Manufacturer: CCL Pharmaceuticals Address: 65, Quaid-e-Azam Industrial Estate Kot Lakhpat, Lahore
	Pharmacotherapeutic Group of (API)	Immunosuppressants
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd.-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	SRA Registration Status: Registered in USA Brand Name: Tacrolimus Capsules 1mg, USP Manufacturer:

		Mylan Pharmaceuticals Inc.
	Detail of previous approval	344th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
448	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(U3J-VBD-LG6X, 2025-08-28)
	Detail of Fee Submitted	93000.0, 2025-06-04,
	The proposed proprietary name / brand name	FLOCINOL 0.025% CREAM
	Label Claim	Each gm Contains; Fluocinolone Acetonide.....0.25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Me too Status: Registered in Pakistan Brand Name: Synalar cream 0.025% Manufacturer: Mass pharma (pvt). ltd Address: 17-km,Ferozepur road,Lahore pakistan
	Pharmacotherapeutic Group of (API)	Cream. Smooth white cream
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan-
	The status in reference regulatory authorities	SRA Registration Status: Registered in United state. Brand Name: Fluocinolone Acetonide cream 0.025% USP Manufacturer: Cosette pharmaceuticals,inc Address: 101 Coolidge St South Plainfield, NJ, 07080-3801 United States
	Detail of previous approval	339th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
449	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Nicholas Pharmaceuticals Plot 34, Street SS-2, National Industrial Zone, Rawat (000886)
	Application Form Dy. No / Tracking ID & date of submission	(LDQ-497-USBN, 2025-09-01)

Detail of Fee Submitted	93000.0, 2025-07-25,
The proposed proprietary name / brand name	VIGA 100mg Tablets
Label Claim	Each film coated Tablet contains: Sildenafil as Citrate 100mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 Year25°C
For generic drugs (me-too Status)	Ripple 100mg Tablets
Pharmacotherapeutic Group of (API)	Rakshit Drugs PVT LTD
Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd.-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
The status in reference regulatory authorities	Viagra 100mg Tablet
Detail of previous approval	Ripple 100mg Tablets, M345

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

450	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Davis Pharmaceutical Laboratories Plot No. 121, Industrial Triangle Area, Kahuta Road (000432)
	Application Form Dy. No / Tracking ID & date of submission	(RZ9-GSS-VA55, 2025-09-01)
	Detail of Fee Submitted	93000.0, 2025-07-28,
	The proposed proprietary name / brand name	Siltrate 100mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Sildenafil as Citrate (USP).....100mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Sylano Tablet by Wnsfeild Pharma
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 inhibitor (PDE5-I)
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Estate, Hattar.-
	The status in reference regulatory authorities	Usfda Approved
	Detail of previous approval	Siltrate Tablet, DRB 345

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

451	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Davis Pharmaceutical Laboratories Plot No. 121, Industrial Triangle Area, Kahuta Road (000432)
	Application Form Dy. No / Tracking ID & date of submission	(ZUZ-VDB-LZ5Z, 2025-09-01)
	Detail of Fee Submitted	93000.0, 2025-07-28,
	The proposed proprietary name / brand name	Siltrate 50mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Sildenafil as Citrate (USP).....50mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Sylano Tablet by Wnsfeild Pharma
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 inhibitor (PDE5-I)
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Estate, Hattar.-
	The status in reference regulatory authorities	Usfda Approved
	Detail of previous approval	Siltrate Tablet, DRB 345
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
452	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(UU9-6QT-L22N, 2025-09-04)
	Detail of Fee Submitted	93000.0, 2025-06-26,
	The proposed proprietary name / brand name	Betamed C Ointment
	Label Claim	Each gram contains: Betamethasone as Valerate 0.1% w/w
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	GlaxoWellcome UK Ltd, 980 Great West Road, Brentford, Middlesex, TW8 9GS
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Name, address of Manufacturing site:	Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	GlaxoSmithKline UK Address 980 Great West Road, Brentford, Middlesex, TW8 9GS, UK E-mail
	Minutes of 351st Meeting of Registration Board (23rd – 24th September, 2025) 374	

		customercontactuk@gsk.com Adverse event reporting email uksafety@gsk.com Telephone 0800 221 441 Medical Information e-mail ukmedinfo@gsk.com
	Detail of previous approval	313TH
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
453	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(ZE1-9Y5-8Z8Z, 2025-09-04)
	Detail of Fee Submitted	93000.0, 2025-07-04,
	The proposed proprietary name / brand name	TRIOL 1mcg/ml Injection
	Label Claim	Each ml ampoule contains:-Calcitriol.....1mcg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Rotex Pharamceuticals (Reg. No. 107285)
	Pharmacotherapeutic Group of (API)	Vitamin D3 WHO ATC Code A11CC04
	Name, address of Manufacturing site:	Biogen Life Sciences-8-KM Chakbeli Road Rawat Rawalpindi Pakistan-
	The status in reference regulatory authorities	CALCIJEX® (calcitriol injection) 1 mcg/mL Approved by FDA
	Detail of previous approval	335th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
454	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(SLA-QJY-L2NV, 2025-09-04)
	Detail of Fee Submitted	93000.0, 2025-06-27,

	The proposed proprietary name / brand name	SHEVAZ 1gm Injection
	Label Claim	Each vial contains: Cefepime hydrochloride eq to Cefepime.....1gm With L-Arginine (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Brand Name; Cefstar Injection 1g Reg No.; 076007 Manufacturer Name; M/s Barrett and Hodgson
	Pharmacotherapeutic Group of (API)	Antibacterial drug
	Name, address of Manufacturing site:	Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Maxipime 500mg, 1gm & 2gm Injection USFDA Approved
	Detail of previous approval	339th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
455	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(Q4A-TN5-8JSV, 2025-09-04)
	Detail of Fee Submitted	93000.0, 2025-06-27,
	The proposed proprietary name / brand name	Citol 1mcg Soft gelatin Capsule
	Label Claim	Each Soft gelatin contains:- Paricalcitol.....1mcg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Manufacturer Name Biogen Life Sciences Generic Name Paricalcitol Brand Name Parical 1mcg Softgel Capsules
	Pharmacotherapeutic Group of (API)	Vitamin D analogs
	Name, address of Manufacturing site:	Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	FDA Approved. Zemplar (Paricalcitol soft gelatin) 1 mcg Capsule
	Detail of previous approval	339th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt	

the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

456	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(JP9-GXY-QX7Q, 2025-09-04)
	Detail of Fee Submitted	93000.0, 2025-06-27,
	The proposed proprietary name / brand name	SHEVAZ 500mg Injection
	Label Claim	Each vial contains: Cefepime hydrochloride eq to Cefepime.....500mg With L-Arginine (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Brand Name; Cefstar Injection 500mg Reg No.; 076005 Manufacturer Name; M/s Barrett and Hodgson
	Pharmacotherapeutic Group of (API)	Antibacterial drug
	Name, address of Manufacturing site:	Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Maxipime 500mg, 1gm & 2gm Injection USFDA Approved
	Detail of previous approval	339th
Evaluation Remarks		
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.		
Decision		
Approved		
457	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(PEY-UA2-JXMP, 2025-09-04)
	Detail of Fee Submitted	93000.0, 2025-06-27,
	The proposed proprietary name / brand name	Ceframed 250mg Capsule
	Label Claim	Each capsule Contains: Cephradine as monohydrate.....250mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year30C

	For generic drugs (me-too Status)	Brand Name; Velosef Capsule Manufacturer Name: GSK
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibacterial drug
	Name, address of Manufacturing site:	Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Brand Name; Velosef Capsule Manufacturer Name: GSK
	Detail of previous approval	320th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
458	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(G1T-29H-5WAY, 2025-09-04)
	Detail of Fee Submitted	93000.0, 2025-06-27,
	The proposed proprietary name / brand name	Citol 2 mcg Soft gelatin Capsule
	Label Claim	Each Soft gelatin contains:- Paricalcitol 2mcg (USP Specs
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Manufacturer Name Biogen Life Sciences Generic Name Paricalcitol Brand Name Parical 2 mcg Softgel Capsules
	Pharmacotherapeutic Group of (API)	Vitamin D analogs
	Name, address of Manufacturing site:	Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	FDA Approved. Zemplar (Paricalcitol soft gelatin) 2 mcg Capsule
	Detail of previous approval	339th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
459	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)

Application Form Dy. No / Tracking ID & date of submission	(677-LU5-E4BQ, 2025-09-04)
Detail of Fee Submitted	93000.0, 2025-07-09,
The proposed proprietary name / brand name	M-Alpa 600mg Soft gelatin Capsule
Label Claim	Each Soft gelatin contains:- D1 alpa Tocopheryl acetate.....600mg (USP Specs)
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 Year30C
For generic drugs (me-too Status)	Product Name:: Zescap Capsule 600mg Registration No: 030627 Company Name: M/s. Zafa Pharmaceutical Laboratories (Pvt) Ltd
Pharmacotherapeutic Group of (API)	Fat soluble vitamin (antioxidant)
Name, address of Manufacturing site:	Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-
The status in reference regulatory authorities	FDA Evion 200mg 600mg and 600mg soft gelatin capsule Manufactured by Morton Dow pharmaceuticals
Detail of previous approval	345th

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

460	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(558-2DR-R354, 2025-09-04)
	Detail of Fee Submitted	93000.0, 2025-06-27,
	The proposed proprietary name / brand name	MYCIN CREAM
	Label Claim	Each gm contains: Clindamycin as phosphate..... 20mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Manufacturer Name Biogen Pharma Brand Name Calidin V Registration Number: 066449
	Pharmacotherapeutic Group of (API)	Broad spectrum antibiotics
	Name, address of Manufacturing site:	Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Brand Name: Cleocin vaginal cream Manufacturer Name: Pfizer FDA Approved
	Detail of previous approval	345th

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

461	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(47A-TTB-51J4, 2025-09-04)
	Detail of Fee Submitted	93000.0, 2025-07-04,
	The proposed proprietary name / brand name	BETAMED-G CREAM
	Label Claim	Each gram contains: Betamethasone as dipropionate 0.5mg (0.05% w/w) Gentamicin as Sulphate 1mg (0.1% w/w) (Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Brand Name: Gentanix-B Cream Company Nmae: Biogen Pharma Reg No.: 070201
	Pharmacotherapeutic Group of (API)	Betamethasone dipropionate (Corticosteroids) Gentamicin Sulphate (Antibiotic)
	Name, address of Manufacturing site:	Biogen Life Sciences-8-KM Chakbeli Road Rawat Rawalpindi Pakistan-
	The status in reference regulatory authorities	Mibetin 1 mg/g + 0.5 mg/g Cream, MHRA approved. One gram of cream contains 1 mg gentamicin (as 1.67 mg gentamicin sulfate) and 0.5 mg betamethasone (as 0.64 mg betamethasone dipropionate).
	Detail of previous approval	333rd
Evaluation Remarks		
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.		
Decision		
Approved		
462	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(XRH-3LY-J3N2, 2025-09-04)
	Detail of Fee Submitted	93000.0, 2025-06-27,
	The proposed proprietary name / brand name	TROSAL-D 650/75mg tablets

Label Claim	Each film coated tablet contains; Tramadol HCl..... 75 mg Paracetamol..... 650 mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 Year30C
For generic drugs (me-too Status)	Product Name: Tonoflex-p fort Tablet Composition: Each coated tablet contains; Tramadol HCl..... 75 mg Paracetamol..... 650 mg Sami Pharmaceutical Pakistan (Pvt.) Ltd
Pharmacotherapeutic Group of (API)	Analgesic & antipyretic WHO ATC Code:A04BC0
Name, address of Manufacturing site:	Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-
The status in reference regulatory authorities	SRA Registration Status: UK approved Brand Name: Ultracet® Tramadol/Paracetamol 75 mg / 650 mg Tablets Manufacturer: by M/s Aspire Pharma Ltd. UK
Detail of previous approval	335th

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

463	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(9VE-8N8-157E, 2025-09-04)
	Detail of Fee Submitted	93000.0, 2025-06-27,
	The proposed proprietary name / brand name	Citol 4 mcg Softgelatin
	Label Claim	Each Soft gelatin contains:- Paricalcitol 4mcg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Biogen Life Sciences Paricalcitol Parical 4mcg Softgel Capsules
	Pharmacotherapeutic Group of (API)	Vitamin D analogs
	Name, address of Manufacturing site:	Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Reference: FDA
	Detail of previous approval	339th

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt

the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

464	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(ZQ7-BAR-Y4H2, 2025-09-04)
	Detail of Fee Submitted	93000.0, 2025-06-27,
	The proposed proprietary name / brand name	TRIOL 0.25MCG SOFT GEL CAPSULE
	Label Claim	Each soft gelatin capsule contains:- calcitriol.....0.25mcg (BP Specs)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Martin Dow Limited Calcitriol 0.25mcg Rocaltrol Capsules 0.25mcg 015557
	Pharmacotherapeutic Group of (API)	Vitamin D analogs
	Name, address of Manufacturing site:	Biogen Life Sciences-8-KM Chakbeli Road Rawat Rawalpindi Pakistan-
	The status in reference regulatory authorities	FDA Approved.
	Detail of previous approval	336th

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

465	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(8YR-VPZ-EXAY, 2025-09-04)
	Detail of Fee Submitted	93000.0, 2025-06-27,
	The proposed proprietary name / brand name	TRIOL 0.5mcg SOFT GEL CAPSULE
	Label Claim	Each soft gelatin capsule contains:- calcitriol.....0.5mcg(BP Specs)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Manufacturer Name Generic Name Brand Name Registration No. Martin Dow Limited Calcitriol 0.25mcg

		Rocaltrol Capsules 0.25mcg 015557
	Pharmacotherapeutic Group of (API)	Vitamin D analogs
	Name, address of Manufacturing site:	Biogen Life Sciences-8-KM Chakbeli Road Rawat Rawalpindi Pakistan-
	The status in reference regulatory authorities	FDA Approved. ROCALTROL (calcitriol)
	Detail of previous approval	316th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
466	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(GZ7-LMG-BYLY, 2025-09-04)
	Detail of Fee Submitted	93000.0, 2025-06-26,
	The proposed proprietary name / brand name	FUZAN-B Cream
	Label Claim	EachTube contains: Fusidic Acid.....20mg Betamethasone(as Vale rate) 1 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	BrandName: Registrationholder: RegistrationNumber: FUDIC B Cream SHAIGANPharma 048490
	Pharmacotherapeutic Group of (API)	Pharmacotherapeuticgroup: Anti-inflammatory and antipruritic effects of betamethasone with the potent topical antibacterial action of fusidic acid
	Name, address of Manufacturing site:	Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	331st
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
467	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)

Application Form Dy. No / Tracking ID & date of submission	(84Q-P2Q-U8YJ, 2025-09-04)
Detail of Fee Submitted	93000.0, 2025-06-23,
The proposed proprietary name / brand name	Doparide 12.5mg/ml Injection
Label Claim	Each ml contains: Levosulpiride 12.5mg (In house Specs.)
Reference to Finished product specifications	Manufacturer Specification
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 Year30C
For generic drugs (me-too Status)	Brand Name: Levopraid 25mg/2ml injection Manufacturer Name/Registration holder:M/s Pacific Pharmaceuticals Composition: Each ml contains: Levosulpiride 12.5 mg Dosage: Parenteral (For IV/I
Pharmacotherapeutic Group of (API)	Prokinetic agent
Name, address of Manufacturing site:	Wimits Pharmaceutical Pvt Ltd-Plot # 129,Sunder Industrial Estate Lahore, Pakistan.-
The status in reference regulatory authorities	Brand Name: DISLEP 25 mg solution for injection/infusion Manufacturer Name/Registration holder:M/s Doppel Farmaceutici S.r.l. Via Volturmo, 48 - 20089 Quinto dè Stampi - Rozzano (MI) Italy(USFDA Approved)
Detail of previous approval	340th
Evaluation Remarks	
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
Decision	
Approved	
468	Case Category
	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.
	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission
	(U7R-AJ2-DJ3Q, 2025-09-04)
	Detail of Fee Submitted
	93000.0, 2025-06-23,
	The proposed proprietary name / brand name
	ROBIX INJECTION 500mcg/ml
	Label Claim
	Each ampoule contains: Mecobalamin 500mcg
	Reference to Finished product specifications
	As per Innovators Specification
	Proposed Pack Size
	As per SRO-As per SRO
	Shelf Life (Unit)
	2 Year30C
	For generic drugs (me-too Status)
	Global Pharmaceuticals Islamabad(Mecomax Injection I.V/ I.M)030564
	Pharmacotherapeutic Group of (API)
	Vitamin B12
	Name, address of Manufacturing site:
	Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-

	The status in reference regulatory authorities	Mecobalamin 500mcg Injection (PMDA Japan Approved)
	Detail of previous approval	316th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
469	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(DJ9-1G7-R49R, 2025-09-04)
	Detail of Fee Submitted	93000.0, 2025-06-23,
	The proposed proprietary name / brand name	Ceframed 500mg Capsule
	Label Claim	Each capsule Contains: Cephadrine as monohydrate.....500mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Brand Name; Velosef Capsule Manufacturer Name: GSK
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibacterial drug
	Name, address of Manufacturing site:	Biogen Life Sciences-8-km, ChakbeliRoad, Rawat, Rawalpindi-
	The status in reference regulatory authorities	MHRA approved
	Detail of previous approval	320th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
470	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(RTG-9ES-74TQ, 2025-09-04)
	Detail of Fee Submitted	93000.0, 2025-06-23,
	The proposed proprietary name / brand name	Nalget 20mg/ml Injection
	Label Claim	Each ampoule Contains: Nalbuphine HCl.....20mg

Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 Year30C
For generic drugs (me-too Status)	Global Pharmaceuticals(Global Pharmaceuticals Nalbin Injection 20mg/ml)
Pharmacotherapeutic Group of (API)	Morphinan derivatives
Name, address of Manufacturing site:	Biogen Life Sciences -8-km, Chakbeli Road, Rawat, Rawalpindi-
The status in reference regulatory authorities	Nalbuphine Injection 20mg/ml USFDA Approved
Detail of previous approval	316th

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

471	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(GG1-EGT-LVGY, 2025-09-04)
	Detail of Fee Submitted	93000.0, 2025-06-04,
	The proposed proprietary name / brand name	Torsezan 10mg Table
	Label Claim	Each tablet contains: Torsemide.....10mg (USP specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10x10's-As per SRO,1x10's-As per SRO,2x10's-As per SRO,2x7's-As per SRO,3x10's-As per SRO,4x7's-As per SRO,9x10's-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	wimits
	Pharmacotherapeutic Group of (API)	orsemide is used to help treat fluid retention (edema) and swelling that is caused by congestive heart failure, liver disease, kidney disease. It belongs to the group of medicines called loop diuretics (water pills). (Reference;Basic and Clinical Pharmacology By Bertram G. Katzung)
	Name, address of Manufacturing site:	Wimits Pharmaceutical Pvt Ltd-Plot # 129,Sunder Industrial Estate Lahore, Pakistan.-
	The status in reference regulatory authorities	USFDA approved(Manufacturer Name: Chartwell RX, LLC Manufactured For: Chartwell RX, LLC Congers, NY 10920)
	Detail of previous approval	345th

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt

the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

472	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(P47-6GV-QS92, 2025-09-04)
	Detail of Fee Submitted	93000.0, 2025-06-04,
	The proposed proprietary name / brand name	Torsezan 5mg Tablet
	Label Claim	Each tablet contains: Torsemide.....5mg (USP specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10x10's-As per SRO,1x10's-As per SRO,2x7's-As per SRO,3x10's-As per SRO,4x7's-As per SRO,9x10's-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	wimits
	Pharmacotherapeutic Group of (API)	Torsemide is used to help treat fluid retention (edema) and swelling that is caused by congestive heart failure, liver disease, kidney disease. It belongs to the group of medicines called loop diuretics (water pills). (Reference;Basic and Clinical Pharmacology By Bertram G. Katzung)
	Name, address of Manufacturing site:	Wimits Pharmaceutical Pvt Ltd-Plot # 129,Sunder Industrial Estate Lahore, Pakistan-
	The status in reference regulatory authorities	USFDA approved Manufacturer Name: Chartwell RX, LLC Manufactured For: Chartwell RX, LLC Congers, NY 10920
	Detail of previous approval	345th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
473	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(P2M-PGZ-LY58, 2025-09-04)
	Detail of Fee Submitted	93000.0, 2025-06-04,
	The proposed proprietary name / brand name	Torsezan 20mg Table

Label Claim	Each tablet contains: Torsemide.....20mg (USP specifications)
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	10x10's-As per SRO,1x10's,-As per SRO,2x10's-As per SRO,2x7's,-As per SRO,3x10's-As per SRO,4x7's-As per SRO,9x10's-As per SRO
Shelf Life (Unit)	2 Year30C
For generic drugs (me-too Status)	wimits
Pharmacotherapeutic Group of (API)	orsemide is used to help treat fluid retention (edema) and swelling that is caused by congestive heart failure, liver disease, kidney disease. It belongs to the group of medicines called loop diuretics (water pills). (Reference;Basic and Clinical Pharmacology By Bertram G. Katzung
Name, address of Manufacturing site:	Wimits Pharmaceutical Pvt Ltd-Plot # 129,Sunder Industrial Estate Lahore, Pakistan.-
The status in reference regulatory authorities	USFDA approvedManufacturer Name: Chartwell RX, LLC Manufactured For: Chartwell RX, LLC Congers, NY 10920
Detail of previous approval	345th

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

474	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(HPY-XJU-MDNE, 2025-09-04)
	Detail of Fee Submitted	93000.0, 2025-06-04,
	The proposed proprietary name / brand name	Metadol 50mg IR TABLET
	Label Claim	ach Film Coated Tablet contains: Tapentadol HCl eq. To Tapentadol -----50mg (Innovator,s Specs.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's-As per SRO,2x10's-As per SRO,2x7's-As per SRO,3x10-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Manufacturer Name: M/s Sami Pakistan Brand Name & Strength: Tapento IR 50mg Tablet
	Pharmacotherapeutic Group of (API)	Opioid analgesic
	Name, address of Manufacturing site:	Wimits Pharmaceutical Pvt Ltd-Plot # 129,Sunder Industrial Estate Lahore, Pakistan-
	The status in reference regulatory authorities	HRA approved Manufacturer Name: M/s Grünenthal GmbH, Germany Brand Name & Strength: Palexia IR 50mg Table

	Detail of previous approval	343rd
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
475	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(GXQ-PA4-YV93, 2025-09-04)
	Detail of Fee Submitted	93000.0, 2025-06-04,
	The proposed proprietary name / brand name	Metadol 100mg Tablets
	Label Claim	Each Film Coated Tablet contains: Tapentadol HCl eq. To Tapentadol -----100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's,-As per SRO,2x10's,-As per SRO,2x7's-As per SRO,3x10's-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	M/s Grünenthal GmbH, Germany Brand Name & Strength: Palexia IR 100mg Tablet
	Pharmacotherapeutic Group of (API)	Opioid analgesic
	Name, address of Manufacturing site:	Wimits Pharmaceutical Pvt Ltd-lot # 129,Sunder Industrial Estate Lahore, Pakistan-
	The status in reference regulatory authorities	MHRA approved
	Detail of previous approval	343rd
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
476	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	PERFECT PHARMA (PVT) LTD 5Km, Manga Road, Raiwind, Lahore (000469)
	Application Form Dy. No / Tracking ID & date of submission	(PH7-QLJ-MU3P, 2025-09-04)
	Detail of Fee Submitted	93000.0, 2025-06-17,
	The proposed proprietary name / brand name	FECTOBAL 500MCG/ML INJECTION
	Label Claim	Each ml Contains: MECOBALAMIN 500mcg

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's Ampoules-As per SRO
	Shelf Life (Unit)	2 Year25
	For generic drugs (me-too Status)	Methycobal 500mcg/ml
	Pharmacotherapeutic Group of (API)	Analogue of Vitamin B12
	Name, address of Manufacturing site:	May & Baker (Pvt) Ltd-45 Km Dina Nath Multan Road Lahore-
	The status in reference regulatory authorities	PMDA Approved
	Detail of previous approval	Bakromin 500mcg/ml Injection, Minutes for 321 st meeting of Registration Board (20th – 22nd Septembe
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
477	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	PERFECT PHARMA (PVT) LTD 5Km, Manga Road, Raiwind, Lahore (000469)
	Application Form Dy. No / Tracking ID & date of submission	(PW5-WRR-RGT5, 2025-09-04)
	Detail of Fee Submitted	93000.0, 2025-06-17,
	The proposed proprietary name / brand name	PER-ON 8MG/4ML INJECTION
	Label Claim	Each 4ml Ampoule Contain ONDANSETRON as HYDROCHLORIDE DIHYDRATE.....8MG
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's Ampoule-As per SRO
	Shelf Life (Unit)	2 Year25
	For generic drugs (me-too Status)	Onset 8MG/4ml Injection
	Pharmacotherapeutic Group of (API)	Anti Anemic Drug
	Name, address of Manufacturing site:	May & Baker (Pvt) Ltd-45 Km Dina Nath Multan Road Lahore-
	The status in reference regulatory authorities	MHRA Approved.
	Detail of previous approval	BAKTRON 8mg/4ml Injection Minutes for 321 st meeting of Registration Board (20th – 22nd September,
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
478	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

Name, address of Applicant.	Pine Pharmaceuticals Plot No, 40, S-4, Rawat Industrial Estate, Islamabad (000955)
Application Form Dy. No / Tracking ID & date of submission	(W5R-D53-EAD6, 2025-09-04)
Detail of Fee Submitted	93000.0, 2025-06-17,
The proposed proprietary name / brand name	Carbopin 500mg/10ml Injection/Infusion
Label Claim	Each 10ml ampoule contains: Ferric carboxymaltose corresponding to elemental iron.....500mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 YearBelow 30°C
For generic drugs (me-too Status)	Fercari Hilton Pharma. Fercari Dispersion for Injection/Infusion 500 mg
Pharmacotherapeutic Group of (API)	Anti-Anemic drug
Name, address of Manufacturing site:	M/s Seraph Pharmaceutical-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
The status in reference regulatory authorities	Ferinject., Ferinject ® Dispersion for Injection/Infusion is Approved in USFDA
Detail of previous approval	IronInject Injection 10ml Approved in 331st Meeting Registration Board

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

479	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	McOlson Research Laboratories Pvt. Ltd Plot No. 02, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhpura Pakistan (000664)
	Application Form Dy. No / Tracking ID & date of submission	(2P7-LGL-EWYZ, 2025-09-04)
	Detail of Fee Submitted	93000.0, 2025-05-29,
	The proposed proprietary name / brand name	Pixora 45 mg Tablets
	Label Claim	Each Film Coated Tablet Contains: Gifapixant (as Citrate): 45 mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's, 10's, 20's, 28'-As per SRO
	Shelf Life (Unit)	2 YearBelow 30C
	For generic drugs (me-too Status)	Gefahil 45 mg Tablets by Hilton Pharma
	Pharmacotherapeutic Group of (API)	Cough Suppressant
	Name, address of Manufacturing site:	Dyson Research Laboratories (Pvt) Ltd.-28-Km, Ferozepur Road, Lahore-
	The status in reference regulatory authorities	https://mhraproducts4853.blob.core.windows.net/docs/b7c
	Detail of previous approval	Gefnua 45 mg Tablets (Meeting No. 347, case No. 552)

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision**Approved**

480	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(X7A-NM3-XA6W, 2025-09-04)
	Detail of Fee Submitted	93000.0, 2025-06-04,
	The proposed proprietary name / brand name	ULMED 1G/5ML ORAL SUSPENSION
	Label Claim	Each 5ml of oral suspension contains: Sucralfate 1g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Ulsanic 1g/5ml Suspension(Highnoon Laboratories Ltd)
	Pharmacotherapeutic Group of (API)	Gastrointestinal tract and metabolism; anti-peptic ulcer and gastroesophageal reflux disease.
	Name, address of Manufacturing site:	SERAPH PHARMACEUTICAL-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
	The status in reference regulatory authorities	ANTEPSIN 1g/5ml Suspension(LABORATORI BALDACCI S.p.A., Via S. Michele degli Scalzi, 73 - PISA AIFA Italy Approved.)
	Detail of previous approval	344th
481	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(4S9-P2W-VSUR, 2025-09-04)
	Detail of Fee Submitted	93000.0, 2025-06-04,
	The proposed proprietary name / brand name	STATMED 100,000IU ORAL SUSPENSION
	Label Claim	Each ml contains; Nystatin 100,000IU
	Reference to Finished product specifications	United States Pharmacopeia

Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 Year30C
For generic drugs (me-too Status)	Nystanil 100,000 I.U Oral Suspension(Winthrox Laboratories Pvt. Ltd)
Pharmacotherapeutic Group of (API)	Antifungal
Name, address of Manufacturing site:	SERAPH PHARMACEUTICAL-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
The status in reference regulatory authorities	Nystatin Oral Suspension 100,000I.U(Sandoz Limited Park View, Riverside Way Watchmoor Park Camberley, Surrey GU15 3YL United Kingdom approved in MHRA)
Detail of previous approval	339th

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

482	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Genetics Pharmaceuticals Pvt. Ltd 539-A Sundar Industrial Estate Raiwind Road Lahore (000845)
	Application Form Dy. No / Tracking ID & date of submission	(NUE-XHZ-L25T, 2025-09-04)
	Detail of Fee Submitted	93000.0, 2025-04-18,
	The proposed proprietary name / brand name	Fablous 500mg/10ml
	Label Claim	Each ml Contains: Iron as ferric carboxymaltose.....50mg or (Each 10ml contains: Iron as ferric carboxymaltose.....500mg)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10mlx1's -As per SRO
	Shelf Life (Unit)	2 YearBelow 25°C
	For generic drugs (me-too Status)	Fercari (Ferric carboxymaltose 50mg/ml) injection
	Pharmacotherapeutic Group of (API)	M/s NANJING HENCER Pharmaceutical Co., Ltd.
	Name, address of Manufacturing site:	M/s Cunningham Pharmaceuticals (Pvt.) Ltd. -81-Sundar Industrial Estate, Raiwind Road, Lahore, Pakistan.-
	The status in reference regulatory authorities	INJECTAFER® (ferric carboxymaltose injection), for intravenous use
	Detail of previous approval	Fero-ject, 344 meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

Approved

483	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Magns Pharmaceuticals Plot # 7B Value Addition City Sahianwala Road Khurrianwala (000849)
	Application Form Dy. No / Tracking ID & date of submission	(95G-62V-BV7A, 2025-09-04)
	Detail of Fee Submitted	93000.0, 2025-03-25,
	The proposed proprietary name / brand name	Magset
	Label Claim	Each 2ml Contains: Ondansetron as Hydrochloride dihydrate = 4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2 ml x 1,s-As per SRO
	Shelf Life (Unit)	2 Yearstore below 30 oC
	For generic drugs (me-too Status)	Onset injection by Pharmedic
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s May & Baker (Pvt) Ltd., -45 Km, Dina Nath, Multan Road, Lahore.-
	The status in reference regulatory authorities	MHRA & USFDA approved
	Detail of previous approval	321 st meeting of registration board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
484	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Carer Pharmaceuticals industries Plot no.27, Main Road Rawat Industrial Estate, Rawat (000925)
	Application Form Dy. No / Tracking ID & date of submission	(AVD-PXG-Q5HV, 2025-09-04)
	Detail of Fee Submitted	93000.0, 2025-02-17,
	The proposed proprietary name / brand name	Carpenem
	Label Claim	Each vial contains: Meropenem trihydrate eq to meropenem..... 1g (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1,S-As per SRO
	Shelf Life (Unit)	2 YearStore between 15C-30C
	For generic drugs (me-too Status)	MOPEN Hilton Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Dew-max Pharmaceuticals (Pvt) Ltd-Plot No. Street SS-4 Main Industrial area Rawat, Islamabad.-
	The status in reference regulatory authorities	FDA
	Detail of previous approval	Dewnem 1g Inj. DRRAP Meeting NO 312

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision**Approved**

485	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	SHAWAN PHARMACEUTICALS PLOT # 37, NS-1. NATIONAL INDUSTRIAL ZONE. RAWAT (000627)
	Application Form Dy. No / Tracking ID & date of submission	(8WG-M76-ZZ5G, 2025-09-03)
	Detail of Fee Submitted	93000.0, 2024-12-16,
	The proposed proprietary name / brand name	Terbin 1% lotion
	Label Claim	Each gm contains: Terbinafine hydrochloride 10.0mg (Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	20ml, 30ml, 60ml-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	Cutis Lotion, M/s Tabros Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Biogen Life Sciences -Biogen Life Sciences: 8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Lamisil Lotion 1% by M/s GSK Netherland
	Detail of previous approval	TERBIGEN 1% Lotion, Minutes of 335th meeting of Registration Board (25th April, 2024) 389
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
486	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Paramount Pharmaceuticals 36- Industrial Triangle Kahuta Road Islamabad (000439)
	Application Form Dy. No / Tracking ID & date of submission	(DHB-LME-HEWX, 2025-09-03)
	Detail of Fee Submitted	93000.0, 2025-01-22,
	The proposed proprietary name / brand name	Siden 100 mg Tablet
	Label Claim	Each tablet contains Sildenafil (as Citrate) 100 mg
	Reference to Finished product specifications	United States Pharmacopeia

	Proposed Pack Size	4's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Greys Pharmaceuticals-Plot 2, Street N-3, National Industrial Zone, Rawat, Pakistan-
	The status in reference regulatory authorities	Approved
	Detail of previous approval	Selden 100 mg
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
487	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Paramount Pharmaceuitcals 36- Industrial Triangle Kahuta Road Islamabad (000439)
	Application Form Dy. No / Tracking ID & date of submission	(9G1-42Q-YLWP, 2025-09-03)
	Detail of Fee Submitted	93000.0, 2025-01-22,
	The proposed proprietary name / brand name	Siden 50 mg Tablet
	Label Claim	Each Tablet contains Sildenafil (as Citrate) 50 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Greys Pharmaceuticals-Plot 2, Street N-3, National Industrial Zone, Rawat, Pakistan-
	The status in reference regulatory authorities	Approved
	Detail of previous approval	345
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
488	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(3X3-Q5E-D3JP, 2025-09-03)

Detail of Fee Submitted	93000.0, 2025-06-26,
The proposed proprietary name / brand name	Medpenam 500mg Injection
Label Claim	Each vial contains: Doripenem Monohydrate equivalent to Doripenem.....500mg (JP Specs)
Reference to Finished product specifications	Any Other
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 Year30C
For generic drugs (me-too Status)	Doripenem 500mg Injection
Pharmacotherapeutic Group of (API)	Carbapenem
Name, address of Manufacturing site:	Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-
The status in reference regulatory authorities	Finibax IV 0.5g Approved in PMDA JAPAN
Detail of previous approval	316th

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

489	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(2U4-H7V-884T, 2025-09-03)
	Detail of Fee Submitted	93000.0, 2025-06-26,
	The proposed proprietary name / brand name	FUZAN-H Cream
	Label Claim	Each gram cream contains: Fusidic Acid (BP).....20mg (2%w/w) Hydrocortisone Acetate.....10mg (1%w/w)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Brand Name: Fusimax-H 2%+1% Cream Registration holder: Maxitech Pharma Registration Number: 83733
	Pharmacotherapeutic Group of (API)	Antibiotics & corticosteroid For Topical Use
	Name, address of Manufacturing site:	Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Fucidin H cream LEO Laboratories Limited Maidenhead Berkshire SL6 3UD UK. MHRA approved.
	Detail of previous approval	331st

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other

conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

490	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Pine Pharmaceuticals Plot No, 40, S-4, Rawat Industrial Estate, Islamabad (000955)
	Application Form Dy. No / Tracking ID & date of submission	(5WP-P13-QT8Z, 2025-09-03)
	Detail of Fee Submitted	93000.0, 2025-06-23,
	The proposed proprietary name / brand name	Tanzopin Injection IV 4.5 gm
	Label Claim	Each vial contains; Piperacillin (as sodium salt) equivalent to..... 4 g and Tazobactam (as sodium salt) equivalent to..... 0.5 g.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Tanzopin Injection 4.5 gm I.V Plot No, 221, Mehran Town Sector 23 Korangi Industrial Area, Karachi, Karachi City, Sindh 74900
	Pharmacotherapeutic Group of (API)	Antibacterials for systemic use
	Name, address of Manufacturing site:	Evolution Pharmaceuticals (Pvt.) Ltd.-Plot #: 25 & 26, Street #: S-3, RCCI, National Industrial Zone, Rawat, Islamabad - Pakistan-
	The status in reference regulatory authorities	Zosyn (Piperacillin and tazobactam) The Old Dairy, Brynkinalt Business Centre, Brynkinalt, Chirk, Wrexham, LL14 5NS, UK
	Detail of previous approval	343rd Meeting of Registration Board
491	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Kanel Pharma Plot No. 6, Street No. SS-3, National Industrial Zone, Rawat (000758)
	Application Form Dy. No / Tracking ID & date of submission	(AHR-GQ6-SX21, 2025-09-03)
	Detail of Fee Submitted	93000.0, 2025-07-21,
	The proposed proprietary name / brand name	Tofakan 50mg Tablet
	Label Claim	Each film coated tablet contains: Tofacitinib Citrate eq. to Tofacitinib 5mg
	Reference to Finished product specifications	As per Innovators Specification

Proposed Pack Size	As Per SRO-As per SRO
Shelf Life (Unit)	2 YearControlled Room Temperature
For generic drugs (me-too Status)	Tofab 5mg Tablet By Genome Pharmaceuticals (Pvt.) Ltd
Pharmacotherapeutic Group of (API)	Antirheumatics
Name, address of Manufacturing site:	M/S SERAPH PHARMACEUTICAL-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
The status in reference regulatory authorities	USFDA Approved
Detail of previous approval	Toproz 5mg Tablet, Meeting 336th

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

492	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Kanel Pharma Plot No. 6, Street No. SS-3, National Industrial Zone, Rawat (000758)
	Application Form Dy. No / Tracking ID & date of submission	(G91-GEA-4UUY, 2025-09-03)
	Detail of Fee Submitted	93000.0, 2025-07-30,
	The proposed proprietary name / brand name	Formikan 400mcg+12mcg Capsule
	Label Claim	Each Rotacap Rota Capsule contains: Budesonide (USP) 400Mcg / Formoterol Fumarate (USP) 12Mcg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearControlled Room Temperature
	For generic drugs (me-too Status)	Venticort Rotacaps 400mcg + 12mcg Highnoon Labs (Reg#089365)
	Pharmacotherapeutic Group of (API)	Long-Acting Beta Agonists
	Name, address of Manufacturing site:	M/s Winbrains Research Laboratories-Plot # 69/1, Block B, Phase I&II, Industrial Estate, Hattar, Haripur, KPK-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	Combrain 400/12mcg Capsule, 339th Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	

493	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Jenner Pharmceuticals Pvt. Ltd Plot No. 03, M-2 Pharmazone, 26th Km Lahore Sharikpur Road

	Sheikhupura (000823)
Application Form Dy. No / Tracking ID & date of submission	(MXD-13P-YPN9, 2025-09-03)
Detail of Fee Submitted	93000.0, 2025-08-04,
The proposed proprietary name / brand name	Sildenafil Tablets 50mg
Label Claim	Each Film Coated Tablet Contains: Sildenafil as Citrate (USP): 50mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	As Per SRO-As per SRO
Shelf Life (Unit)	2 YearStore below 30oC
For generic drugs (me-too Status)	Sildenafil 50 mg Tablets by Weather Folds Pharmaceuticals
Pharmacotherapeutic Group of (API)	Phosphodiesterase 5 (PDE5) inhibitors. ATC code: G04BE03
Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-69/2, Phase-II, Industrial Estate, Haripur, KPK-
The status in reference regulatory authorities	MHRA
Detail of previous approval	Sildenafil 50mg Tablet M-345

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

494	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Jenner Pharmaceuticals Pvt. Ltd Plot No. 03, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhupura (000823)
	Application Form Dy. No / Tracking ID & date of submission	(AH3-5XX-A1W3, 2025-09-03)
	Detail of Fee Submitted	93000.0, 2025-08-04,
	The proposed proprietary name / brand name	Sildenafil Tablets 100mg
	Label Claim	Each Film Coated Tablet Contains: Sildenafil as Citrate (USP): 100 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30oC
	For generic drugs (me-too Status)	Sildenafil 100 mg Tablets by Weather Folds Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Phosphodiesterase 5 (PDE5) inhibitors. ATC code: G04BE03
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-69/2, Phase-II, Industrial Estate, Haripur, KPK-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Sildenafil 100mg Tablet M-345

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

495	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welwrd Pharmaceuticals Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar (000574)
	Application Form Dy. No / Tracking ID & date of submission	(AUV-LMS-T6NM, 2025-09-03)
	Detail of Fee Submitted	93000.0, 2025-07-19,
	The proposed proprietary name / brand name	BILTEX 10mg Tablet
	Label Claim	Each Orodispersible Tablet contains: Bilastine 10MG (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year20-25C
	For generic drugs (me-too Status)	Brand Name of Approved Medicines Orodispersible Tablet Bilix 10 mg Manufacturer M/s AGP Limited Strength 10mg tablet Composition Each Orodispersible tablet contains: Bilastine 10mg
	Pharmacotherapeutic Group of (API)	Benzimidazoles
	Name, address of Manufacturing site:	M/s Wezen Pharmaceuticals-Plot No. 23 & 24, S-1, RCCI, Industrial Estate, Rawat-
	The status in reference regulatory authorities	https://www.medicines.org.uk/emc/product/4551/smpc#gr
	Detail of previous approval	BILTEX 10mg Orodispersible Tablet Minutes of 335th meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
496	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welwrd Pharmaceuticals Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar (000574)
	Application Form Dy. No / Tracking ID & date of submission	(P3T-V47-BT9G, 2025-09-03)
	Detail of Fee Submitted	93000.0, 2025-07-19,
	The proposed proprietary name / brand name	BILTEX 20mg Orodispersible Tablet

Label Claim	Each Uncoated Tablet contains: Bilastine.....20MG (Product Complies Innovator's Specs)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As Per SRO-As per SRO
Shelf Life (Unit)	2 Year20-25C
For generic drugs (me-too Status)	Bilaxten 20 mg Tablet by AGP
Pharmacotherapeutic Group of (API)	Antihistamines for systemic use,
Name, address of Manufacturing site:	M/s Wezen Pharmaceuticals-Plot No. 23 & 24, S-1, RCCI, Industrial Estate, Rawat-
The status in reference regulatory authorities	MHRA approved formulation
Detail of previous approval	BILTEX 20mg Tablet Minutes of 335th meeting of Registration Board

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

497	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welwrd Pharmaceuticals Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar (000574)
	Application Form Dy. No / Tracking ID & date of submission	(MJD-RTE-B13P, 2025-09-03)
	Detail of Fee Submitted	93000.0, 2025-07-19,
	The proposed proprietary name / brand name	DEUTA PLUS CAPSULE
	Label Claim	Each hard gelatin capsule contains: Dutasteride (as soft gelatin capsule) 0.5 mg Tamsulosin hydrochloride (as modified release pellets) 0.4 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year20-25C
	For generic drugs (me-too Status)	Maxflow-D Capsule by M/s CCL Pharmaceutical (Reg. 091571)
	Pharmacotherapeutic Group of (API)	Alpha-adrenoreceptor antagonists
	Name, address of Manufacturing site:	M/s Biogen Life Sciences-8-Km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Dutasteride/Tamsulosin hydrochloride 0.5 mg / 0.4 mg hard capsules (MHRA)
	Detail of previous approval	Dutaride-T Capsule Minutes of 335th meeting of Registration Board

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other

conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

498	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welwrd Pharmaceuticals Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar (000574)
	Application Form Dy. No / Tracking ID & date of submission	(7LR-7J1-D6AU, 2025-09-03)
	Detail of Fee Submitted	93000.0, 2025-07-19,
	The proposed proprietary name / brand name	PHYTO-K 10mg/ml INJECTION
	Label Claim	Each 1ml Ampoule Contains: Phytionadione.....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year20-25C
	For generic drugs (me-too Status)	Vit-K 10mg/ml Injectable Emulsion by M/s Genix Pharma (Reg# 82260)
	Pharmacotherapeutic Group of (API)	Fat soluble vitamin
	Name, address of Manufacturing site:	M/s Wnsfeild Pharmaceuticals-Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar.-
	The status in reference regulatory authorities	Vitamin K1 10mg/ml by M/s Hospira USFDA Approved.
	Detail of previous approval	Phyto-K 10mg/ml Injection Minutes of 343rd meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
499	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welwrd Pharmaceuticals Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar (000574)
	Application Form Dy. No / Tracking ID & date of submission	(EJV-TNY-9QG5, 2025-09-03)
	Detail of Fee Submitted	93000.0, 2025-07-19,
	The proposed proprietary name / brand name	Mirolin 2.5mg Tablet
	Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to Mirogabalin.....2.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year20-25C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	N02BF Gabapentinoids indicated for Neuropathic pain

	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt) Ltd.-Plot # 129, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan-
	The status in reference regulatory authorities	Tarlige Tablets 2.5mg of M/s Daiichi Sankyo Co., Ltd (PMDA Approved)
	Detail of previous approval	Mirogab 2.5mg Tablet Minutes of 344th meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
500	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welwrd Pharmaceuticals Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar (000574)
	Application Form Dy. No / Tracking ID & date of submission	(PM1-2EM-9GVR, 2025-09-03)
	Detail of Fee Submitted	93000.0, 2025-07-21,
	The proposed proprietary name / brand name	Mirogab 5mg Tablet
	Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to Mirogabalin.....5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year20-25C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	N02BF Gabapentinoids indicated for Neuropathic pain Reference to
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt) Ltd.-Plot # 129, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan-
	The status in reference regulatory authorities	Tarlige Tablets 2.5mg of M/s Daiichi Sankyo Co., Ltd (PMDA Approved)
	Detail of previous approval	Mirogab 5mg Tablet Minutes of 344th meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
501	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

Name, address of Applicant.	Welwrd Pharmaceuticals Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar (000574)
Application Form Dy. No / Tracking ID & date of submission	(H9H-9W4-Q4TQ, 2025-09-03)
Detail of Fee Submitted	93000.0, 2025-07-21,
The proposed proprietary name / brand name	Mirogab 10mg Tablet
Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to Mirogabalin.....10mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As Per SRO-As per SRO
Shelf Life (Unit)	2 Year20-25C
For generic drugs (me-too Status)	NA
Pharmacotherapeutic Group of (API)	N02BF Gabapentinoids indicated for Neuropathic pain
Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt) Ltd.-Plot # 129, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan-
The status in reference regulatory authorities	Tarlige Tablets 2.5mg of M/s Daiichi Sankyo Co., Ltd (PMDA Approved)
Detail of previous approval	Mirogab 10mg Tablet Minutes of 344th meeting of Registration Board

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

502	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welwrd Pharmaceuticals Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar (000574)
	Application Form Dy. No / Tracking ID & date of submission	(AZN-MWA-DPDW, 2025-09-03)
	Detail of Fee Submitted	93000.0, 2025-07-21,
	The proposed proprietary name / brand name	Mirolin 15mg Tablet
	Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to Mirogabalin 15mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year20-25C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	N02BF Gabapentinoids indicated for Neuropathic pain
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt) Ltd.-Plot # 129, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan-
	The status in reference regulatory authorities	Tarlige Tablets 15mg of M/s Daiichi Sankyo Co., Ltd (PMDA Approved)

Detail of previous approval	Mirogab 15mg Tablet Minutes of 344th meeting of Registration Board

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

503	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(9T6-WW7-1XTE, 2025-09-03)
	Detail of Fee Submitted	93000.0, 2025-06-26,
	The proposed proprietary name / brand name	METHRIN 5% Lotion
	Label Claim	Each ml contains: Permethrin.....50 mg (5% w/v)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Manufacturer Name Biogen phrama Brand Name Scabizim 50mg Lotion Composition Each ml contains: Permethrin.....50 mg (5% w/v) Dosage Form Lotion
	Pharmacotherapeutic Group of (API)	Pharmacologic classification: Ectoparasitocides, Incl. Scabicides, Insecticides And Repellents
	Name, address of Manufacturing site:	Biogen Life Sciences- 8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Permethrin 5% w/v Cream MHRA approved Manufactured by Bristol-Myers Squibb Company Buffalo, NY USA 14213 U.S.Patent Nos.: 5,648,394 and 4,720,489
	Detail of previous approval	339th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
504	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Genetics Pharmaceuticals Pvt. Ltd 539-A Sundar Industrial Estate Raiwind Road Lahore (000845)
	Application Form Dy. No / Tracking ID & date of submission	(7U9-73H-M26S, 2025-09-03)

Detail of Fee Submitted	93000.0, 2025-02-25,
The proposed proprietary name / brand name	Revigra
Label Claim	Each ml contains: Sildenafil as citrate 10mg/ml
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 YearBelow 30°C
For generic drugs (me-too Status)	silagro powder for oral suspension
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Focus and Rulz Pharmaceuticals. Pvt. Ltd-Plot no.44 Industrial Triangle, kahuta road Islamabad-
The status in reference regulatory authorities	Revatio 10mg/ml powder for oral suspension-UK
Detail of previous approval	Silpah 10mg/ml Suspension (124675) DRB 340

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

505	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welmark Pharmaceuticals Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan (000614)
	Application Form Dy. No / Tracking ID & date of submission	(XYP-JX2-PPNT, 2025-09-03)
	Detail of Fee Submitted	93000.0, 2025-07-26,
	The proposed proprietary name / brand name	Mirolin 15mg Tablet
	Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to Mirogabalin.....15mg (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 25 C
	For generic drugs (me-too Status)	Brand Name of Approved Medicines MIRO Manufacturer NABI QASIM Pharmaceuticals Strength 15mg Composition Mirogabalin as Besylate.....15mg Tablet Registration Number 120267
	Pharmacotherapeutic Group of (API)	Applied as Cross Refer Product against Already Approved CTD
	Name, address of Manufacturing site:	M/S Wimits Pharmaceuticals, (Pvt) Ltd.,-Plot No. 129, Sunder Industrial Estate Raiwind Road, Lahore-
	The status in reference regulatory authorities	Applied as Cross Refer Product against Already Approved CTD
	Detail of previous approval	Mirogab 15mg Tablet Minutes of 344th meeting of Registration Board

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

506	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welmark Pharmaceuticals Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan (000614)
	Application Form Dy. No / Tracking ID & date of submission	(W9J-L52-DGBV, 2025-09-03)
	Detail of Fee Submitted	93000.0, 2025-07-26,
	The proposed proprietary name / brand name	Mirolin 5mg Tablet
	Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to Mirogabalin.....5mg (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 25 C
	For generic drugs (me-too Status)	Brand Name of Approved Medicines MIRO Manufacturer NABI QASIM Pharmaceuticals Strength 5mg Composition Mirogabalin as Besylate.....5mg Tablet Registration Number 120269
	Pharmacotherapeutic Group of (API)	Applied as Cross Refer Product against Already Approved CTD
	Name, address of Manufacturing site:	M/S Wimits Pharmaceuticals, (Pvt) Ltd.,-Plot No. 129, Sunder Industrial Estate Raiwind Road, Lahore-
	The status in reference regulatory authorities	Applied as Cross Refer Product against Already Approved CTD
	Detail of previous approval	Mirogab 5mg Tablet Minutes of 344th meeting of Registration Board

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

507	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welmark Pharmaceuticals Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan (000614)
	Application Form Dy. No / Tracking ID & date of submission	(RPL-4ZZ-QD9U, 2025-09-03)

Detail of Fee Submitted	93000.0, 2025-07-26,
The proposed proprietary name / brand name	Restom 60mg Tablet
Label Claim	Each film coated tablets contains: Resmetirom 60mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 YearBelow 25 C
For generic drugs (me-too Status)	Rezkew 60mg, 80mg, 100mg Tablet by Jenner Pharmaceuticals Pvt Ltd. Reg No. 127443, 127444, 127445
Pharmacotherapeutic Group of (API)	Applied as Cross Refer Product against Already Approved CTD
Name, address of Manufacturing site:	M/S Jenner Pharmaceuticals (Pvt) Ltd., -Plot No. 3, M-2 Pharmazone, 26-KM, Lahore, Sharaqpur Road, District Sheikhupura-
The status in reference regulatory authorities	Applied as Cross Refer Product against Already Approved CTD
Detail of previous approval	Resmetra Minutes of 347th meeting of Registration Board

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

508	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welmark Pharmaceuticals Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan (000614)
	Application Form Dy. No / Tracking ID & date of submission	(Q6T-5VP-XH84, 2025-09-03)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	MEDRON 5MG TABLET
	Label Claim	Each Film Coated Tablet Contains: Midodrine Hydrochloride (USP).....5mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Alpha-Adrenergic Agonists.
	Name, address of Manufacturing site:	M/S Wnsfeild Pharmaceuticals, -Plot No. 122, Block - A, Phase - V, Industrial Estate, Hattar, KPK, Pakistan-

	The status in reference regulatory authorities	https://www.medicines.org.uk/emc/product/9703/smpc
	Detail of previous approval	MEDRON 5mg Tablet Minutes of 343rd meeting of Registration Board (3rd-5th December, 2024)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
509	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welmark Pharmaceuticals Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan (000614)
	Application Form Dy. No / Tracking ID & date of submission	(NAS-VJZ-R2JN, 2025-09-03)
	Detail of Fee Submitted	93000.0, 2025-07-26,
	The proposed proprietary name / brand name	Mirolin 2.5mg Tablet
	Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to Mirogabalin.....2.5mg (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 25 C
	For generic drugs (me-too Status)	Name of Approved Medicines MIRO Manufacturer NABI QASIM Pharmaceuticals Strength 2.5mg Composition Mirogabalin as Besylate.....2.5mg Tablet Registration Number 120270
	Pharmacotherapeutic Group of (API)	Applied as Cross Refer Product against Already Approved CTD
	Name, address of Manufacturing site:	M/S Wimits Pharmaceuticals, (Pvt) Ltd.,-Plot No. 129, Sunder Industrial Estate Raiwind Road, Lahore-
	The status in reference regulatory authorities	Applied as Cross Refer Product against Already Approved CTD
	Detail of previous approval	Mirogab 2.5mg Tablet Minutes of 344th meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
510	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

Name, address of Applicant.	Welmark Pharmaceuticals Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan (000614)
Application Form Dy. No / Tracking ID & date of submission	(MSD-7MD-4L2G, 2025-09-03)
Detail of Fee Submitted	93000.0, 2025-07-18,
The proposed proprietary name / brand name	Deuta Plus Soft Gelatin Capsule
Label Claim	Each hard gelatin capsule contains: Dutasteride (as soft gelatin capsule) 0.5 mg Tamsulosin hydrochloride (as modified release pellets) 0.4 mg (As per innovator's Specifications)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 YearStability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
For generic drugs (me-too Status)	Maxflow-D Capsule by M/s CCL Pharmaceutical (Reg. 091571)
Pharmacotherapeutic Group of (API)	Alpha-adrenoreceptor antagonists
Name, address of Manufacturing site:	M/S Biogen Pharmaceuticals-8-Km Chakbeli Road, Rawat, Rawalpindi-
The status in reference regulatory authorities	Brand Name Marketing Authorization holder: Regulatory Authority: Dutasteride/Tamsulosin hydrochloride 0.5 mg / 0.4 mg hard capsules Milpharm Limited Medicines and Healthcare products Regulatory Agency (MHRA)
Detail of previous approval	Dutaride-T Capsule Minutes of 335th meeting of Registration Board (25th April, 2024)

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

511	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welmark Pharmaceuticals Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan (000614)
	Application Form Dy. No / Tracking ID & date of submission	(LDZ-WA8-RU5H, 2025-09-03)
	Detail of Fee Submitted	97200.0, 2025-08-20,
	The proposed proprietary name / brand name	Combrain 400mcg + 12mcg Rota Capsule
	Label Claim	Each Rotacap Rota Capsule contains: Budesonide (USP).....400Mcg Formoterol Fumarate (USP) 12Mcg (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification

Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 YearBelow 25 C
For generic drugs (me-too Status)	Brand Name of Approved Medicines Venticort Rotacaps 400mg + 12mcg Highnoon Labs (Reg#089365)
Pharmacotherapeutic Group of (API)	Applied as Cross Refer Product against Already Approved CTD
Name, address of Manufacturing site:	M/S Winbrains Research Laboratories, -Plot no. 69/1, Block B, Phase I & II, Industrial Estate, Hattar, KPK -
The status in reference regulatory authorities	Applied as Cross Refer Product against Already Approved CTD
Detail of previous approval	Combrain 400/12mcg DPI Capsule Minutes for 339th meeting of Registration Board

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

512	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welmark Pharmaceuticals Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan (000614)
	Application Form Dy. No / Tracking ID & date of submission	(7G6-PB7-1YEW, 2025-09-03)
	Detail of Fee Submitted	93000.0, 2025-07-26,
	The proposed proprietary name / brand name	RESTOM TABLETS 100MG
	Label Claim	Each film coated tablets contains: Resmetirom 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearReal time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
	For generic drugs (me-too Status)	Each film coated tablets contains: Resmetirom 100mg
	Pharmacotherapeutic Group of (API)	Applied as Cross Refer Product against Already Approved CTD
	Name, address of Manufacturing site:	M/S Jenner Pharmaceuticals (Pvt) ltd., -Plot No. 3, M-2 Pharmazone, 26-KM, Lahore, Sharaqpur Road, District Sheikhupura-
	The status in reference regulatory authorities	Applied as Cross Refer Product against Already Approved CTD
	Detail of previous approval	Diffra Tablets 100mg Minutes of 347th meeting of Registration Board

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt

the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

513	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welmark Pharmaceuticals Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan (000614)
	Application Form Dy. No / Tracking ID & date of submission	(6X1-7YS-T2YJ, 2025-09-03)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	TOFOCIB 5mg TABLET
	Label Claim	Each Film Coated Tablet contains: Tofacitinib Citrate eq, to Tofacitinib.....5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	For generic drugs (me-too Status)	Brand Name of Approved Medicines Tofajak 5mg Tablets Manufacturer Hirani's Pharmaceuticals Strength 5mg Tablet Composition Each Film Coated Tablet contains: Tofacitinib as Citrate 5mg
	Pharmacotherapeutic Group of (API)	Immunosuppressant
	Name, address of Manufacturing site:	M/S Wnsfeild Pharmaceuticals, -Plot No. 122, Block - A, Phase - V, Industrial Estate, Hattar, KPK, Pakistan-
	The status in reference regulatory authorities	USFDA Approved.
	Detail of previous approval	Tofocib 5mg Tablet Minutes of 343rd meeting of Registration Board
514	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
514	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welmark Pharmaceuticals Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan (000614)
	Application Form Dy. No / Tracking ID & date of submission	(5JT-NEL-E8XD, 2025-09-03)
	Detail of Fee Submitted	93000.0, 2025-07-26,
	The proposed proprietary name / brand name	Mirolin 10mg Tablet

Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to Mirogabalin.....10mg (Product Complies Innovator's Specs)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 YearBelow 25 C
For generic drugs (me-too Status)	Brand Name of Approved Medicines MIRO Manufacturer NABI QASIM Pharmaceuticals Strength 10mg Composition Mirogabalin as Besylate.....10mg Tablet Registration Number 120268
Pharmacotherapeutic Group of (API)	Applied as Cross Refer Product against Already Approved CTD
Name, address of Manufacturing site:	M/S Wimits Pharmaceuticals, (Pvt) Ltd.,-Plot No. 129, Sunder Industrial Estate Raiwind Road, Lahore-
The status in reference regulatory authorities	Applied as Cross Refer Product against Already Approved CTD
Detail of previous approval	Mirogab 10mg Tablet Minutes of 344th meeting of Registration Board

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

515	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welmark Pharmaceuticals Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan (000614)
	Application Form Dy. No / Tracking ID & date of submission	(114-Y68-RBNG, 2025-09-03)
	Detail of Fee Submitted	93000.0, 2025-07-26,
	The proposed proprietary name / brand name	RESTOM TABLETS 80MG
	Label Claim	Each film coated tablets contains: Resmetirom 80mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearReal time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
	For generic drugs (me-too Status)	Rezkew 60mg, 80mg, 100mg Tablet by Jenner Pharmaceuticals Pvt Ltd. Reg No. 127443, 127444, 127445
	Pharmacotherapeutic Group of (API)	Applied as Cross Refer Product against Already Approved CTD
	Name, address of Manufacturing site:	M/S Jenner Pharmaceuticals (Pvt) Ltd., -Plot No. 3, M-2 Pharmazone, 26-KM, Lahore, Sharaqpur Road, District Sheikhpura-

	The status in reference regulatory authorities	Applied as Cross Refer Product against Already Approved CTD
	Detail of previous approval	Diffra Tablets 80mg Minutes of 347th meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
516	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	PERFECT PHARMA (PVT) LTD 5Km, Manga Road, Raiwind, Lahore (000469)
	Application Form Dy. No / Tracking ID & date of submission	(58H-ZZM-99N4, 2025-09-03)
	Detail of Fee Submitted	93000.0, 2025-06-12,
	The proposed proprietary name / brand name	ESSFECT 40MG DRY POWDER VIAL
	Label Claim	Each vial Contains Esomeprazole Sodium eq. to Esomeprazole 40mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's -As per SRO
	Shelf Life (Unit)	2 Year25
	For generic drugs (me-too Status)	Nexum 40mg vial
	Pharmacotherapeutic Group of (API)	PPI
	Name, address of Manufacturing site:	May & Baker (Pvt) Ltd-45 Km Dina Nath Multan Road Lahore-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	Esozium 40mg Dry Powder Injection, Minutes of 327th meeting of Registration Board (13th April, 2023)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
517	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	PERFECT PHARMA (PVT) LTD 5Km, Manga Road, Raiwind, Lahore (000469)
	Application Form Dy. No / Tracking ID & date of submission	(ADE-SE8-NSDH, 2025-09-03)
	Detail of Fee Submitted	93000.0, 2025-06-02,

The proposed proprietary name / brand name	DICLOPER 75MG SOLUTION FOR INJECTION
Label Claim	Each 3ml Contain Diclofenac Sodium 75mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	5's-As per SRO
Shelf Life (Unit)	2 Year25
For generic drugs (me-too Status)	Dicloran Injection
Pharmacotherapeutic Group of (API)	NSAID
Name, address of Manufacturing site:	May & Baker (Pvt) Ltd-45 Km Dina Nath Multan Road Lahore-
The status in reference regulatory authorities	EMA Approved
Detail of previous approval	Maykofin 75mg Injection , Minutes of 322nd meeting of Registration Board (8th & 10th November,2022)

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

518	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Kanel Pharma Plot No. 6, Street No. SS-3, National Industrial Zone, Rawat (000758)
	Application Form Dy. No / Tracking ID & date of submission	(2MG-LAA-WRSX, 2025-09-03)
	Detail of Fee Submitted	93000.0, 2025-06-25,
	The proposed proprietary name / brand name	KEXLAMIDE
	Label Claim	Each 2 ml contains: Dexmedetomidine as Hydrochloride 200mcg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearControlled Room Temperature
	For generic drugs (me-too Status)	Precedex Injection By Brookes
	Pharmacotherapeutic Group of (API)	Miscellaneous anxiolytics, sedatives and hypnotics
	Name, address of Manufacturing site:	M/S SERAPH PHARMACEUTICAL-Plot No 210, Industrial triangle, Kahuta road, Islamabad-Pakistan-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	DEXMEDA 200mcg/2ml Injection, Meeting 335th

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

519	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Kanel Pharma Plot No. 6, Street No. SS-3, National Industrial Zone, Rawat (000758)
	Application Form Dy. No / Tracking ID & date of submission	(MWR-A2S-NZBX, 2025-09-03)
	Detail of Fee Submitted	93000.0, 2025-06-25,
	The proposed proprietary name / brand name	METHROL
	Label Claim	Each vial contains:- Methylprednisolone Sodium Succinate 40mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearControlled Room Temperature
	For generic drugs (me-too Status)	SOLU MEDROL INJECTION By Pfizer
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Name, address of Manufacturing site:	M/S Wenovo Pharmaceuticals-Plot # 31,32, Punjab Small Industrial Estate, Taxila, Rawalpindi,-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Methyl 40mg Injection, Meeting 339th
Evaluation Remarks		
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.		
Decision		
Approved		
520	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (000644)
	Application Form Dy. No / Tracking ID & date of submission	(Q44-MXD-HZ94, 2025-09-03)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	BILTEX 20mg Tablet
	Label Claim	Each Uncoated Tablet contains: Bilastine.....20MG (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Bilitino Tablet by Wezen
	Pharmacotherapeutic Group of (API)	Benzimidazoles
	Name, address of Manufacturing site:	Wezen Pharmaceuticals-Plot No. 23 & 24, S-1, RCCI, Industrial Estate, Rawat.-
	The status in reference regulatory authorities	UK MHRA Approved
	Detail of previous approval	Biltex, DRB 335
Evaluation Remarks		
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for		

cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

521	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Kanel Pharma Plot No. 6, Street No. SS-3, National Industrial Zone, Rawat (000758)
	Application Form Dy. No / Tracking ID & date of submission	(DWA-UWU-97W3, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-10,
	The proposed proprietary name / brand name	Artekan 120mg Injection
	Label Claim	Each vial contains: Artesunate....120mg
	Reference to Finished product specifications	The International Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearControlled Room Temperature
	For generic drugs (me-too Status)	Arcenate Injection 120mg Reg. no. 100929 M/s Sami Pharma Karachi.
	Pharmacotherapeutic Group of (API)	Artemisinin and Derivatives
	Name, address of Manufacturing site:	M/S BIO-LABS PVT LTD-Plot No. 145, Industrial Triangle Kahuta Road Islamabad-
	The status in reference regulatory authorities	WHO & FDA Approved
	Detail of previous approval	BIOART 120mg IV Injection, Meeting 331st
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
522	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Kanel Pharma Plot No. 6, Street No. SS-3, National Industrial Zone, Rawat (000758)
	Application Form Dy. No / Tracking ID & date of submission	(3BS-LN9-LPV7, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-10,
	The proposed proprietary name / brand name	Artekan 60mg Injection
	Label Claim	Each vial contains: Artesunate.....60mg
	Reference to Finished product specifications	The International Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearControlled Room Temperature
	For generic drugs (me-too Status)	Arcenate Injection 60mg Reg. no. 100928 M/s Sami Pharma Karachi.
	Pharmacotherapeutic Group of (API)	Artemisinin and Derivatives

	Name, address of Manufacturing site:	M/S BIO-LABS PVT LTD-Plot No. 145, Industrial Triangle Kahuta Road Islamabad-
	The status in reference regulatory authorities	WHO & FDA Approved
	Detail of previous approval	BIOART 60mg IV Injection, Meeting 331st
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
523	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Kanel Pharma Plot No. 6, Street No. SS-3, National Industrial Zone, Rawat (000758)
	Application Form Dy. No / Tracking ID & date of submission	(3E6-M8T-HHS6, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-10,
	The proposed proprietary name / brand name	Artekan 30mg Injection
	Label Claim	Each vial contains: Artesunate 30mg
	Reference to Finished product specifications	The International Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year Controlled Room Temperature
	For generic drugs (me-too Status)	Arcenate Injection 30mg Reg. no. 100927 M/s Sami Pharma Karachi.
	Pharmacotherapeutic Group of (API)	Artemisinin and Derivatives
	Name, address of Manufacturing site:	M/S BIO-LABS PVT LTD-Plot No. 145, Industrial Triangle Kahuta Road Islamabad-
	The status in reference regulatory authorities	WHO & FDA Approved
	Detail of previous approval	BIOART 30mg IV Injection, Meeting 331st
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
524	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wallace Pharma Evolutions Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (000951)
	Application Form Dy. No / Tracking ID & date of submission	(GJN-MAT-QA2V, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-22,
	The proposed proprietary name / brand name	Ozepra 40mg Capsule

Label Claim	Each Capsule contains: OMEPRAZOLE as enteric coated pellets (USP) 40MG (Product Complies USP Specs)
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 YearStore below 25°C
For generic drugs (me-too Status)	Jumep Capsule by Jupiter Pharma
Pharmacotherapeutic Group of (API)	PPI
Name, address of Manufacturing site:	Welcome Pakistan Trading Pharma Pvt Ltd-Chakri Interchange Gangawala, Rawalpindi-
The status in reference regulatory authorities	USFDA Approved
Detail of previous approval	Ozepra Capsule, DRB 336

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

525	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wallace Pharma Evolutions Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (000951)
	Application Form Dy. No / Tracking ID & date of submission	(UYV-AZT-7BU3, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-22,
	The proposed proprietary name / brand name	Ozepra 20mg Capsule
	Label Claim	Each Capsule contains: OMEPRAZOLE as enteric coated pellets (USP) 20mg (Product Complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Jumep Capsule by Jupiter Pharma
	Pharmacotherapeutic Group of (API)	PPI
	Name, address of Manufacturing site:	Welcome Pakistan Trading Pharma Pvt Ltd-Chakri Interchange Gangawala, Rawalpindi-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Ozepra Capsule, DRB 339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

Approved

526	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welmark Pharmaceuticals Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan (000614)
	Application Form Dy. No / Tracking ID & date of submission	(Q11-RMU-J4ST, 2025-09-02)
	Detail of Fee Submitted	97200.0, 2025-08-30,
	The proposed proprietary name / brand name	Empzark 10mg Tablet
	Label Claim	Each film coated tablet contains: Empagliflozin 10mg Innovators specs
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 25 C
	For generic drugs (me-too Status)	Diampa 10mg Tablets by Getz Pharma (Reg # 093073)
	Pharmacotherapeutic Group of (API)	Applied as Cross Refer Product against Already Approved CTD
	Name, address of Manufacturing site:	M/s Welwrd Pharmaceuticals-Plot No.3, Block No.A, Phase I-II, Industrial Estate Hattar.-
	The status in reference regulatory authorities	Applied as Cross Refer Product against Already Approved CTD
	Detail of previous approval	Empawrd 10mg Tablet (Empagliflozn) DRB Meeting 308
Evaluation Remarks		
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.		
Decision		
Approved		
527	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welwink Pharmaceuticals G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751)
	Application Form Dy. No / Tracking ID & date of submission	(LQA-2VZ-BAV6, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	Prostone 100mg Tablet
	Label Claim	Each Uncoated Tablet contains: Progesterone (USP).....100MG (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25c
	For generic drugs (me-too Status)	Lunagest Tablet by Weather Folds Pharma
	Pharmacotherapeutic Group of (API)	Progestins

	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Prostone 100mg Tablet, DRB 344
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
528	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welwink Pharmaceuticals G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751)
	Application Form Dy. No / Tracking ID & date of submission	(EYP-TSA-2QGD, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	DEUTA PLUS 0.4mg + 0.5mg Capsule
	Label Claim	Each hard gelatin capsule contains: Dutasteride (as soft gelatin capsule) 0.5 mg Tamsulosin hydrochloride (as modified release pellets) 0.4 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25c
	For generic drugs (me-too Status)	Maxflow-D Capsule by M/s CCL Pharmaceutical (Reg. 091571)
	Pharmacotherapeutic Group of (API)	Alpha-adrenoreceptor antagonists
	Name, address of Manufacturing site:	Biogen Life Sciences-8-KM, Chak Beli Road, Rawat,-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Dutaride-T Capsule, DRB 335
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
529	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welwink Pharmaceuticals G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751)
	Application Form Dy. No / Tracking ID & date of submission	(25X-G2N-XXAS, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-18,

The proposed proprietary name / brand name	Medron 5mg Tablet
Label Claim	Each Film Coated Tablet Contains: Midodrine Hydrochloride (USP).....5mg (Product complies USP Specs)
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 YearStore Below 25c
For generic drugs (me-too Status)	Midotab By Wnsfeild
Pharmacotherapeutic Group of (API)	Alpha-adrenoreceptor antagonists
Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar,-
The status in reference regulatory authorities	USFDA Approved
Detail of previous approval	Medron Tablet, DRB 343

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

530	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welwink Pharmaceuticals G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751)
	Application Form Dy. No / Tracking ID & date of submission	(ZZ6-2EH-RBVJ, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	Empeg-ML 12.5mg + 2.5mg + 1000mg XR Tablet
	Label Claim	Each Film Coated Extended Release Tablet contains: Empagliflozin.....12.5mg Linagliptin.....2.5MG (As immediate release core) Metformin Hydrochloride*.....1000MG (As extended release core) (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25c
	For generic drugs (me-too Status)	Ezliz XR Tablet by Welmark Pharma
	Pharmacotherapeutic Group of (API)	Sodium-glucose co-transporter 2 (SGLT2) inhibitors Dipeptidyl peptidase-4 (DPP-4) inhibitors Biguanide
	Name, address of Manufacturing site:	Welmark Pharmaceuticals-Plot No. 122, Phase-V, Block-B, Industrial Estate, Hattar-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Empeg-ML Tablet, DRB 340

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt

the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

531	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welwink Pharmaceuticals G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751)
	Application Form Dy. No / Tracking ID & date of submission	(4JL-ZYE-12G7, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	Empeg-ML 25mg + 5mg + 1000mg XR Tablet
	Label Claim	Each Film Coated Extended Release Tablet contains: Empagliflozin.....25mg Linagliptin.....5MG (As immediate release core) Metformin Hydrochloride*.....1000MG (As extended release core) (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25c
	For generic drugs (me-too Status)	Ezliz XR Tablet by Welmark Pharma
	Pharmacotherapeutic Group of (API)	Sodium-glucose co-transporter 2 (SGLT2) inhibitors Dipeptidyl peptidase-4 (DPP-4) inhibitors Biguanide
	Name, address of Manufacturing site:	Welmark Pharmaceuticals-Plot No. 122, Phase-V, Block-B, Industrial Estate, Hattar-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Empeg-ML Tablet, DRB 340
Evaluation Remarks		
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.		
Decision		
Approved		
532	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welwink Pharmaceuticals G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751)
	Application Form Dy. No / Tracking ID & date of submission	(DT1-Q77-5Y96, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	Empeg-ML 10mg + 5mg + 1000mg XR Tablet
	Label Claim	Each Film Coated Extended Release Tablet contains: Empagliflozin.....10MG Linagliptin.....5MG (As immediate release core) Metformin Hydrochloride*.....1000MG (As extended release core) (Product Complies Innovator's Specs)

Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 YearStore Below 25c
For generic drugs (me-too Status)	Ezliz XR Tablet by Welmark Pharma
Pharmacotherapeutic Group of (API)	Sodium-glucose co-transporter 2 (SGLT2) inhibitors Dipeptidyl peptidase-4 (DPP-4) inhibitors Biguanide
Name, address of Manufacturing site:	Welmark Pharmaceuticals-Plot No. 122, Phase-V, Block-B, Industrial Estate, Hattar-
The status in reference regulatory authorities	USFDA Approved
Detail of previous approval	Empeg-ML Tablet, DRB 340

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

533

Case Category	Contract Manufacturing (Incharge Evaluation Cell)
Name, address of Applicant.	Welwink Pharmaceuticals G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751)
Application Form Dy. No / Tracking ID & date of submission	(UZH-ZS4-8U8G, 2025-09-02)
Detail of Fee Submitted	93000.0, 2025-07-18,
The proposed proprietary name / brand name	Empeg-ML 5mg + 2.5mg + 1000mg XR Tablet
Label Claim	Each Film Coated Extended Release Tablet contains: Empagliflozin.....5MG Linagliptin.....2.5MG (As immediate release core) Metformin Hydrochloride*.....1000MG (As extended release core) (Product Complies Innovator's Specs)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 YearStore Below 25c
For generic drugs (me-too Status)	Ezliz XR Tablet by Welmark Pharma
Pharmacotherapeutic Group of (API)	Sodium-glucose co-transporter 2 (SGLT2) inhibitors Dipeptidyl peptidase-4 (DPP-4) inhibitors Biguanide
Name, address of Manufacturing site:	Welmark Pharmaceuticals-Plot No. 122, Phase-V, Block-B, Industrial Estate, Hattar-
The status in reference regulatory authorities	USFDA Approved
Detail of previous approval	Empeg-ML Tablet, DRB 340

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

	Decision	
	Approved	
534	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welwink Pharmaceuticals G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751)
	Application Form Dy. No / Tracking ID & date of submission	(NGH-SMB-JJLE, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	C-Kolin 250mg Injection
	Label Claim	Each Ampoule (2mL) Contains: Citicoline as Sodium Salt (USP).....250Mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25c
	For generic drugs (me-too Status)	Coli wan Injection 250mg by SWAN PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	Psychostimulants and Nootropics
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar.-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	C-Kolin, DRB 347
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
535	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welwink Pharmaceuticals G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751)
	Application Form Dy. No / Tracking ID & date of submission	(G4M-YJ5-9A52, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	C-Kolin 1gm Injection
	Label Claim	Each Ampoule (4ML) Contains: Citicoline as Sodium Salt (USP).....1000mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25c
	For generic drugs (me-too Status)	NEUROTEC INJECTION by SCHAZOO LABORATORIES
	Pharmacotherapeutic Group of (API)	Psychostimulants and Nootropics

	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar.-
	The status in reference regulatory authorities	UK MHRA Approved
	Detail of previous approval	C-Kolin, DRB 343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
536	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welwink Pharmaceuticals G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751)
	Application Form Dy. No / Tracking ID & date of submission	(PNB-AQE-RSA1, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	Biltex 10mg Disp Tablet
	Label Claim	Each Orodispersible Tablet contains: Bilastine 10MG (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25c
	For generic drugs (me-too Status)	Biltino 10mg Tablet by Wezen
	Pharmacotherapeutic Group of (API)	Benzimidazoles
	Name, address of Manufacturing site:	Wezen Pharmaceuticals-Plot No. 23 & 24, S-1, RCCI, Industrial Estate, Rawat-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Biltex, DRB 335
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
537	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welwink Pharmaceuticals G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751)
	Application Form Dy. No / Tracking ID & date of submission	(WWS-RT6-M9U4, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-18,

	The proposed proprietary name / brand name	Biltex 20mg Tablet
	Label Claim	Each Uncoated Tablet contains: Bilastine.....20MG (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25c
	For generic drugs (me-too Status)	Biltino 20mg Tablet
	Pharmacotherapeutic Group of (API)	Benzimidazoles
	Name, address of Manufacturing site:	Wezen Pharmaceuticals-Plot No. 23 & 24, S-1, RCCI, Industrial Estate, Rawat-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Biltex, DRB 335
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
538	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wnsfeild Pharmaceuticals Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK (000610)
	Application Form Dy. No / Tracking ID & date of submission	(VGQ-GTN-HT3T, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	Biltex 10mg Disp Tablet
	Label Claim	Each Orodispersible Tablet contains: Bilastine 10MG (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°c
	For generic drugs (me-too Status)	Biltino Tablet by Wezen Pharma
	Pharmacotherapeutic Group of (API)	Benzimidazoles
	Name, address of Manufacturing site:	Wezen Pharmaceuticals-Plot no. 23 & 24, S-1, RCCI Industrial Estate, Rawat-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Biltex, DRB 335
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

Approved

539	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wnsfeild Pharmaceuticals Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK (000610)
	Application Form Dy. No / Tracking ID & date of submission	(BEV-S1X-EHMN, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	Biltex 20mg Tablet
	Label Claim	Each Uncoated Tablet contains: Bilastine.....20MG (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Biltino Tablet by Wezen Pharma
	Pharmacotherapeutic Group of (API)	Benzimidazoles
	Name, address of Manufacturing site:	Wezen Pharmaceuticals -Plot No. 23 & 24, S-1, RCCI Industrial Estate, Rawat-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Biltex, DRB 335
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
540	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (000790)
	Application Form Dy. No / Tracking ID & date of submission	(BPH-494-BGW6, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-21,
	The proposed proprietary name / brand name	Dueta Plus
	Label Claim	Each hard gelatin capsule contains: Dutasteride (as soft gelatin capsule) 0.5 mg Tamsulosin hydrochloride (as modified release pellets) 0.4 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Maxflow-D Capsule by M/s CCL Pharmaceutical (Reg. 091571)
	Pharmacotherapeutic Group of (API)	Alpha-adrenoreceptor antagonists
	Name, address of Manufacturing site:	Biogen Life Sciences-8-Km, Chakbeli Road, Rawat-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Dutari,de-T Capsule, DRB 335

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision**Approved**

541	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (000790)
	Application Form Dy. No / Tracking ID & date of submission	(5BS-W4R-XS2W, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-21,
	The proposed proprietary name / brand name	Biltex 20mg Tablet
	Label Claim	Each Uncoated Tablet contains: Bilastine.....20MG (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25c
	For generic drugs (me-too Status)	Biltino Tablet by Wezen Pharma
	Pharmacotherapeutic Group of (API)	Benzimidazoles
	Name, address of Manufacturing site:	Wezen Pharmaceuticals -Plot No. 23 & 24, S-1, RCCI industrial Estate, Rawat-
	The status in reference regulatory authorities	UK MHRA Approved
	Detail of previous approval	Biltex, DRB 335
542	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (000790)
	Application Form Dy. No / Tracking ID & date of submission	(2W9-Q3J-8NVW, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-21,
	The proposed proprietary name / brand name	Biltex 10mg Disp Tablet
	Label Claim	Each Orodispersible Tablet contains: Bilastine 10MG (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25c
	For generic drugs (me-too Status)	Biltino Tablet by Wezen Pharma
	Pharmacotherapeutic Group of (API)	Benzimidazoles
	Name, address of Manufacturing site:	Wezen Pharmaceuticals -Plot No. 23 & 24, S-1, RCCI industrial Estate, Rawat-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Biltex, DRB 335
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
543	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wezen Pharmaceuticals Industrial Estate Rawat (000882)
	Application Form Dy. No / Tracking ID & date of submission	(YPY-PSP-NR5A, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-24,
	The proposed proprietary name / brand name	Mirolin 5mg Tablet
	Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to Mirogabalin.....5mg (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°c
	For generic drugs (me-too Status)	Miro Tablet by Nabi Qasim
	Pharmacotherapeutic Group of (API)	Anti convulsants
	Name, address of Manufacturing site:	Wimits Pharmaceuticals-Plot No. 129, Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	PMDA JAPAN
	Detail of previous approval	Mirogab, DRB 344
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
544	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wezen Pharmaceuticals Industrial Estate Rawat (000882)

Application Form Dy. No / Tracking ID & date of submission	(NPD-B7L-47TM, 2025-09-02)
Detail of Fee Submitted	93000.0, 2025-07-24,
The proposed proprietary name / brand name	Mirolin 10mg Tablet
Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to Mirogabalin.....10mg (Product Complies Innovator's Specs)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 YearStore below 25°C
For generic drugs (me-too Status)	Miro Tablet by Nabi Qasim
Pharmacotherapeutic Group of (API)	Anti convulsants
Name, address of Manufacturing site:	Wimits Pharmaceuticals-Plot No. 129, Sunder Industrial Estate, Raiwind Road, Lahore-
The status in reference regulatory authorities	PMDA JAPAN
Detail of previous approval	Mirogab, DRB 344

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

545	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wezen Pharmaceuticals Industrial Estate Rawat (000882)
	Application Form Dy. No / Tracking ID & date of submission	(HWJ-L7V-UJ4R, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-24,
	The proposed proprietary name / brand name	Mirolin 15mg Tablet
	Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to Mirogabalin.....15mg (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Miro Tablet by Nabi Qasim
	Pharmacotherapeutic Group of (API)	Anti convulsants
	Name, address of Manufacturing site:	Wimits Pharmaceuticals-Plot No. 129, Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	PMDA JAPAN
	Detail of previous approval	Mirogab, DRB 344

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt

the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

546	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wezen Pharmaceuticals Industrial Estate Rawat (000882)
	Application Form Dy. No / Tracking ID & date of submission	(EVD-37A-ZHTY, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-21,
	The proposed proprietary name / brand name	Ondanz 4mg/5ml Syrup
	Label Claim	Each 5ml Contains: Ondansetron as Ondansetron Hydrochloride Dihydrate (USP).....4mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Ondan syrup 4mg/5ml by BioMark Pharma
	Pharmacotherapeutic Group of (API)	Serotonin 5-Ht3 Receptor Antagonists
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Ondanz, DRB 339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
547	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wezen Pharmaceuticals Industrial Estate Rawat (000882)
	Application Form Dy. No / Tracking ID & date of submission	(N5N-8JM-AM9W, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-21,
	The proposed proprietary name / brand name	Ondanz 8mg Injection
	Label Claim	Each Ampoule (4ml) Contains: Ondansetron as Hydrochloride Dihydrate (USP).....8mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Doston Injection by Vision Pharma

	Pharmacotherapeutic Group of (API)	Serotonin 5-Ht3 Receptor Antagonists
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Ondanz, DRB 339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
548	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wezen Pharmaceuticals Industrial Estate Rawat (000882)
	Application Form Dy. No / Tracking ID & date of submission	(DBX-WN8-AWE7, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-21,
	The proposed proprietary name / brand name	Ondanz 4mg Injection
	Label Claim	Each Ampoule (2mL) Contains: Ondansetron as Hydrochloride Dihydrate.....4mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Doston Injection by Vision Pharma
	Pharmacotherapeutic Group of (API)	Serotonin 5-Ht3 Receptor Antagonists
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Ondanz, DRB 343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
549	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wezen Pharmaceuticals Industrial Estate Rawat (000882)
	Application Form Dy. No / Tracking ID & date of submission	(TTH-GQ4-4NT2, 2025-09-02)

Detail of Fee Submitted	93000.0, 2025-07-21,
The proposed proprietary name / brand name	Ondanz 4mg Tablet
Label Claim	Each Film Coated Tablet Contains: Ondansetron as Hydrochloride Dihydrate (USP).....4mg (Product complies USP Specs)
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 YearStore below 25°C
For generic drugs (me-too Status)	Oniron 4mg Tablet by Genome Pharma
Pharmacotherapeutic Group of (API)	Serotonin 5-Ht3 Receptor Antagonists
Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Estate, Hattar, KPK-
The status in reference regulatory authorities	USFDA Approved
Detail of previous approval	Ondanz, DRB 343

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

550	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wezen Pharmaceuticals Industrial Estate Rawat (000882)
	Application Form Dy. No / Tracking ID & date of submission	(17D-N9P-HQNN, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-21,
	The proposed proprietary name / brand name	Ondanz 8mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Ondansetron as Hydrochloride Dihydrate (USP).....8mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Oniron 8mg Tablet by Genome Pharma
	Pharmacotherapeutic Group of (API)	Serotonin 5-Ht3 Receptor Antagonists
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Ondanz, DRB 343

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other

conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

551	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wezen Pharmaceuticals Industrial Estate Rawat (000882)
	Application Form Dy. No / Tracking ID & date of submission	(S3V-ZAV-ET79, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-24,
	The proposed proprietary name / brand name	Mirolin 2.5mg Tablet
	Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to Mirogabalin.....2.5mg (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Miro Tablet by Nabi Qasim
	Pharmacotherapeutic Group of (API)	Anti convulsants
	Name, address of Manufacturing site:	Wimits Pharmaceuticals-Plot No. 129, Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	PMDA JAPAN
	Detail of previous approval	Mirogab, DRB 344
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
552	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welcome Pakistan Trading Pharma (Pvt) Ltd Chakri Interchange, Gangawala (000987)
	Application Form Dy. No / Tracking ID & date of submission	(RUQ-A8M-BHMA, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-17,
	The proposed proprietary name / brand name	Provest 100mg Tablet
	Label Claim	Each Uncoated Tablet contains: Progesterone (USP).....100MG (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25c
	For generic drugs (me-too Status)	Lunagest Tablet by Weather Folds Pharma
	Pharmacotherapeutic Group of (API)	Progestins

	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Area, Hattar.-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Prostone Tablet , DRB 344
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
553	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welcome Pakistan Trading Pharma (Pvt) Ltd Chakri Interchange, Gangawala (000987)
	Application Form Dy. No / Tracking ID & date of submission	(JBS-WBA-D121, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	Tofacib 5mg Tablet
	Label Claim	Each Film Coated Tablet contains: Tofacitinib Citrate eq. to Tofacitinib.....5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25c
	For generic drugs (me-too Status)	Tofajak 5mg Tablets by Hirani's Pharma
	Pharmacotherapeutic Group of (API)	Janus kinase (JAK) inhibitors
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot NO. 122, Block-A, Phase-V, Industrial Estate, Hattar, KPK. -
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Tofocib 5mg Tablet, DRB 343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
554	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welcome Pakistan Trading Pharma (Pvt) Ltd Chakri Interchange, Gangawala (000987)
	Application Form Dy. No / Tracking ID & date of submission	(D9D-4M8-1G53, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-18,

The proposed proprietary name / brand name	Medron 5mg Tablet
Label Claim	Each Film Coated Tablet Contains: Midodrine Hydrochloride (USP).....5mg (Product complies USP Specs)
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 YearStore below 25c
For generic drugs (me-too Status)	Midotab by Wnsfeild Pharma
Pharmacotherapeutic Group of (API)	Alpha-Adrenergic Agonists.
Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot NO. 122, Block-A, Phase-V, Industrial Estate, Hattar, KPK. -
The status in reference regulatory authorities	USFDA Approved
Detail of previous approval	Medron, DRB 343

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

555	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welcome Pakistan Trading Pharma (Pvt) Ltd Chakri Interchange, Gangawala (000987)
	Application Form Dy. No / Tracking ID & date of submission	(43B-4PQ-3EUN, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	Savelo 800mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Sevelamer Carbonate.....800mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25c
	For generic drugs (me-too Status)	Ranvela 800mg Tablet by Sanofi Pakistan
	Pharmacotherapeutic Group of (API)	Phosphate Binders
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot NO. 122, Block-A, Phase-V, Industrial Estate, Hattar, KPK. -
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Savelo Tablet, DRB 340

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

556	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welcome Pakistan Trading Pharma (Pvt) Ltd Chakri Interchange, Gangawala (000987)
	Application Form Dy. No / Tracking ID & date of submission	(3HU-HJU-A1EQ, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	Phyto-K 10mg/ml Injection
	Label Claim	Each Ampoule (1mL) Contains: Phytionadione (USP) 10mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25c
	For generic drugs (me-too Status)	KEFEI INJECTION by HAJI MEDICINES CO RAWALPINDI
	Pharmacotherapeutic Group of (API)	Hemostatics
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot NO. 122, Block-A, Phase-V, Industrial Estate, Hattar, KPK. -
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Phyto-K, DRB 343
Evaluation Remarks		
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.		
Decision		
Approved		
557	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (000644)
	Application Form Dy. No / Tracking ID & date of submission	(EEJ-2YE-PMW8, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	BILTEX 10MG DISP TABLET
	Label Claim	Each Orodispersible Tablet contains: Bilastine 10MG (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Bilitino Tablet by Wezen
	Pharmacotherapeutic Group of (API)	Benzimidazoles
	Name, address of Manufacturing site:	Wezen Pharmaceuticals-Plot No. 23 & 24, S-1, RCCI, Industrial Estate, Rawat.-
	The status in reference regulatory authorities	USFDA Approved

	Detail of previous approval	Biltex, DRB 335
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
558	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (000644)
	Application Form Dy. No / Tracking ID & date of submission	(8MZ-GGV-8UBN, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	Phyto-K 10mg/ml Injection
	Label Claim	Each Ampoule (1mL) Contains: Phytionadione (USP) 10mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	KEFEI INJECTION Reg No. 021195
	Pharmacotherapeutic Group of (API)	Hemostatics
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Phyto-K, DRB 343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
559	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wallace Pharma Evolutions Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (000951)
	Application Form Dy. No / Tracking ID & date of submission	(NBS-6GQ-NJWD, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-22,
	The proposed proprietary name / brand name	Ezimep 40mg Capsule
	Label Claim	Each Capsule contains: Esomeprazole as enteric coated pellets (USP) 40mg (Product Complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia

	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Sold Capsule by Regal Pharma
	Pharmacotherapeutic Group of (API)	PPI
	Name, address of Manufacturing site:	Welcome Pakistan Trading Pharma Pvt Ltd-Chakri Interchange Gangawala, Rawalpindi-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Ezimep Capsule, DRB 339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
560	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wallace Pharma Evolutions Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (000951)
	Application Form Dy. No / Tracking ID & date of submission	(HB1-382-T9Y8, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-22,
	The proposed proprietary name / brand name	Phyto-K 10mg/ml Injection
	Label Claim	Each Ampoule (1mL) Contains: Phytonadione (USP) 10mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	KEFEI INJECTION by HAJI MEDICINES CO RAWALPINDI
	Pharmacotherapeutic Group of (API)	Hemostatics
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK.-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Phyto-K, DRB 343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
561	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wallace Pharma Evolutions Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (000951)

Application Form Dy. No / Tracking ID & date of submission	(2VT-HS2-598D, 2025-09-02)
Detail of Fee Submitted	93000.0, 2025-07-22,
The proposed proprietary name / brand name	Ezimep 20mg Capsule
Label Claim	Each Capsule contains: Esomeprazole as enteric coated pellets (USP) 20mg (Product Complies USP Specs)
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 YearStore below 25°C
For generic drugs (me-too Status)	Sold Capsule by Regal Pharma
Pharmacotherapeutic Group of (API)	PPI
Name, address of Manufacturing site:	Welcome Pakistan Trading Pharma Pvt Ltd-Chakri Interchange Gangawala, Rawalpindi-
The status in reference regulatory authorities	USFDA Approved
Detail of previous approval	Ezimep Capsule, DRB 339

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

562	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wallace Pharma Evolutions Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (000951)
	Application Form Dy. No / Tracking ID & date of submission	(GU3-9JU-8MUU, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-22,
	The proposed proprietary name / brand name	Dueta Plus
	Label Claim	Each hard gelatin capsule contains: Dutasteride (as soft gelatin capsule) 0.5 mg Tamsulosin hydrochloride (as modified release pellets) 0.4 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Maxflow-D Capsule CCL Pharmaceuticals (Pvt.) Ltd. 091571
	Pharmacotherapeutic Group of (API)	Alpha-adrenoreceptor antagonists ATC Code G04CA52
	Name, address of Manufacturing site:	Biogen Life Sciences-8-Km, Chakbeli Road, Rawat-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Dutaride-T Capsule, DRB 335

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other

conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

563	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wallace Pharma Evolutions Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (000951)
	Application Form Dy. No / Tracking ID & date of submission	(9TN-781-3XW7, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-22,
	The proposed proprietary name / brand name	Biltex 20mg Tablet
	Label Claim	Each Uncoated Tablet contains: Bilastine.....20MG (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Biltino Tablet by Wezen Pharma
	Pharmacotherapeutic Group of (API)	Benzimidazoles
	Name, address of Manufacturing site:	Wezen Pharmaceuticals-Plot No. 23 & 24, S-1, RCCI Industrial Estate, Rawat-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Biltex, DRB 335
564	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wallace Pharma Evolutions Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (000951)
	Application Form Dy. No / Tracking ID & date of submission	(887-GX4-1SHW, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-17,
	The proposed proprietary name / brand name	P-Gest 100mg Tablet
	Label Claim	Each Uncoated Tablet contains: Progesterone (USP).....100MG (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Lunagest Tablet by Weather Folds Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Progestins
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-

	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Prostone 100mg Tablet , DRB 344
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
565	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winthrox Laboratories Pvt. Ltd K-219-A, SITE, Super Highway Phase II, Karachi (000807)
	Application Form Dy. No / Tracking ID & date of submission	(81E-P5L-R8LX, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-07-02,
	The proposed proprietary name / brand name	Fusid Cream (2%)
	Label Claim	Each gram Cream Contains: Fusidic Acid (BP).....20mg (2% w/w) (Product complies BP Specs)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Fucidin (Fusidic acid) by Leo Pharma Denmark UK-MHRA Reference: https://www.medicines.org.uk/emc/product/3364/smpc
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	M/s Biogen Life Sciences -8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Advanz Pharma Capital House, 1st floor, 85 King William Street, London, EC4N 7BL, UKUS – FDA Reference: https://www.medicines.org.uk/emc/product/3364/smpc
	Detail of previous approval	Fusigen Cream 2% approved in 313th Meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
566	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winthrox Laboratories Pvt. Ltd K-219-A, SITE, Super Highway Phase II, Karachi (000807)
	Application Form Dy. No / Tracking ID & date of submission	(88Q-247-Q6TL, 2025-09-02)

	Detail of Fee Submitted	93000.0, 2025-06-19,
	The proposed proprietary name / brand name	Medoxa 150mg/ml Injection
	Label Claim	Each 1 ml ampoule Contains: Medroxyprogesterone acetate 150 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	MEDROXY DEPO 150 mg/ml Injection 1ml. Registration holder: Global Pharmaceuticals
	Pharmacotherapeutic Group of (API)	A Derivative of Progesterone.
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhpura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	Brand Name DEPO-PROVERA Marketing Authorization holder: PFIZER Regulatory Authority: DEPO-PROVERA 150 mg/ml Injectable Suspension ® is Approved in USFDA.
	Detail of previous approval	Medrox Injection approved in 336th Meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
567	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winthrox Laboratories Pvt. Ltd K-219-A, SITE, Super Highway Phase II, Karachi (000807)
	Application Form Dy. No / Tracking ID & date of submission	(A4T-B1S-ZJL7, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-06-19,
	The proposed proprietary name / brand name	Nalora Tablet 5mg
	Label Claim	Each Tablet contains: Norethisterone.....5mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Primolut N (Norethisterone) 5mg Tablet OBS Pharma (Pvt.) Ltd. Registration # 000677
	Pharmacotherapeutic Group of (API)	Progestational hormone
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhpura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	Primolut N Tablet 5mg Manufacture Name: Bayer plc Address: 400 South Oak Way, Reading, Berkshire, RG2 6AD MHRA Approved
	Detail of previous approval	Just-N 5mg Tablet approved in 347th Meeting of DRB
	Evaluation Remarks	

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

568	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winthrox Laboratories Pvt. Ltd K-219-A, SITE, Super Highway Phase II, Karachi (000807)
	Application Form Dy. No / Tracking ID & date of submission	(WHY-5XB-G3JA, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-06-19,
	The proposed proprietary name / brand name	Elinor Tablet 2mg/0.5mg
	Label Claim	Composition: Each of the 10 light brown tablets contains: estradiol valerate 2 mg norgestrel 0.5 mg Each of the 11 white tablets contains: estradiol valerate 2 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	PROGYLUTON (Estradiol Valerate-Norgestral) Tablet Manufacture Name: Bayer Weimar GmbH und Co., KG, Weimar, Germany. Marketed by: Bayer Pakistan (Pvt.) Limited, Plot No. 23, Sector No. 22, Korangi indu
	Pharmacotherapeutic Group of (API)	estrogen hormones /agonist of the progesterone receptor
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhpura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	Registration holder's name and address: Bayer Israel Ltd., 36 Hacharash St., Hod Hasharon 4527702. Manufacturer's name and address: Bayer Weimar GmbH und Co. KG, Weimar, Germany.
	Detail of previous approval	Estragest Tablet approved in 347th Meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
569	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winthrox Laboratories Pvt. Ltd K-219-A, SITE, Super Highway Phase II, Karachi (000807)
	Application Form Dy. No / Tracking ID & date of submission	(95Y-Q4G-5VM5, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-06-19,

The proposed proprietary name / brand name	DELVYN TABLET 10mg
Label Claim	Each film coated tablet contains 10 mg of Dydrogesterone
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
For generic drugs (me-too Status)	Dydrogest 10mg Tablet.OBS Pakistan (Pvt) Ltd., C-14 Mangopir Road SITE Karachi. , Karachi.
Pharmacotherapeutic Group of (API)	Genito Urinary system and sex hormones
Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhpura Road, Lahore-Pakistan-
The status in reference regulatory authorities	Duphaston 10 mg film-coated tablets. Mylan IRE Healthcare Limited. Duphaston 10 mg film-coated tablets ® is Approved in HPRA of Ireland.
Detail of previous approval	D-Gest Tablet 10mg in 336th Meeting of DRB

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

570	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winthrox Laboratories Pvt. Ltd K-219-A, SITE, Super Highway Phase II, Karachi (000807)
	Application Form Dy. No / Tracking ID & date of submission	(UJV-X3B-MPHQ, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-06-19,
	The proposed proprietary name / brand name	Elenza Tablet 2mg/0.035mg
	Label Claim	Each Sugar coated tablet contains Cyproterone acetate 2 mg & Ethinylestradiol 0.035mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Diane 35 tablet, Bayer Pakistan (Pvt.) Ltd
	Pharmacotherapeutic Group of (API)	Anti-androgen/Oestrogen.
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhpura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	DIANE-35, Bayer Australia Ltd. DIANE-35 2 mg/0.035 mg tablets ® is Approved in TGA of Australia.
	Detail of previous approval	Cyprodol 2mg/35mcg Tablet in 343rd Meeting of DRAP

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other

conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

571	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(4XR-MXH-2D4X, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-06-27,
	The proposed proprietary name / brand name	Betamed C Cream
	Label Claim	Each gram contains: Betamethasone as Valerate 0.1% w/w
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Biogen Life Sciences
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Name, address of Manufacturing site:	Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	GlaxoSmithKline UK Address 980 Great West Road, Brentford, Middlesex, TW8 9GS, UK E-mail customercontactuk@gsk.com Adverse event reporting email uksafety@gsk.com Telephone 0800 221 441 Medical Information e-mail ukmedinfo@gsk.com
	Detail of previous approval	313TH
Evaluation Remarks		
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.		
Decision		
Approved		
572	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Jinnah Pharmaceuticals Pvt Ltd 13 Km Lahore Road Multan (000578)
	Application Form Dy. No / Tracking ID & date of submission	(139-38P-72LV, 2025-09-02)
	Detail of Fee Submitted	93000.0, 2025-01-25,
	The proposed proprietary name / brand name	Vonoprajin
	Label Claim	Each Film Coated Tablet Contain:- Vonoprazan as fumarate 20mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year15-30C

For generic drugs (me-too Status)	VPN-20 Tablet Reg No. 110204 by Helix Pharma Karachi
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	World Biz Pharmaceutical Company-Plot No 340, Multan Industrial Area Multan-
The status in reference regulatory authorities	PMDA Japan Approve
Detail of previous approval	M-339

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

573	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winthrox Laboratories Pvt. Ltd K-219-A, SITE, Super Highway Phase II, Karachi (000807)
	Application Form Dy. No / Tracking ID & date of submission	(1XG-T1Y-AB39, 2025-09-08)
	Detail of Fee Submitted	93000.0, 2025-07-28,
	The proposed proprietary name / brand name	MAXSURE-CAPSULE
	Label Claim	Each hard gelatin capsule contains: Dutasteride (as soft gelatin capsule) 0.5 mg Tamsulosin hydrochloride (as modified release pellets) 0.4 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Brand Name: Registration holder: Registration Number: Maxflow-D Capsule CCL Pharmaceuticals (Pvt.) Ltd. 091571
	Pharmacotherapeutic Group of (API)	Alpha-adrenoreceptor antagonists
	Name, address of Manufacturing site:	Biogen Life Sciences-8-KM, Chak Beli Road, Rawat,-
	The status in reference regulatory authorities	Dutasteride/Tamsulosin hydrochloride 0.5 mg / 0.4 mg hard capsules (MHRA)
	Detail of previous approval	Minutes of 335th meeting of Registration Board (25th April, 2024) as Dutaride-T Capsule
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
574	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

Name, address of Applicant.	NAVEGAL LABORATORIES 41/1-A-2, PHASE-1, INDUSTRIAL ESTATE HATTAR, KPK, PAKISTAN (000591)
Application Form Dy. No / Tracking ID & date of submission	(1YU-VDM-D8N7, 2025-09-08)
Detail of Fee Submitted	93000.0, 2025-07-21,
The proposed proprietary name / brand name	ENUSOL 250MG Injection
Label Claim	Each Vial Contains: Hydrocortisone equivalent Hydrocortisone Sodium Succinate (USP).....250mg (Product complies USP Specs)
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	As Per SRO-As per SRO
Shelf Life (Unit)	2 YearStore below 25°C
For generic drugs (me-too Status)	CORTISONE INJECTION by VISION PHARMACEUTICALS
Pharmacotherapeutic Group of (API)	Corticosteroids
Name, address of Manufacturing site:	Wenovo Pharmaceuticals-Plot No. 31 & 32, Punjab Small Industrial Estate, Taxila, Rawalpindi-
The status in reference regulatory authorities	Usfda Approved
Detail of previous approval	Hykor 250mg Injection, DRB 339

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

575	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	TABROS PHARMA (PVT). LTD. Plot No. L-20/B, Sector 22, F.B. Industrial Area (000106)
	Application Form Dy. No / Tracking ID & date of submission	(2Y6-E6Z-5245, 2025-09-08)
	Detail of Fee Submitted	93000.0, 2025-07-29,
	The proposed proprietary name / brand name	Form 100mg Tablet
	Label Claim	Each Film coated tablet contains: Sildenafil citrate 140.45mg equivalent to Sildenafil.....100mg. (USP Specification.)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's-De-Controlled,1x2's-De-Controlled,1x4's-De-Controlled,2x10's-De-Controlled
	Shelf Life (Unit)	2 YearSTORE BELOW 30oC
	For generic drugs (me-too Status)	Ripple 100mg Tablet Solaris Life Sciences (Pvt.) Ltd Registration No.127631
	Pharmacotherapeutic Group of (API)	Pharmacotherapeutic Group: Selective inhibitor of cyclic GMP-specific phosphodiesterase (Type V) with

		vasodilator action; Urologicals; Drugs used in erectile dysfunction.
	Name, address of Manufacturing site:	M/s Solaris Life Sciences (Pvt.) Ltd-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi – Pakistan -
	The status in reference regulatory authorities	Viagra 100mg Tablet VIATRIS USFDA Approved
	Detail of previous approval	Ripple 100mg Tablet 345th DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
576	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	TABROS PHARMA (PVT). LTD. Plot No. L-20/B, Sector 22, F.B. Industrial Area (000106)
	Application Form Dy. No / Tracking ID & date of submission	(41W-ARZ-MAXZ, 2025-09-08)
	Detail of Fee Submitted	93000.0, 2025-07-29,
	The proposed proprietary name / brand name	Form 25mg Tablet
	Label Claim	Each Film coated tablet contains: Sildenafil citrate 35.1125mg equivalent to Sildenafil.....25mg. (USP Specification.)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's-De-Controlled, 1x2's-De-Controlled, 1x4's-De-Controlled, 2x10's-De-Controlled
	Shelf Life (Unit)	2 YearSTORE BELOW 30oC
	For generic drugs (me-too Status)	Ripple 25mg Tablet Solaris Life Sciences (Pvt.) Ltd Registration No.127629
	Pharmacotherapeutic Group of (API)	Pharmacotherapeutic Group: Selective inhibitor of cyclic GMP-specific phosphodiesterase (Type V) with vasodilator action; Urologicals; Drugs used in erectile dysfunction.
	Name, address of Manufacturing site:	M/s Solaris Life Sciences (Pvt.) Ltd-, Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi – Pakistan-
	The status in reference regulatory authorities	Viagra 25mg Tablet VIATRIS USFDA Approved
	Detail of previous approval	RIPPLE 25MG TABLETS 345th DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

Approved

577	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	NAVEGAL LABORATORIES 41/1-A-2, PHASE-1, INDUSTRIAL ESTATE HATTAR, KPK, PAKISTAN (000591)
	Application Form Dy. No / Tracking ID & date of submission	(5E1-VW8-DHUX, 2025-09-08)
	Detail of Fee Submitted	93000.0, 2025-07-21,
	The proposed proprietary name / brand name	NAVACE 160mg Tablet
	Label Claim	Each Uncoated Tablet Contains: Megestrol Acetate (USP).....160 mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Preogace 160mg Tablet by Medinet Pharma Rawalpindi
	Pharmacotherapeutic Group of (API)	Progesterone
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	Usfda Approved
	Detail of previous approval	Mygest 160mg Tablet, DRB 324
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
578	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	NAVEGAL LABORATORIES 41/1-A-2, PHASE-1, INDUSTRIAL ESTATE HATTAR, KPK, PAKISTAN (000591)
	Application Form Dy. No / Tracking ID & date of submission	(5LS-8DR-ARE8, 2025-09-08)
	Detail of Fee Submitted	93000.0, 2025-07-21,
	The proposed proprietary name / brand name	Pepégál Capsules 30mg
	Label Claim	Each Capsule Contains: Dexlansoprazole Dual Delayed Released Pellets eq. to Dexlansoprazole.....30MG (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Dexxo Capsule by Weather Folds Pharma.
	Pharmacotherapeutic Group of (API)	PPI
	Name, address of Manufacturing site:	Welcome Pakistan Trading Pharma (Pvt) Ltd-Chakri Interchange, Gangawala, Rawalpindi-

	The status in reference regulatory authorities	Usfda Approved
	Detail of previous approval	Dexxo Capsule, DRB 336
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
579	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Steris Pharmaceuticals Plot No 9 Near Synpac Hattar Private Industrial Estate Haripur Road Hattar (000995)
	Application Form Dy. No / Tracking ID & date of submission	(5V7-WEU-11H6, 2025-09-08)
	Detail of Fee Submitted	93000.0, 2025-03-13,
	The proposed proprietary name / brand name	Prosec-S
	Label Claim	Each Sachet contains: Omeprazole 40mg Sodium bicarbonate 1680mg (Innovator Spec's)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 25
	For generic drugs (me-too Status)	Yes
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd-Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, Rawalpindi-Pakistan-
	The status in reference regulatory authorities	USA, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&AppNo=021636
	Detail of previous approval	OME 40mg+1680mg Sachet, Minutes of 344th meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
580	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Pine Pharmaceuticals Plot No, 40, S-4, Rawat Industrial Estate, Islamabad (000955)
	Application Form Dy. No / Tracking ID & date of submission	(5YA-VTZ-DVGJ, 2025-09-08)

Detail of Fee Submitted	93000.0, 2025-06-24,
The proposed proprietary name / brand name	Terbipine 1% Cutaneous Solution
Label Claim	Each gram contains: Terbinafine (as hydrochloride) 10mg
Reference to Finished product specifications	Any Other
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 YearBelow 30°C
For generic drugs (me-too Status)	Terbiderm 1% topical solution M/s ATCO Limited
Pharmacotherapeutic Group of (API)	Anti fungal for systemic use
Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd-Plot No. 17, Special Industrial Zone (EPZ), Risalpur-
The status in reference regulatory authorities	Lamisil once 1% cutaneous solution Haleon UK Trading Limited The Heights Weybridge Surrey KT13 0NY United Kingdom MHRA
Detail of previous approval	343rd Meeting of Registration Board

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

581	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	NAVEGAL LABORATORIES 41/1-A-2, PHASE-1, INDUSTRIAL ESTATE HATTAR, KPK, PAKISTAN (000591)
	Application Form Dy. No / Tracking ID & date of submission	(766-11G-SAPY, 2025-09-08)
	Detail of Fee Submitted	93000.0, 2025-07-21,
	The proposed proprietary name / brand name	PREMESO 1gm Injection
	Label Claim	Each Vial Contains: Methylprednisolone as Sodium Succinate (USP).....1000mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Solu Medrol Injection by Pfizer
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Name, address of Manufacturing site:	Wenovo Pharmaceuticals-Plot No. 31 & 32, Punjab Small Industrial Estate, Taxila, Rawalpindi-
	The status in reference regulatory authorities	Usfda Approved
	Detail of previous approval	Methyl Injection, DRB 339

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt

the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

582	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Carer Pharmaceuticals industries Plot no.27, Main Road Rawat Industrial Estate, Rawat (000925)
	Application Form Dy. No / Tracking ID & date of submission	(7JH-3UZ-GLP7, 2025-09-08)
	Detail of Fee Submitted	93000.0, 2025-02-17,
	The proposed proprietary name / brand name	Carpenem
	Label Claim	Each vial contains: Meropenem trihydrate eq to meropenem..... 500mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1,S-As per SRO
	Shelf Life (Unit)	2 YearStore between 15C-30C
	For generic drugs (me-too Status)	Merrem Injection of Global Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Dew-max Pharmaceuticals (Pvt) Ltd-Plot No. Street SS-4 Main Industrial area Rawat, Islamabad.-
	The status in reference regulatory authorities	FDA
	Detail of previous approval	Dewnem 500mg Inj. DRRAP Meeting NO 312
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
583	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Allmed (Pvt.) Ltd Plot # 590 Sunder Industrial Estate Raiwind Road Lahore-Pakistan (000645)
	Application Form Dy. No / Tracking ID & date of submission	(81B-AEG-ZLX8, 2025-09-08)
	Detail of Fee Submitted	93000.0, 2024-12-30,
	The proposed proprietary name / brand name	Prazmed
	Label Claim	Each film-coated tablet contains Vonoprazan Fumarate equivalent to Vonoprazan.....10 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30 C
	For generic drugs (me-too Status)	Vonozan 10mg Tablets by Getz Pharma (Pvt.) Limited 29-30/27, K.I.A., Karachi, Pakistan Reg.# 108570
	Pharmacotherapeutic Group of (API)	

Name, address of Manufacturing site:	DeMont Research Laboratories (Pvt) Ltd-20-Km, Lahore Sharikpur Road, Sheikhpura-
The status in reference regulatory authorities	Takecab 10mg Tablet by Takeda Pharmaceutical Company Limited Japan
Detail of previous approval	M-350

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

584	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	wellbornpharmachem&biologicals Plot No.51/1,52/2 Phase I & II Industrial Estate, Hattar-Pakistan (000657)
	Application Form Dy. No / Tracking ID & date of submission	(8JN-QT4-EDSY, 2025-09-08)
	Detail of Fee Submitted	93000.0, 2025-01-24,
	The proposed proprietary name / brand name	Seldiborn
	Label Claim	Each film coated tablet contain : Sildenafil.... 50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4,S-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 C
	For generic drugs (me-too Status)	viagra 50mg tablet
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Grays Pharmaceuticals-plot No 2, street no N-3, National industrial zone Rawat-
	The status in reference regulatory authorities	VIAGRA50mg tablet
	Detail of previous approval	345
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
585	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Seraph Pharmaceutical Plot No 210, Industrial Triangle Kahuta Road, Islamabad. (000860)
	Application Form Dy. No / Tracking ID & date of submission	(9J3-P9P-GWZV, 2025-09-08)
	Detail of Fee Submitted	93000.0, 2025-06-17,
	The proposed proprietary name / brand name	Fosfin 3g Sachet

Label Claim	Each Sachet Contains; Fosfomycin Trometamol eq. to. Fosfomycin 3g
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 YearStore below 30C
For generic drugs (me-too Status)	Focin Ultra sachet by Tabros Pharma (Pvt.) Ltd
Pharmacotherapeutic Group of (API)	antibiotics.
Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan-
The status in reference regulatory authorities	Switzerland approved
Detail of previous approval	Fosfo 3g sachet , Meeting No. 347th

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

586	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	TABROS PHARMA (PVT). LTD. Plot No. L-20/B, Sector 22, F.B. Industrial Area (000106)
	Application Form Dy. No / Tracking ID & date of submission	(A2J-NSY-LWYP, 2025-09-08)
	Detail of Fee Submitted	93000.0, 2025-07-29,
	The proposed proprietary name / brand name	Form 50mg Tablet
	Label Claim	Each Film coated tablet contains: Sildenafil citrate 70.225mg equivalent to Sildenafil.....50mg. (USP Specification.)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's-De-Controlled,1x2's-De-Controlled,1x4's-De-Controlled,2x10's-De-Controlled
	Shelf Life (Unit)	2 YearSTORE BELOW 30oC
	For generic drugs (me-too Status)	Ripple 50mg Tablet Solaris Life Sciences (Pvt.) Ltd Registration No.127630
	Pharmacotherapeutic Group of (API)	Pharmacotherapeutic Group: Selective inhibitor of cyclic GMP-specific phosphodiesterase (Type V) with vasodilator action; Urologicals; Drugs used in erectile dysfunction.
	Name, address of Manufacturing site:	M/s Solaris Life Sciences (Pvt.) Ltd-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi – Pakistan -
	The status in reference regulatory authorities	Viagra 50mg Tablet VIATRIS USFDA Approved
	Detail of previous approval	RIPPLE 50MG TABLETS 345th DRB

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt

the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

587	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winthrox Laboratories Pvt. Ltd K-219-A, SITE, Super Highway Phase II, Karachi (000807)
	Application Form Dy. No / Tracking ID & date of submission	(AZH-SZY-X8A3, 2025-09-08)
	Detail of Fee Submitted	93000.0, 2025-07-28,
	The proposed proprietary name / brand name	Triamcin in Orabase Ointment
	Label Claim	Each gm contains: Triamcinolone Acetonide 1.00mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Manufacturer Name GlaxoSmithKline Pakistan Limited Brand Name Kenalog in Orabase Ointment Registration Number: 009452
	Pharmacotherapeutic Group of (API)	Corticosteroids for local oral treatment
	Name, address of Manufacturing site:	Biogen Life Sciences-8-Km, Chakbeli Road, Rawat.-
	The status in reference regulatory authorities	FDA Approved.
	Detail of previous approval	TRIAMIGEN 0.1% Orabase Ointment
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
588	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	NAVEGAL LABORATORIES 41/1-A-2, PHASE-1, INDUSTRIAL ESTATE HATTAR, KPK, PAKISTAN (000591)
	Application Form Dy. No / Tracking ID & date of submission	(BTN-9SY-EPRU, 2025-09-08)
	Detail of Fee Submitted	93000.0, 2025-07-21,
	The proposed proprietary name / brand name	ZIVABAC 2.5gm Injection
	Label Claim	Each Vial Contains: Ceftazidime as Pentahydrate.....2000mg Avibactam as Sodium Salt.....500mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO

	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	ZAVICEFTA 2.5GM INJECTION
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Estate, Hattar.-
	The status in reference regulatory authorities	Usfda Approved
	Detail of previous approval	Cefzect, DRB 330
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
589	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	AGP Limited B-23-C, S.I.T.E., Karachi (000348)
	Application Form Dy. No / Tracking ID & date of submission	(DNG-LAP-VLR4, 2025-09-08)
	Detail of Fee Submitted	93000.0, 2025-05-27,
	The proposed proprietary name / brand name	Tamcap Plus Capsule
	Label Claim	Each hard gelatin capsule contains: Dutasteride (as soft gelatin capsule) 0.5 mg Tamsulosin hydrochloride (as modified release pellets).....0.4 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x7's, 1x10's, 2x7's-De-Controlled
	Shelf Life (Unit)	2 YearDo not store over 30°C. Protect from Direct sunlight, heat & moisture.
	For generic drugs (me-too Status)	Maxflow-D Capsule by CCL Pharmaceuticals (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Alpha-adrenoreceptor antagonists
	Name, address of Manufacturing site:	M/s Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Dutasteride/Tamsulosin hydrochloride 0.5 mg / 0.4 mg hard capsules by Milpharm Limited
	Detail of previous approval	Dutaride-T Capsule by M/s Biogen life sciences, DRB 335
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
590	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

Name, address of Applicant.	Global Pharmaceuticals Pvt Ltd Plot Number 204-205 Industrial Triangle Kahuta Road (000417)
Application Form Dy. No / Tracking ID & date of submission	(E98-QAZ-SBTA, 2025-09-08)
Detail of Fee Submitted	93000.0, 2025-07-18,
The proposed proprietary name / brand name	Glorid 1mg Tablet
Label Claim	Each film coated tablet contains:
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	14's-De-Controlled,1x10's -De-Controlled,28's-De-Controlled,2x10's-De-Controlled,3x10's-De-Controlled
Shelf Life (Unit)	2 YearStore below 30°C.
For generic drugs (me-too Status)	Prucalp 1mg Tablet
Pharmacotherapeutic Group of (API)	Gastroprokinetic Drug
Name, address of Manufacturing site:	Seraph Pharmaceutical-Plot No 210, Industrial triangle, Kahuta road, Islamabad-
The status in reference regulatory authorities	US-FDA
Detail of previous approval	Prucalp 1mg Tablet (Meeting 331st)

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

591	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winthrox Laboratories Pvt. Ltd K-219-A, SITE, Super Highway Phase II, Karachi (000807)
	Application Form Dy. No / Tracking ID & date of submission	(ES5-2WD-DR4R, 2025-09-08)
	Detail of Fee Submitted	93000.0, 2025-07-02,
	The proposed proprietary name / brand name	Fusid-H Cream
	Label Claim	Each gram cream contains: Fusidic Acid (BP).....20mg (2% w/w) Hydrocortisone Acetate.....10mg (1% w/w)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Fusimax H cream Manufactured by Maxitech
	Pharmacotherapeutic Group of (API)	Antibiotic/ Corticosteriods
	Name, address of Manufacturing site:	M/s Biogen Life Sciences -8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Marketing Authorization Holder and Manufacturer Marketing Authorization Holder: LEO Laboratories Limited, Hurley, Berkshire SL6 6RJ, UK Manufacturer: LEO Laboratories Limited, Dublin 12, Ireland
	Detail of previous approval	Fusigen-H Cream approved in 331st Meeting of DRB

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision**Approved**

592	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	NAVEGAL LABORATORIES 41/1-A-2, PHASE-1, INDUSTRIAL ESTATE HATTAR, KPK, PAKISTAN (000591)
	Application Form Dy. No / Tracking ID & date of submission	(G1V-MDR-JVM9, 2025-09-08)
	Detail of Fee Submitted	93000.0, 2025-07-21,
	The proposed proprietary name / brand name	PREMESO 125mg Injection
	Label Claim	Each Vial Contains: Methylprednisolone as Sodium Succinate (USP).....125mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Solu Medrol Injection by Pfizer
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Name, address of Manufacturing site:	Wenovo Pharmaceuticals-Plot No. 31 & 32, Punjab Small Industrial Estate, Taxila, Rawalpindi-
	The status in reference regulatory authorities	Usfda Approved
	Detail of previous approval	Methyl Injection, DRB 339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
593	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Global Pharmaceuticals Pvt Ltd Plot Number 204-205 Industrial Triangle Kahuta Road (000417)
	Application Form Dy. No / Tracking ID & date of submission	(GBR-V4J-HW48, 2025-09-08)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	Glorid 2mg Tablet
	Label Claim	Each film coated tablet contains:
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	14's-De-Controlled,1x10's -De-Controlled,28's-De-Controlled,2x10's-De-Controlled,3 x 10's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30°C.
	For generic drugs (me-too Status)	Prucalp 2mg Tablet
	Pharmacotherapeutic Group of (API)	Gastropkinetic Drug
	Name, address of Manufacturing site:	Seraph Pharmaceutical-Plot No 210, Industrial triangle, Kahuta road, Islamabad-
	The status in reference regulatory authorities	US-FDA
	Detail of previous approval	Prucalp 2mg Tablet (Meeting 331st)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
594	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	NAVEGAL LABORATORIES 41/1-A-2, PHASE-1, INDUSTRIAL ESTATE HATTAR, KPK, PAKISTAN (000591)
	Application Form Dy. No / Tracking ID & date of submission	(GGD-PMT-P1RY, 2025-09-08)
	Detail of Fee Submitted	93000.0, 2025-07-21,
	The proposed proprietary name / brand name	NAVENEM 2gm INJECTION
	Label Claim	Each vial contains:- Meropenem (as trihydrate).....2gm (Blended with sodium carbonate) (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Carbapenem-Antibiotics
	Name, address of Manufacturing site:	Wallace Pharma Evolutions-Kala wala stop, 20-KM, Lahore Jaranwala Road Lahore.-
	The status in reference regulatory authorities	Usfda Approved
	Detail of previous approval	Meronim 2gm Inj, DRB 335
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
595	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

Name, address of Applicant.	NAVEGAL LABORATORIES 41/1-A-2, PHASE-1, INDUSTRIAL ESTATE HATTAR, KPK, PAKISTAN (000591)
Application Form Dy. No / Tracking ID & date of submission	(HB6-BHV-UE75, 2025-09-08)
Detail of Fee Submitted	93000.0, 2025-07-21,
The proposed proprietary name / brand name	FERAVI-F 500mg/10ml Injection
Label Claim	Each 10ml Vial Contains: Iron as Ferric Carboxymaltose.....500mg (Product complies Innovator's Specs)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As Per SRO-As per SRO
Shelf Life (Unit)	2 YearStore below 25°C
For generic drugs (me-too Status)	FERINJECT 500mg/10ml INJECTION by RH Pharma
Pharmacotherapeutic Group of (API)	Phosphate Binders
Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK-
The status in reference regulatory authorities	Usfda Approved
Detail of previous approval	Ferrina Injection, DRB 343

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

596	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	NAVEGAL LABORATORIES 41/1-A-2, PHASE-1, INDUSTRIAL ESTATE HATTAR, KPK, PAKISTAN (000591)
	Application Form Dy. No / Tracking ID & date of submission	(J14-8M3-MHHJ, 2025-09-08)
	Detail of Fee Submitted	93000.0, 2025-07-21,
	The proposed proprietary name / brand name	PREMESO 500mg Injection
	Label Claim	Each Vial Contains: Methylprednisolone as Sodium Succinate (USP).....500Mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Solu Medrol Injection by Pfizer
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Name, address of Manufacturing site:	Wenovo Pharmaceuticals-Plot No. 31 & 32, Punjab Small Industrial Estate, Taxila, Rawalpindi-
	The status in reference regulatory authorities	Usfda Approved
	Detail of previous approval	Methyl Injection, DRB 339

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision**Approved**

597	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	NAVEGAL LABORATORIES 41/1-A-2, PHASE-1, INDUSTRIAL ESTATE HATTAR, KPK, PAKISTAN (000591)
	Application Form Dy. No / Tracking ID & date of submission	(JHX-73X-SHSV, 2025-09-08)
	Detail of Fee Submitted	93000.0, 2025-07-21,
	The proposed proprietary name / brand name	ENUSOL 100MG Injection
	Label Claim	Each Vial Contains: Hydrocortisone equivalent Hydrocortisone Sodium Succinate (USP).....100MG (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	CORTISONE 100MG INJECTION by VISION PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Name, address of Manufacturing site:	Wenovo Pharmaceuticals-Plot No. 31 & 32, Punjab Small Industrial Estate, Taxila, Rawalpindi-
	The status in reference regulatory authorities	Usfda Approved
	Detail of previous approval	Hykor 100mg Injection, DRB 339
598	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winthrox Laboratories Pvt. Ltd K-219-A, SITE, Super Highway Phase II, Karachi (000807)
	Application Form Dy. No / Tracking ID & date of submission	(JW1-B6H-ET5N, 2025-09-08)
	Detail of Fee Submitted	93000.0, 2025-07-14,
	The proposed proprietary name / brand name	Clinox Lotion

	Label Claim	Each ml of lotion contains: Clindamycin as phosphate..... 10mg (BP Specs)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Manufacturer Name Medera Pharmaceutical Pvt Ltd Brand Name Climed T Registration Number: 115341
	Pharmacotherapeutic Group of (API)	Broad spectrum antibiotics
	Name, address of Manufacturing site:	Name: M/s Biogen Life Sciences -Address: 8-km, Chakbeli Road, Rawat, Rawalpindi Telephone: + 92 51 4493471-
	The status in reference regulatory authorities	Brand Name: Dalacin T Lotion Manufacturer Name: Pfizer MHRA Approved.
	Detail of previous approval	Clinovaa Lotion Approved in 347th Meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
599	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	NAVEGAL LABORATORIES 41/1-A-2, PHASE-1, INDUSTRIAL ESTATE HATTAR, KPK, PAKISTAN (000591)
	Application Form Dy. No / Tracking ID & date of submission	(MMR-ZDW-MY6T, 2025-09-08)
	Detail of Fee Submitted	93000.0, 2025-07-21,
	The proposed proprietary name / brand name	INTOCI 1gm Injection
	Label Claim	Each Ampoule (4ML) Contains: Citicoline as Sodium Salt (USP).....1000mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	NEUROTEC INJECTION by SCHAZOO LABORATORIES
	Pharmacotherapeutic Group of (API)	Anti-Parkinson
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	ANSM FRANCE APPROVED
	Detail of previous approval	C-Kolin 1gm, DRB 343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other	

conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

600	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Global Pharmaceuticals Pvt Ltd Plot Number 204-205 Industrial Triangle Kahuta Road (000417)
	Application Form Dy. No / Tracking ID & date of submission	(NRS-VJW-92ZN, 2025-09-08)
	Detail of Fee Submitted	97200.0, 2025-08-27,
	The proposed proprietary name / brand name	Clasron Cream
	Label Claim	Each Gram contains: Clascoterone.....10mg (1%)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10g-De-Controlled,15g-De-Controlled,5g-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30 centigrade
	For generic drugs (me-too Status)	Clascon Cream by Ferozson's Laboratories
	Pharmacotherapeutic Group of (API)	Topical androgen receptor inhibitors
	Name, address of Manufacturing site:	Global Pharmaceuticals Pakistan-Plot No. 8, Street No. S-8 RCCI, industrial Estate, Rawat-Islamabad.-
	The status in reference regulatory authorities	Winlevi Cream (FDA) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=1673a84b-7f5c-47ab-a99c-1e3db21a6a09
	Detail of previous approval	Wliev Cream (347the minutes of meeting)
Evaluation Remarks		
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.		
Decision		
Approved		
601	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	NAVEGAL LABORATORIES 41/1-A-2, PHASE-1, INDUSTRIAL ESTATE HATTAR, KPK, PAKISTAN (000591)
	Application Form Dy. No / Tracking ID & date of submission	(Q63-H4Y-24Q6, 2025-09-08)
	Detail of Fee Submitted	93000.0, 2025-07-21,
	The proposed proprietary name / brand name	ELIMNAR 2.25gm Injection
	Label Claim	Each Vial Contains: Piperacillin as Sodium (USP) 2000mg Tazobactam as Sodium (USP) 250mg (Product Complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C

	For generic drugs (me-too Status)	Zosyn INJECTION by Regent Karachi by Cirin Pharma Hattar
	Pharmacotherapeutic Group of (API)	Combinations of penicillins, incl. beta-lactamase inhibitors
	Name, address of Manufacturing site:	Wallace Pharma Evolutions-Kala wala stop, 20-KM, Lahore Jaranwala Road Lahore.-
	The status in reference regulatory authorities	UK Mhra Approved
	Detail of previous approval	Tazocin Injection ,DRB 331
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
602	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	NAVEGAL LABORATORIES 41/1-A-2, PHASE-1, INDUSTRIAL ESTATE HATTAR, KPK, PAKISTAN (000591)
	Application Form Dy. No / Tracking ID & date of submission	(QDL-683-BR95, 2025-09-08)
	Detail of Fee Submitted	93000.0, 2025-07-21,
	The proposed proprietary name / brand name	GALKE INJECTION 10mg/ml
	Label Claim	ach Ampoule (1mL) Contains: Phytonadione (USP) 10mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	KEFEI INJECTION by HAJI MEDICINES CO RAWALPINDI
	Pharmacotherapeutic Group of (API)	Hemostatics
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	Usfda Approved
	Detail of previous approval	Phyto-K, DRB 343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
603	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

Name, address of Applicant.		NAVEGAL LABORATORIES 41/1-A-2, PHASE-1, INDUSTRIAL ESTATE HATTAR, KPK, PAKISTAN (000591)
Application Form Dy. No / Tracking ID & date of submission		(QDN-BY2-DADJ, 2025-09-08)
Detail of Fee Submitted		93000.0, 2025-07-21,
The proposed proprietary name / brand name		Pepégál Capsules 60mg
Label Claim		Each Capsule Contains: Dexlansoprazole Dual Delayed Released Pellets eq. to Dexlansoprazole.....60mg (Product complies Innovator's Specs)
Reference to Finished product specifications		As per Innovators Specification
Proposed Pack Size		As Per SRO-As per SRO
Shelf Life (Unit)		2 YearStore below 25°C
For generic drugs (me-too Status)		Dexxo Capsule by Weather Folds Pharma.
Pharmacotherapeutic Group of (API)		PPI
Name, address of Manufacturing site:		Welcome Pakistan Trading Pharma (Pvt) Ltd-Chakri Interchange, Gangawala, Rawalpindi-
The status in reference regulatory authorities		Usfda Approved
Detail of previous approval		Dexxo Capsule, DRB 336
Evaluation Remarks		
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.		
Decision		
Approved		
604	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	NAVEGAL LABORATORIES 41/1-A-2, PHASE-1, INDUSTRIAL ESTATE HATTAR, KPK, PAKISTAN (000591)
	Application Form Dy. No / Tracking ID & date of submission	(QY3-D6H-BYB5, 2025-09-08)
	Detail of Fee Submitted	93000.0, 2025-07-21,
	The proposed proprietary name / brand name	PREMESO 40mg Injection
	Label Claim	Each Vial Contains: Methylprednisolone as Sodium Succinate (USP).....40mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Solu Medrol Injection by Pfizer
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Name, address of Manufacturing site:	Wenovo Pharmaceuticals-Plot No. 31 & 32, Punjab Small Industrial Estate, Taxila, Rawalpindi-
	The status in reference regulatory authorities	Usfda Approved
	Detail of previous approval	Methyl Injection, DRB 339

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision**Approved**

605	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	KARSONS PHARMACEUTICALS PLOT NO 1 STREET NO SS-3, NATIONAL INDUSTRIAL ZONE RAWAT (000854)
	Application Form Dy. No / Tracking ID & date of submission	(SWX-BNA-7PT6, 2025-09-08)
	Detail of Fee Submitted	93000.0, 2025-06-24,
	The proposed proprietary name / brand name	VONAZ 10mg TABLET
	Label Claim	Each film coated tablets contains: Vonoprazan Fumarate equivalent to Vonoprazan.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14'S-As per SRO,20'S-As per SRO,30'S-As per SRO
	Shelf Life (Unit)	2 Year15 °C - 30 °C
	For generic drugs (me-too Status)	Vonozan 10mg tablet
	Pharmacotherapeutic Group of (API)	Potassium-competitive acid blocker
	Name, address of Manufacturing site:	LINTA PHARMACEUTICALS PVT LTD-Plot No. 03, Street No. S-5 National Industrial Zone, Rawat, Islamabad, Pakistan-
	The status in reference regulatory authorities	TAKECAB (JAPAN)
	Detail of previous approval	VONOPRAZ (MEETING NO 336)
606	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winthrox Laboratories Pvt. Ltd K-219-A, SITE, Super Highway Phase II, Karachi (000807)
	Application Form Dy. No / Tracking ID & date of submission	(U68-HJH-S3JU, 2025-09-08)
	Detail of Fee Submitted	93000.0, 2025-07-02,
	The proposed proprietary name / brand name	Fusid B Cream
	Label Claim	Each gm contains: Fusidic Acid.....20mg Betamethasone (as Valerate).....1 mg

Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
For generic drugs (me-too Status)	Brand Name: FUDIC B Cream Registration holder: SHAIGAN Pharma Registration Number: 048490
Pharmacotherapeutic Group of (API)	Anti-inflammatory and antipruritic
Name, address of Manufacturing site:	M/s Biogen Life Sciences-8-km,Chakbeli Road,Rawat,Rawalpindi-
The status in reference regulatory authorities	Marketing Authorization Holder and Manufacturer Marketing Authorization Holder: LEO Laboratories Limited, Hurley, Berkshire, SL6 6RJ, UK. Manufacturer: LEO Laboratories Limited, Dublin 12, Ireland.
Detail of previous approval	Fusigen-B Cream Approved in 331st Minutes of DRB

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

607	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winthrox Laboratories Pvt. Ltd K-219-A, SITE, Super Highway Phase II, Karachi (000807)
	Application Form Dy. No / Tracking ID & date of submission	(V5H-49P-XUHV, 2025-09-08)
	Detail of Fee Submitted	93000.0, 2025-07-14,
	The proposed proprietary name / brand name	Clinox Cream
	Label Claim	Each gm contains: Clindamycin as phosphate..... 20mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Manufacturer Name Brand Name Biogen Pharma Calidin V Registration Number: 066449
	Pharmacotherapeutic Group of (API)	Broad spectrum antibiotics
	Name, address of Manufacturing site:	Biogen Life Sciences - 8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Brand Name: Cleocin vaginal cream Manufacturer Name: Pfizer FDA Approved
	Detail of previous approval	Clinovaa Cream approved in 345th Meeting of DRB

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

	Decision	
	Approved	
608	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(VZL-L3N-A1Z4, 2025-09-08)
	Detail of Fee Submitted	93000.0, 2025-07-12,
	The proposed proprietary name / brand name	M-Alpa 400mg Soft gelatin Capsule
	Label Claim	Each Soft gelatin contains:- DI alpa Tocopheryl acetate.....400mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Product Name:: Zescap Capsule 600mg Registration No: 030627 Company Name: M/s. Zafa Pharmaceutical Laboratories (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	Fat soluble vitamin (antioxidant)
	Name, address of Manufacturing site:	Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Evion 200mg 400mg and 600mg soft gelatin capsule Manufactured by Morton Dow pharmaceuticals
	Detail of previous approval	345th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
609	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	KARSONS PHARMACEUTICALS PLOT NO 1 STREET NO SS-3, NATIONAL INDUSTRIAL ZONE RAWAT (000854)
	Application Form Dy. No / Tracking ID & date of submission	(YW9-5SM-X552, 2025-09-08)
	Detail of Fee Submitted	93000.0, 2025-06-24,
	The proposed proprietary name / brand name	VONAZ 20 mg TABLET
	Label Claim	Each film coated tablets contains: Vonoprazan Fumarate equivalent to Vonoprazan.....20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14'S-As per SRO,20'S-As per SRO,30'S-As per SRO
	Shelf Life (Unit)	2 Year15 °C - 30 °C
	For generic drugs (me-too Status)	Vonozan 20mg tablet
	Pharmacotherapeutic Group of (API)	Potassium-competitive acid blocker

	Name, address of Manufacturing site:	LINTA PHARMACEUTICALS PVT LTD-Plot No. 03, Street No. S-5 National Industrial Zone, Rawat, Islamabad, Pakistan-
	The status in reference regulatory authorities	TAKECAB (JAPAN)
	Detail of previous approval	VONOPRAZ (MEETING NO 336)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
610	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	NAVEGAL LABORATORIES 41/1-A-2, PHASE-1, INDUSTRIAL ESTATE HATTAR, KPK, PAKISTAN (000591)
	Application Form Dy. No / Tracking ID & date of submission	(Z4S-E2R-4VQH, 2025-09-08)
	Detail of Fee Submitted	93000.0, 2025-07-21,
	The proposed proprietary name / brand name	ELIMNAR 4.5gm Injection
	Label Claim	Each Vial Contains: Piperacillin as Sodium (USP) 4g Tazobactam as Sodium (USP) 500mg (Product Complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Zosyn INJECTION by Regent Karachi by Cirin Pharma Hattar
	Pharmacotherapeutic Group of (API)	Combinations of penicillins, incl. beta-lactamase inhibitors
	Name, address of Manufacturing site:	Wallace Pharma Evolutions-Kala wala stop, 20-KM, Lahore Jaranwala Road Lahore.-
	The status in reference regulatory authorities	Usfda Approved
	Detail of previous approval	Tazocin Injection ,DRB 331
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
611	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Pine Pharmaceuticals Plot No, 40, S-4, Rawat Industrial Estate, Islamabad (000955)

Application Form Dy. No / Tracking ID & date of submission	(Z92-M88-M334, 2025-09-08)
Detail of Fee Submitted	93000.0, 2025-06-24,
The proposed proprietary name / brand name	Muscopin 4mg/2ml Injection
Label Claim	Each 2ml ampoule contains: Thiocolchicoside 4mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 YearBelow 30°C
For generic drugs (me-too Status)	Muscoril Injection 4mg/2ml Searle Pharmaceuticals
Pharmacotherapeutic Group of (API)	Muscle relaxants
Name, address of Manufacturing site:	M/s Seraph Pharmaceutical-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
The status in reference regulatory authorities	Myorel 4mg/2ml injection ANSM FRANCE
Detail of previous approval	335th Meeting of Registration Board

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

612	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Kanel Pharma Plot No. 6, Street No. SS-3, National Industrial Zone, Rawat (000758)
	Application Form Dy. No / Tracking ID & date of submission	(15A-RX6-VRZE, 2025-09-09)
	Detail of Fee Submitted	97200.0, 2025-08-12,
	The proposed proprietary name / brand name	Tiopim 18mcg Rota Capsule
	Label Claim	Each Rotacapsule contains: Tiotropium as Bromide Monohydrate...18mcg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearControlled Room Temperature
	For generic drugs (me-too Status)	Trovair 18mcg capsule By Highnoon Laboratories
	Pharmacotherapeutic Group of (API)	Anticholinergic
	Name, address of Manufacturing site:	M/s Winbrains Research Laboratories-Plot # 69/1, Block B, Phase I&II, Industrial Estate, Hattar, Haripur, KPK-
	The status in reference regulatory authorities	Spiriva 18mcg inhalation powder MHRA approved
	Detail of previous approval	Tybro 18mcg Rota Capsule, 336th Meeting

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

	Decision	
	Approved	
613	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Kanel Pharma Plot No. 6, Street No. SS-3, National Industrial Zone, Rawat (000758)
	Application Form Dy. No / Tracking ID & date of submission	(4H5-821-GQQD, 2025-09-09)
	Detail of Fee Submitted	97200.0, 2025-09-01,
	The proposed proprietary name / brand name	METHROL 500MG INJECTION
	Label Claim	Each vial contains:- Methylprednisolone Sodium Succinate 500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearControlled Room Temprature
	For generic drugs (me-too Status)	SOLU MEDROL INJECTION By Pfizer
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Name, address of Manufacturing site:	M/S Wenovo Pharmaceuticals-Plot # 31,32, Punjab Small Industrial Estate, Taxila, Rawalpindi -
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Methyl 500mg Injection, Meeting 339th
Evaluation Remarks		
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.		
	Decision	
	Approved	
614	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Hoechst Pakistan Limited Plot 23, Sector 22, Korangi Industrial Area, (000007)
	Application Form Dy. No / Tracking ID & date of submission	(5YR-L66-4WNJ, 2025-09-09)
	Detail of Fee Submitted	97200.0, 2025-08-12,
	The proposed proprietary name / brand name	Xatramax-D Capsules 0.5mg/0.4mg
	Label Claim	Each hard gelatin capsule contains: Dutasteride (as softgel capsule) 0.5mg Tamsulosin HCl (as 0.2% modified release pellets) 0.4mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x10's-As per SRO,1x10's-As per SRO,1x7's-As per SRO,2x7's,-As per SRO,3x10's-As per SRO,4x7's-As per SRO
	Shelf Life (Unit)	2 YearStore at controlled room temperature 20°C - 25°C.
	For generic drugs (me-too Status)	Tamsol-D Capsule by Global Pharmaceuticals Pvt Ltd (Reg. No. 080305)
	Pharmacotherapeutic Group of (API)	Alpha-adrenoreceptor antagonists

	Name, address of Manufacturing site:	Global Pharmaceutical Pvt. Ltd-Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad-
	The status in reference regulatory authorities	JALYN capsule approved by US FDA
	Detail of previous approval	TAMSIN-D 0.5/0.4 mg Capsule approved in 337th meeting minutes Dated 28th June 2024
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
615	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Regal Pharmaceuticals Plot No. 2-A, Street No. S-5 National Industrial Zone RCCI Rawat (000839)
	Application Form Dy. No / Tracking ID & date of submission	(152-DBU-9R6N, 2025-09-10)
	Detail of Fee Submitted	93000.0, 2025-07-10,
	The proposed proprietary name / brand name	Merox 5mg tablet
	Label Claim	Each film coated tablet contains: Mirogabalin besylate eq to Mirogabalin.....5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per sro-As per SRO
	Shelf Life (Unit)	2 YearStore BELOW 27 c0
	For generic drugs (me-too Status)	Tarlige 5mg tablet
	Pharmacotherapeutic Group of (API)	Gaa and its derivatives
	Name, address of Manufacturing site:	Wimits Pharmaceuticals-Plot No 129, Sunder Industrial Estate, Lahore.-
	The status in reference regulatory authorities	PMDA approved
	Detail of previous approval	Mirogap 5mg tablet/ 344th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
616	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Caliph Pharmaceuticals (Pvt) Ltd. Plot 17, Special Industrial Zone (EPZ), Risalpur, KPK (000748)
	Application Form Dy. No / Tracking ID & date of submission	(1QD-7XS-5TJJ, 2025-09-10)
	Detail of Fee Submitted	93000.0, 2025-07-11,

	The proposed proprietary name / brand name	MEMLIK 10mg/5ml Oral Solution
	Label Claim	Each 5ml contains: Memantine hydrochloride 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year25°C
	For generic drugs (me-too Status)	Afdol 10mg/5ml oral solution
	Pharmacotherapeutic Group of (API)	Lantech Pharmaceuticals Limited
	Name, address of Manufacturing site:	Seraph Pharmaceutical-Plot No. 210, Industrial Triangle Kahuta Road, Islamabad-
	The status in reference regulatory authorities	Memantine hydrochloride Oral Solution By SETON PHARMA , 1967 Highway 34 Suite 103 Wall Township, NJ 07719 United States, approved in FDA.
	Detail of previous approval	MEMXIO 10mg/5ml oral solution, M336
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
617	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Neutro Pharma (Pvt.) Ltd., 9.5-Km, Sheikhpura Road, Lahore (000576)
	Application Form Dy. No / Tracking ID & date of submission	(31A-LGL-LEE9, 2025-09-10)
	Detail of Fee Submitted	93000.0, 2025-06-12,
	The proposed proprietary name / brand name	Paricalcitol 4mcg sg capsule
	Label Claim	Each soft gelatin capsule contains:- Paricalcitol.....4 mcg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	30-As per SRO
	Shelf Life (Unit)	2 Yearstore at 25c
	For generic drugs (me-too Status)	Parical 4mcg sg capsule
	Pharmacotherapeutic Group of (API)	Vitamin D analog
	Name, address of Manufacturing site:	M/S Biogen Life Sciences-8-Km chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Approved
	Detail of previous approval	parical 4mcg sg capsule
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

Approved

618	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Davis Pharmaceutical Laboratories Plot No. 121, Industrial Triangle Area, Kahuta Road (000432)
	Application Form Dy. No / Tracking ID & date of submission	(5VZ-PSP-QM85, 2025-09-10)
	Detail of Fee Submitted	93000.0, 2025-07-28,
	The proposed proprietary name / brand name	Dexxo 30mg Capsule
	Label Claim	Each Capsule Contains: Dexlansoprazole Dual Delayed Released Pellets eq. to Dexlansoprazole.....30MG (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Dexxo Capsule by Weather Folds Pharma.
	Pharmacotherapeutic Group of (API)	PPI
	Name, address of Manufacturing site:	Welcome Pakistan Trading Pharma (Pvt) Ltd-Chakri Interchange, Gangawala, Rawalpindi-
	The status in reference regulatory authorities	Usfda Approved
	Detail of previous approval	Dexxo Capsule, DRB 336
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
619	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	NAVEGAL LABORATORIES 41/1-A-2, PHASE-1, INDUSTRIAL ESTATE HATTAR, KPK, PAKISTAN (000591)
	Application Form Dy. No / Tracking ID & date of submission	(5YT-UR7-LL85, 2025-09-10)
	Detail of Fee Submitted	93000.0, 2025-07-21,
	The proposed proprietary name / brand name	Navéllé
	Label Claim	Each Uncoated Tablet contains: Progesterone (USP).....100MG (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Lunagest Tablets by Weather Folds
	Pharmacotherapeutic Group of (API)	Progestins (female hormones)
	Name, address of Manufacturing site:	Weather Folds-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	USFDA Approved

	Detail of previous approval	Prostone 100mg Tablet, 344
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
620	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Neutro Pharma (Pvt.) Ltd., 9.5-Km, Sheikhpura Road, Lahore (000576)
	Application Form Dy. No / Tracking ID & date of submission	(6MP-YZ2-USXX, 2025-09-10)
	Detail of Fee Submitted	93000.0, 2025-06-10,
	The proposed proprietary name / brand name	Paricalcitol 2mcg sg capsule
	Label Claim	Each sg capsule contains: Paricalcitol... 2mcg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	30-As per SRO
	Shelf Life (Unit)	2 Yearstore at 25c
	For generic drugs (me-too Status)	Parical 2mcg sg capsule
	Pharmacotherapeutic Group of (API)	Vitamin D analog
	Name, address of Manufacturing site:	M/S Biogen Life Sciences-8-Km chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Approved
	Detail of previous approval	Parical 2mcg sg capsule approved in 339th meeting of registration board held on 6th August to 8th Au
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
621	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Neutro Pharma (Pvt.) Ltd., 9.5-Km, Sheikhpura Road, Lahore (000576)
	Application Form Dy. No / Tracking ID & date of submission	(8HP-99S-S3BW, 2025-09-10)
	Detail of Fee Submitted	93000.0, 2025-06-12,
	The proposed proprietary name / brand name	Calciol 0.25mcg sg capsule
	Label Claim	Each soft gelatin capsule contains: Calcitriol 0.25mcg (BP Specs)

Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	30-As per SRO
Shelf Life (Unit)	2 Yearstore at 25c
For generic drugs (me-too Status)	Rocaltrol capsules 0.25mcg
Pharmacotherapeutic Group of (API)	Vitamin D analog
Name, address of Manufacturing site:	M/S Biogen Life Sciences-8-Km chakbeli Road, Rawat, Rawalpindi-
The status in reference regulatory authorities	Approved
Detail of previous approval	Calcigen 0.25mcg softgel capsule

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

622	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Davis Pharmaceutical Laboratories Plot No. 121, Industrial Triangle Area, Kahuta Road (000432)
	Application Form Dy. No / Tracking ID & date of submission	(9BP-B1X-UR79, 2025-09-10)
	Detail of Fee Submitted	93000.0, 2025-07-28,
	The proposed proprietary name / brand name	Tazopip 4.5gm Injection
	Label Claim	Each Vial Contains: Piperacillin as Sodium (USP) 4g Tazobactam as Sodium (USP) 500mg (Product Complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Zosyn 4.5gm INJECTION of M/s Regent Laboratories Reg# 070759
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 inhibitor (PDE5-I)
	Name, address of Manufacturing site:	Wallace Pharma Evolutions-Kala wala stop, 20-KM, Lahore Jaranwala Road Lahore.-
	The status in reference regulatory authorities	Usfda Approved
	Detail of previous approval	Tazocin Injection ,DRB 331

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

623	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

Name, address of Applicant.	Seraph Pharmaceutical Plot No 210, Industrial Triangle Kahuta Road, Islamabad. (000860)
Application Form Dy. No / Tracking ID & date of submission	(9DL-N1V-VDZU, 2025-09-10)
Detail of Fee Submitted	93000.0, 2025-07-10,
The proposed proprietary name / brand name	Metzol 5mg Tablets
Label Claim	Each Tablet Contains; Metolazone.....5mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 YearStore below 30C
For generic drugs (me-too Status)	Brand Name:Metxone Tablets 5 mg Manufacturer:Genome Pharmaceutical (pvt)Limited
Pharmacotherapeutic Group of (API)	quinazoline-sulfonamide
Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd.-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
The status in reference regulatory authorities	FDA approved
Detail of previous approval	Metzon 5mg Tablet , 343rd Meeting

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

624	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Regal Pharmaceuticals Plot No. 2-A, Street No. S-5 National Industrial Zone RCCI Rawat (000839)
	Application Form Dy. No / Tracking ID & date of submission	(AN8-W4J-NDEE, 2025-09-10)
	Detail of Fee Submitted	93000.0, 2025-07-10,
	The proposed proprietary name / brand name	Venoreg
	Label Claim	Each film coated modified release tablet contains: Aspirin....100mg (Enteric coat core) Vonoprazan as Fumarate.... 10mg (Immediate release coat)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	As per sro-As per SRO
	Shelf Life (Unit)	2 YearStore BELOW 27 c0
	For generic drugs (me-too Status)	Cabpirin 10/100mg tablet
	Pharmacotherapeutic Group of (API)	Reduces thrombosis in gastric ulcer patients.
	Name, address of Manufacturing site:	Wimits Pharmaceuticals-Plot No 129, Sunder Industrial Estate, Lahore.-
	The status in reference regulatory authorities	PMDA approved
	Detail of previous approval	Vozan-AS 100mg/10mg, 340th

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for
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cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

625	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Panacea Pharmaceuticals plot No 04, Street S-6 National industrial Zone RCCI rawat islamabad (000600)
	Application Form Dy. No / Tracking ID & date of submission	(D2G-NAV-5PLB, 2025-09-10)
	Detail of Fee Submitted	93000.0, 2025-07-18,
	The proposed proprietary name / brand name	Onitron 8mg Injection
	Label Claim	Each 4 ml ampoule contains: Ondansetron as HCl Dihydrate.....8 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Onset™. Pharmedic Laboratories Pvt Ltd.
	Pharmacotherapeutic Group of (API)	Anti-Emetic
	Name, address of Manufacturing site:	Seraph Pharmaceutical-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
	The status in reference regulatory authorities	Zofran® Injection is Approved in USFDA
	Detail of previous approval	RestOn Injection 8 mg/4 ml. 330th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
626	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	UniMark Pharmaceuticals Pvt. Ltd. Plot No. 7-A, Street No. S-7, National Industrial Zone, Rawat (000557)
	Application Form Dy. No / Tracking ID & date of submission	(DZJ-ME7-MB7X, 2025-09-10)
	Detail of Fee Submitted	93000.0, 2025-07-09,
	The proposed proprietary name / brand name	Urifos 3gm Sachet
	Label Claim	Each sachet contains fosfomycin tromethamine eq. to fosfomycin 3gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	2 Year15° to 30°C
	For generic drugs (me-too Status)	Focin Ultra sachet of M/S Tabros Pharma
	Pharmacotherapeutic Group of (API)	Antibacterial

	Name, address of Manufacturing site:	Solaris Life Sciences-Plot 8, Street S-1, RCCI industrial estate rawat-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	M-347
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
627	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	UniMark Pharmaceuticals Pvt. Ltd. Plot No. 7-A, Street No. S-7, National Industrial Zone, Rawat (000557)
	Application Form Dy. No / Tracking ID & date of submission	(HDY-1T7-9U1W, 2025-09-10)
	Detail of Fee Submitted	93000.0, 2025-07-09,
	The proposed proprietary name / brand name	Strot 2gm Sachet
	Label Claim	Each sachet contains strontium ranelate 2gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	2 Year 15° to 30°C
	For generic drugs (me-too Status)	Osstium 2gm Sachet of M/S ATCO Pharma
	Pharmacotherapeutic Group of (API)	Dual action bone agent for osteoporosis.
	Name, address of Manufacturing site:	Solaris Life Sciences-Plot 8, Street S-1, RCCI industrial estate rawat-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	M-343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
628	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	English Pharmaceutical Indsutries link Kattar bund road , Thokar Naiz baig, Multan Road Lahore (000339)
	Application Form Dy. No / Tracking ID & date of submission	(L17-Q4S-W6DG, 2025-09-10)
	Detail of Fee Submitted	93000.0, 2025-07-23,
	The proposed proprietary name / brand name	ENGPAN 500MG INJECTION

Label Claim	Each vial contains: Meropenem (as trihydrate) 500mg (Blended with sodium carbonate)
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	1's-As per SRO
Shelf Life (Unit)	2 Year25°C
For generic drugs (me-too Status)	MEREM 500mg Injection by Global Pharma
Pharmacotherapeutic Group of (API)	Broad-spectrum carbapenem antibiotic
Name, address of Manufacturing site:	NICHOLAS PHARMACEUTICALS-Plot # 34, Street No. SS-2, National Industrial Zone, Rawat, Islamabad-
The status in reference regulatory authorities	Meronem IV 500 mg by Pfizer Limited (MHRA Approved)
Detail of previous approval	Already approved in Minutes of 307th meeting of Registration Board

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

629	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Davis Pharmaceutical Laboratories Plot No. 121, Industrial Triangle Area, Kahuta Road (000432)
	Application Form Dy. No / Tracking ID & date of submission	(M6L-WZ4-BB5X, 2025-09-10)
	Detail of Fee Submitted	93000.0, 2025-07-28,
	The proposed proprietary name / brand name	Tazocin 2.25gm Injection
	Label Claim	Each Vial Contains: Piperacillin as Sodium (USP) 2000mg Tazobactam as Sodium (USP) 250mg (Product Complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Zosyn 2.25gm INJECTION of M/s Regent Laboratories Reg# 070759
	Pharmacotherapeutic Group of (API)	Combinations of penicillins, incl. beta-lactamase inhibitors
	Name, address of Manufacturing site:	Wallace Pharma Evolutions-Kala wala stop, 20-KM, Lahore Jaranwala Road Lahore.-
	The status in reference regulatory authorities	Usfda Approved
	Detail of previous approval	Tazocin Injection ,DRB 331

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other

conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

630	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Regal Pharmaceuticals Plot No. 2-A, Street No. S-5 National Industrial Zone RCCI Rawat (000839)
	Application Form Dy. No / Tracking ID & date of submission	(P1Q-PJT-QZX4, 2025-09-10)
	Detail of Fee Submitted	93000.0, 2025-07-10,
	The proposed proprietary name / brand name	Tepneg IR 100mg
	Label Claim	Each film coated tablet contains: Tapentadol HCL eq to Tapentadol....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per sro-As per SRO
	Shelf Life (Unit)	2 YearStore BELOW 27 c0
	For generic drugs (me-too Status)	Tapento 100mg IR Tablet
	Pharmacotherapeutic Group of (API)	Opioid Analgesic
	Name, address of Manufacturing site:	Wimits Pharmaceuticals-Plot No 129, Sunder Industrial Estate, Lahore.-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Tydol 100mg IR tablet, 343rd
Evaluation Remarks		
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.		
Decision		
Approved		
The Registration Board approved the grant of registration of the applied product with the condition that manufacturer shall ensure the following directions for use on the labelling of the drug product in a clear manner:		
"To be used by patients 18 years of age or older for the management of moderate to severe chronic pain."		
631	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Neutro Pharma (Pvt.) Ltd., 9.5-Km, Sheikhpura Road, Lahore (000576)
	Application Form Dy. No / Tracking ID & date of submission	(PQ1-Y3H-5P1P, 2025-09-10)
	Detail of Fee Submitted	93000.0, 2025-06-10,
	The proposed proprietary name / brand name	Paricalcitol 1mcg sg capsule
	Label Claim	Each sg capsule contains: Paricalcitol... 1mcg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	30-As per SRO

	Shelf Life (Unit)	2 Yearstore at 25c
	For generic drugs (me-too Status)	Parical 1mcg sg capsule
	Pharmacotherapeutic Group of (API)	Vitamin D analog
	Name, address of Manufacturing site:	M/S Biogen Life Sciences-8-Km chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Approved
	Detail of previous approval	Parical 1mcg sg capsule approved in 339th meeting of registration board held on 6th August to 8th Au
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
632	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	English Pharmaceutical Indsutries link Kattar bund road , Thokar Naiz baig, Multan Road Lahore (000339)
	Application Form Dy. No / Tracking ID & date of submission	(PV5-S21-BP1Z, 2025-09-10)
	Detail of Fee Submitted	93000.0, 2025-07-23,
	The proposed proprietary name / brand name	ENGPAN 1GM INJECTION
	Label Claim	Each vial contains: Meropenem (as trihydrate) 1g (Blended with sodium carbonate)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year25°C
	For generic drugs (me-too Status)	MEREM 1gm Injection by Global Pharma
	Pharmacotherapeutic Group of (API)	Broad-spectrum carbapenem antibiotic
	Name, address of Manufacturing site:	NICHOLAS PHARMACEUTICALS-Plot # 34, Street No. SS-2, National Industrial Zone, Rawat, Islamabad-
	The status in reference regulatory authorities	Meronem IV 1g by Pfizer Limited (MHRA Approved)
	Detail of previous approval	Already approved in Minutes of 307th meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
633	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Davis Pharmaceutical Laboratories Plot No. 121, Industrial Triangle Area, Kahuta Road (000432)

Application Form Dy. No / Tracking ID & date of submission	(Q5S-39L-5LTG, 2025-09-10)
Detail of Fee Submitted	93000.0, 2025-07-28,
The proposed proprietary name / brand name	Dexxo 60mg Capsule
Label Claim	Each Capsule Contains: Dexlansoprazole Dual Delayed Released Pellets eq. to Dexlansoprazole.....60mg (Product complies Innovator's Specs)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As Per SRO-As per SRO
Shelf Life (Unit)	2 YearStore below 25°C
For generic drugs (me-too Status)	Dexxo Capsule by Weather Folds Pharma.
Pharmacotherapeutic Group of (API)	PPI
Name, address of Manufacturing site:	Welcome Pakistan Trading Pharma (Pvt) Ltd-Chakri Interchange, Gangawala, Rawalpindi-
The status in reference regulatory authorities	Usfda Approved
Detail of previous approval	Dexxo Capsule, DRB 336

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

634	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medwell Pharmaceuticals 1 km, terbella road, lawrencepur, faqirabad Attock (000699)
	Application Form Dy. No / Tracking ID & date of submission	(QD1-RPN-ZD3V, 2025-09-10)
	Detail of Fee Submitted	93000.0, 2025-07-25,
	The proposed proprietary name / brand name	Phyto-K 10mg/ml Injection
	Label Claim	Each Ampoule (1mL) Contains: Phytonadione (USP) 10mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	KEFEI INJECTION by HAJI MEDICINES CO RAWALPINDI
	Pharmacotherapeutic Group of (API)	Hemostatics
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	Usfda Approved
	Detail of previous approval	Phyto-K, DRB 343

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt

the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

635	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	May and Baker (Pvt.) Ltd 23-Ghouri Block, Bahria Town, Lahore (000953)
	Application Form Dy. No / Tracking ID & date of submission	(QNG-3Z3-28ZV, 2025-09-10)
	Detail of Fee Submitted	97200.0, 2025-08-06,
	The proposed proprietary name / brand name	Tazocillin 4.5g
	Label Claim	Each vial contains: Piperacillin as sodium.....4g Tazobactam as sodium 0.5g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year25C
	For generic drugs (me-too Status)	Tazop Injection of Global Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Penicillin antibiotic
	Name, address of Manufacturing site:	M/s Global Pharmaceuticals (Pvt.) Ltd., -Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad-
	The status in reference regulatory authorities	Piperacillin and tazobactam Injection (USFDA Approved)
	Detail of previous approval	TALBACT Injection 4.50gm Injection , DRB Meeting No.316
Evaluation Remarks		
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.		
Decision		
Approved		
636	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Regal Pharmaceuticals Plot No. 2-A, Street No. S-5 National Industrial Zone RCCI Rawat (000839)
	Application Form Dy. No / Tracking ID & date of submission	(SNA-58D-EBM7, 2025-09-10)
	Detail of Fee Submitted	93000.0, 2025-07-10,
	The proposed proprietary name / brand name	Resmro 80mg tablet
	Label Claim	Each film coated tablet contains: Remetirom.... 80mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per sro-As per SRO
	Shelf Life (Unit)	2 YearStore BELOW 27 c0
	For generic drugs (me-too Status)	Resdiffra 80mg tablet
	Pharmacotherapeutic Group of (API)	THR beta agonist

	Name, address of Manufacturing site:	Wimits Pharmaceuticals-Plot No 129, Sunder Industrial Estate, Lahore.-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Resmit 80mg tablet, 347th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
637	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Palpex Pharmaceuticals pvt ltd FD-46 A8 , ST 1 SECTOR 38 , KORANGI CREEK INDUSTRIAL PARK (000858)
	Application Form Dy. No / Tracking ID & date of submission	(2W1-L8Z-P2Z4, 2025-09-15)
	Detail of Fee Submitted	97200.0, 2025-08-14,
	The proposed proprietary name / brand name	ONPEX 8MG TABLET
	Label Claim	Each film coated tablet contains: Ondansetron (as hydrochloride dihydrate) 8mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year25°C
	For generic drugs (me-too Status)	Zofran Tablet 8mg
	Pharmacotherapeutic Group of (API)	Anugraha Chemicals
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt.) Ltd.-Plot 17, Special Industrial Zone (EPZ), Risalpur, Kpk-
	The status in reference regulatory authorities	Zofran Tablet 8mg
	Detail of previous approval	CALSETRON 8mg Tablet, M322
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
638	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Palpex Pharmaceuticals pvt ltd FD-46 A8 , ST 1 SECTOR 38 , KORANGI CREEK INDUSTRIAL PARK (000858)
	Application Form Dy. No / Tracking ID & date of submission	(B24-E9B-PAVA, 2025-09-15)

	Detail of Fee Submitted	97200.0, 2025-08-14,
	The proposed proprietary name / brand name	ONPEX 4MG/5ML SYRUP
	Label Claim	Each 5 ml of syrup contains: Ondansetron (as hydrochloride dihydrate) 4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year25°C
	For generic drugs (me-too Status)	Onseron Syrup 4mg/5ml
	Pharmacotherapeutic Group of (API)	Anugraha Chemicals
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt.) Ltd.-Plot 17, Special Industrial Zone (EPZ), Risalpur, Kpk-
	The status in reference regulatory authorities	Zofran Syrup 4mg/5ml
	Detail of previous approval	Calsetron 4mg/5ml Syrup, M331
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
639	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Palpex Pharmaceuticals pvt ltd FD-46 A8 , ST 1 SECTOR 38 , KORANGI CREEK INDUSTRIAL PARK (000858)
	Application Form Dy. No / Tracking ID & date of submission	(RYN-SA3-7X22, 2025-09-15)
	Detail of Fee Submitted	97200.0, 2025-08-14,
	The proposed proprietary name / brand name	DESLOP 0.5MG/ML SYRUP
	Label Claim	Each ml of syrup contains: Desloratadine 0.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year25°C
	For generic drugs (me-too Status)	Neo-Antial Syrup 0.5mg/ml
	Pharmacotherapeutic Group of (API)	Morepen Laboratories Limited,
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt.) Ltd.-Plot 17, Special Industrial Zone (EPZ), Risalpur, Kpk-
	The status in reference regulatory authorities	Clarinx Syrup 0.5mg/ml
	Detail of previous approval	: KARDINE 0.5MG/ML SYRUP, M331
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

Approved

640	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Palpex Pharmaceuticals pvt ltd FD-46 A8 , ST 1 SECTOR 38 , KORANGI CREEK INDUSTRIAL PARK (000858)
	Application Form Dy. No / Tracking ID & date of submission	(ZVU-QGS-4B4Z, 2025-09-15)
	Detail of Fee Submitted	97200.0, 2025-08-14,
	The proposed proprietary name / brand name	Hydra 1% Lotion
	Label Claim	Each ml of lotion contains: Hydrocortisone 1%
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year25°C
	For generic drugs (me-too Status)	LactiCare-HC Lotion 1% (Reg No. 019738)
	Pharmacotherapeutic Group of (API)	Tianjin Jinjin Pharmaceutical Co., Ltd
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt.) Ltd.-Plot 17, Special Industrial Zone (EPZ), Risalpur, Kpk-
	The status in reference regulatory authorities	Hydroskin 1% Lotion
	Detail of previous approval	HCCAL Lotion 1%, M331
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
641	Decision	
	Approved	
	Case Category	Routine (Incharge Evaluation Cell)
	Name, address of Applicant.	Maxitech Pharma (Pvt) Ltd. E-178, S.I.T.E., Super Highway Phase-II, Karachi (000851)
	Application Form Dy. No / Tracking ID & date of submission	(T8J-JLA-LNWD, 2024-03-27)
	Detail of Fee Submitted	30000.0, 2024-03-07,
	The proposed proprietary name / brand name	Fusidate 250mg Tablet
	Label Claim	Each Film coated Tablet Contains: Sodium Fusidate.....250 mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	14,s or as per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 degree celsius
	For generic drugs (me-too Status)	Fusiderm 250 mg Tablet by Martin Dow Limited
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	ERCROS, S.A.
	Detail of stability batches of drug product	Provided
	Documents for the procurement of API with approval from DRAP	Provided
Minutes of 351st Meeting of Registration Board		(23rd – 24th September, 2025)
		490

(in case of Import)	
Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
The status in reference regulatory authorities	Fucidin 250 mg Tablet by LEO Laboratories Limited, Maidenhead, Berkshire, UK
GMP status of the firm	Provided
Evidence of approval of manufacturing facility	Provided

Evaluation Remarks

Sr. No.	Observation	Reply by the firm
1.	COA of the drug substance used in trail batches from drug substance manufacturer shall be submitted.	Copy of COA of drug substance is submitted
2.	Submit evidence of cold chain during transportation of the drug substance and evidence of cold storage for the drug substance.	evidence of cold chain during transportation of the drug substance is Submitted
3.	· Justification shall be submitted 0% release in acidic and acetate buffer mediums of CDP with respect to the solubility of the drug substance. · Details of the comparator product i.e. batch number, manufacturing date etc. against which CDP and PE studies are performed shall be submitted. · Pharmaceutical equivalence studies shall be submitted.	Justification The 0% release observed in acidic pH 1.2 and acetate buffer pH4.5 media is attributed to the PH dependent solubility of sodium fusidate.in low poh conditions the sodium salt converts to unionized fusidic acid which has very poor aqueous solubility and cannot achieve sink conditions in standard disullotion volumes,resulting in negliglable drug release for both test and reference products.ar PH 6.8 where ionization improves solubility, dissolution occurs expected and allow meaningful products comparision. Comparator product brand name Fusiderm tablet 250mg mfg date. 10/2023 exp date. 10/2026 manufacture. Martin Dow
4.	Analytical method validation studies shall be submitted instead of verification studies.	Firms has submitted analytical method validation studies for the applied products.
5.	Stability summary sheets as per decision of 293rd meeting along with raw data and chromatograms for each time point shall be submitted.	Submitted
6.	Documents for procurement of API with approval from DRAP shall be submitted.	Submitted

Decision

Approved

642	Case Category	New Section (Incharge Evaluation Cell)
	Name, address of Applicant.	Oncogen Pharma (Pvt) Limited WH-26 & 27-A3 , Korangi Creek Industrial Park (KCIP) (000960)
	Application Form Dy. No / Tracking ID & date of submission	(P96-WMB-S2RD, 2025-06-19)
	Detail of Fee Submitted	37000.0, 2025-05-27,
	The proposed proprietary name / brand name	Doxorin Injection 10mg/5ml
	Label Claim	Each 5ml contains: Doxorubicin Hydrochloride.....10mg

	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C (Don't Freeze). Protect from light
	For generic drugs (me-too Status)	Adrim 10mg Injection
	Pharmacotherapeutic Group of (API)	Doxorubicin belongs to the pharmacological group of anthracyclines, a class of cytotoxic antibiotics commonly used in chemotherapy with ATC code
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Stability studies of 03 batches i.e P07.NP.ST.001, P07.NP.ST.002 & P07.NP.ST.003 is enclosed in module 3
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 and clearance certificate is attached in module 3
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Doxorubicin 10mg/5mL Injection is equivalent to the reference product Adrim 10mg Injection
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies of 36 months is enclosed in module 3
	The status in reference regulatory authorities	USFDA approved
	GMP status of the firm	Last GMP inspection was carried on 08th December 2023 and found good compliant unit
	Evidence of approval of manufacturing facility	Liquid Injectable (with lyophilizer facility) (oncology) approved on 02nd November 2023
	Evaluation Remarks	
	From a quality perspective, it is determined that the product meets all applicable standards regarding identity, strength, quality, and purity.	
	Decision	
	Approved	
643	Case Category	New Section (Incharge Evaluation Cell)
	Name, address of Applicant.	Oncogen Pharma (Pvt) Limited WH-26 & 27-A3 , Korangi Creek Industrial Park (KCIP) (000960)
	Application Form Dy. No / Tracking ID & date of submission	(D1G-DED-BDEH, 2025-06-20)
	Detail of Fee Submitted	37000.0, 2025-05-27,
	The proposed proprietary name / brand name	Doxorin Injection 50mg/25ml
	Label Claim	Each 25ml contains: Doxorubicin Hydrochloride.....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearStore at 2-8°C (Don't Freeze). Protect from light
	For generic drugs (me-too Status)	Adrim 20mg Injection
	Pharmacotherapeutic Group of (API)	Doxorubicin belongs to the pharmacological group of anthracyclines, a class of cytotoxic antibiotics commonly used in chemotherapy with ATC code
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Stability studies of 03 batches i.e P08.NP.ST.001, P08.NP.ST.002 & P08.NP.ST.003 is enclosed in module 3

	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 and clearance certificate is attached in module 3
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Doxorubicin 50mg/25mL Injection is equivalent to the reference product Adrim 20mg Injection
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies of 36 months is enclosed in module 3
	The status in reference regulatory authorities	USFDA approved
	GMP status of the firm	Last GMP inspection was carried on 07th December 2023 and found good compliant unit
	Evidence of approval of manufacturing facility	Liquid Injectable (with lyophilizer facility) (oncology) approved on 02nd November 2023
	Evaluation Remarks	
	From a quality perspective, it is determined that the product meets all applicable standards regarding identity, strength, quality, and purity.	
	Decision	
	Approved	
644	Case Category	Export Facilitation (Incharge Evaluation Cell)
	Name, address of Applicant.	Efroze Chemical Industries Pvt. Ltd. 146/23, Korangi Industrial Area, Karachi (000151)
	Application Form Dy. No / Tracking ID & date of submission	(SQ6-UZD-JRNJ, 2024-08-28)
	Detail of Fee Submitted	30000.0, 2024-06-27,
	The proposed proprietary name / brand name	Tridex Caspule 60mg
	Label Claim	Each capsule contain: Dexlansoprazole DDR pellets eq. to Dexlansoprazole 60mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30's-De-Controlled
	Shelf Life (Unit)	24 Month(s)25-30°C
	For generic drugs (me-too Status)	Dextop Capsule 60mg
	Pharmacotherapeutic Group of (API)	A02BC06; Alimentary tract and metabolism
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vision Pharmaceuticals
	Detail of stability batches of drug product	03 batches 1500 capsules at Zone IVa conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided. Dextop Capsules Searle Pakistan, Batch number FSE 002
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
	The status in reference regulatory authorities	Dexilant Capsule 60mg
	GMP status of the firm	DS: Vision DP: Efroze
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The instant application is priority under export facilitation as per letter No.F.1-6/2019-PR-I (EFD) dated 12.08.2025. The firm was asked to provide Comparative Dissolution Profile for which they have submitted CDP against Dextop Capsules Searle Pakistan, Batch number FSE 002.	
	Decision	

	Approved	
645	Case Category	Export Facilitation (Incharge Evaluation Cell)
	Name, address of Applicant.	Efroze Chemical Industries Pvt. Ltd. 146/23, Korangi Industrial Area, Karachi (000151)
	Application Form Dy. No / Tracking ID & date of submission	(7MU-Q2X-5ERS, 2024-08-28)
	Detail of Fee Submitted	30000.0, 2024-06-27,
	The proposed proprietary name / brand name	Tridex Capsule 30mg
	Label Claim	Each Capsule Contains: Dexlansoprazole DDR Pellets Eq. to Dexlansoprazole 30mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30's-De-Controlled
	Shelf Life (Unit)	24 Month(s)25-30°C
	For generic drugs (me-too Status)	Dextop Capsule 30mg
	Pharmacotherapeutic Group of (API)	A02BC06: Alimentary Tract and metabolism
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vision Pharmaceuticals
	Detail of stability batches of drug product	03 btaches on Zone IV-a condition
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
	The status in reference regulatory authorities	Dexilant Capsule 30mg
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	Provided
	Evaluation Remarks	
	The instant application is priority under export facilitation as per letter No.F.1-6/2019-PR-I (EFD) dated 12.08.2025. The firm was asked to provide Comparative Dissolution Profile for which they have submitted CDP. From a quality perspective, it is determined that the product meets all applicable standards regarding identity, strength, quality, and purity.	
	Decision	
	Approved	
646	Case Category	Routine (Maham Misbah)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(SYY-UU8-X23B, 2024-04-18)
	Detail of Fee Submitted	30000.0, 2024-02-27,
	The proposed proprietary name / brand name	Ibuprofen 400mg Tablet
	Label Claim	Each Film Coated Tablet contains Ibuprofen.....400mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO

Shelf Life (Unit)	2 Year(s)Store at cool &dry place below 30
For generic drugs (me-too Status)	BRUFEN 400MG TAB M/s Abbott Laboratories (Pakistan) Limited Reg#001541
Pharmacotherapeutic Group of (API)	Propionic acid derivatives
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Citi Pharma Ltd. Address 3 Km Head Balloki Road, Phool Nagar, Kasur -55050 Punjab
Detail of stability batches of drug product	2500 tablets; 3 batches
Documents for the procurement of API with approval from DRAP (in case of Import)	Local purchase, hence, not applicable.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP submitted against BRUFEN 400MG TAB by M/s Abbott Laboratories (Pakistan) Limited
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone Iva
The status in reference regulatory authorities	Ibuprofen Bril 400mg Tablet M/s Axcount Generika Gmbh Max-Planck-Street 36 D 61381 Friedrichsdorf G
GMP status of the firm	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 is submitted which specifies the following sections: Tablet (general)
Evidence of approval of manufacturing facility	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 is submitted which specifies the following sections: Tablet (general)

Evaluation Remarks

Serial no.	Observation/Shortcoming	Response of applicant
1	Valid DML or GMP certificate of API supplier (M/s Citi Pharma) shall be submitted.	Submitted
2	executed BMRs shall be submitted	Submitted

Decision

Approved

647	Case Category	New Section (Maham Misbah)
	Name, address of Applicant.	Rite Bio Sciences (Pvt) Ltd. Plot No. 9-A, Street No. N-5, RCCI Rawat (000871)
	Application Form Dy. No / Tracking ID & date of submission	(3TS-SNW-H2LT, 2024-12-27)
	Detail of Fee Submitted	37000.0, 2024-11-18,
	The proposed proprietary name / brand name	OLANCO 6/25mg CAPSULES
	Label Claim	Each Capsule contains: OLANZAPINE.....6mg FLUXETINE AS HCL 25mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's,14,s, 2's, 28's-As per SRO
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Dipof Cap. 6/25mg manufactured by Pharmevo
	Pharmacotherapeutic Group of (API)	WHO ATC code N06CA03: Antidepressants in combination with psycholeptics (Olanzapine) WHO ATC

	code N06AB03: Selective serotonin reuptake inhibitors (Fluoxetine)
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	M/s. Smilax Laboratories Limited Hyderabad, India, PALAM PHARMA PVT. LTD 12/C, Phase I, G.I.D.C. Estate, Vatva, Ahmedabad, India
Detail of stability batches of drug product	batches 3: batch size: 1500 capsules
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted for both APIs.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE & CDP submitted against Dipof Cap. 6/25mg manufactured by Pharmevo
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone Iva
The status in reference regulatory authorities	Product by M/s TEVA Pharma is USFDA Approved
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 22-08-2023 specifies Tablet (general) section.
Evidence of approval of manufacturing facility	GMP certificate issued on the basis of inspection conducted on 22-08-2023 specifies Tablet (general) section.

Evaluation Remarks

Serial no.	Observations	Response of applicant
1	3.2.P.8: Clearance certificate for both APIs issued by the relevant field office of DRAP shall be submitted.	Submitted
2	3.2.P.8: 6-month time point real time and accelerated stability studies data shall be submitted.	Submitted

Decision

Approved

648	Case Category	New Section (Maham Misbah)
	Name, address of Applicant.	Rite Bio Sciences (Pvt) Ltd. Plot No. 9-A, Street No. N-5, RCCI Rawat (000871)
	Application Form Dy. No / Tracking ID & date of submission	(DEL-G5A-A7U9, 2024-12-27)
	Detail of Fee Submitted	37000.0, 2024-11-18,
	The proposed proprietary name / brand name	OLANCO 12/25mg CAPSULES
	Label Claim	Each Capsule contains: OLANZAPINE 12mg FLUXETIN AS HCL 25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's, 14's, 2's, 28's-As per SRO
	Shelf Life (Unit)	2 Year(s) Room Temperature
	For generic drugs (me-too Status)	Product Name: Neolepra-F 12mg/25mg Capsule Registration No: 104766 Company Name: Genetics Pharmaceuticals Pvt. Ltd Company Address: 539-A Sundar Industrial Estate Raiwind Road Lahore
	Pharmacotherapeutic Group of (API)	WHO ATC code N06CA03: Antidepressants in combination with psycholeptics (Olanzapine) WHO ATC

	code N06AB03: Selective serotonin reuptake inhibitors (Fluoxetine)
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	M/s. Smilax Laboratories Limited Hyderabad, India, PALAM PHARMA PVT. LTD 12/C, Phase I, G.I.D.C. Estate, Vatva, Ahmedabad, India
Detail of stability batches of drug product	3 batches of 1500 capsules each
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted for both APIs
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP submitted against Neolepra-F 12/25mg Capsule by Genetics Pharmaceuticals (Pvt) Ltd,
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	As per Zone IVa
The status in reference regulatory authorities	SYMBYAX (olanzapine and fluoxetine hydrochloride) capsule for oral use Initial U.S. Approval: 2003
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 22-08-2023 specifies Tablet (general) section.
Evidence of approval of manufacturing facility	GMP certificate issued on the basis of inspection conducted on 22-08-2023 specifies Tablet (general) section.

Evaluation Remarks

Serial no.	Observations	Response of applicant
1	3.2.P.8: Clearance certificate for both APIs issued by the relevant field office of DRAP shall be submitted.	Submitted
2	3.2.P.8: 6-month time point real time and accelerated stability studies data shall be submitted.	Submitted

Decision

Approved

649	Case Category	New Section (Maham Misbah)
	Name, address of Applicant.	Rite Bio Sciences (Pvt) Ltd. Plot No. 9-A, Street No. N-5, RCCI Rawat (000871)
	Application Form Dy. No / Tracking ID & date of submission	(WRM-9HB-JZR8, 2024-12-27)
	Detail of Fee Submitted	37000.0, 2024-10-19,
	The proposed proprietary name / brand name	OLANCO 3/25mg CAPSULES
	Label Claim	Each Capsule contains: OLANZAPINE 3mg FLUXETIN AS HCL 25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's, 14's , 28's , -As per SRO
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Product Name: Olanzagat 3mg+25mg Capsule Registration No: 114345 Company Name: Getz Pharma (Pvt.) Limited
	Pharmacotherapeutic Group of (API)	WHO ATC code N06CA03: Antidepressants in combination with psycholeptics (Olanzapine) WHO ATC

	code N06AB03: Selective serotonin reuptake inhibitors (Fluoxetine)
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	M/s. Smilax Laboratories Limited Hyderabad, India, PALAM PHARMA PVT. LTD 12/C, Phase I, G.I.D.C. Estate, Vatva, Ahmedabad, India
Detail of stability batches of drug product	3 batches; 1500 units each
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted for both APIs
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE & CDP submitted against Olanzapet Tablet 3/25mg
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	As per Zone Iva
The status in reference regulatory authorities	USFDA Approved (ANDA No. 0777742)
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 22-08-2023 specifies Tablet (general) section.
Evidence of approval of manufacturing facility	GMP certificate issued on the basis of inspection conducted on 22-08-2023 specifies Tablet (general) section.

Evaluation Remarks

Sr. No.	Observations	Response of applicant
1	3.2.P.8: Clearance certificate for both APIs issued by the relevant field office of DRAP shall be submitted.	Submitted
2	3.2.P.8: 6-month time point real time and accelerated stability studies data shall be submitted.	Submitted

Decision

Approved

650

Case Category	Priority As Per 257-M of RB (Muhammad Sarfraz Nawaz)
Name, address of Applicant.	MSA PHARMA 1304, Green Acre, Pine Avenue (05-352-0066)
Application Form Dy. No / Tracking ID & date of submission	(47Y-6XG-QGAV, 2025-03-27)
Detail of Fee Submitted	300000.0, 2025-01-15,
The proposed proprietary name / brand name	Tucaxen 150mg Tablet
Label Claim	Each film-coated tablet contains...Tucatinib 150mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	30's-As per SRO
Shelf Life (Unit)	2 YearStore below 30°C.
For generic drugs (me-too Status)	Not available
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Everest Pharmaceuticals Limited.-Plot No: B-45, 46 & 33, BSCIC I/A, Kanchpur, Narayanganj, -Bangladesh
Pharmaceutical Equivalence and Comparative Dissolution Profile	

Name, address of Marketing Authorization Holder:	Everest Pharmaceuticals Limited., Factory: Plot No: B-45, 46 & 33, BSCIC I/A, Kanchpur, Narayanganj, Bangladesh. Head office Address: Rahman's Regnum Centre (11th Floor) 191/1, Tejgaon C/A, Dhaka-1208, Bangladesh, Bangladesh
Details of Certificates (CoPP/FSC/cGMP):	
Details of Authorization Letter :	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
The status in reference regulatory authorities	Tukysa 150mg Film-coated Tablet (USA)

Evaluation Remarks

Decision

Approved

As per current import policy, the firm shall submit the original legalized CoPP and a Letter of Authorization before issuance of the letter.

651

Case Category	Priority As Per 257-M of RB (Muhammad Sarfraz Nawaz)
Name, address of Applicant.	MSA PHARMA 1304, Green Acre, Pine Avenue (05-352-0066)
Application Form Dy. No / Tracking ID & date of submission	(6WT-X7J-R6WU, 2025-03-27)
Detail of Fee Submitted	300000.0, 2025-01-15,
The proposed proprietary name / brand name	Sotoxen 120mg Tablet
Label Claim	Each film-coated Tablet contains....Sotorasib 120mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1x56's-As per SRO
Shelf Life (Unit)	2 YearStore below 30°C.
For generic drugs (me-too Status)	Not Applicable
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Everest Pharmaceuticals Limited.-Plot No: B-45, 46 & 33, BSCIC I/A, Kanchpur, Narayanganj, -Bangladesh
Pharmaceutical Equivalence and Comparative Dissolution Profile	
Name, address of Marketing Authorization Holder:	Everest Pharmaceuticals Limited., Factory: Plot No: B-45, 46 & 33, BSCIC I/A, Kanchpur, Narayanganj, Bangladesh. Head office Address: Rahman's Regnum Centre (11th Floor) 191/1, Tejgaon C/A, Dhaka-1208, Bangladesh, Bangladesh
Details of Certificates (CoPP/FSC/cGMP):	
Details of Authorization Letter :	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
The status in reference regulatory authorities	Lumykras 120mg Film-coated Tablet (Netherland)

Evaluation Remarks

Decision

Approved

As per current import policy, the firm shall submit the original legalized CoPP and a Letter of Authorization before

	issuance of the letter.	
652	Case Category	Priority As Per 257-M of RB (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	MSA PHARMA 1304, Green Acre, Pine Avenue (05-352-0066)
	Application Form Dy. No / Tracking ID & date of submission	(L8U-U42-DEXY, 2025-04-03)
	Detail of Fee Submitted	300000.0, 2025-01-15,
	The proposed proprietary name / brand name	Trifluxen Tablet
	Label Claim	Each film-coated Tablet contains...Trifluridine 15mg + Tipiracil Hydrochloride 7.065mg eq. to Tipiracil 6.140mg)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C.
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Everest Pharmaceuticals Limited.p-Plot No: B-45, 46 & 33, BSCIC I/A, Kanchpur, Narayanganj, -Bangladesh
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	Everest Pharmaceuticals Limited., Factory: Plot No: B-45, 46 & 33, BSCIC I/A, Kanchpur, Narayanganj, Bangladesh. Head office Address: Rahman's Regnum Centre (11th Floor) 191/1, Tejgaon C/A, Dhaka-1208, Bangladesh, Bangladesh
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Lonsurf Tablet (Trifluridine 15mg+Tipiracil 6.14mg), Japan
653	Evaluation Remarks	
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	Decision	
	Approved	
	As per current import policy, the firm shall submit the original legalized CoPP and a Letter of Authorization before issuance of the letter.	
653	Case Category	Priority As Per 257-M of RB (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	MSA PHARMA 1304, Green Acre, Pine Avenue (05-352-0066)
	Application Form Dy. No / Tracking ID & date of submission	(SZH-P8J-D5PY, 2025-09-02)
	Detail of Fee Submitted	300000.0, 2025-06-16,
	The proposed proprietary name / brand name	Lenvanex 10mg Capsule

Label Claim	Each hard capsule contains....10 mg of Lenvatinib (as mesilate)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	30's-As per SRO
Shelf Life (Unit)	2 YearStore below 30°C.
For generic drugs (me-too Status)	Lenvaxin 10mg Capsule (Himmel Pharmaceuticals Pvt. Ltd)
Pharmacotherapeutic Group of (API)	MSN Laboratories Private Limited, India
Name, address of Manufacturing site:	Everest Pharmaceuticals Limited.-Plot No: B-45, 46 & 33, BSCIC I/A, Kanchpur, Narayanganj, -Bangladesh
Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in Relavant section of Module 3.
Name, address of Marketing Authorization Holder:	Everest Pharmaceuticals Limited., Factory: Plot No: B-45, 46 & 33, BSCIC I/A, Kanchpur, Narayanganj, Bangladesh. Head office Address: Rahman's Regnum Centre (11th Floor) 191/1, Tejgaon C/A, Dhaka-1208, Bangladesh, Bangladesh
Details of Certificates (CoPP/FSC/cGMP):	19.07.2023 to 19.07.2025 (For Manufacturing Facility)
Details of Authorization Letter :	Not Applicable for Finished drug Product importer.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	36 Months
The status in reference regulatory authorities	Lenvima 10mg Hard Capsule (Eisai manufacturing limited, UK)

Evaluation Remarks

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Decision

Approved

As per current import policy, the firm shall submit the original legalized CoPP and a Letter of Authorization before issuance of the letter.

654

Case Category	Priority As Per 257-M of RB (Muhammad Sarfraz Nawaz)
Name, address of Applicant.	MSA PHARMA 1304, Green Acre, Pine Avenue (05-352-0066)
Application Form Dy. No / Tracking ID & date of submission	(9VQ-B4W-2TW9, 2025-09-02)
Detail of Fee Submitted	300000.0, 2025-06-16,
The proposed proprietary name / brand name	Lenvaxen 4 Capsule
Label Claim	Each hard capsule contains 4 mg of Lenvatinib (as mesilate)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	30's-As per SRO
Shelf Life (Unit)	2 YearDo not store above 30°C. Store in the original blister in order to protect from moisture.
For generic drugs (me-too Status)	Lenvaxin 4mg Capsule (Himmel Pharmaceuticals Pvt. Ltd)
Pharmacotherapeutic Group of (API)	MSN Laboratories Private Limited, India
Name, address of Manufacturing site:	Everest Pharmaceuticals Limited.-Head office Address: Rahman's Regnum Centre (11th Floor) 191/1, Tejgaon

	C/A, Dhaka-1208, Bangladesh-Bangladesh
Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in Relavant section of Module 3.
Name, address of Marketing Authorization Holder:	Everest Pharmaceuticals Limited., Factory: Plot No: B-45, 46 & 33, BSCIC I/A, Kanchpur, Narayanganj, Bangladesh. , Bangladesh
Details of Certificates (CoPP/FSC/cGMP):	19.07.2023 to 19.07.2025 (For Manufacturing Facility)
Details of Authorization Letter :	Not Applicable for Finished drug Product importer.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	36 Months
The status in reference regulatory authorities	Lenvima 4mg Hard Capsule (Eisai manufacturing limited, UK)
Evaluation Remarks	
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Decision	
Approved	
As per current import policy, the firm shall submit the original legalized CoPP and a Letter of Authorization before issuance of the letter.	
655	
Case Category	Priority As Per 257-M of RB (Muhammad Sarfraz Nawaz)
Name, address of Applicant.	MSA PHARMA 1304, Green Acre, Pine Avenue (05-352-0066)
Application Form Dy. No / Tracking ID & date of submission	(E44-2NX-JM5M, 2025-09-02)
Detail of Fee Submitted	300000.0, 2025-06-11,
The proposed proprietary name / brand name	Ascimib Tablet
Label Claim	Each 40 mg film-coated tablet contains... Asciminib hydrochloride, equivalent to 40 mg Asciminib
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	30's-As per SRO
Shelf Life (Unit)	2 YearStore below 30°C.
For generic drugs (me-too Status)	Not Applicable
Pharmacotherapeutic Group of (API)	Henan Jin Huaitang Biological Engineering Co.,Ltd, China
Name, address of Manufacturing site:	Everest Pharmaceuticals Limited.-Plot No: B-45, 46 & 33, BSCIC I/A, Kanchpur, Narayanganj, -China
Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in Relavant section of Module 3.
Name, address of Marketing Authorization Holder:	Everest Pharmaceuticals Limited., Factory: Plot No: B-45, 46 & 33, BSCIC I/A, Kanchpur, Narayanganj, Bangladesh. Head office Address: Rahman's Regnum Centre (11th Floor) 191/1, Tejgaon C/A, Dhaka-1208, Bangladesh, Bangladesh
Details of Certificates (CoPP/FSC/cGMP):	19.07.2023 to 19.07.2025 (For Manufacturing Facility)
Details of Authorization Letter :	Not Applicable for Finished drug Product importer.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	24 Months

	The status in reference regulatory authorities	Scemblix 40mg Film-Coated Tablets (Novartis Pharmaceuticals, UK)
	Evaluation Remarks	
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	Decision	
	Approved	
	As per current import policy, the firm shall submit the original legalized CoPP and a Letter of Authorization before issuance of the letter.	
656	Case Category	Priority As Per 257-M of RB (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	HIMMEL PHARMACEUTICALS (PVT.) LTD Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Zazaria e Pakistan Lahore (05-352-0065)
	Application Form Dy. No / Tracking ID & date of submission	(PL7-3TX-18PR, 2025-08-08)
	Detail of Fee Submitted	300000.0, 2025-07-31,
	The proposed proprietary name / brand name	Bendamustine AqVida 100mg/ml Concentrate for Solution for Infusion
	Label Claim	Each ml of concentrate contains..... Bendamustine 100 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	24 MonthStore in a refrigerator (2°C – 8°C).
	For generic drugs (me-too Status)	Bendamustine HCl 100mg as lyophilized Powder for Injection (ATCO)
	Pharmacotherapeutic Group of (API)	Biophore India Pharmaceuticals Pvt. Ltd. (India)
	Name, address of Manufacturing site:	AqVida GmbH -Werkstr.21 23942 Dassow-Germany
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in Relavant section of Module 3.
	Name, address of Marketing Authorization Holder:	AqVida GmbH , Kaiser-Wilhelm-Str.89, 20355 Hamburg, Germany
	Details of Certificates (CoPP/FSC/cGMP):	08.12.2022 to 08.12.2025 (For Manufacturing Facility)
	Details of Authorization Letter :	Not Applicable for Finished drug Product importer.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	60 Months
	The status in reference regulatory authorities	Levact 100mg/ml Powder for Concentrate for Solution for Infusion (Bendamustine HCl)
	Evaluation Remarks	
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	Decision	
	Approved	
	As per current import policy, the firm shall submit the original legalized CoPP and a Letter of Authorization before issuance of the letter.	
657	Case Category	Priority As Per 257-M of RB (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Hakimsons (Pvt)., Ltd. A-58/B , SITE Karachi (055)

Application Form Dy. No / Tracking ID & date of submission	(HHX-UW2-EA72, 2025-08-20)
Detail of Fee Submitted	300000.0, 2025-05-20,
The proposed proprietary name / brand name	SKYTINIB 12.5 Capsules
Label Claim	Each Capsule Contains : Sunitinib 12.5mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1x10's , 3x10's & 4x-De-Controlled
Shelf Life (Unit)	24 MonthStore below 30°C
For generic drugs (me-too Status)	SUTENT by Pfizer , SUNETIC by PharmaSol
Pharmacotherapeutic Group of (API)	Antineoplastic agent - VEGF Inhibitor, Tyrosine Kinase Inhibitors
Name, address of Manufacturing site:	M/s Eugia Pharma Specialities Limited.-Unit-1 Survey No. 550, 551 & 552, Kolthur Village, Shamirpet Mandal, Medchal-Malkajgiri District, Telangana, India, Pin-500101-India
Pharmaceutical Equivalence and Comparative Dissolution Profile	As enclosed in Section 2.3.P.2.2 of MODULE-II & Section 3.2.P.2.2 of MODULE-III
Name, address of Marketing Authorization Holder:	M/s Hakimsons (Pvt)., Ltd., A-58/B , S.I.T.E, Manghopir Road, Karachi., Pakistan
Details of Certificates (CoPP/FSC/cGMP):	As enclosed in Sub-Section 1.3.5 of MODULE - I
Details of Authorization Letter :	Not Applicable as Import Finished Product
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	As enclosed in Section - 2.3.S.7 of MODULE-II & Section - 3.2.S.7 of MODULE-III
The status in reference regulatory authorities	SUTENT 12.5mg Capsules by USFDA for Pfizer Inc.

Evaluation Remarks

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Decision

Approved

As per current import policy, the firm shall submit the original legalized CoPP and a Letter of Authorization before issuance of the letter.

658

Case Category	Priority As Per 257-M of RB (Muhammad Sarfraz Nawaz)
Name, address of Applicant.	Hakimsons (Pvt)., Ltd. A-58/B , SITE Karachi (055)
Application Form Dy. No / Tracking ID & date of submission	(U2L-YB8-5VGQ, 2025-08-20)
Detail of Fee Submitted	300000.0, 2025-05-20,
The proposed proprietary name / brand name	SKYTINIB 25 Capsules
Label Claim	Each Capsule Contains: Sunitinib 25mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1x10's , 3x10's & 4x-De-Controlled
Shelf Life (Unit)	24 Monthstore below 30C
For generic drugs (me-too Status)	SUTENT by Pfizer , SUNETIC by PharmaSol
Pharmacotherapeutic Group of (API)	Antineoplastic agent - VEGF Inhibitor, Tyrosine Kinase Inhibitors
Name, address of Manufacturing site:	M/s Eugia Pharma Specialities Limited.-Unit-1 Survey No. 550, 551 & 552, Kolthur Village, Shamirpet Mandal,

	Medchal-Malkajgiri District, Telangana, India, Pin-500101-India
Pharmaceutical Equivalence and Comparative Dissolution Profile	As enclosed in Section 2.3.P.2.2 of MODULE-II & Section 3.2.P.2.2 of MODULE-III
Name, address of Marketing Authorization Holder:	M/s Hakimsons (Pvt)., Ltd., A-58/B , S.I.T.E, Manghopir Road, Karachi., Pakistan
Details of Certificates (CoPP/FSC/cGMP):	As enclosed in Sub-Section 1.3.5 of MODULE - I
Details of Authorization Letter :	Not Applicable as Import Finished Product
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	As enclosed in Section - 2.3.S.7 of MODULE-II & Section - 3.2.S.7 of MODULE-III
The status in reference regulatory authorities	SUTENT 25mg Capsules by USFDA for Pfizer Inc.
Evaluation Remarks	
.	
Decision	
Approved	
As per current import policy, the firm shall submit the original legalized CoPP and a Letter of Authorization before issuance of the letter.	
659	
Case Category	Priority As Per 257-M of RB (Muhammad Sarfraz Nawaz)
Name, address of Applicant.	Hakimsons (Pvt)., Ltd. A-58/B , SITE Karachi (055)
Application Form Dy. No / Tracking ID & date of submission	(AN3-Z67-HHWE, 2025-08-20)
Detail of Fee Submitted	300000.0, 2025-05-20,
The proposed proprietary name / brand name	SKYTINIB 50 Capsules
Label Claim	Each Capsule Contains : Sunitinib 50mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1x10's , 3x10's & 4x-De-Controlled
Shelf Life (Unit)	24 Monthstore below 30C
For generic drugs (me-too Status)	SUTENT by Pfizer , SUNETIC by PharmaSol
Pharmacotherapeutic Group of (API)	Antineoplastic agent - VEGF Inhibitor, Tyrosine Kinase Inhibitors
Name, address of Manufacturing site:	M/s Eugia Pharma Specialities Limited.-Unit-1 Survey No. 550, 551 & 552, Kolthur Village, Shamirpet Mandal, Medchal-Malkajgiri District, Telangana, India, Pin-500101-India
Pharmaceutical Equivalence and Comparative Dissolution Profile	As enclosed in Section 2.3.P.2.2 of MODULE-II & Section 3.2.P.2.2 of MODULE-III
Name, address of Marketing Authorization Holder:	M/s Hakimsons (Pvt)., Ltd., A-58/B , S.I.T.E, Manghopir Road, Karachi., Pakistan
Details of Certificates (CoPP/FSC/cGMP):	As enclosed in Sub-Section 1.3.5 of MODULE - I
Details of Authorization Letter :	Not Applicable as Import Finished Product
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	As enclosed in Section - 2.3.S.7 of MODULE-II & Section - 3.2.S.7 of MODULE-III
The status in reference regulatory authorities	SUTENT 50mg Capsules by USFDA for Pfizer Inc.
Evaluation Remarks	
.	
Decision	

Approved

As per current import policy, the firm shall submit the original legalized CoPP and a Letter of Authorization before issuance of the letter.

660	Case Category	Priority As Per 257-M of RB (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan (01-374-0006)
	Application Form Dy. No / Tracking ID & date of submission	(QLL-9MH-33SV, 2025-04-25)
	Detail of Fee Submitted	300000.0, 2025-01-10,
	The proposed proprietary name / brand name	ZUVITOP-100
	Label Claim	Each 5 ml contains: Etoposide USP..... 100mg Sterile Non Aqueous base..... qs.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's (5ml Vial)-As per SRO
	Shelf Life (Unit)	24 MonthStore at controlled room temperature 15% to 30°C. Protect from light.
	For generic drugs (me-too Status)	Registration number: 087698, Ebewe (100mg/5ml vial), Each ml contains: Etoposide 20mg, MAH: Novartis Pharma (Pakistan) Ltd. Manufacturer: Ebewe Pharma Ges.M.B.H. Nfg. Kg, Mondseestrabe 11, At-4866 Un
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Zuvius Lifesciences Pvt. Ltd.-At.Kharuni-Lodhimajra Road, Vill. Nandpur, Baddi, Distt. Solan, (H.P.)-173205 India-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	Zuvius Lifesciences Pvt. Ltd., At-Kharuni-Lodhimajra Road, Vill. Nandpur, Baddi, Distt. Solan (H.P.)173205 India, India
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	TOPOSAR (Etoposide injection USP) 100mg/5ml (20mg/ml) Manufactured by Teva Parenteral Medicines, Inc. USFDA Approved
	Evaluation Remarks	
	.	
	Decision	
	Deferred	
	The case is referred to the Legal Affairs Division for their comments on the loan-based license.	
661	Case Category	New Section (Najia Saleem)
	Name, address of Applicant.	Air Pharmaceuticals(Pvt.)Ltd Plot No's 74, 75-A, Small Industrial Estate, Kasur (000977)
	Application Form Dy. No / Tracking ID & date of submission	(6M6-8BR-JVZL, 2025-07-25)
	Detail of Fee Submitted	37000.0, 2025-06-05,

The proposed proprietary name / brand name	Esimizole
Label Claim	Each capsule contains: Esomeprazole Magnesium Trihydrate (enteric coated pellets) equivalent to Esomeprazole 20mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	7's, 14's & 28's -De-Controlled
Shelf Life (Unit)	2 Year(s)Store in a cool and dry place and protect from direct sunlight
For generic drugs (me-too Status)	NOVOTEpH 20mg
Pharmacotherapeutic Group of (API)	PPI
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Vision pharmaceuticals (pvt.)Ltd
Detail of stability batches of drug product	RND/Cap24-1/T001/S1, RND/Cap24-1/T001/S2, RND/Cap24-1/T001/S3
Documents for the procurement of API with approval from DRAP (in case of Import)	N/A, Source of pellets: Ms Vision pharmaceuticals (pvt.) Ltd limited invoice# 242501400
Pharmaceutical Equivalence and Comparative Dissolution Profile	Both PE & CDP against NovoTEpH Capsule 20mg B#FLM001 attached
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 36 months real time stability data as per zone IV-A conditions is attached
The status in reference regulatory authorities	NEXIUM capsule 20mg, AstraZeneca pharmaceuticals LP Wilmington ,DE19850
GMP status of the firm	valid
Evidence of approval of manufacturing facility	DML#000977(Attached)

Evaluation Remarks

Decision

Approved

662	Case Category	New Section (Najia Saleem)
	Name, address of Applicant.	Air Pharmaceuticals(Pvt.)Ltd Plot No's 74, 75-A, Small Industrial Estate, Kasur (000977)
	Application Form Dy. No / Tracking ID & date of submission	(8SH-WQM-D6DT, 2025-07-25)
	Detail of Fee Submitted	37000.0, 2025-06-05,
	The proposed proprietary name / brand name	Esimizole
	Label Claim	Each capsule contains: Esomeprazole Magnesium Trihydrate (enteric coated pellets) equivalent to Esomeprazole 40mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14's -De-Controlled,28's -De-Controlled,7's, -De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in a cool and dry place and protect from direct sunlight
	For generic drugs (me-too Status)	NOVOTEpH 40mg
	Pharmacotherapeutic Group of (API)	PPI
	Name, address of Manufacturing site:	Self Manufacturing

	Name & address of API manufacturer	Vision pharmaceuticals (pvt.)Ltd
	Detail of stability batches of drug product	RND/Cap24-1/T002/S1, RND/Cap24-1/T002/S2, RND/Cap24-1/T002/S3
	Documents for the procurement of API with approval from DRAP (in case of Import)	N/A, Source of pellets: Vision pharmaceuticals (pvt.) Ltd limited invoice# 242501400
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Both PE & CDP against NovoTEpH Capsule 40mg B#143N001 attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	6 months accelerated and 36-month real time stability data as per zone IV-A conditions is attached
	The status in reference regulatory authorities	NEXIUM capsule 40mg, AstraZeneca pharmaceuticals LP Wilmington ,DE19850
	GMP status of the firm	valid and Attached
	Evidence of approval of manufacturing facility	DML#000977(Attached)
	Evaluation Remarks	
	Decision	
	Approved	
663	Case Category	New Section (Najia Saleem)
	Name, address of Applicant.	Air Pharmaceuticals(Pvt.)Ltd Plot No's 74, 75-A, Small Industrial Estate, Kasur (000977)
	Application Form Dy. No / Tracking ID & date of submission	(YWA-3J7-A3MH, 2025-07-30)
	Detail of Fee Submitted	37000.0, 2025-06-30,
	The proposed proprietary name / brand name	Falcon
	Label Claim	Each capsule contains: Fluconazole.....150mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's & 5's -De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in a cool and dry place and protect from direct sunlight
	For generic drugs (me-too Status)	ONAMED 150 capsule
	Pharmacotherapeutic Group of (API)	Antifungal
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Raj pioneer laboratories (india) PVT LTD
	Detail of stability batches of drug product	RND/Cap24-1/T009/S1, RND/Cap24-1/T009/S2, RND/Cap24-1/T009/S3; 2000 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Export invoice and clearance certificate in the name of Ms Novamed is submitted. Raj pioneer (India) (EXP0166/23-24) Applicant has taken loan without timely intimation to DRAP
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Both PE & CDP against ONAMED Capsule 150mg B#20218 attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	stability data as per zone IV-A conditions till shelf life is attached
	The status in reference regulatory authorities	Fluconazole Capsule 150mg Distributed Teva UK Ltd.
	GMP status of the firm	Capsule (General) additional section granted on 04-02-2025

	Evidence of approval of manufacturing facility	DML#000977 issued dated 25-10-23
	Evaluation Remarks	
	Firm has submitted loan letter for API (without timely intimation of Loan), hence may be verified accordingly.	
	Decision	
	Approved	
	subject to verification of loan letter.	
664	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	STAR LABORATORIES PVT. LTD. 23KM MULTAN ROAD LAHORE (000130)
	Application Form Dy. No / Tracking ID & date of submission	(3S5-MU6-U1HZ, 2024-11-15)
	Detail of Fee Submitted	37000.0, 2024-11-14,
	The proposed proprietary name / brand name	Marbocin 10% injection
	Label Claim	Each ml contains:- Marbofloxacin 100 mg (Innovator's specification.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	20ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C.
	For generic drugs (me-too Status)	carboxy 10% injection (reg.112117)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP certificate based on evaluation conducted on 30-05-2023
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
665	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	STAR LABORATORIES PVT. LTD. 23KM MULTAN ROAD LAHORE (000130)
	Application Form Dy. No / Tracking ID & date of submission	(V5V-GUJ-2SQD, 2024-11-15)
	Detail of Fee Submitted	37000.0, 2024-11-14,
	The proposed proprietary name / brand name	Marbocin 10% injection
	Label Claim	Each ml contains:-Marbofloxacin 100 mg(Innovator's specification.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C.
	For generic drugs (me-too Status)	074054 MARBOSTAR 10% SOLUTION "M/S. HUZAIFA INTERNATIONAL, SARGODHA
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	Minutes of 351st Meeting of Registration Board	(23rd – 24th September, 2025)

	GMP status of the firm	GMP certificate based on evaluation conducted on 30-05-2023
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
666	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	STAR LABORATORIES PVT. LTD. 23KM MULTAN ROAD LAHORE (000130)
	Application Form Dy. No / Tracking ID & date of submission	(T8P-USH-V6GB, 2024-11-15)
	Detail of Fee Submitted	37000.0, 2024-11-14,
	The proposed proprietary name / brand name	Marbocin 10% injection
	Label Claim	Each ml contains:- Marbofloxacin 100 mg (Innovator's specification.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C.
	For generic drugs (me-too Status)	Marcin Injection (Reg.088117)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP certificate based on evaluation conducted on 30-05-2023
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
667	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	STAR LABORATORIES PVT. LTD. 23KM MULTAN ROAD LAHORE (000130)
	Application Form Dy. No / Tracking ID & date of submission	(X6Q-UST-ZJUI, 2024-05-21)
	Detail of Fee Submitted	30000.0, 2024-05-06,
	The proposed proprietary name / brand name	Trifen Drench
	Label Claim	Each ml contains:- Triclabendazole (B.P vet)...50 mgIvermectin (B.P).... 1mgFenbendazole (B.P Vet).... 50 mg (Innovator's. Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store between 15°C - 25°C.In a cool and dry place.

	For generic drugs (me-too Status)	Triverfen Drench (049627)SELMORE PHARMACEUTICALS (PVT),Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP certificate based on evaluation conducted on 30-05-2023
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
668	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	STAR LABORATORIES PVT. LTD. 23KM MULTAN ROAD LAHORE (000130)
	Application Form Dy. No / Tracking ID & date of submission	(45S-779-QVRD, 2024-04-02)
	Detail of Fee Submitted	30000.0, 2024-02-13,
	The proposed proprietary name / brand name	BUTRIN INJECTION
	Label Claim	Each ml contains:- Butaphosphan.....100mg Cyanocobalamin.....50mcg Taurine.....37.3mg Nicotinamide.....23mg DL- Methionine.....18.7mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C.Keep away from heat,moisture and reach of children.
	For generic drugs (me-too Status)	122532 "FASFO-100 INJECTION M/S. ETERNA PHARMA (PVT) LTD., MIRPUR, AJK.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP certificate based on evaluation conducted on 30-05-2023
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
669	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	HAAKS Vethum (Pvt) Ltd. Plot No. 60 (B-II), M-3 Industrial City, FIEDMC, Faisalabad (001002)
	Application Form Dy. No / Tracking ID & date of submission	(DT8-B27-VJWJ, 2025-03-05)

Detail of Fee Submitted	37000.0, 2025-02-26,
The proposed proprietary name / brand name	TYLOXY-DOX
Label Claim	Each 100gm. contains:Doxycycline Hyclate 40g(Eq. to Doxycycline 34.66g)Colistin Sulphate 10gTylosin Tartrate 20g(Eq. to Tylosin 17.18g)Bromhexine HCl 2g(Eq. to Bromhexine 1.823g)(As per Innovator Specification)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1 Kg, 100 gm, 250gm,-De-Controlled
Shelf Life (Unit)	2 Year(s)Normal
For generic drugs (me-too Status)	058962 BROCOTYD POWDER UNIVET PHARMACEUTICAL RAWALPINDI
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	Good
Evidence of approval of manufacturing facility	

Evaluation Remarks

Demanded pack sizes: 100 gm, 250gm, 500 gm, 1 Kg, 5 Kg, 10 Kg, 25 Kg

Decision

Approved

With already issued brand name for same combination and up to 1Kg pack size.

670	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	HAAKS Vethum (Pvt) Ltd. Plot No. 60 (B-II), M-3 Industrial City, FIEDMC, Faisalabad (001002)
	Application Form Dy. No / Tracking ID & date of submission	(QNA-A41-4QD8, 2025-03-05)
	Detail of Fee Submitted	37000.0, 2025-02-26,
	The proposed proprietary name / brand name	SENSODOX-50
	Label Claim	Each 100gm contains:Doxycycline Hyclate 50gm(Eq. to Doxycycline 43.32gm)(Innovator Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Kg, 100 gm, 250gm,-De-Controlled
	Shelf Life (Unit)	2 Year(s)Normal
	For generic drugs (me-too Status)	082498 "DOX PLUS 50% WATER SOLUBLE POWDER M/S. BIO-LABS (PVT) LTD., ISLAMABAD.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Good
	Evidence of approval of manufacturing facility	

Evaluation Remarks

Demanded pack sizes: 100 gm, 250gm, 500 gm, 1 Kg, 5 Kg, 10Kg, 20Kg, 25 Kg

Decision

Approved

with already issued brand name for same molecule and up to 1Kg pack size.

671	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	HAAKS Vethum (Pvt) Ltd. Plot No. 60 (B-II), M-3 Industrial City, FIEDMC, Faisalabad (001002)
	Application Form Dy. No / Tracking ID & date of submission	(NMG-1ZU-864E, 2025-07-03)
	Detail of Fee Submitted	37000.0, 2025-07-02,
	The proposed proprietary name / brand name	CLOXY 480
	Label Claim	Each 100g contains:Colistin Sulfate 480,000,000 IU(Innovator Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Kg,5 Kg, 500 gm, 250gm, 100 gm, 10 Kg, 20Kg, 25-De-Controlled
	Shelf Life (Unit)	2 Year(s)Normal
	For generic drugs (me-too Status)	122232 ONE COLI ORAL POWDER M/S. ONE HEALTH PHARMA, SINDH.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Good
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Demanded pack sizes: 100 gm, 250gm, 500 gm, 1 Kg, 5 Kg, 10Kg, 20 Kg 25 Kg	
672	Decision	
	Approved	
	up to 1Kg pack size.	
	Case Category	New Section (Najia Saleem)
	Name, address of Applicant.	Air Pharmaceuticals(Pvt.)Ltd Plot No's 74, 75-A, Small Industrial Estate, Kasur (000977)
	Application Form Dy. No / Tracking ID & date of submission	(S7Y-E27-YRG1, 2025-07-25)
	Detail of Fee Submitted	37000.0, 2025-05-13,
	The proposed proprietary name / brand name	Mikast
	Label Claim	Each sachet Contains Montelukast sodium eq to montelukast.....4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's ,20's , 30's & -De-Controlled
	Shelf Life (Unit)	2 Year(s)store away from direct sunlight
	For generic drugs (me-too Status)	Myteka 4mg sachet
	Pharmacotherapeutic Group of (API)	leukotriene receptor antagonists
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Morepen laboratories limited
	Detail of stability batches of drug product	6 months data for three batches (RND/SCT25-1/T001/S1,RND/SCT25-1/T001/S2,RND/SCT25-1/T001/S3 300 sachets each)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted Loan letter for API from Ms Novamed and no intimation to DRAP for obtaining loan

Pharmaceutical Equivalence and Comparative Dissolution Profile	Both PE & CDP data against Myteka sachet 4mg B.NO 151740 attached
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	stability data till shelf life attached
The status in reference regulatory authorities	SINGULAIR MERK &CO.,INC whitehouse station ,NJ08889,USA
GMP status of the firm	valid
Evidence of approval of manufacturing facility	DML#000977(Attached)

Evaluation Remarks

Firm have submitted Loan letter for API and no intimation for obtaining loan, hence may be verified accordingly.

Decision

Approved

subject to verification of loan letter.

673	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	Air Pharmaceuticals(Pvt.)Ltd Plot No's 74, 75-A, Small Industrial Estate, Kasur (000977)
	Application Form Dy. No / Tracking ID & date of submission	(UZ8-WUS-EUQG, 2025-05-05)
	Detail of Fee Submitted	37000.0, 2025-04-21,
	The proposed proprietary name / brand name	Laprazole
	Label Claim	Each capsule contains Lansoprazole Enteric coated pellets eq to lansoprazole 30mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's ,20's , 30's , -De-Controlled
	Shelf Life (Unit)	2 Year(s)Store away from direct sunlight, heat and moisture below 30C
	For generic drugs (me-too Status)	Inhibitol 30 mg capsule
	Pharmaceutical Group of (API)	Vision Pharmaceuticals Pvt. Ltd
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vision Pharmaceuticals
	Detail of stability batches of drug product	RNDCAP24-001/T5/S1,RNDCAP24-001/T5/S2,RNDCAP24-001/T5/S3
	Documents for the procurement of API with approval from DRAP (in case of Import)	Local procurement from Vision Islamabad (Invoice#242501544)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Both PE & CDP against Laprazole 30mg capsules of Ms Novamed B# 19824 attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	stability data till shelf life attached
	The status in reference regulatory authorities	PREVACID CAPSULE 30 mg, Takeda Pharmaceuticals America, Inc
	GMP status of the firm	valid
	Evidence of approval of manufacturing facility	DML#000977 (Attached)

Evaluation Remarks

Sr. No	Observation	Firm's response
1.	Submit both accelerated and real time stability studies data at 6th-month	Submitted

		time point, along with supported documents.	
Decision			
Approved			
674	Case Category	Import (Najia Saleem)	
	Name, address of Applicant.	Ubaidullah Enterprises 37GC Shah Rukn-e-alam colony (04-361-0171)	
	Application Form Dy. No / Tracking ID & date of submission	(13N-48J-P8TU, 2024-12-17)	
	Detail of Fee Submitted	75000.0, 225000.0 2024-12-16, 2025-07-08	
	The proposed proprietary name / brand name	UE ENRO	
	Label Claim	Each ml contains: Enrofloxacin.....100 mg	
	Reference to Finished product specifications	United States Pharmacopeia	
	Proposed Pack Size	200ltrs-De-Controlled,100ml,-De-Controlled,1ltr, -De-Controlled,250ml,-De-Controlled,500ml,-De-Controlled,50ml, -De-Controlled,5ltr,-De-Controlled	
	Shelf Life (Unit)	3 Year(s)Normal	
	For generic drugs (me-too Status)	Ceriflox 10% oral solution(020788) Star Laboratories (Pvt) Ltd.	
	Pharmacotherapeutic Group of (API)	Antibiotic	
	Name, address of Manufacturing site:	Shijiazhuang ZDHD Stock-Raising Co., Ltd,-No.1 Yinhai Road, Xingtai Weixian County, industrial District, Xintai city Hebei -China	
	Name, address of Marketing Authorization Holder:	Ubaidullah Enterprises, 45 GC Shah Rukn-e-Alam Colony Multan, Pakistan	
	Details of Certificates (CoPP/FSC/cGMP):	Scanned copy of GMP certificate valid till 17-08-2027; Scanned copy of FSC valid till: 17-09-2029	
	Details of Authorization Letter :	Scanned copy of exclusive distribution agreement dated 01-11-2024	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	6 months accelerated and 36 months real time stability data of three batches as per zone IV-A conditions	
	Evaluation Remarks		
Since the firm has submitted scanned distribution agreement, FSC and GMP certificate, original legalized documents shall be submitted before issuance of registration letter.			
Decision			
Approved			
subject to compliance with current import policy for finished drugs. Moreover, firm shall submit original legalized valid distribution agreement, FSC and GMP certificate, before issuance of registration letter, since the already submitted copies are scanned.			
675	Case Category	Import (Najia Saleem)	
	Name, address of Applicant.	Ubaidullah Enterprises 37GC Shah Rukn-e-alam colony (04-361-0171)	
	Application Form Dy. No / Tracking ID & date of submission	(J4Q-XRG-S5SZ, 2024-12-28)	

Detail of Fee Submitted	75000.0, 225000.0 2024-12-24, 2025-07-08
The proposed proprietary name / brand name	UE DOXY 50
Label Claim	Each Kg contains: Doxycycline Hyclate.....500gm
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	10gm,50gm,100gm,500g-De-Controlled
Shelf Life (Unit)	3 Year(s)Normal
For generic drugs (me-too Status)	122238
Pharmacotherapeutic Group of (API)	Antibiotic
Name, address of Manufacturing site:	Shijiazhuang ZDHD Stock-Raising Co., Ltd,-No.1 Yinhai Road, Xingtai Weixian County, industrial District, Xintai city Hebei -China
Name, address of Marketing Authorization Holder:	Ubaidullah Enterprises, 45 GC Shah Rukn-e-Alam Colony Multan, Pakistan
Details of Certificates (CoPP/FSC/cGMP):	Scanned copies of GMP and FSC submitted
Details of Authorization Letter :	Scanned copy of distribution agreement dated 01-11- 2024
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	6 months acc and 36 months real time data submitted as per zone IV-A conditions

Evaluation Remarks

Since scanned copies of FSC, GMP and distribution agreement are submitted, the firm shall submit original legalized documents before issuance of registration letter.

Decision

Approved

subject to compliance with current import policy for finished drugs. Moreover, firm shall submit original legalized valid distribution agreement, FSC and GMP certificate, before issuance of registration letter, since the already submitted copies are scanned.

676	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	Solaris Life Sciences Private Limited , Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992)
	Application Form Dy. No / Tracking ID & date of submission	(4TM-YGJ-22G3, 2024-12-19)
	Detail of Fee Submitted	30000.0, 7000.0 2024-04-29, 2024-11-05
	The proposed proprietary name / brand name	Clovagizol 10% Vaginal Cream
	Label Claim	Each gram contains: Clotrimazole 100mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Gynosporin 10% Vaginal Cream, Manufacturer: Nabiqasim Industries (Pvt.) Ltd. Registration No. 44471
	Pharmacotherapeutic Group of (API)	WHO ATC Code: G01AF02: GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches; Batch size: 200 tubes of 5g each
	Documents for the procurement of API with approval from DRAP	Clearance certificate is issued to M/s Separh. Loan agreement between loan giver and M/s Solaris is

(in case of Import)	submitted. Evidence of intimation of loan to DRAP is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE is submitted against Gynosporin 10% Vaginal Cream, Manufacturer: Nabiqasim Industries (Pvt.) Ltd.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per Zone IVa
The status in reference regulatory authorities	Canesten Thrush Internal Cream, Manufacturer: Bayer PLC UK Ltd. PL 00010/0016R. MHRA Approved
GMP status of the firm	New License issued wef 17-01-2024.
Evidence of approval of manufacturing facility	Tablet (General), Capsule (general), Dry powder suspension (general), Sachet powder (general), Cream ointment/gel/lotion (general/steroid).

Evaluation Remarks

Decision

Approved

677	Case Category	New Section (Najia Saleem)
	Name, address of Applicant.	Horizon Healthcare (pvt.) ltd. 35-A Small Industrial Estate - Taxila (000856)
	Application Form Dy. No / Tracking ID & date of submission	(M45-63G-7HES, 2025-07-23)
	Detail of Fee Submitted	75000.0, 2025-06-05,
	The proposed proprietary name / brand name	Cyclozon Ophthalmic Emulsion UD (0.05%)
	Label Claim	Each 0.4ml Contain: Cyclosporin....0.2mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	30's single use cont-As per SRO
	Shelf Life (Unit)	2 Year(s)Should be protected from light & heat. Store below 30 °C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Steroid-Sparing Immunosuppressant
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Teva API TEVA Czech Industries S.R.O.
	Detail of stability batches of drug product	CED-001, CED-002 Each of 5000 UD Containers
	Documents for the procurement of API with approval from DRAP (in case of Import)	K-424188841283
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed with TEVA Cyclosporin Ophthalmic Emulsion
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated and Real time stability studies conducted on Zone IV-A stability conditions
	The status in reference regulatory authorities	US FDA
	GMP status of the firm	w.e.f 17-08-22 applied for renewal 21-12-2023
	Evidence of approval of manufacturing facility	DML#000856 w.e.f 24-04-2017 applied for renewal 10-02-2022

Evaluation Remarks

Decision

Approved

678	Case Category	Import (Najia Saleem)
	Name, address of Applicant.	MB Marketing Gulshan e gulab colony behind al basit medical center near pull wasal chowk suraj miani road multan cant Bosan Town (04-361-0159)
	Application Form Dy. No / Tracking ID & date of submission	(RQH-22L-E2MT, 2024-06-25)
	Detail of Fee Submitted	300000.0, 2024-06-13,
	The proposed proprietary name / brand name	Florfen20%
	Label Claim	Each Litre contains Florfenicol.....200g
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	1L-De-Controlled
	Shelf Life (Unit)	3 Year(s)Cool and dry place
	For generic drugs (me-too Status)	122222 MYFENCOL LIQUID of M/s. Avicenna Laboratories Pvt. Ltd., Sheikhpura
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	NAM PHARMA SDN. BHD.-5,LEBUH PERUSAHAAN KLEBANG 11 TAMAN PERINDUSTRIAN ANTARABANGSA IGB 31200 CHEMOR,PERAK, MALAYSIA-Malaysia
	Name, address of Marketing Authorization Holder:	MB Marketing, Al noor marriage club main suraj miani road near pull wasil Multan Pakistan, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Scanned copies of FSC and GMP submitted
	Details of Authorization Letter :	scanned copy of sole distributor agreement dated 01-04-2024 submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	6 months accelerated and 36 months real time stability data as per zone IV-B conditions
	Evaluation Remarks	
	Firm shall submit original FSC, GMP, LOA since already submitted scanned copies.	
	Decision	
	Approved	
	subject to compliance with current import policy for finished drugs. Moreover, firm shall submit original legalized valid LOA, FSC and GMP certificate, before issuance of registration letter, since the already submitted copies are scanned.	
679	Case Category	Import (Najia Saleem)
	Name, address of Applicant.	MB Marketing Gulshan e gulab colony behind al basit medical center near pull wasal chowk suraj miani road multan cant Bosan Town (04-361-0159)
	Application Form Dy. No / Tracking ID & date of submission	(TRX-RB6-XHA7, 2024-06-25)
	Detail of Fee Submitted	300000.0, 2024-06-13,
	The proposed proprietary name / brand name	E-10 Oral solution
	Label Claim	Each 1000ml contain Enrofloxacin.....100g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1000ML-De-Controlled
Minutes of 351st Meeting of Registration Board (23rd – 24th September, 2025)		518

Shelf Life (Unit)	3 Year(s)Cool and dry place
For generic drugs (me-too Status)	122254 ONERO 10% ORAL LIQUID M/S. ONE HEALTH PHARMA, SINDH.
Pharmacotherapeutic Group of (API)	Antibiotic
Name, address of Manufacturing site:	NAM PHARMA SDN. BHD.-5,LEBUH PERUSAHAAN KLEBANG 11 TAMAN PERINDUSTRIAN ANTARABANGSA IGB 31200 CHEMOR,PERAK, MALAYSIA-Malaysia
Name, address of Marketing Authorization Holder:	MB Marketing, Al noor marriage club main suraj miani road near pull wasil Multan Pakistan, Pakistan
Details of Certificates (CoPP/FSC/cGMP):	Scanned copies of FSC and GMP certificate are submitted
Details of Authorization Letter :	scanned copy of sole distributor agreement dated 01-04-2024 submitted
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	6 months accelerated and 36 months real time stability data as per zone IV-B conditions
Evaluation Remarks	
Since firm has submitted scanned copies of LOA, GMP and FSC, original legalized documents shall be submitted before issuance of registration letter.	
Decision	
Approved	
subject to compliance with current import policy for finished drugs. Moreover, firm shall submit original legalized valid LOA, FSC and GMP certificate, before issuance of registration letter, since the already submitted copies are scanned.	
680	Case Category
	Import (Najia Saleem)
	Name, address of Applicant.
	MB Marketing Gulshan e gulab colony behind al basit medical center near pull wasal chowk suraj miani road multan cant Bosan Town (04-361-0159)
	Application Form Dy. No / Tracking ID & date of submission
	(LDY-9GZ-1LAZ, 2024-12-27)
	Detail of Fee Submitted
	300000.0, 2024-12-17,
	The proposed proprietary name / brand name
	Droxy-50
	Label Claim
	Each kg contains. Doxycycline Hyclate ...500 g
	Reference to Finished product specifications
	As per Innovators Specification
	Proposed Pack Size
	1kg-De-Controlled
	Shelf Life (Unit)
	3 Year(s)Cool and dry place
	For generic drugs (me-too Status)
	023470 Doxyveto- 50 S Soluble Powder Vmd Pakistan Rawalpindi
	Pharmacotherapeutic Group of (API)
	Antibiotic
	Name, address of Manufacturing site:
	NAM PHARMA SDN. BHD.-NAM Pharma SDN.BHD. 5,LEBUH PERUSAHAAN KLEBANG 11 TAMAN PERINDUSTRIAN ANTARABANGSA .GB 31200 CHEMOR,PERAK,MALAYSIA-Malaysia
	Name, address of Marketing Authorization Holder:
	MB Marketing, MB Marketing Al Noor Marriage Club, Pull Wasil Main Suraj Miani Road Multan, Pakistan., Pakistan
	Details of Certificates (CoPP/FSC/cGMP):
	Scanned copies of FSC and GMP submitted
	Details of Authorization Letter :
	scanned copy of sole distributor agreement dated 01-04-2024 submitted

Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	6 months accelerated and 36 months real time stability data as per zone IV-B conditions

Evaluation Remarks

Firm shall submit original legalized GMP, FSC and LOA before issuance of registration letter since already submitted documents are scanned copies.

Decision

Approved

subject to compliance with current import policy for finished drugs. Moreover, firm shall submit original legalized valid LOA, FSC and GMP certificate, before issuance of registration letter, since the already submitted copies are scanned.

681	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	Solaris Life Sciences Private Limited , Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992)
	Application Form Dy. No / Tracking ID & date of submission	(P5D-ALD-ATAG, 2025-04-18)
	Detail of Fee Submitted	37000.0, 2024-11-14,
	The proposed proprietary name / brand name	Solofer Capsule 30mg
	Label Claim	Each capsule contains: Iron (as Ferric Maltol).....30mg (Innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Ferric Maltol 30mg Capsule (AGP Limited)
	Pharmacotherapeutic Group of (API)	Iron Supplement
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches 1500 capsule each
	Documents for the procurement of API with approval from DRAP (in case of Import)	E-10177252864968
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP data submitted against Ferric Maltol 30mg Capsules of AGP Limited Solaris life Sciences (Pvt.) Ltd. Batch No C0718 24HT67 Exp Date 05-2026
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 month accelerated and real time data submitted as per zone IV-A conditions
	The status in reference regulatory authorities	Accrufer 30 mg Capsules (USFDA Approved)
	GMP status of the firm	GMP certificate based on evaluation conducted on 15-01-2025
	Evidence of approval of manufacturing facility	Section approval letter dated 17-01-2024

Evaluation Remarks

Sr. No.	Observation	Firm's response
1	Justify, in light of guidelines and scientific literature, why USFDA recommended 2 tiers dissolution method and media were not selected for the applied product.	According to USFDA guidelines: https://www.fda.gov/media/70936/download Hard gelatin capsules show a decrease in the dissolution profile over the time either due to crosslinking of gelatin in water medium, SGF / SIF or medium with pH below 6.8. Therefor addition of

		enzymes required in dissolution medium to prevent crosslinking in gelatin. As per Chemistry review of the product (Ferric Maltol):https://www.accessdata.fda.gov/drugsatfda_docs/nada/2019/212320Orig1s000ChemR.pdf USFDA approved dissolution method (USP II (paddle) with sinker, 75 rpm, and two tire dissolution medium i.e. Tier 1: KCl/HCl Buffer, pH 1.2 Tier 2: KCl/HCl buffer with addition of Pepsin (700,000 to 750,000 unit/L, 900 mL). The dissolution method with Tier-2 dissolution medium can only be preceded where Tier-1 dissolution fails due to crosslinking and evidence of cross-linking in gelatin capsules is available. The evidence of cross-linking in gelatin capsules shall be provided Including photographic documentation or capsule switching test to confirm crosslinking. As per submitted dissolution data, using Tier-1 dissolution medium (KCl/HCl Buffer, pH 1.2) the results of dissolution are according to the specified limits (more than 85%) within 30 minutes, no decrease in the dissolution results was observed during stability studies, therefore the Tire-2 dissolution medium not adopted for the dissolution studies.
2	Justify selecting Alu-PVC container closure system mentioned in executed BMRs and section 3.2.P.8.3 in stability studies data, in place of HDPE bottles as recommended by literature of innovator product.	Stability studies of solofer capsule 30mg are performed in Alu-Alu blister, packed in cardboard unit carton and there was no interaction/significant changes observed in the product stability due to packing materials. Considering the stability of product, there is no specific requirements of HDPE bottles for the packing and storage of this product. The Alu-Alu packing is more suitable for unit dose protection of capsules dosage form as compared to HDPE bottle
Decision		
Approved		
682	Case Category	New Section (Najia Saleem)

Name, address of Applicant.	Horizon Healthcare (pvt.) ltd. 35-A Small Industrial Estate - Taxila (000856)
Application Form Dy. No / Tracking ID & date of submission	(SJQ-1T4-PE7E, 2025-07-23)
Detail of Fee Submitted	75000.0, 2025-06-05,
The proposed proprietary name / brand name	Tafrost-T UD Eye Drops (0.3ml)
Label Claim	One single dose container (0.3 mL) of eye drops, solution contains: Tafluprost.....4.5mcg (0.0015% w/v) Timolol as Maleate.....1.50mg (0.5% w/v)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	10 x 0.3 mL sterile -As per SRO
Shelf Life (Unit)	2 Year(s)Store below 5°C ±3°C.
For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	Antiglaucoma preparations and miotics, beta blocking agents
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	CENTURY PHARMACEUTIALS LTD.,Precise Biopharma Pvt. Ltd.
Detail of stability batches of drug product	TMD-001, TMD-002 Each of 5000 containers
Documents for the procurement of API with approval from DRAP (in case of Import)	Attached with invoice number: CPLEXP/T/23/1905
Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed with Taptiqom Eye drops unit dose
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated and Real time stability studies conducted on required conditions
The status in reference regulatory authorities	UK (MHRA)
GMP status of the firm	w.e.f 17-08-22 applied for renewal 21-12-2023
Evidence of approval of manufacturing facility	DML#000856 w.e.f 24-04-2017 applied for renewal 10-02-2022
Evaluation Remarks	
Decision	
Approved	

683	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	S.J & G. Fazul Ellahie (pvt) limited. E-46, S.I.T.E., Karachi (000083)
	Application Form Dy. No / Tracking ID & date of submission	(VMX-7XU-V39L, 2024-04-29)
	Detail of Fee Submitted	30000.0, 2024-03-04,
	The proposed proprietary name / brand name	Onzon
	Label Claim	Each film coated tablet contains: Ondansetron HCl dihydrate eq. to Ondansetron.....8mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)IVA

For generic drugs (me-too Status)	Ondonix 8mg Tablets Reg# 081451
Pharmacotherapeutic Group of (API)	Antiemetic
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	CTX Lifesciences Pvt. Limited
Detail of stability batches of drug product	3 batches of 1000 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP data submitted against Zofran 8mg Tablet (Batch No. 882422A) of Ms Novartis
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and real time stability data as per zone IV-B conditions
The status in reference regulatory authorities	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=076183
GMP status of the firm	GMP certificate based on evaluation conducted on 29-05-2023
Evidence of approval of manufacturing facility	

Evaluation Remarks

Decision

Approved

684	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Trigon Pharmaceuticals (Private) Ltd 8-k.m thokar raiwind road Lahore (000342)
	Application Form Dy. No / Tracking ID & date of submission	(SS4-RGX-1SVY, 2024-02-21)
	Detail of Fee Submitted	30000.0, 2024-02-01,
	The proposed proprietary name / brand name	TCON 4mg/5ml Syrup
	Label Claim	Each 5ml contains: Ondansetron as Hydrochloride Dihydrate.....4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30 C
	For generic drugs (me-too Status)	Ondanles 4mg/5ml syrup of M/s Neomedix
	Pharmacotherapeutic Group of (API)	Antiemetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. ANUGRAHA CHEMICALS No. D-47 to D-50 & C-62 to C-63, KSSIDC Industrial Estate, Doddaballapur, Bengaluru Rural District-561203.
	Detail of stability batches of drug product	3 batches of 1500 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Import)	ADC attested commercial invoice submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE data submitted against ZOFRAN SYRUP B.N 19k056
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 month accelerated and 60 months real time data submitted as per zone IV-A conditions

	The status in reference regulatory authorities	Ondansetron 4mg/5ml Syrup of M/s Focus Pharmaceuticals, MHRA approved
	GMP status of the firm	GMP certificate based on evaluation conducted on 02-05-2025
	Evidence of approval of manufacturing facility	GMP certificate confirms section approval
	Evaluation Remarks	
	Decision	
	Approved	
685	Case Category	New Section (Najia Saleem)
	Name, address of Applicant.	Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi (000333)
	Application Form Dy. No / Tracking ID & date of submission	(XD7-JSL-2H5R, 2025-09-11)
	Detail of Fee Submitted	38700.0, 2025-08-20,
	The proposed proprietary name / brand name	COLY-S 1MIU Lyophilized Powder for IV Infusion/Injection
	Label Claim	Each Vial contains: Colistimethate Sodium (1MIU) eq. to Colistin Base Activity.....34mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	(1x1's)-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Colistim 1MIU lyophilized powder for IV Infusion/Injection (Pharmasol Private limited. Sundar Industrial Estate, Lahore)
	Pharmacotherapeutic Group of (API)	Polymyxin antibiotic agent
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	108NS02 108NS03 108NS04
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 04-12-2024 is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE data submitted against Colistim of Ms Pharmasol
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	CMS1802001, CMS1802002, CMS1802003
	The status in reference regulatory authorities	Colistimethate 1MIU Injection (Xellia Pharmaceuticals Denmark)
	GMP status of the firm	20 February, 2024
	Evidence of approval of manufacturing facility	28 March, 2025
	Evaluation Remarks	
	Decision	
	Approved	

Case Category		New License (Najia Saleem)
Name, address of Applicant.		Solaris Life Sciences Private Limited , Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992)
Application Form Dy. No / Tracking ID & date of submission		(48B-PRT-M47G, 2025-04-21)
Detail of Fee Submitted		37000.0, 2025-01-24,
The proposed proprietary name / brand name		Solobs 250mg/5ml Oral Suspension
Label Claim		Each 5ml contains: Fosfomycin calcium eq.to Fosfomycin.....250mg (JP Specifications)
Reference to Finished product specifications		Any Other
Proposed Pack Size		As per SRO-As per SRO
Shelf Life (Unit)		2 Year(s)Below 30°C
For generic drugs (me-too Status)		Focin 250mg/5ml Dry Suspension (Tabros Pharmaceuticals)
Pharmacotherapeutic Group of (API)		Antibiotic
Name, address of Manufacturing site:		Self Manufacturing
Name & address of API manufacturer		NORTHEAST PHARMACEUTICA
Detail of stability batches of drug product		3 batches 150 bottles each
Documents for the procurement of API with approval from DRAP (in case of Import)		Fosfomycin Calcium API was borrowed from two different sources as per the details below: 1. Batch No. MCC-2304011, Quantity: 1.0 Kg, borrowed from M/s Biogen Pharma, 8-KM Chakbeli Road, Rawat, Rawalpindi, on 17-04-2024. 2. Batch No. DY0292300229, Quantity: 1.0 Kg, borrowed from M/s Caliph Pharmaceuticals, Plot 17, Special Industrial Zone, Risalpur, KPK, on 12-06-2024. Intimations for both sources have been duly submitted to DRAP. However, supplier of both sources is same i.e. NORTHEAST PHARMACEUTICA China
Pharmaceutical Equivalence and Comparative Dissolution Profile		PE and CDP against Focin Suspension manufactured by Tabros Pharmaceuticals
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		submitted as per zone IV-A
The status in reference regulatory authorities		Fosfocina Suspensión 250mg/5ml (Registered in Spain CIMA Approved)
GMP status of the firm		DML granted on 17-01-2024
Evidence of approval of manufacturing facility		Dry powder suspension General section
Evaluation Remarks		
Sr. No.	Observation	Firm's response
1	The API lot number specified in the submitted CoA, batch analysis (section 3.2.S.4.4) and stability data sheets differs from the one provided in the loan agreement and clearance document. Please provide clarification on this discrepancy.	Fosfomycin Calcium API was borrowed from two different sources as per the details below: 1. Batch No. MCC-2304011, Quantity: 1.0 Kg, borrowed from M/s Biogen Pharma, 8-KM Chakbeli Road, Rawat, Rawalpindi, on 17-04 2024. 2. Batch No. DY0292300229, Quantity: 1.0 Kg, borrowed from M/s Caliph Pharmaceuticals, Plot 17, Special Industrial Zone, Risalpur, KPK, on 12-06-2024. Intimations for both

		sources have been duly submitted to DRAP. Fosfomycin Calcium Batch No. MCC-2304011 from Biogen Pharma was used in the stability batches of SOLOBS 250 mg/5 mL Oral Suspension, as reflected in the Batch Analysis, Certificate of Analysis (CoA), Stability Data, and BMR submitted in the CTD dossier. However, due to an oversight, the borrowing documentation of Batch No. DY0292300229 from M/s Caliph Pharmaceuticals was mistakenly submitted instead.
2	Submit complete utilization record of Fosfomycin Calcium (API) borrowed from both sources	API borrowed from Biogen pharma and Caliph pharma has same source / Manufacturer i.e. Northeast, Pharmaceutical Group co. ltd, No.29 Shexiliu Dong Road, Economic Technological Development District, Shenyang, .P.R (China), as mentioned in the DRAP clearance and COA submitted in CTD.

Decision

Approved

687

Case Category	Routine (Najia Saleem)
Name, address of Applicant.	Nabiqasim Industries (Pvt) Ltd., 17/24, Korangi Industrial Area, Karachi. (000105)
Application Form Dy. No / Tracking ID & date of submission	(EA1-66M-6NPX, 2024-04-29)
Detail of Fee Submitted	150000.0, 2024-04-04,
The proposed proprietary name / brand name	Vesiva-T MR Tablet 6mg / 0.4mg
Label Claim	Each film coated bilayered modified release tablet contains: Solifenacin Succinate Immediate Release.....6mg Tamsulosin Hydrochloride Extended Release 0.4mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	7, 10, 14, 20, 28, 3-As per SRO
Shelf Life (Unit)	2 Year(s) Store below 30°C
For generic drugs (me-too Status)	Yes
Pharmacotherapeutic Group of (API)	alpha-adrenoceptor antagonists
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Solifenacin Succinate Granules 6.0 w/w (ALPHAMED FORMULATIONS PRIVATE LIMITED), Tamsulosin Hydrochloride Granules 0.178% w/w (ALPHAMED FORMULATIONS PRIVATE LIMITED)
Detail of stability batches of drug product	06 months accelerated and 06 months real time stability data submitted for two batches of 5000 tablets each

Documents for the procurement of API with approval from DRAP (in case of Import)	Invoices, import license and ADC clearance certificates submitted
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP data submitted against Tamsolin-S 0.4/6mg tablet of Ms Getz Pharma (Batch No. 065FB9)
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 24 months real time stability data submitted for both APIs
The status in reference regulatory authorities	EMA Approved [Vesomni 6 mg/0.4 mg modified-release tablets (Solifenacin Succinate + Tamsulosin
GMP status of the firm	GMP certificate based on evaluation conducted on 22-05-2023
Evidence of approval of manufacturing facility	section approval letter and GMP certificate submitted

Evaluation Remarks

Sr. No.	Observations	Firm's response
1	Submitted drug substance specification Tamsulosin granules does not include test of dissolution hence it's not evident that the Tamsulosin granules are modified release or otherwise, justify.	The firm has submitted declaration letter from Drug Substance Manufacturer stating that "With reference to supply of Tamsulosin HCl granules 0.178%, our specification doesn't include a dissolution test, as we are supplying ready to compress granules not finished products which require further processing at customers end before performing the dissolution test" Furthermore, Dissolution profile of the granules established at FPP stage for Tamsulosin, which are modified release and evident from time intervals in Dissolution for Tamsulosin stated in the product testing method.
2	Submitted COAs from both drug substance and drug product manufacturer also does not verify the release profile of Tamsulosin granules as "modified release".	COA of API from both drug substance and drug product are submitted again.

Decision

Approved

688	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	Fizi Pharmaceuticals & Laboratories 8Km raiwind road lahore (000732)
	Application Form Dy. No / Tracking ID & date of submission	(S7S-Z4W-DZRA, 2025-07-18)
	Detail of Fee Submitted	37000.0, 2025-07-17,
	The proposed proprietary name / brand name	Fizimet Forte or Fiziozyme or fizicore Injection 250ml
	Label Claim	Each 100ml Contains: L-Carnitine HCl eq to L-carnitine...500mg thioctic acid...20mg Pyridoxine HCl..15mg Cyanocobalamin..3mg DL-

		acetylmethionine...2000mg L-arginine...240mg L-ornithine HCl eq. to L-ornithine...120mg L-Citrulline ..120mg L-lysine HCl..62.5mg Glycine....150mg Taurine...150mg Aspartic Acid....150mg Glutamic Acid...150mg Fructose...5000mg Sorbitol...8000mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	250ml De-Controlled-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30 Degree Celsius
	For generic drugs (me-too Status)	Metalize Forte Injection. M/S Eterna Pharma (Pvt).Ltd Registration No: 113547 &DML 000923
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Attached
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
689	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Pivotal pharmaceuticals (Pvt) Ltd. Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi (001006)
	Application Form Dy. No / Tracking ID & date of submission	(VHD-WMT-5521, 2025-06-27)
	Detail of Fee Submitted	37000.0, 2025-05-26,
	The proposed proprietary name / brand name	Doxytal 20/40 Oral Powder
	Label Claim	Each 1 kg Contains: Tylosin Tartrate.....20 % Doxycycline HCl 40 %
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1000gm-De-Controlled,100gm-De-Controlled,15kg-De-Controlled,20kg-De-Controlled,250gm-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,50gm-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Tydoxin Forte Powder, Reg# 101490, M/S. SELMORE PHARMACEUTICALS (PVT)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Grant of DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
690	Case Category	New License (Sabahat Zehra)

Name, address of Applicant.	Pivotal pharmaceuticals (Pvt) Ltd. Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi (001006)
Application Form Dy. No / Tracking ID & date of submission	(M2P-2G2-HU1G, 2025-07-27)
Detail of Fee Submitted	37000.0, 2025-07-21,
The proposed proprietary name / brand name	TYLOVALO Granules
Label Claim	Each gm. Contains:Acetyl Isovaleryl Tylosin Tartrate.....50 mg
Reference to Finished product specifications	Manufacturer Specification
Proposed Pack Size	100gm-De-Controlled,10gm-De-Controlled,15kg-De-Controlled,1kg-De-Controlled,20gm-De-Controlled,20kg-De-Controlled,250gm-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,50gm-De-Controlled
Shelf Life (Unit)	2 Year(s)Room Temperature
For generic drugs (me-too Status)	TYLVOTART Soluble Granules Reg#106755
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	Grant of DML
Evidence of approval of manufacturing facility	

Evaluation Remarks

Decision

Approved

691	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Pivotal pharmaceuticals (Pvt) Ltd. Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi (001006)
	Application Form Dy. No / Tracking ID & date of submission	(E3H-NU2-36MJ, 2025-07-27)
	Detail of Fee Submitted	37000.0, 2025-07-21,
	The proposed proprietary name / brand name	TYLOVALO FORTE GRANULES
	Label Claim	Each gm Contains:Acetyl Isovaleryl Tylosin Tartrate..... 850mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	100gm-De-Controlled,10gm-De-Controlled,15kg-De-Controlled,1kg-De-Controlled,20gm-De-Controlled,20kg-De-Controlled,250gm-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,50gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	TYLVOTART Soluble Granules Reg#03939 of Grand pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Grant of DML
	Evidence of approval of manufacturing facility	

	Evaluation Remarks	
	Decision	
692	Approved	
	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Pivotal pharmaceuticals (Pvt) Ltd. Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi (001006)
	Application Form Dy. No / Tracking ID & date of submission	(N9L-8AD-T3BU, 2025-06-27)
	Detail of Fee Submitted	37000.0, 2025-06-23,
	The proposed proprietary name / brand name	Fosfo Skil Powder
	Label Claim	Each 100 gm. Contains:Fosfomycin calcium.....20 gm.Tylosin Tartrate.....5 gm.Fructose 1, 6 diphosphate ...18 gm.Sodium Phosphate.....15 gm.Magnesium Phosphate.....10 gm.
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1000gm-De-Controlled,100gm -De-Controlled,10gm-De-Controlled,15kg-De-Controlled,20gm-De-Controlled,20kg-De-Controlled,250gm-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,50gm-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Rold Fos Forte W/s Powder Reg No: 109283 by Haarolds Pharmaceuticals (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Grant of DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
693	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Pivotal pharmaceuticals (Pvt) Ltd. Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi (001006)
	Application Form Dy. No / Tracking ID & date of submission	(ABA-TNH-N5BQ, 2025-06-27)
	Detail of Fee Submitted	37000.0, 2025-05-26,
	The proposed proprietary name / brand name	Di-Gest Powder
	Label Claim	Each gm contains: ACETANILIDE.....150 mg. Propionic Acid Calcium....250 mg. MAGNESIUM OXIDE....125 mg. Propionic Acid Sodium.....400 mg. IRON II SULPHATE 0.40 mg. COBALT SULPHATE.....0.40 mg. ZINC SULPHATE 0.10

	mg. SODIUM MOLYBDATE.....0.10 mg. MAGNESIUM SULPHATE0...0.20 mg. SODIUM CHLORIDE.....20.00 mg. COPPER SULPHATE... 0.45 mg.
Reference to Finished product specifications	Manufacturers Specification
Proposed Pack Size	1000gm-De-Controlled,100gm-De-Controlled,10gm-De-Controlled,10kg-De-Controlled,15kg-De-Controlled,20kg-De-Controlled,250gm-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,50gm-De-Controlled,5kg-De-Controlled
Shelf Life (Unit)	2 YearRoom Temperature
For generic drugs (me-too Status)	Gestone Powder (Reg. # 044911)
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	Grant of DML
Evidence of approval of manufacturing facility	

Evaluation Remarks

Decision

Approved

694

Case Category	New License (Sabahat Zehra)
Name, address of Applicant.	Pivotal pharmaceuticals (Pvt) Ltd. Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi (001006)
Application Form Dy. No / Tracking ID & date of submission	(7EB-T9G-PR5R, 2025-06-26)
Detail of Fee Submitted	37000.0, 2025-05-26,
The proposed proprietary name / brand name	D-Ox 2.265% Oral Liquid
Label Claim	Each 1 L Contains: Oxfendazole (BP Vet) 22.65 gm. /1000ml
Reference to Finished product specifications	Manufacturer Specification
Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,120ml-De-Controlled,2.5 Litter-De-Controlled,20 Litter-De-Controlled,25 Litter-De-Controlled,250ml-De-Controlled,30ml-De-Controlled,5 Litter-De-Controlled,500ml-De-Controlled,60ml-De-Controlled
Shelf Life (Unit)	2 Year(s)Room Temperature
For generic drugs (me-too Status)	SYSTAMEX DRENCH reg#014182
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	Grant of DML
Evidence of approval of manufacturing facility	

Evaluation Remarks

Decision

Approved

695	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Pivotal pharmaceuticals (Pvt) Ltd. Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi (001006)
	Application Form Dy. No / Tracking ID & date of submission	(96X-QB5-8W4H, 2025-06-26)
	Detail of Fee Submitted	37000.0, 38700.0 2025-05-26, 2025-08-12
	The proposed proprietary name / brand name	Hi-Care Oral Liquid
	Label Claim	Each ml contains: L-CARNITINE (BP).....50 mg BETAINE HCI (USP).....20 mg INOSITOL (BP).....7 mg CHOLINE CHLORIDE (BP).....100 mg SORBITOL (BP).....200 mg MAGNESIUM SULPHATE (BP).....10 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,120ml-De-Controlled,2.5 Litter-De-Controlled,20 Litter-De-Controlled,25 Litter-De-Controlled,30ml-De-Controlled,5 Litter-De-Controlled,500ml-De-Controlled,60ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Hepawin Liquid Reg# 089857
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Grant of DML
	Evidence of approval of manufacturing facility	
696	Evaluation Remarks	
	Decision	
	Approved	
	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Pivotal pharmaceuticals (Pvt) Ltd. Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi (001006)
	Application Form Dy. No / Tracking ID & date of submission	(DJ6-PJ9-M2B9, 2025-07-08)
	Detail of Fee Submitted	37000.0, 2025-05-26,
	The proposed proprietary name / brand name	Enrotal 10 % Oral Liquid
696	Label Claim	Each 1 L Contains: ENROFLOXACIN 10% w/v (100 mg/ml)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,120ml-De-Controlled,2.5 Litter-De-Controlled,20 Litter-De-Controlled,25 Litter-De-Controlled,250ml-De-Controlled,30ml-De-Controlled,5 Litter-De-Controlled,500ml-De-Controlled,60ml-De-Controlled
	Shelf Life (Unit)	2 YearRoom Temperature

	For generic drugs (me-too Status)	ENRONOOR Oral Liquid
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Grant of DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
697	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Pivotal pharmaceuticals (Pvt) Ltd. Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi (001006)
	Application Form Dy. No / Tracking ID & date of submission	(65J-T4W-48SX, 2025-07-06)
	Detail of Fee Submitted	37000.0, 2025-05-26,
	The proposed proprietary name / brand name	Cinflex 10/50 Oral Liquid
	Label Claim	Each 1 L Contains:ENROFLOXACIN ...100 mg/mlCOLISTIN SULPHATE... 50 MIU/ml
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,120ml-De-Controlled,2.5 Litter-De-Controlled,20 Litter-De-Controlled,25 Litter-De-Controlled,250ml-De-Controlled,30ml-De-Controlled,5 Litter-De-Controlled,500ml-De-Controlled,60ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	ACMECOLIFLOX 10-50 Oral Liquid Reg#122649
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Grant of DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
698	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Pivotal pharmaceuticals (Pvt) Ltd. Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi (001006)
	Application Form Dy. No / Tracking ID & date of submission	(69N-WQH-TY7U, 2025-07-08)
	Detail of Fee Submitted	37000.0, 2025-05-26,
	The proposed proprietary name / brand name	Enrotal Oral Liquid
	Label Claim	Each 1 L Contains: ENROFLOXACIN 20% w/v (200 mg/ml)

	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,120ml-De-Controlled,2.5 Litter-De-Controlled,20 Litter-De-Controlled,25 Litter-De-Controlled,250ml-De-Controlled,30ml-De-Controlled,5 Litter-De-Controlled,500ml-De-Controlled,60ml-De-Controlled
	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	ENRONOOR Oral Liquid
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Grant of DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
699	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Pivotal pharmaceuticals (Pvt) Ltd. Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi (001006)
	Application Form Dy. No / Tracking ID & date of submission	(MZB-3SZ-SWY1, 2025-07-08)
	Detail of Fee Submitted	37000.0, 2025-05-26,
	The proposed proprietary name / brand name	Triout Oral Liquid
	Label Claim	Each 100 ml contains Trimethoprim.....8%, Sulphadiazine.....40%.
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,120ml-De-Controlled,2.5 Litter-De-Controlled,20 Litter-De-Controlled,25 Litter-De-Controlled,250ml-De-Controlled,30ml-De-Controlled,5 Litter-De-Controlled,500ml-De-Controlled,60ml-De-Controlled
	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	Sulfatrim Suspension (Reg. # 020137)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Grant of DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
700	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Pivotal pharmaceuticals (Pvt) Ltd. Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi (001006)

Application Form Dy. No / Tracking ID & date of submission	(TWW-PW5-RTLT, 2025-08-12)
Detail of Fee Submitted	38700.0, 2025-08-12,
The proposed proprietary name / brand name	GUMBO FIX POWDER
Label Claim	Each 100 gm. Contains: Nicotinamide.....0.32 gm. Menadione Bisulfite.....0.115 gm. Potassium Citrate.....18.0 gm. Sodium Citrate.....12.0 gm. Vitamin B1.....0.03 gm. Vitamin B2.....0.015 gm. Vitamin C.....1.10 gm.
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1000gm-De-Controlled,100gm-De-Controlled,10gm-De-Controlled,15kg-De-Controlled,20gm-De-Controlled,20kg-De-Controlled,250gm-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,50gm-De-Controlled,5kg-De-Controlled
Shelf Life (Unit)	2 YearRoom Temperature
For generic drugs (me-too Status)	ANTI GUMBO Powder (Reg. # 046581) M/S Leads Pharma
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	Grant of DML
Evidence of approval of manufacturing facility	

Evaluation Remarks

Product contain menadione (vitamin K3) as ingredient.

Decision

Approved

701	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Pivotal pharmaceuticals (Pvt) Ltd. Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi (001006)
	Application Form Dy. No / Tracking ID & date of submission	(WV6-VLW-GVDW, 2025-07-31)
	Detail of Fee Submitted	37000.0, 2025-07-31,
	The proposed proprietary name / brand name	TYLCONOR ORAL SOLUTION
	Label Claim	Each 100 ml Contains: Norfloxacin 10 % Tylosin Tartrate.....5 % Colistin Sulphate.....250 MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Litter-De-Controlled,100ml-De-Controlled,2.5 Litter-De-Controlled,20 Litter-De-Controlled,20ml-De-Controlled,25 Litter-De-Controlled,250ml-De-Controlled,5 Litter-De-Controlled,500ml-De-Controlled,50ml-De-Controlled
	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	Norcotyl Oral Solution (Reg No. 071021) BioGen Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site;	--

	GMP status of the firm	Grant of DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
702	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Pivotal pharmaceuticals (Pvt) Ltd. Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi (001006)
	Application Form Dy. No / Tracking ID & date of submission	(MT5-YHB-68P6, 2025-06-27)
	Detail of Fee Submitted	37000.0, 2025-05-26,
	The proposed proprietary name / brand name	Neoxytal Forte Oral Powder
	Label Claim	Each kg Contains: Florfenicol.....100 gm. Neomycin Sulphate.....150 gm. Oxytetracycline HCl.....300 gm.
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1000gm-De-Controlled,100gm-De-Controlled,15kg-De-Controlled,20kg-De-Controlled,250gm-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,50gm-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	FENOX PLUS Oral Powder
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Grant of DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
703	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Pivotal pharmaceuticals (Pvt) Ltd. Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi (001006)
	Application Form Dy. No / Tracking ID & date of submission	(UUM-L4M-1NJ8, 2025-06-27)
	Detail of Fee Submitted	37000.0, 2025-05-26,
	The proposed proprietary name / brand name	HTM-Ultra Oral Powder
	Label Claim	Each 1 kg Contains:Hexamethylenetetramine.....95.5 gm.(Methenamine)Riboflavin.....1.0 gm.Calcium Pantothenate.....0.5 gm.Nicotinamide.....2.5 gm.
	Reference to Finished product specifications	Manufacturer Specification

	Proposed Pack Size	1000gm -De-Controlled,100gm-De-Controlled,15kg-De-Controlled,20kg-De-Controlled,250gm-De-Controlled,25kg-De-Controlled,500gm -De-Controlled,50gm-De-Controlled,5kg -De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	ARENAL Powder Reg#035197
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Grant of DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
704	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Pivotal pharmaceuticals (Pvt) Ltd. Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi (001006)
	Application Form Dy. No / Tracking ID & date of submission	(QRQ-RBQ-VDU4, 2025-06-27)
	Detail of Fee Submitted	37000.0, 2025-06-23,
	The proposed proprietary name / brand name	Fosfo Skil Fort Powder
	Label Claim	Each 100 gm. Contains:Fosfomycin calcium.....20 gm.Tylosin Tartrate.....10 gm.Fructose 1, 6 diphosphate ...18 gm.Sodium Phosphate.....15 gm.Magnesium sulphate.....10 gm.
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1000gm-De-Controlled,100gm-De-Controlled,10gm-De-Controlled,15kg-De-Controlled,20gm-De-Controlled,20kg-De-Controlled,250gm-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,50gm-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	FOSOMAX Powder (Reg. # 063808)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Grant of DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
705	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	ACME PHARMACEUTICALS Plot No. 29, Street SS-2, RCCI Industrial Estate Rawat (000967)

Application Form Dy. No / Tracking ID & date of submission	(ZPP-HZY-ABMJ, 2025-01-15)
Detail of Fee Submitted	37000.0, 2025-01-13,
The proposed proprietary name / brand name	VITATOL 32 MILES SOLUTION
Label Claim	For Submission of Specimen of Label For Registration of Veterinary Drug Namely; "Vititol 32 Miles Solution" Brand of "Toltrazuril 25mg, Vitamin A 2.5mg, Vitamin K3 5mg" (Each ml contains)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	50ml, 100ml, 200ml, -De-Controlled
Shelf Life (Unit)	2 Yearstorage at room temperature
For generic drugs (me-too Status)	Available
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	Good Level
Evidence of approval of manufacturing facility	

Evaluation Remarks

Decision

Approved

706	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Pivotal pharmaceuticals (Pvt) Ltd. Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi (001006)
	Application Form Dy. No / Tracking ID & date of submission	(ES3-D6X-6USL, 2025-07-09)
	Detail of Fee Submitted	37000.0, 2025-05-26,
	The proposed proprietary name / brand name	Neotal72% Oral Powder
	Label Claim	Each 1 kg Contains: NEOMYCIN SULPHATE 72% w/w.....720 gm. /1000gm.
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	100gm-De-Controlled,10gm-De-Controlled,15kg-De-Controlled,1kg-De-Controlled,20gm-De-Controlled,20kg-De-Controlled,250gm-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,50gm-De-Controlled,5gm-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	NEOMYCIN 720 Oral Water Soluble Powder (Reg. # 053945)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Grant of DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

Approved

707	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Majestic Pharma plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad (000873)
	Application Form Dy. No / Tracking ID & date of submission	(GBS-LME-Q2VN, 2025-01-27)
	Detail of Fee Submitted	37000.0, 2025-01-25,
	The proposed proprietary name / brand name	MAJICOL-50 ORAL WATER SOLUBLE POWDER
	Label Claim	Each 100gm contains: Colistin Sulphate..... 500,000,000 IU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000gm-De-Controlled,100gm-De-Controlled,250gm-De-Controlled,5000gm-De-Controlled,500gm-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temperature and avoid from heat and sunlight.
	For generic drugs (me-too Status)	Colibect Water Soluble Powder (075791) (
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
708	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Majestic Pharma plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad (000873)
	Application Form Dy. No / Tracking ID & date of submission	(T7U-URR-NE4V, 2025-01-27)
	Detail of Fee Submitted	37000.0, 2025-01-25,
	The proposed proprietary name / brand name	COLIMAJ-20 ORAL LIQUID
	Label Claim	Each 1000ml contains: Colistin Sulphate ----- 2,000,000,000 IU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 Lit-De-Controlled,1000ml-De-Controlled,100ml-De-Controlled,250ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temperature and avoid from heat and sunlight.
	For generic drugs (me-too Status)	Colibar Oral Liquid (075784)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--

	GMP status of the firm	Satisfactory level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
709	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Amarant Pharmaceuticals Private Limited 158 D. Tore, Gadap Road, Super Highway, Karachi (000584)
	Application Form Dy. No / Tracking ID & date of submission	(VB2-U6H-EJ8N, 2024-09-06)
	Detail of Fee Submitted	30000.0, 2024-08-23,
	The proposed proprietary name / brand name	Frusalex Lite Water Soluable Powder
	Label Claim	Frusalex Lite Water Soluable Powder Each 1000gm contains : Furosemide (B.P)....20gm Potassium Chloride (USP) ...4.0gm Calcium Carbonate (BP).....45gm Magnesium Sulphate (USP).....1gm Product complies with Manufacturer's Specification
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1kg ,5kg-De-Controlled
	Shelf Life (Unit)	2 Yearbelow 25°C or 30°C
	For generic drugs (me-too Status)	FUROSEBAR Water Soluble Powder
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
710	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Evergreen Pharmaceutical 69/70-B, Glaxo Town Industrial Estate.(Opposite Annam Weaving Mills) 20-Km Ferozpur Road, Lahore. (000736)
	Application Form Dy. No / Tracking ID & date of submission	(SG3-V62-3DWG, 2025-01-31)
	Detail of Fee Submitted	37000.0, 2025-01-30,
	The proposed proprietary name / brand name	OZOLE DRENCH
	Label Claim	Each ml contains: Oxfendazole 22.65 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100 ML-De-Controlled,1000 ML-De-Controlled,250 ML-De-Controlled,500 ML-De-Controlled,5000 ML-De-Controlled

Shelf Life (Unit)	2 Year(s)Store below 25 degree in a cool & dry place.
For generic drugs (me-too Status)	Oxamex 2.265% Reg# 078388 Suspension by Hawk Bio Pharma (Pvt.) Ltd., Islamabad
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	Firm is operating at satisfactory level of GMP Compliance at the time of inspection.
Evidence of approval of manufacturing facility	

Evaluation Remarks

Decision

Approved

711	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Evergreen Pharmaceutical 69/70-B, Glaxo Town Industrial Estate.(Opposite Annam Weaving Mills) 20-Km Ferozpur Road, Lahore. (000736)
	Application Form Dy. No / Tracking ID & date of submission	(HJQ-H5L-4QRU, 2025-01-31)
	Detail of Fee Submitted	37000.0, 2025-01-30,
	The proposed proprietary name / brand name	TRACLA PLUS DRENCH
	Label Claim	Each ml contains: Triclabendazole 50 mg Levamisole HCl 37.5 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML-De-Controlled,1000 ML-De-Controlled,250 ML-De-Controlled,500 ML-De-Controlled,5000 ML-De-Controlled
	Shelf Life (Unit)	2 YearStore below 25 degree in a cool & dry place.
	For generic drugs (me-too Status)	Endoex 8.75% Liquid by Hawk Bio Pharma (Pvt.) Ltd., Islamabad
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm is operating at satisfactory level of GMP Compliance at the time of inspection.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
712	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Evergreen Pharmaceutical 69/70-B, Glaxo Town Industrial Estate.(Opposite Annam Weaving Mills) 20-Km Ferozpur Road, Lahore. (000736)
	Application Form Dy. No / Tracking ID & date of submission	(B3R-EAT-WZZT, 2025-01-31)

Detail of Fee Submitted	37000.0, 2025-01-30,
The proposed proprietary name / brand name	MEZOLE PLUS DRENCH
Label Claim	Each ml contains: Oxyclozanide 30 mg Levamisole HCl 15 mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	100 ML-De-Controlled,1000 ML-De-Controlled,250 ML-De-Controlled,2500 ML-De-Controlled,500 ML-De-Controlled,5000 ML-De-Controlled
Shelf Life (Unit)	2 Year(s)Store below 25 degree in a cool & dry place.
For generic drugs (me-too Status)	Solozan Suspension Reg#078390
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	Firm is operating at satisfactory level of GMP Compliance at the time of inspection.
Evidence of approval of manufacturing facility	

Evaluation Remarks

Decision

Approved

713	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Majestic Pharma plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad (000873)
	Application Form Dy. No / Tracking ID & date of submission	(3GT-7Y8-9YT9, 2025-01-29)
	Detail of Fee Submitted	37000.0, 2025-01-28,
	The proposed proprietary name / brand name	MEGATONE ORAL WATER SOLUBLE POWDER
	Label Claim	Each 1000gm contain: Calcium propionate 201gm Sodium propionate.....402.7gm Magnesium Sulphate.....124gm Iron Sulphate.....0.41gm Sodium chloride.....264.3gm Vitamin A.....750000IU Vitamin D3 350000IU Zinc Sulphate.....0.11gm Manganese Sulphate.....0.21gm Copper Sulphate.....0.45gm Cobalt chloride.....0.41gm Sodium selenite.....0.11gm Di-calcium phosphate.....3000mg Vitamin E.....1000mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000gm-De-Controlled,100gm-De-Controlled,250gm-De-Controlled,5000gm-De-Controlled,500gm-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temperature and avoid from heat and sunlight.

	For generic drugs (me-too Status)	Sanatone Water Soluble Oral Powder (035128)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
714	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	POULVET PHARMACEUTICAL (PVT) LTD 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN (000970)
	Application Form Dy. No / Tracking ID & date of submission	(ZBW-X65-88MN, 2025-01-13)
	Detail of Fee Submitted	37000.0, 2024-12-17,
	The proposed proprietary name / brand name	Poul Flox-30 Water Soluble Powder
	Label Claim	Each gm contains Florfenicol - 150mg Oxytetracycline HCl - 150mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10gm, 100gm, 250gm, -De-Controlled
	Shelf Life (Unit)	2 YearAT ROOM TEMPERATURE
	For generic drugs (me-too Status)	Floxybar-30 Water Soluble Powder of Baariq Pharmaceuticals (Reg#072601)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR,DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG,DRAP,LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
715	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	POULVET PHARMACEUTICAL (PVT) LTD 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN (000970)
	Application Form Dy. No / Tracking ID & date of submission	(UXM-AZW-SYZQ, 2025-01-13)

Detail of Fee Submitted	37000.0, 2024-12-17,
The proposed proprietary name / brand name	POUL ENHANCER ORAL SOLUTION
Label Claim	EACH LITER CONTAINS VITAMIN A- 4000000IU VITAMIN D3-800000IU VITAMINE-1600MG VITAMIN B1-2000MG VITAMIN B2-1000MG VITAMIN B6-1000MG VITAMIN B12-1000MCG VITAMIN C-1000MG VITAMIN K3-1000MG CALCIUM PANTOTHENATE-5000MG NICOTINAMIDE-5000MG FOLIC ACID-100MG DL- METHINONIN-10000MG CHOLINE CHLORIDE- 50000MG LYCINE HCl-1000MG BIOTIN-25MG
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	100ml, 150ml, 250ml,-De-Controlled
Shelf Life (Unit)	2 YearAT ROOM TEMPERATURE
For generic drugs (me-too Status)	ENERGIZER ORAL SOLUTION OF BIOGEN PHARMACEUTICALS (REG#063814)
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	INSPECTION WAS CONDUCTED ON DATED 09-09- 2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR,DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG,DRAP,LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT)
Evidence of approval of manufacturing facility	

Evaluation Remarks

Decision

Approved

716	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	POULVET PHARMACEUTICAL (PVT) LTD 0.5- KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN (000970)
	Application Form Dy. No / Tracking ID & date of submission	(L7V-BZR-U1YU, 2025-01-13)
	Detail of Fee Submitted	37000.0, 2024-12-17,
	The proposed proprietary name / brand name	Fasfo Poul Oral Powder
	Label Claim	Each 100 gm contains fosfomycin calcium - 20gm Tylosin Tartrate - 5gm Fructose 1,6 di-phosphate -18gm Sodium Phosphate - 15gm Magnesium Phosphate - 10gm Sodium Chloride (qs) - 100gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm, 250gm, 500gm,-De-Controlled
	Shelf Life (Unit)	2 Year(s)AT ROOM TEMPERATURE
	For generic drugs (me-too Status)	Fofact powder reg#075626 UNIVET pharma
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	--
	GMP status of the firm	INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR, DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG, DRAP, LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
717	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Majestic Pharma plot # 21, Phase 1A, M-3 Industrial state Sahianwala Faisalabad (000873)
	Application Form Dy. No / Tracking ID & date of submission	(6LS-UWN-QW2Q, 2025-02-15)
	Detail of Fee Submitted	37000.0, 2025-02-14,
	The proposed proprietary name / brand name	MAJICHLOR-CNS ORAL WATER SOLUBLE POWDER
	Label Claim	Each gm contains: Chlortetracycline HCl 200 mg Neomycin Sulphate 60 mg Colistin Sulphate 10 mg Streptomycin Sulphate 20 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000gm-De-Controlled, 100gm-De-Controlled, 250gm-De-Controlled, 5000gm-De-Controlled, 500gm-De-Controlled
	Shelf Life (Unit)	2 Year Store at room temperature and avoid from heat and sunlight.
	For generic drugs (me-too Status)	Streptochlor Water Soluble Powder (080738)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Formulation contain four antibiotics.	
	Decision	
	Deferred	
	The sub-committee on veterinary drugs recommended that, for applicants who have already been granted registration for 4 antibiotics combination products, a meeting should be conducted with stakeholders to standardize or regularize the approved formulation in line with international practices. They should be advised to provide valid international references in support of their product, if available.	
718	Case Category	Routine (Sabahat Zehra)

Name, address of Applicant.	Majestic Pharma plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad (000873)
Application Form Dy. No / Tracking ID & date of submission	(DVA-S9N-MTQB, 2025-02-15)
Detail of Fee Submitted	37000.0, 2025-02-14,
The proposed proprietary name / brand name	VERMOPLEX-M ORAL SUSPENSION
Label Claim	Composition: Levamisole HCl ----- 1.5% w/v Oxyclozanide ----- 3.0% w/v Sodium Selenite ----- 0.035% w/v Cobalt Chloride ----- 0.075% w/v
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	10 Lit-De-Controlled,1000ml-De-Controlled,100ml-De-Controlled,250ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled
Shelf Life (Unit)	2 YearStore at room temperature and avoid from heat and sunlight.
For generic drugs (me-too Status)	Vety-Vermicide Oral Liquid (019937)
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	Satisfactory level of GMP Compliance
Evidence of approval of manufacturing facility	

Evaluation Remarks

Decision

Approved

719	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(1J7-7DR-A7J3, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Closole suspension
	Label Claim	Each ml contains Levamisole as HCl 100mg Closantel 100mg (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1 litre-De-Controlled,100 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	closavet suspension (Santex pharma)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	

Evaluation Remarks

Closole suspension already registered on Reg# 062140

	Decision	
	Approved	
	Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.	
720	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(1NZ-AHY-BJ6R, 2025-09-13)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Genta 10 super injection
	Label Claim	Each 100ml contains Gentamycin sulphate 10gm (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	50 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Genta Shell 10% Injection(Inshal pharmaceutical Industries)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
721	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(31P-NSM-PT2D, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	Oxy gold injection
	Label Claim	Each ml contains Oxytetracycline HCl (BP) 50mg (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	50 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Terrasym-50 Injection (Symans pharma)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory

	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	OXY GOLD INJECTION 50ml already registered on Reg# 053901	
	Decision	
	Approved	
	Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.	
722	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(33V-ASE-8HWZ, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	Oxy gold injection
	Label Claim	Each ml contains Oxytetracycline HCl (BP) 50mg (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	100 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Terrasym-50 Injection (Symans pharma)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	OXY GOLD INJECTION 100ml already registered on Reg# 053901	
	Decision	
	Approved	
	Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.	
723	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(3LJ-SE4-GGUQ, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Enrobak 10 oral solution
	Label Claim	Each 100ml contains Enrofloxacin 10gm (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1 litre-De-Controlled,100 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture

	For generic drugs (me-too Status)	Enrosym oral solution (Symens company)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	ENROBAK 10 ORAL SOLUTION already registered on Reg # 034541	
	Decision	
	Approved	
	Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.	
724	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(3LZ-7J4-4L4N, 2025-09-13)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	Frusatin w/s powder
	Label Claim	Each 1000gm contains Furosemide 25gm (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1 kg-De-Controlled,10 kg-De-Controlled,100 gm-De-Controlled,25 kg-De-Controlled,250 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Lasics w/s Powder (ICI Pakistan)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Frusatin w/s powder already registered on Reg# 058912	
	Decision	
	Approved	
	Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.	
725	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(419-2AT-51WH, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	Colistin 60 injection

	Label Claim	Each 100ml contains Colistin sulphate (B.P VET) 60MIU (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	50 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Colistan Forte Injection (Leads pharma)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	COLISTIN 60 INJECTION already registered on Reg # 053907	
	Decision	
	Approved	
	Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.	
726	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(3QL-VPP-9H8S, 2025-09-13)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	Tylobid w/s powder
	Label Claim	Each 1000gm contains Doxycycline HCl 400gm Tylosin tartrate 200gm Bromhexine HCl 10gm (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1 kg-De-Controlled,10 kg-De-Controlled,100 gm-De- Controlled,25 kg-De-Controlled,250 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Tyloxox-Brom w/s Powder (Vetline pvt ltd)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
727	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)

Application Form Dy. No / Tracking ID & date of submission	(4NZ-322-TWNU, 2025-09-12)
Detail of Fee Submitted	38700, 2025-09-11,
The proposed proprietary name / brand name	Levaser CS Liquid
Label Claim	Each 100ml contains Levamisole HCl 1.5gm Cobalt sulphate 0.382gm Sodium selenite 0.030gm (Manufacturer's Specification)
Reference to Finished product specifications	Manufacturers Specification
Proposed Pack Size	1 litre-De-Controlled,100 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,500 ml-De-Controlled
Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
For generic drugs (me-too Status)	Levamax-c (Bimeda Pakistan)
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	Satisfactory
Evidence of approval of manufacturing facility	
Evaluation Remarks	
Levaser CS Liquid already registered on Reg# 058884	
Decision	
Approved	
Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.	
Case Category	New License (Sabahat Zehra)
Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
Application Form Dy. No / Tracking ID & date of submission	(53X-2P5-SRM1, 2025-09-12)
Detail of Fee Submitted	38700, 2025-09-11,
The proposed proprietary name / brand name	Albak C Suspension
Label Claim	Each 100ml contains Albendazole (BP)..... 2.5gm Cobalt chloride (BP) ... 0.075gm (BP Vet Specification)
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	1 litre-De-Controlled,100 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,500 ml-De-Controlled
Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
For generic drugs (me-too Status)	Albenda cs suspension (biolab)
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	Satisfactory
Evidence of approval of manufacturing facility	
Evaluation Remarks	
Albak C Suspension already registered on Reg# 053910	
Decision	
Approved	
Minister of Health, Government of Punjab, Pakistan (2025-09-12)	

729	Case Category Name, address of Applicant. Application Form Dy. No / Tracking ID & date of submission Detail of Fee Submitted The proposed proprietary name / brand name Label Claim Reference to Finished product specifications Proposed Pack Size Shelf Life (Unit) For generic drugs (me-too Status) Pharmacotherapeutic Group of (API) Name, address of Manufacturing site: GMP status of the firm Evidence of approval of manufacturing facility Evaluation Remarks Decision Approved	New License (Sabahat Zehra) Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552) (56S-JWD-Z96U, 2025-09-12) 38700, 2025-09-11, BROCONOR LIQUID Each 100ml contains Norfloxacin 20gm Colistin sulphate 60MIU Bromhexine HCl 0.5gm (Manufacturer's Specification) Manufacturers Specification 1 litre-De-Controlled,100 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,500 ml-De-Controlled 2 Yearstore at controlled room temperature.protect from heat,light and ,moisture Floxicol-B Liquid (Biogen Pharma) -- Satisfactory
730	Case Category Name, address of Applicant. Application Form Dy. No / Tracking ID & date of submission Detail of Fee Submitted The proposed proprietary name / brand name Label Claim Reference to Finished product specifications Proposed Pack Size Shelf Life (Unit) For generic drugs (me-too Status) Pharmacotherapeutic Group of (API) Name, address of Manufacturing site: GMP status of the firm Evidence of approval of manufacturing facility Evaluation Remarks	New License (Sabahat Zehra) Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552) (59Q-A31-6MPX, 2025-09-12) 38700, 2025-09-11, Oxfa K Suspension Each 100ml contains Oxfendazole (B.P VET) 2.265% Vitamin K 0.5% (Manufacturer's Specification) Manufacturers Specification 1 litre-De-Controlled,100 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,500 ml-De-Controlled 2 Yearstore at controlled room temperature.protect from heat,light and ,moisture oxy cob drench (MedHouse) -- Satisfactory

Decision**Approved**

Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.

731	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(5HS-RWA-32NW, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	CRD KILL INJECTION
	Label Claim	Each ml contains Tylosin Tartrate 50mg Colistin sulphate 10mg DihydroStreptomycin 100mg (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	50 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Gentafate Injection (inshal pharmaceutical Industries)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
732	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(5UE-J8Y-R81S, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	LOXIBAK 10% injection
	Label Claim	Each ml contains Meloxicam 10mg (B.P VET Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	50 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Meloxishell Injection (Inshal pharmaceutical Industries)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--

	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	LOXIBAK 10% injection already registered on Reg# 062155	
	Decision	
	Approved	
733	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(6AG-475-N69L, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Piperapure-1000 powder
	Label Claim	Each gm contains Piperazine Citrate 1000mg (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1 kg-De-Controlled,100 gm-De-Controlled,25 gm-De-Controlled,25 kg-De-Controlled,250 gm-De-Controlled,5 kg-De-Controlled,50 gm-De-Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Pipa-vet (hi-gro pharma)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	PIPERAPURE 1000 Powder alredy registered on Reg# 034530	
	Decision	
	Approved	
	Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.	
734	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(6LE-9E6-XP7W, 2025-09-13)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Ivobak C injection
	Label Claim	Each ml contains Ivermectin (B.P) 10mg Clorsulon 100mg (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	50 ml-De-Controlled

Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
For generic drugs (me-too Status)	Ivotek super injection (star laboratories)
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	Satisfactory
Evidence of approval of manufacturing facility	

Evaluation Remarks

Ivobak C injection already registered on Reg # 062156

Decision

Approved

Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.

735	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(6LW-N8H-G6XD, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Bromohexine 5% Solution
	Label Claim	Each ml contains Bromhexine HCl 50mg (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1 litre-De-Controlled,100 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Bromohawk 5% liquid (Hawk biopharma pvt ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	

Evaluation Remarks

The BROMBAK SOLUTION/ BROMOHEXIN 5% SOLUTION has been registered on Reg# 049786

Decision

Approved

Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.

736	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(6P4-ZEZ-A7R8, 2025-09-13)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Ivobak C injection

	Label Claim	Each ml contains Ivermectin (B.P) 10mg Clorsulon 100mg (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	100 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Ivotek super injection (star laboratories)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Ivobak C injection already registered on Reg # 062156	
	Decision	
	Approved	
	Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.	
737	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(6QH-GBH-BG99, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Bendzole 3% Suspension
	Label Claim	Each 100ml contains Albendazole (USP) 3.0% Cobalt chloride 0.050% Sodium selenite 0.030% (BP Vet Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1 litre-De-Controlled,100 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Albenzole plus (Windsor pharma)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	N/A
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Bendzole 3% Suspension already registered on Reg# 063819	
	Decision	
	Approved	
738	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)

	Application Form Dy. No / Tracking ID & date of submission	(6WD-U6N-P686, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	TRICLOBAK SUSPENSION
	Label Claim	Each 100ml contains Triclabendazole 5.0gm Levamisole HCl (B.P) 3.75gm (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1 litre-De-Controlled,100 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Tribex drench (Evergreen Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	TRICLOBAK SUSPENSION already registered on Reg# 049696	
	Decision	
	Approved	
	Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.	
739	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(6Z1-J2D-YTGJ, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	Ivobak injection
	Label Claim	Each ml contains Ivermectin (B.P) 10mg (B.P VET Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100 ML-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Ivomec injection (MSD)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Ivobak injection 100ml already approved on Reg# 053908	
	Decision	
	Approved	
740	Case Category	New License (Sabahat Zehra)

Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
Application Form Dy. No / Tracking ID & date of submission	(7D3-MZH-GL6X, 2025-09-12)
Detail of Fee Submitted	38700, 2025-09-11,
The proposed proprietary name / brand name	Vermok Drench
Label Claim	Each ml contains Ivermectin 0.8mg (Manufacturer's Specification)
Reference to Finished product specifications	Manufacturers Specification
Proposed Pack Size	1 litre-De-Controlled,100 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,500 ml-De-Controlled
Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
For generic drugs (me-too Status)	Ivotek drench (Symens pharma)
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	Satisfactory
Evidence of approval of manufacturing facility	

Evaluation Remarks

Vermok Drench already registered on Reg# 062182

Decision

Approved

Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.

741	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(7J4-9A4-VM6X, 2025-09-13)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	Norplus Liquid
	Label Claim	Each 100ml contains Norfloxacin 10gm Sulfamethoxypyridazine 15gm Trimethoprim 03gm (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1 litre-De-Controlled,100 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Norfit oral solution(Univet Pvt ltd)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	

Evaluation Remarks

NORPLUS LIQUID already registered on Reg# 034534

Decision

Approved

Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.

742	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(7W1-4X4-S9YB, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Levacid oral solution
	Label Claim	Each 100ml contains Levamisole HCl 1.5gm (B.P VET Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1 litre-De-Controlled,100 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	vernil oral suspension(Star laboratories)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Levacid oral solution has already registered on Reg# 048161	
	Decision	
	Approved	
743	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(7WE-6JV-7DEW, 2025-09-13)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	Amiclo Bolus
	Label Claim	Each Bolus contains: Niclosamide 1250mg (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10x5s-De-Controlled,20x5s-De-Controlled,4x5s-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Niclover Bolus 1250mg (Selemore pharma)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory

	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Amiclo Bolus already registered on Reg# 111525	
	Decision	
	Approved	
744	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(86D-SUB-BGQ1, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Nilzamaar Suspension
	Label Claim	Each 100ml contains Oxyclozanide 3% Levamisole 1.5% Cobalt chloride 0.055% (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1 litre-De-Controlled,100 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Nilzan plus suspension (ICI Pakistan)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Nilzamaar Suspension already registered on Reg# 063833	
	Decision	
	Approved	
	Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.	
745	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(8MV-7UG-57EB, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Noxabak 25 oral liquid
	Label Claim	Each 100ml contains Norfloxacin 25gm (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1 litre-De-Controlled,100 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Floxvet 20% oral (Animal Nexus)
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Noxabak 25 oral liquid already registered on Reg# 063828	
	Decision	
	Approved	
	Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.	
746	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(8S3-ZUL-X24Y, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	TG-65 INJECTION
	Label Claim	Each 100ml contains Gentamycin sulphate 5gm Colistin sulphate 50MIU Tylosin tartrate 10gm (Manufacturer's Specification)
	Reference to Finished product specifications	The International Pharmacopeia
	Proposed Pack Size	50 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Tylgenta-C Injection (Hi-gro pharma)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	TG-65 INJECTION already registered on Reg# 071065	
	Decision	
	Approved	
747	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(8YX-142-1VLA, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Oxy 950 powder
	Label Claim	Each kg contains: Oxytetracycline HCl 950gm (USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 kg-De-Controlled,10 kg-De-Controlled,100 gm-De-Controlled,25 kg-De-Controlled,250 gm-De-Controlled,5

		kg-De-Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Oxymix w/s powder (symans pharmaceuticals)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	OXY 950 POWDER already registered on Reg # 034526	
	Decision	
	Approved	
748	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(9EW-HLP-75BT, 2025-09-13)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Lincomat injection
	Label Claim	Each ml contains Lincomycin as HCl 50mg Spectinomycin 100mg (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	100 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Speclin Injection (Inshal pharmaceutical Industries)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
749	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(9T1-X3T-68QM, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Oramectin liquid
	Label Claim	Each ml contains Ivermectin 10mg (BP VET Specification)
	Reference to Finished product specifications	British Pharmacopeia

	Proposed Pack Size	1 litre-De-Controlled,100 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	vetz vectin oral liquid
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Oramectin liquid already registered on Reg# 062141	
	Decision	
	Approved	
750	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(9TE-1Y6-X83W, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	OXY-L20 INJECTION
	Label Claim	Each ml contains Oxytetracycline as dihydrate 200mg Lidocaine HCl 20mg (Manufacturer's Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	OXYSHELL 20% INJECTION
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	OXY L 20 INJECTION already registered on Reg# 034547	
	Decision	
	Approved	
751	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(ANJ-XBD-YL3U, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Betadox powder

	Label Claim	Each 1000gm contains Doxycycline HCl BP 200gm Tylosin tartrate BP 100gm Colistin sulphate BP 450MIU Bromohexine HCl BP 04gm (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1 kg-De-Controlled,10 kg-De-Controlled,100 gm-De- Controlled,25 kg-De-Controlled,250 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Doxylene w/s powder (inshal pharma)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
752	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(ATH-G3R-D1V2, 2025-09-13)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	LOXIBAK 10% injection
	Label Claim	Each ml contains Meloxicam 10mg (B.P VET Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Meloxishell Injection (Inshal pharmaceutical Industries)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	LOXIBAK 10% injection already registered on Reg# 062155	
	Decision	
	Approved	
753	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)

Application Form Dy. No / Tracking ID & date of submission	(AZ7-HLD-JEGX, 2025-09-13)
Detail of Fee Submitted	38700, 2025-09-12,
The proposed proprietary name / brand name	Pulmocare w/s powder
Label Claim	Each 1000g contains Doxycycline HCl BP 200gm Tylosin tartrate BP 100gm Colistin sulphate BP 480MIU Bromhexine HCl BP 03gm Phenylbutazone BP 10gm (Manufacturer's Specification)
Reference to Finished product specifications	Manufacturers Specification
Proposed Pack Size	1 kg-De-Controlled,100 gm-De-Controlled,250 gm-De-Controlled,500 gm-De-Controlled
Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
For generic drugs (me-too Status)	Respi-care forte w/s powder (Uni-vet pvt ltd)
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	Satisfactory
Evidence of approval of manufacturing facility	

Evaluation Remarks

Pulmocare w/s powder already registered on Reg# 053906

Decision

Approved

Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.

754	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(B8Y-UD7-LW8Z, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	FLUTIC Injection
	Label Claim	Each ml contains Flunixin meglumin eq. to Flunixin 50mg (USP Specifications) Dated: 11-05-2023
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Benamine 50 Injection (inshal pharmaceutical industries)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	

Evaluation Remarks

FLUTIC Injection already registered on Reg# 062152

Decision

Approved

755	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(BL4-A7S-4TXR, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Doxyman W/S Powder
	Label Claim	Each 1000gm contains Doxycycline HCl 200gm Tylosin tartrate 100gm Amantadine 50gm (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1 kg-De-Controlled,10 kg-De-Controlled,100 gm-De-Controlled,25 kg-De-Controlled,250 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Doxytyram ws powder (Barrett Hodgson Pakistan)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Formulation contains amantadine as ingredient in combination with other drugs	
756	Decision	
	Rejected	
	Rejected the instant case in absence of any recognized scientific rational regarding simultaneous use of antibiotic with antiviral drugs, in any RRA.	
	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(BNJ-5NM-6R3Z, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Albak granules
	Label Claim	Each kg contains Albendazole 200gm (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gm-De-Controlled,5 gm-De-Controlled,x50s-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Benzo/vet Granule (Nawan Laboratories)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory

	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Albak granules already registered on Reg# 048163	
	Decision	
	Approved	
757	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(BP3-SMS-4YY7, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	Ivobak injection
	Label Claim	Each ml contains Ivermectin (B.P) 10mg (B.P VET Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10 ML-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Ivomec injection (MSD)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Ivobak injection 10ml already registered on Reg# 053908	
	Decision	
	Approved	
758	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(BRE-NT5-PSZX, 2025-09-17)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	Di Flush powder
	Label Claim	Each gm contains Ammonium chloride 450mg Magnesium Sulphate 250mg Sodium sulphate 250mg Sorbitol 50mg (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1 kg-De-Controlled,10 kg-De-Controlled,100 gm-De-Controlled,25 kg-De-Controlled,250 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture

	For generic drugs (me-too Status)	Diureyl w/s Powder (Biogen Pharma)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Di Flush powder already registered on Reg# 062174	
	Decision	
	Approved	
	Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.	
759	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(D7Q-RJ8-NH9R, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Tilmicobak oral Liquid
	Label Claim	Each 100ml contains Tilmicosin phosphate 25gm (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1 litre-De-Controlled,100 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Tilmofas oral liquid (Animal Nexus)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The TILMICOBAK ORAL LIQUID is alredy registered on Reg# 075706	
	Decision	
	Approved	
	Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.	
760	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(EWA-853-WLZH, 2025-09-13)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Oxy forte LA injection
	Label Claim	Each ml contains Oxytetracycline as HCl BP 300mg Flunixin Meglumin USP 20mg (Manufacturer's

	Specification)
Reference to Finished product specifications	Manufacturers Specification
Proposed Pack Size	100 ml-De-Controlled
Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
For generic drugs (me-too Status)	OTC Forte LA Injection (Eterna pharma)
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	Satisfactory
Evidence of approval of manufacturing facility	

Evaluation Remarks

Oxy forte LA injection already registered on Reg# 062185

Decision

Approved

Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.

761	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(GTG-ZTL-D1RZ, 2025-09-13)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	Lincofort water soluble powder
	Label Claim	Each gm contains: Lincomycin HCl 100mg Colistin sulphate 800,000IU (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1 kg-De-Controlled,10 kg-De-Controlled,100 gm-De-Controlled,25 kg-De-Controlled,250 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Lincosole oral powder (A&K pharma)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	

Evaluation Remarks

Decision

Approved

762	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(J53-3PB-H2QA, 2025-09-12)

Detail of Fee Submitted	38700, 2025-09-11,
The proposed proprietary name / brand name	Frusa super powder
Label Claim	Each 1000gm contains Furosemide 25gm Sodium chloride 35gm Magnesium sulphate 35gm Manganese sulphate 1gm Potassium chloride 4gm Calcium carbonate 45gm (Manufacturer's Specification)
Reference to Finished product specifications	Manufacturers Specification
Proposed Pack Size	1 kg-De-Controlled,10 kg-De-Controlled,100 gm-De-Controlled,25 kg-De-Controlled,250 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled
Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
For generic drugs (me-too Status)	Frusa nide powder (inshal pharma)
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	Satisfactory
Evidence of approval of manufacturing facility	

Evaluation Remarks

Decision

Approved

763	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(JEP-YQ2-4DSR, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	Sulfaprime injection
	Label Claim	Each ml contains Sulfadiazine B.P 400mg Trimethoprim B.P 80mg (B.P VET Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Kerry TS plus Injection(Biolabs)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Sulfaprime injection already registered on Reg# 062153	
	Decision	
	Approved	

764	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(JG5-UZW-RW5J, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	COLINOR ORAL LIQUID
	Label Claim	Each 100ml contains Norfloxacin 20gm Colistin sulphate 50MIU (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1 litre-De-Controlled,100 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Floxicol oral liquid (Biogen pharma)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
Evaluation Remarks		
Decision		
Approved		
765	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(JPB-GNR-ABBM, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	Sulfaprime injection
	Label Claim	Each ml contains Sulfadiazine B.P 400mg Trimethoprim B.P 80mg (B.P VET Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	50 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Kerry TS plus Injection(Biolabs)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
Evaluation Remarks		
Sulfaprime injection already registered on Reg# 062153		
Decision		

Approved

766	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(LVT-S6J-YBLW, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	COFLOX ORAL LIQUID
	Label Claim	Each 100ml contains Enrofloxacin 10gm Colistin sulphate 50MIU (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1 litre-De-Controlled,100 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Risticol oral solution (Ras Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
767	Decision	
	Approved	
	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(M9D-M9M-54ZP, 2025-09-13)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Genta 10 super injection
	Label Claim	Each 100ml contains Gentamycin sulphate 10gm (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	100 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Genta Shell 10% Injection(Inshal pharmaceutical Industries)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	

	Evaluation Remarks	
	Decision	
	Approved	
768	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(MXX-HQA-DLXW, 2025-09-13)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Gentylobak injection
	Label Claim	Each ml contains Gentamycin (as sulphate) 50mg Tylosin (as tartrate) 100mg (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Tygent Injection (Selmore pharma)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
769	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(N3P-318-MNVE, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	SENTABAK BOLUS
	Label Claim	Each Bolus contains: Closental..... 500mg (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10x5s-De-Controlled,20x5s-De-Controlled,4x5s-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Flukinil bolus (Selmore pharma)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--

	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
	The SENTABAK BOLUS is already registered on Reg# 111300	
770	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(NYZ-AXL-W9YQ, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Albak 152 Bolus
	Label Claim	Each Bolus contains: Albendazole 152mg (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10x5s-De-Controlled,20x5s-De-Controlled,4x5s-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Albensei-S Bolus 152mg (Selmore pharma)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
771	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(Q9S-1QG-Q4H2, 2025-09-13)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Oxy forte LA injection
	Label Claim	Each ml contains Oxytetracycline as HCl BP 300mg Flunixin Meglumin USP 20mg (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	50 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture

	For generic drugs (me-too Status)	OTC Forte LA Injection (Eterna pharma)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Oxy forte LA injection already registered on Reg# 062185	
	Decision	
	Approved	
	Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.	
772	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Aamster Laboratories Plot # 18, Street # SS-2 RCCI Industrial Estate, Rawat - Islamabad (000908)
	Application Form Dy. No / Tracking ID & date of submission	(G38-DJQ-J1BU, 2025-02-07)
	Detail of Fee Submitted	37000.0, 2025-02-06,
	The proposed proprietary name / brand name	AMS-TIN ORAL PASTE
	Label Claim	Each ml contains (As Per Innovator Spec.) Abamectin 4mg Praziquantel 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled,10ml-De-Controlled,20ml-De-Controlled,30ml-De-Controlled,50ml-De-Controlled,5ml-De-Controlled
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	BIOTAK ORAL PASTE (109881) BIOGEN PHARMA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The Panel Recommends renewal of Drug Manufacturing License
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	As the applicant drug is paste and the firm replied that theywill manufacture it in liquid section. GMP report doesnot contain any semisolid preparation section or miscellaneous section.	
	Decision	
	Rejected	
	Rejected because of unavailability of the required section for manufacturing of product.	
773	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Aamster Laboratories Plot # 18, Street # SS-2 RCCI Industrial Estate, Rawat - Islamabad (000908)
	Application Form Dy. No / Tracking ID & date of submission	(G7N-AYV-V95D, 2025-02-07)
	Detail of Fee Submitted	37000.0, 2025-02-06,
	The proposed proprietary name / brand name	AMS-DEL SOLUTION

	Label Claim	Each ml contains (As Per Innovators Spec.) Deltamethrin 25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,150ml-De-Controlled,250ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	DELTABAK SOLUTION (062180) ATTABAK PHARMA ISLAMABAD
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The Panel Recommends renewal of Drug Manufacturing License
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
774	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(RPS-SSW-YSDH, 2025-09-13)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Ivobak C injection
	Label Claim	Each ml contains Ivermectin (B.P) 10mg Clorsulon 100mg (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	10 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Ivotek super injection (star laboratories)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Ivobak C injection already registered on Reg # 062156	
	Decision	
	Approved	
	Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.	
775	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)

Application Form Dy. No / Tracking ID & date of submission	(RNT-B54-SSNJ, 2025-09-12)
Detail of Fee Submitted	38700, 2025-09-11,
The proposed proprietary name / brand name	Amcox powder
Label Claim	Each 100gm contains Amprolium HCl (USP) 90gm (USP Specification)
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	10 kg-De-Controlled,100 gm-De-Controlled,1000 gm-De-Controlled,25 kg-De-Controlled,250 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled
Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
For generic drugs (me-too Status)	Ampromed 90% w/s powder (ICI Pakistan)
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	Satisfactory
Evidence of approval of manufacturing facility	

Evaluation Remarks

Amcox powder already registered on Reg# 053917

Decision

Approved

776	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(SBM-YQZ-W9DG, 2025-09-13)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	CRD RAZE W/S POWDER
	Label Claim	Each 1000gm contains Doxycycline HCl BP 200gm Tylosine tartrate BP 100gm Colistin sulphate BP 500MIU Bromohexine HCl BP 5gm (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1 kg-De-Controlled,10 kg-De-Controlled,100 gm-De-Controlled,25 kg-De-Controlled,250 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Chloridox oral powder (Ras Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	

Evaluation Remarks

CRD RAZE WS POWDER already registered on Reg# 049712

Decision

Approved

Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.

777	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(SGR-P4A-54B6, 2025-09-13)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Lincomat injection
	Label Claim	Each ml contains Lincomycin as HCl 50mg Spectinomycin 100mg (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	50 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Speclin Injection (Inshal pharmaceutical Industries)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
778	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(UL3-7JJ-VATG, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Neobak -72 water soluble powder
	Label Claim	Each 1000gm contains Neomycin (as sulphate) B.P 720gm (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1 kg-De-Controlled,100 gm-De-Controlled,250 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Neozoc 720 (zoic intl pakistan)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	

Evaluation Remarks																																					
Neobak -72 water soluble powder already registered on Reg # 049701																																					
Decision																																					
Approved																																					
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780	<table> <tr> <td>Case Category</td><td>New License (Sabahat Zehra)</td></tr> <tr> <td>Name, address of Applicant.</td><td>Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)</td></tr> <tr> <td>Application Form Dy. No / Tracking ID & date of submission</td><td>(UMH-GJ4-RB5J, 2025-09-13)</td></tr> <tr> <td>Detail of Fee Submitted</td><td>38700, 2025-09-11,</td></tr> <tr> <td>The proposed proprietary name / brand name</td><td>IVO Z injection</td></tr> <tr> <td>Label Claim</td><td>Each ml contains Ivermectin 20mg (BP VET Specification)</td></tr> <tr> <td>Reference to Finished product specifications</td><td>British Pharmacopeia</td></tr> <tr> <td>Proposed Pack Size</td><td>50 ml-De-Controlled</td></tr> <tr> <td>Shelf Life (Unit)</td><td>2 Yearstore at controlled room temperature.protect from heat,light and ,moisture</td></tr> <tr> <td>For generic drugs (me-too Status)</td><td>Ivovectin Injection (Vetz Pharmaceuticals)</td></tr> <tr> <td>Pharmacotherapeutic Group of (API)</td><td></td></tr> <tr> <td>Name, address of Manufacturing site:</td><td>--</td></tr> </table>	Case Category	New License (Sabahat Zehra)	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)	Application Form Dy. No / Tracking ID & date of submission	(UMH-GJ4-RB5J, 2025-09-13)	Detail of Fee Submitted	38700, 2025-09-11,	The proposed proprietary name / brand name	IVO Z injection	Label Claim	Each ml contains Ivermectin 20mg (BP VET Specification)	Reference to Finished product specifications	British Pharmacopeia	Proposed Pack Size	50 ml-De-Controlled	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture	For generic drugs (me-too Status)	Ivovectin Injection (Vetz Pharmaceuticals)	Pharmacotherapeutic Group of (API)		Name, address of Manufacturing site:	--												
Case Category	New License (Sabahat Zehra)																																				
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Application Form Dy. No / Tracking ID & date of submission	(UMH-GJ4-RB5J, 2025-09-13)																																				
Detail of Fee Submitted	38700, 2025-09-11,																																				
The proposed proprietary name / brand name	IVO Z injection																																				
Label Claim	Each ml contains Ivermectin 20mg (BP VET Specification)																																				
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Proposed Pack Size	50 ml-De-Controlled																																				
Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture																																				
For generic drugs (me-too Status)	Ivovectin Injection (Vetz Pharmaceuticals)																																				
Pharmacotherapeutic Group of (API)																																					
Name, address of Manufacturing site:	--																																				

	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
781	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(UNR-XAD-2TAD, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	FLUTIC Injection
	Label Claim	Each ml contains Flunixin meglumin eq. to Flunixin 50mg (USP Specifications) Dated: 11-05-2023
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Benamine 50 Injection (inshal pharmaceutical industries)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	FLUTIC Injection already registered on Reg# 062152	
	Decision	
	Approved	
782	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(W2L-X91-6NV9, 2025-09-13)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	Meloxi DS injection
	Label Claim	Each ml contains Meloxicam 20mg (B.P VET Specification)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	50 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	veticam plus Injection (vetz pharmaceuticals)
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
783	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(WLA-3RW-BZ21, 2025-09-13)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Gentylobak injection
	Label Claim	Each ml contains Gentamycin (as sulphate) 50mg Tylosin (as tartrate) 100mg (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Tygent Injection (Selmore pharma)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Gentylobak injection already registered on Reg# 048169	
	Decision	
	Approved	
784	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(ZYU-3JU-59RL, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	Sulfaprime injection
	Label Claim	Each ml contains Sulfadiazine B.P 400mg Trimethoprim B.P 80mg (B.P VET Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat, light and moisture.
	For generic drugs (me-too Status)	Kerry TS plus Injection(Biolabs)

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Sulfaprime injection already registered on Reg# 062153	
	Decision	
	Approved	
785	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(345-562-8RMX, 2025-09-13)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	Colibak W/S Powder
	Label Claim	Each 100gm contains Colistin sulphate (B.P) 480,000,000 IU (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1 kg-De-Controlled,10 kg-De-Controlled,100 gm-De-Controlled,25 kg-De-Controlled,250 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Coli Coly oral powder (Biogen pharma)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
786	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(3ZX-NXE-Y8HQ, 2025-09-13)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	Neostrep powder
	Label Claim	Each gm contains Neomycin sulphate 60mg Oxytetracycline HCl 200mg Streptomycin Sulphate 20mg (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification

Proposed Pack Size	1 kg-De-Controlled,10 kg-De-Controlled,100 gm-De-Controlled,25 kg-De-Controlled,250 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled
Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
For generic drugs (me-too Status)	Oxy Mycin powder (iNshal pharmaceutical Industries)
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	Satisfactory
Evidence of approval of manufacturing facility	

Evaluation Remarks

Decision

Approved

787	Case Category	New License (Saima Hussain)
	Name, address of Applicant.	Misraq Pharmaceuticals Pvt Ltd. Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad. (000985)
	Application Form Dy. No / Tracking ID & date of submission	(2XT-U99-97AZ, 2024-09-19)
	Detail of Fee Submitted	30000.0, 2024-08-06,
	The proposed proprietary name / brand name	Mizole
	Label Claim	Each 100ml Vial Contains: Metronidazole...500mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)15-30 degree Celsius
	For generic drugs (me-too Status)	Flagyl Injection by Sanofi-Aventis Limited, Pakistan
	Pharmacotherapeutic Group of (API)	nitroimidazole antimicrobials.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	TRD-MTZ-001 TRD-MTZ-002 01-2024 01-2026 10/100 1s (100ml USP Type I Clear Glass Vials) TRD-MTZ-003 01-2024 01-2026 10/100 1s (100ml USP Type I Clear Glass Vials)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm informed that they have taken loan from M/s. Medisure Lab. and attached delivery challan dated 26-07-2024.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies has been performed against Flagyl 500mg/100ml Injection Manufactured by Sanofi-Aventis Pakistan Limited-Karachi. (Batch No: AD056) MFG. Date Jan2024 Exp. Date Dec-2026
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone IV condition is attached
	The status in reference regulatory authorities	Metrozine Injection, TGA, Australia approved
	GMP status of the firm	New DML issue dated 26-10-2023
	Evidence of approval of manufacturing facility	Issuance of DML letter submitted in which mentioned that firm has General Liquid Injectable Ampoule/Vial

Evaluation Remarks

Sr.no.	Observations/Shortcomings	Response of the Firm
1.	Submit assay verification report of drug substance performed by drug product manufacturer in the requisite section.	Firm submitted assay verification report of drug substance performed by drug product manufacturer.
2.	Justify the out-of-specification (OOS) result obtained for the Sulphated Ash test, as the British Pharmacopoeia (BP) specifies a maximum limit of 0.1%, whereas the result reported in the batch analysis of the drug substance, as tested by the drug product manufacturer, is 0.78%. Provide a scientific explanation for this significant deviation.	Firm replied that “The reported value of 0.78% for sulphated ash in the COA was a typographical error. The actual tested result, as per the analytical worksheet, is 0.078%, which complies with the BP limit of NMT 0.1%. The COA has been corrected, and necessary steps have been taken to prevent such clerical errors in the future.
3.	Provide detailed manufacturing method of applied drug product in section 3.2.P.3.3.	Firm submitted the detailed manufacturing method of drug product.
4.	Justify how the Relative Retention Time (RRT) was determined during the assay for identification, as claimed in the submitted specification of drug product, given that the assay was performed using a UV spectrophotometer, which does not provide chromatographic separation or retention times.	Firm replied that We would like to clarify that the identification test for the finished product is performed by FTIR spectroscopy, as clearly described in the approved SOP (Section 4.2.A). The method involves extraction and comparison of the infrared spectrum of the residue with that of a reference standard per BP. There is no mention or use of Relative Retention Time (RRT) in the identification method, nor in the Certificate of Analysis (COA). Supporting documents, including the SOP, COA, and FTIR spectrum, are attached to verify that RRT is not used or applicable to the current identification procedure. However the specification table given in section 3.2.P.5.1 clearly mentioned the acceptance criteria as” The relative retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay”.
5.	Justify the use of the gel clot method for conducting the sterility test, as claimed in the submitted specification of drug product (3.2.P.5.1) , when the British Pharmacopoeia (BP) General Chapter on Sterility recommends performing the test using the membrane filtration or direct inoculation techniques.	Firm replied that The gel clot method is not used for the sterility test. It is applicable only to the Bacterial Endotoxin Test (BET). The sterility test for the drug product is performed using the membrane filtration method, in full accordance with the British Pharmacopoeia (BP) General Chapter on Sterility. This method is appropriate for sterile pharmaceutical products such as infusions.
6.	Justify for not including the Bacterial Endotoxin Test, Particulate Contamination Test, and Nitrite Test in the drug product specification (3.2.P.5.1), despite being recommended in the BP monograph for Metronidazole Infusion. Also, justify for not performing the	Revised analytical report of drug product submitted by the firm including the Bacterial Endotoxin Test, Particulate Contamination Test, and Nitrite Test.

	identification test via FTIR as specified in the same monograph.	
7.	Submit the raw data sheets as performance evidence for the Bacterial Endotoxin Test, Sterility Test, and pH Test, as only the assay raw data sheets have been provided. Ensure that the submitted data includes all relevant observations, test conditions, and results to demonstrate compliance with pharmacopoeial requirements.	Firm submitted the raw data sheets as performance evidence for the Bacterial Endotoxin Test, Sterility Test, and pH Test.
8.	Clarify the rationale for using an alternate calculation formula and confirm whether the method, including dilution scheme and absorbance measurements, complies with BP requirements for UV spectrophotometric assay.	Firm replied that The assay of the drug product (Metronidazole Infusion) was performed in accordance with the British Pharmacopoeia (BP) using UV spectrophotometry at 277 nm, following the BP monograph instructions, The individual BP monograph does not provide a detailed calculation formula but refers to the general UV assay approach in Appendix II B. Therefore, the calculation was carried out using the BP-recommended principle: This approach was slightly reformatted for internal SOP use to incorporate the known A (1%,1cm) value (375) and the specific dilution factors used, ensuring simplification and clarity for routine use. The integrity and accuracy of the assay result remain consistent with BP methodology. We confirm that: · The method, dilutions, and wavelength strictly follow the BP monograph, · The calculation method is mathematically equivalent to BP's recommended approach.
9.	Justify the use of distilled water for manufacturing the trial batches, as documented in the Batch Manufacturing Record (BMR), despite the approved formulation specifying Water for Injection (WFI). Since the product is a sterile infusion preparation, explain the rationale for using distilled water instead of WFI, and assess the potential impact on the sterility, pyrogen status, and overall quality of the drug product.	Firm replied that, We have used WFI at every single stage of trial batches manufacturing including container/closures. · In the batch manufacturing order we have mentioned WFI as the main solvent. · But in the standard manufacturing procedure, distilled water is mentioned which is purely overlooked during the composition of the BMR and we accept our mistake. · Now we are assuring the competent authority that we have used WFI at every stage of trial batch manufacturing. · For evidence we are attaching WFI certificate of analysis from our QC department which has been used during the manufacturing process.
10.	Additionally, the BMR indicates that the filled vials were subjected to autoclaving at 121°C for 30 minutes, whereas the drug product manufacturing method submitted in your response states that the conditions for terminal sterilization are 121°C / 15 PSI for 15 minutes. Clarify these discrepancies regarding the grade of water used and the terminal sterilization	Firm replied that Please accept our apologies regarding the overlooking of the data. We Misaq Pharmaceuticals hereby attaching terminal sterilization cycle data for the trial batches # TRD-MTZ-001/TRD-TMZ-002 & TRD-TMZ-003 along with the autoclave validation report.

	conditions, and justify any deviations from the approved or submitted manufacturing process.	
11.	It has been observed that the date mentioned on the submitted delivery challan for the API is 26-07-2024, whereas the trial batches were reportedly manufactured in January 2024, as evident from the submitted stability data sheets and batch manufacturing records. Clarify how the trial batches were manufactured prior to the documented receipt of API.	Firm in their reply stated that Respected evaluator, please accept our apologies regarding the typographical mistakes during issuance of challan by supplier. We have requested them to issue us a corrected challan which has been received and submitted for your consideration.

Decision

Deferred

The case is deferred for verification of loan letter from M/s. Medisure Laboratories alongwith date of delivery of API to M/s. Misaq.

788	Case Category	Import (Saima Hussain)
	Name, address of Applicant.	Organs Pharma Block A, 6th Floor Plot No. FD-35-36-A7, National Industrial Park, Korangi Creek (0616)
	Application Form Dy. No / Tracking ID & date of submission	(36N-PE4-2GTE, 2024-02-22)
	Detail of Fee Submitted	150000.0, 150000.0 2022-12-08, 2024-03-20
	The proposed proprietary name / brand name	Progesing Oily Solution for deep IM injection
	Label Claim	Brand Name: Progesing Oily Solution for Deep IM Injection Generic Name: Progesterone (B.P) 100 mg / 2 ml Composition: Each 2 ml contains Active ingredient: Progesterone (B.P) 100 mg, Excipients Eth
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10 Ampoules (2ml of -As per SRO
	Shelf Life (Unit)	24 Month(s)Store at a temperature not exceeding 30°C
	For generic drugs (me-too Status)	1. (001271) PROGESTERONE INJECTION RICHTER PHARMA , 2. (013621)PROGESTERONE INJ VENUS PHARMA (1.5.8)
	Pharmacotherapeutic Group of (API)	Hormones
	Name, address of Manufacturing site:	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES C-Manufacturing site: Factory 1: First Industrial Area B1 Factory 2: Block Number Extension of B1-Industries Zone B1 10th of Ramadan city-Sharkia, Egypt, P. O. Box 149-10th. -Egypt
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE against the innovator product Gestone® injection
	Name, address of Marketing Authorization Holder:	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES C, Manufacturing site: Factory 1: First Industrial Area B1 Factory 2: Block Number Extension of B1-Industries Zone B1 10th of Ramadan city-Sharkia, Egypt, P. O. Box 149-10th. , Egypt
	Details of Certificates (CoPP/FSC/cGMP):	GMP certificate of Manufacturer Abroad M/s. Egyptian international Pharmaceutical Industries Company (EIPICO) Certificate Number: P-1050/2022 dated 13/12/2022 valid until 13/12/2023.
	Details of Authorization Letter :	NA

Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		Submitted
The status in reference regulatory authorities		Gestone 50mg/MI (Ampoule contains Progesterone BP, 50mg in 1ml.), ParaPharm Development Limited, MHR
Evaluation Remarks		
Sr.no.	Observations/Shortcomings	Response of the Firm
1.	Justify the use of medium-chain triglycerides (MCTs) in the parenteral preparation intended for intramuscular administration, considering that the manufacturer, in section 3.2.P.2.1.2, has stated that MCTs have been utilized in the production of parenteral formulations designed for intravenous administration. Applicant was again asked to that "You have cited the Handbook of Pharmaceutical Excipients as a reference to support the use of Miglyol; however, the handbook specifically states that Miglyol 810 and Miglyol 812 have been used in the preparation of emulsions, solutions, or suspensions intended for intravenous administration. In contrast, the intended route of administration for your applied formulation is intramuscular. Furthermore, you have used Miglyol 840, whereas the grades referenced in the handbook are Miglyol 810 and 812. Justify the use of Miglyol 840 in your formulation and provide supporting evidence for its safety and suitability for intramuscular administration".	Initially firm replied that Medium chain Triglycerides (MCTs) Miglyol are used in a variety of pharmaceutical formulations including oral, parenteral, and Topical products, and are generally regarded as essentially nontoxic and no irritant materials. In acute toxicology studies in animals and humans, no irritant or other adverse reactions have been observed; for example, when they were patch-tested on more than 100 individuals, no irritation was produced on either healthy or eczematous skin. (Hand book of pharmaceutical excipient) Miglyol with lower toxicity & viscosity to ensure a proper quality attributes like clarity, rheological behavior, partition coefficient & injectability. Firm replied in response to the second query that The formulation of Progesing Ampoule was originally developed using Miglyol 840 as the vehicle. The product has successfully passed all stability study requirements in accordance with ICH guidelines. Since its first marketing authorization, no safety-related complaints or adverse reactions attributable to Miglyol 840 have been reported in post-marketing surveillance. (Attached PBRER- Periodic Benefit-Risk Evaluation Report for GCC for your reference) The product is currently registered and marketed in Egypt (country of origin) and several GCC countries, including Oman, Kuwait, Bahrain with Miglyol 840 as the approved excipient for intramuscular injection. by OI Oleo GmbH company and available on the market. (Attached company brochure)
2.	Provide a justification for not including a preservative in the applied formulation, considering that the reference product, Gestone Injection, includes benzyl alcohol as a preservative at a significant concentration of 100 mg per dosage unit (equivalent to 100 mg/mL).	Firm replied that Progesing 100 mg/2ml developed as oily solution by using ethanol and miglyol 840 this oily phase isn't susceptible for bacterial contamination and it is administered as single use for IM injection, so there is no need for a preservative.
3.	When an official monograph for the applied formulation is available in the British Pharmacopoeia (BP), provide a justification for conducting the visible particle test, particulate matter test, sterility test, and bacterial endotoxin test in accordance with the general chapters of the United States Pharmacopeia (USP).	Firm replied that Kindly be informed that the reference for performing the visible particle test and particulate matter test have been updated to BP. Regarding to sterility test, and bacterial endotoxin test the reference have been updated to be InHouse as the official monograph in BP < Progesterone Injection > doesn't contain test for them and the limit of bacterial endotoxin test has been calculated according to USP monograph so it

		was submitted in the previous steps as USP and the monograph is attached.
4.	Please provide a scientific justification for not performing microbiological testing, including sterility and bacterial endotoxin tests, at the six-month time point under accelerated stability conditions for the proposed injectable solution.	Revised stability data sheets submitted.

Decision

Approved

Registration Board approved the product subject to compliance of current Import Policy for finished drugs. Further, firm shall submit valid, original and legalized CoPP/free sale certificate and Letter of Authorization prior issuance of Registration letter.

789	Case Category	New Molecule/Formulation (Saima Hussain)
	Name, address of Applicant.	Kaizen Pharmaceuticals (Pvt) Ltd Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi (000755)
	Application Form Dy. No / Tracking ID & date of submission	(DRD-QHB-AWYG, 2025-07-30)
	Detail of Fee Submitted	75000.0, 2025-07-02,
	The proposed proprietary name / brand name	INTONING (IBRUTINIB) 140MG TABLET
	Label Claim	Each Film coated Tablet Contains: Ibrutinib 140mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	28's-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30°C in a cool and dry place
	For generic drugs (me-too Status)	Not applicable as it is a new drug product
	Pharmacotherapeutic Group of (API)	Protein kinase inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Anhui Haikang Pharmaceutical., Co.,Ltd ADDRESS:N0.21 HUANCHENG WEST ROAD, DAGUAN DISTRICT, ANQING CITY, ANHUI PROVINCE, 246000 CHINA
	Detail of stability batches of drug product	Accelerated Stability Study {0, 3 & 6 months (completed)}, Long term / Real time stability study {0,3,6 & 9) months (completed)}
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	pharmaceutical equivalence and CDP has been provided,
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	provided
	The status in reference regulatory authorities	Medicines and Healthcare Regulatory Agency (MHRA)
	GMP status of the firm	valid
	Evidence of approval of manufacturing facility	attached

Evaluation Remarks

IMBRUVICA is a kinase inhibitor indicated for the treatment of: • Adult patients with chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) (1.1). • Adult patients with chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) with 17p deletion (1.2). • Adult patients with Waldenström's macroglobulinemia (WM) (1.3). • Adult and pediatric patients age 1 year and older with chronic graft versus host disease (cGVHD) after failure of one or more lines of systemic therapy.CLL/SLL and WM: 420 mg taken orally

once daily (2.1). • cGVHD: o Patients 12 years and older: 420 mg taken orally once daily (2.1). o Patients 1 to less than 12 years of age: 240 mg/m² taken orally once daily (up to a dose of 420 mg) (2.1). Tablets or capsules should be taken orally with a glass of water. Do not open, break, or chew the capsules. Do not cut, crush, or chew the tablets. See full prescribing information for oral suspension administration instructions (2.1).

Sr.no.	Observations/Shortcomings	Response of the Firm
1.	Justify for not including the test of S-isomer of Ibrutinib and chiral purity test while performing the quality analysis of drug substance by the drug product manufacturer, since the test is part of the specification of drug substance manufacturer.	Firm replied that "We assure your good office that we will perform the required test for our commercial consignment, since the availability of racemic reference standard is committed by API Manufacturer. Commitment letter of API Manufacturer is attached".
2.	Please clarify the sample preparation step equivalent to one tablet content powder weight in the assay procedure, specifically the phrase: 'Accurately weigh to into 100 mL Volumetric flask with diluent' What type of powder is being referred to as equivalent to the weight of one tablet i.e., is it the finely powdered whole tablets, a blend, or another material?"	Firm clarified that "As mentioned in the method 'Accurately weigh to equivalent to one tablet content powder weight into 100 mL Volumetric flask with diluent' refers to the sample to be drawn from blend of 20 crushed tablets. Revised method is submitted.
3.	Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP.	Firm submit the License to import the active ingredient issued by DRAP dated 28/09/2024 along with commercial invoice that has not attested by DRAP and Fedx receipt.

Decision

Deferred

Deferred for on-site inspection of the firm for the authenticity/verification of submitted pharmaceutical development data and stability data. Further, firm shall perform the test of S-isomer of Ibrutinib and chiral purity test on the remaining quantity of drug substance and submit the report accordingly.

790	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	Maxitech Pharma (Pvt) Ltd. E-178, S.I.T.E., Super Highway Phase-II, Karachi (000851)
	Application Form Dy. No / Tracking ID & date of submission	(BJY-768-3A8B, 2024-03-19)
	Detail of Fee Submitted	30000.0, 2023-12-21,
	The proposed proprietary name / brand name	ERTUMET 7.5mg+1000mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Ertugliflozin.....7.5mg Metformin HCl.....1000mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	14's (as per SRO)-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature below 30
	For generic drugs (me-too Status)	Ertuvia-M 7.5mg+1000mg Tablet
	Pharmacotherapeutic Group of (API)	Anti-Diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	TR-001 1000 Tablets ,TR-002 1000 Tablets , TR-003 1000 Tablets

Documents for the procurement of API with approval from DRAP (in case of Import)	Not submitted
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP performed against the Ertuvia-M 7.5mg +1000mg (2L36 05-2022 05-2024) of M/s. Ferozsons Laboratories Limited.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone iv condition is submitted by the firm.
The status in reference regulatory authorities	Segluromet 7.5mg+1000mg Tablet by Merck Sharp & Dohme B.V
GMP status of the firm	Firm submit the GMP certificate dated 31-08-2022.
Evidence of approval of manufacturing facility	Firm submit the GMP certificate dated 31-08-2022, in which mentioned that firm has tablet (general) section.

Evaluation Remarks

Sr.no.	Shortcomings	Response of the Firm
1.	Ertugliflozin LPGA: Submit the specification and detailed analytical procedure of the drug substance used by the drug product manufacturer for the analysis of the drug substance. The submitted dossier includes only the assay verification report without a complete description of the solution preparation method or chromatographic conditions. Additionally, the assay verification report appears to pertain to Ertugliflozin rather than Ertugliflozin L-pyroglutamic acid (Ertugliflozin LPGA). Therefore, clarification is required regarding the identity and analytical method of the drug substance being used.	Updated Specification of Ertugliflozin is attached. Additionally, the chromatographic Condition used in the assay verification report is the same as mentioned in the specification of ertugliflozin L-pyroglutamic acid under assay test. Additionally, we already submitted the assay verification report of ertugliflozin L-pyroglutamic Acid because ertugliflozin occurs as ertugliflozin L-pyroglutamic Acid.
2.	Provide justification for not including LPGA content test in the quality analysis of the Ertugliflozin API by the drug product manufacturer, considering that it is a critical parameter in the quality assessment of Ertugliflozin LPGA	Firm submitted the revised specification and testing method of drug substance of ertugliflozin without the analytical report and their obtained result.
3.	Please justify the following deviations from the USP assay method for Metformin Hydrochloride despite the claim that the API is complied with USP specification both by drug substance manufacturer and drug product manufacturer: · Mobile phase: USP uses phosphate buffer: acetonitrile (95:5, pH 3.0), whereas your method uses water: acetonitrile: TFA in gradient mode. · Diluent: USP uses mobile phase; you used acetonitrile. · Detection wavelength: USP specifies 215 nm; your method uses 250 nm. · Column: USP specifies L9 (4.6 × 250 mm, 10 µm); you used C18 (4.6 × 150 mm, 5 µm). · Flow rate and injection volume: USP uses 1.5 mL/min and 20 µL; your method uses 1.0 mL/min and 10 µL. · Calculation formula: USP uses response ratio; your method uses peak area	Firm submit the revised assay method without any justification/clarification.

	with weight-based calculations. System suitability: USP includes tailing and %RSD limits; your method does not specify.	
4.	Metformin HCl: Submit the long term stability data of drug substance till the claimed re-test , since you have submitted the data of only 6 months.	The firm has again submitted stability data for the drug substance at long-term storage conditions for only 6 months, instead of providing data covering the complete re-test period as required.
5.	In the drug substance section, it is stated that USP-complied Metformin HCl was procured; however, the composition table in section 3.2.P.1 indicates the use of BP-complied Metformin HCl used in the manufacturing of drug product. Please clarify this inconsistency. Additionally, since Ertugliflozin L-PGA does not have an official monograph in any recognized pharmacopoeia, Justify how it is referred to as USP-complied in section 3.2.P.1 for use in the drug product	Firm submit the revised composition table in the requisite section.
6.	Innovator data classifies Ertugliflozin L-PGA as BCS Class I and Metformin HCl as BCS Class III, both exhibiting high solubility across physiological pH and >85% release within 15 minutes. In contrast, the CDP data for the proposed formulation shows <80% release at 30 minutes in pH 1.2 and 4.5. Justify the observed dissolution behavior of the proposed formulation in light of the solubility and release characteristics reported in the innovator's literature.	Firm replied that , “On Evaluation the discrepancy is found in the CDP valuation process. The error impacted the overall results and has since been corrected. Remediation steps, including correction in the CDP report has been taken and the report is attached. This report clarifies the behavior and release pattern of both active in all mediums with the reference product”.
7.	As per standard analytical practice, assay sample preparation is typically performed using a quantity of powdered tablet equivalent to one tablet, or a specific quantity of powdered tablet in which the amounts of both APIs are known, to ensure accurate and representative concentrations in the final dilution. However, your method involves using 3 intact tablets directly in a 500 mL volumetric flask for sample preparation. Please justify this deviation from standard practice, explain how this approach ensures accurate quantification of both APIs in the final solution, and clarify how the concentrations of both APIs are assessed in the final dilution. Later firm was asked to justify the use of intact tablets over powdered form with reference to relevant guidelines (e.g., ICH Q2(R2), USP <905>). Also clarify how the final concentration of actives is accurately known and representative of the label claim without verifying individual tablet content.	Firm replied that Taking intact tablet for assay sample preparation is more accurate than taking powdered quantity because taking intact tablets contains all amount of active and can easily be transferred into volumetric flask and reduces the chance of error. While taking intact tablets, we consider that all the amount of active, equivalent to 3 tablets have been transferred into volumetric flask and final dilution be prepared as per procedure. In response of second query firm replied that “ On review of our testing method, we revise our testing method of assay in which we change the intact tablet sample preparation method to powdered tablet instead of intact tablet. The Revised Testing method has been attached”
8.	The sample preparation method used during the precision parameter of the assay validation for the drug product differs from	Initially firm replied, The method used during the precision parameter of the assay validation for the drug product is same as used for routine analysis.

	the sample preparation method described in the assay procedure given in section 3.2.P.5.2. Please clarify and justify this inconsistency, and explain how the validation data supports the intended routine analytical method. Again Firm was asked that, In your response, you have stated that the same sample preparation method has been used for both the assay and precision parameters. However, it has been observed that the final sample concentrations differ between the two sections. Specifically, for Ertugliflozin, the concentration is stated as 0.0144 mg/mL in Section 3.2.P.5.2, while it is reported as 0.015 mg/mL in the precision section. Similarly, for Metformin HCl, the concentration is stated as 0.042 mg/mL in the assay method, and 0.0375 mg/mL in the precision section. Justify this discrepancy in sample concentrations, despite the claim that the same sample preparation method was used.	We calculate the result and mention the result in report as per procedure. Later, firm accept their mistake and replied that “We reviewed both the Assay method verification report of Ertumet 7.5/500 mg tablet and Ertumet 7.5/1000 mg and a discrepancy of typo error was found in the precision parameter, because in the accuracy sample of 100% same concentration was used as per the assay method.
9.	Considering that both Ertugliflozin and Metformin HCl are reported in the innovator literature to be highly soluble across the physiological pH range at 37 ± 0.5 °C, and that the tablets exhibit rapid dissolution with >85% release of both APIs within 15 minutes for all strengths, please rationalize the proposed dissolution specification of NLT 80% (Q) in 30 minutes for both Ertugliflozin and Metformin HCl. Justify how this limit is appropriate in light of the known solubility and rapid release characteristics of the APIs. When again asked, “Please specify the international guidelines (e.g., ICH Q6A, FDA, WHO) followed for setting the dissolution acceptance criteria. As the product is non-pharmacopoeial, and if the innovator’s literature defines dissolution conditions and limits, the same should be adopted. If an in-house method is used, submit the complete method development data along with justification for the selected parameters and explain any deviation from the innovator’s dissolution conditions”.	Firm replied that this is a non-Pharmacopeial method, the dissolution test was conducted in accordance with general method guideline. Later, firm replied that, As product is non-pharmacopeial, we performed CDP of the selection of dissolution medium and condition, our product dissolves and innovator both dissolves greater than 85% in 15 minutes, so as per our DRAP guideline in which when 85% dissolves in 15 minutes we take next sampling point for specification which is 20 minutes for routine dissolution process, So, we revised our Specification and supporting data have been attached. However, the innovator literature revealed that the acceptance criteria for dissolution test is Q= % in 15 minutes.
Decision		
Approved		
Subject to revision of dissolution acceptance in accordance of revision and requisite fee for revision of specifications.		
791	Case Category	Routine (Saima Hussain)

Name, address of Applicant.	Maxitech Pharma (Pvt) Ltd. E-178, S.I.T.E., Super Highway Phase-II, Karachi (000851)
Application Form Dy. No / Tracking ID & date of submission	(BS4-177-NBTP, 2024-03-15)
Detail of Fee Submitted	30000.0, 2023-12-21,
The proposed proprietary name / brand name	ERTUMET 2.5mg+500mg Tablet
Label Claim	Each film coated tablet contains: Ertugliflozin.....2.5mg Metformin HCl.....500mg
Reference to Finished product specifications	Manufacturer Specification
Proposed Pack Size	14's (as per SRO)-As per SRO
Shelf Life (Unit)	2 Year(s)as per zone IV-A (30oC, 65%)
For generic drugs (me-too Status)	Ertuvia-M 2.5mg+500mg Tablet
Pharmacotherapeutic Group of (API)	Anti-Diabetic
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	
Detail of stability batches of drug product	TR-001 1000 Tablets ,TR-002 1000 Tablets , TR-003 1000 Tablets
Documents for the procurement of API with approval from DRAP (in case of Import)	Not submitted
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP performed against the Ertuvia-M 2.5mg +500mg (2L33 05-2022 05-2024) of M/s. Ferozsons Laboratories Limited.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone iv condition is submitted by the firm.
The status in reference regulatory authorities	Segluromet 2.5mg+500mg Tablet by Merck Sharp & Dohme B.V
GMP status of the firm	Firm submit the GMP certificate dated 31-08-2022.
Evidence of approval of manufacturing facility	Firm submit the GMP certificate dated 31-08-2022, in which mentioned that firm has tablet (general) section.

Evaluation Remarks

Sr.no.	Shortcomings	Response of the Firm
1.	Ertugliflozin LPGA: Submit the specification and detailed analytical procedure of the drug substance used by the drug product manufacturer for the analysis of the drug substance. The submitted dossier includes only the assay verification report without a complete description of the solution preparation method or chromatographic conditions. Additionally, the assay verification report appears to pertain to Ertugliflozin rather than Ertugliflozin L-pyroglutamic acid (Ertugliflozin LPGA). Therefore, clarification is required regarding the identity and analytical method of the drug substance being used.	Updated Specification of Ertugliflozin is attached. Additionally, the chromatographic Condition used in the assay verification report is the same as mentioned in the specification of ertugliflozin L-pyroglutamic acid under assay test. Additionally, we already submitted the assay verification report of ertugliflozin L-pyroglutamic Acid because ertugliflozin occurs as ertugliflozin L-pyroglutamic Acid.
2.	Provide justification for not including LPGA content test in the quality analysis of the Ertugliflozin API by the drug product manufacturer, considering that it is a critical	Firm submitted the revised specification and testing method of drug substance of ertugliflozin without the analytical report and their obtained result.

	parameter in the quality assessment of Ertugliflozin LPGA	
3.	Please justify the following deviations from the USP assay method for Metformin Hydrochloride despite the claim that the API is complied with USP specification both by drug substance manufacturer and drug product manufacturer: · Mobile phase: USP uses phosphate buffer: acetonitrile (95:5, pH 3.0), whereas your method uses water: acetonitrile: TFA in gradient mode. · Diluent: USP uses mobile phase; you used acetonitrile. · Detection wavelength: USP specifies 215 nm; your method uses 250 nm. · Column: USP specifies L9 (4.6 × 250 mm, 10 µm); you used C18 (4.6 × 150 mm, 5 µm). · Flow rate and injection volume: USP uses 1.5 mL/min and 20 µL; your method uses 1.0 mL/min and 10 µL. · Calculation formula: USP uses response ratio; your method uses peak area with weight-based calculations. · System suitability: USP includes tailing and %RSD limits; your method does not specify.	Firm submit the revised assay method without any justification/clarification.
4.	Metformin HCl: Submit the long term stability data of drug substance till the claimed re-test , since you have submitted the data of only 6 months.	The firm has again submitted stability data for the drug substance at long-term storage conditions for only 6 months, instead of providing data covering the complete re-test period as required.
5.	In the drug substance section, it is stated that USP-complied Metformin HCl was procured; however, the composition table in section 3.2.P.1 indicates the use of BP-complied Metformin HCl used in the manufacturing of drug product. Please clarify this inconsistency. Additionally, since Ertugliflozin L-PGA does not have an official monograph in any recognized pharmacopoeia, Justify how it is referred to as USP-complied in section 3.2.P.1 for use in the drug product	Firm submit the revised composition table in the requisite section.
6.	Innovator data classifies Ertugliflozin L-PGA as BCS Class I and Metformin HCl as BCS Class III, both exhibiting high solubility across physiological pH and >85% release within 15 minutes. In contrast, the CDP data for the proposed formulation shows <80% release at 30 minutes in pH 1.2 and 4.5. Justify the observed dissolution behavior of the proposed formulation in light of the solubility and release characteristics reported in the innovator's literature.	Firm replied that , “On Evaluation the discrepancy is found in the CDP valuation process. The error impacted the overall results and has since been corrected. Remediation steps, including correction in the CDP report has been taken and the report is attached. This report clarifies the behavior and release pattern of both active in all mediums with the reference product”.
7.	As per standard analytical practice, assay sample preparation is typically performed using a quantity of powdered tablet equivalent to one tablet, or a specific quantity of powdered tablet in which the amounts of	Firm replied that Taking intact tablet for assay sample preparation is more accurate than taking powdered quantity because taking intact tablets contains all amount of active and can easily be transferred into volumetric flask and reduces the

	both APIs are known, to ensure accurate and representative concentrations in the final dilution. However, your method involves using 3 intact tablets directly in a 500 mL volumetric flask for sample preparation. Please justify this deviation from standard practice, explain how this approach ensures accurate quantification of both APIs in the final solution, and clarify how the concentrations of both APIs are assessed in the final dilution. Later firm was asked to justify the use of intact tablets over powdered form with reference to relevant guidelines (e.g., ICH Q2(R2), USP <905>). Also clarify how the final concentration of actives is accurately known and representative of the label claim without verifying individual tablet content.	chance of error. While taking intact tablets, we consider that all the amount of active, equivalent to 3 tablets have been transferred into volumetric flask and final dilution be prepared as per procedure. In response of second query firm replied that “ On review of our testing method, we revise our testing method of assay in which we change the intact tablet sample preparation method to powdered tablet instead of intact tablet. The Revised Testing method has been attached”
8.	The sample preparation method used during the precision parameter of the assay validation for the drug product differs from the sample preparation method described in the assay procedure given in section 3.2.P.5.2. Please clarify and justify this inconsistency, and explain how the validation data supports the intended routine analytical method. Again Firm was asked that, In your response, you have stated that the same sample preparation method has been used for both the assay and precision parameters. However, it has been observed that the final sample concentrations differ between the two sections. Specifically, for Ertugliflozin, the concentration is stated as 0.0144 mg/mL in Section 3.2.P.5.2, while it is reported as 0.015 mg/mL in the precision section. Similarly, for Metformin HCl, the concentration is stated as 0.042 mg/mL in the assay method, and 0.0375 mg/mL in the precision section. Justify this discrepancy in sample concentrations, despite the claim that the same sample preparation method was used.	Initially firm replied, The method used during the precision parameter of the assay validation for the drug product is same as used for routine analysis. We calculate the result and mention the result in report as per procedure. Later, firm accept their mistake and replied that “We reviewed both the Assay method verification report of Ertumet 7.5/500 mg tablet and Ertumet 7.5/1000 mg and a discrepancy of typo error was found in the precision parameter, because in the accuracy sample of 100% same concentration was used as per the assay method.
9.	Considering that both Ertugliflozin and Metformin HCl are reported in the innovator literature to be highly soluble across the physiological pH range at 37 ± 0.5 °C, and that the tablets exhibit rapid dissolution with >85% release of both APIs within 15 minutes for all strengths, please rationalize the proposed dissolution specification of NLT 80% (Q) in 30 minutes for both Ertugliflozin and Metformin HCl. Justify how this limit is appropriate in light of the known solubility and rapid release characteristics of the APIs. When again asked, “Please specify the	Firm replied that this is a non-Pharmacopeial method, the dissolution test was conducted in accordance with general method guideline. Later, firm replied that, As product is non-pharmacopeial, we performed CDP of the selection of dissolution medium and condition, our product dissolves and innovator both dissolves greater than 85% in 15 minutes, so as per our DRAP guideline in which when 85% dissolves in 15 minutes we take next sampling point for specification which is 20 minutes for routine dissolution process, So, we revised our Specification and supporting data have been attached. However, the innovator literature revealed

	international guidelines (e.g., ICH Q6A, FDA, WHO) followed for setting the dissolution acceptance criteria. As the product is non-pharmacopoeial, and if the innovator's literature defines dissolution conditions and limits, the same should be adopted. If an in-house method is used, submit the complete method development data along with justification for the selected parameters and explain any deviation from the innovator's dissolution conditions".	that the acceptance criteria for dissolution test is Q= % in 15 minutes.
10.	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 submit the DRAP attested commercial invoice of Metformin HCl only.

Decision

Approved

Subject to revision of dissolution acceptance in accordance of revision and requisite fee for revision of specifications.

792	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	Maxitech Pharma (Pvt) Ltd. E-178, S.I.T.E., Super Highway Phase-II, Karachi (000851)
	Application Form Dy. No / Tracking ID & date of submission	(R53-95R-NDPR, 2024-03-14)
	Detail of Fee Submitted	30000.0, 2023-12-21,
	The proposed proprietary name / brand name	ERTUMET 7.5mg+500mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Ertugliflozin.....7.5mg Metformin HCl.....500mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	14's (as per SRO)-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature below 30
	For generic drugs (me-too Status)	Ertuvia-M 7.5mg+500mg Tablet
	Pharmacotherapeutic Group of (API)	Anti-Diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	TR-001 1000 Tablets ,TR-002 1000 Tablets , TR-003 1000 Tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	Not submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP performed against the Ertuvia-M 7.5mg + 500mg (2L38 05-2022 05-2024) of M/s. Ferozsons Laboratories Limited.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone iv condition is submitted by the firm.

The status in reference regulatory authorities	Segluromet 7.5mg+500mg Tablet by Merck Sharp & Dohme B.V
GMP status of the firm	Firm submit the GMP certificate dated 31-08-2022.
Evidence of approval of manufacturing facility	Firm submit the GMP certificate dated 31-08-2022, in which mentioned that firm has tablet (general) section.

Evaluation Remarks

Sr.no.	Shortcomings	Response of the Firm
1.	Ertugliflozin LPGA: Submit the specification and detailed analytical procedure of the drug substance used by the drug product manufacturer for the analysis of the drug substance. The submitted dossier includes only the assay verification report without a complete description of the solution preparation method or chromatographic conditions. Additionally, the assay verification report appears to pertain to Ertugliflozin rather than Ertugliflozin L-pyroglutamic acid (Ertugliflozin LPGA). Therefore, clarification is required regarding the identity and analytical method of the drug substance being used.	Updated Specification of Ertugliflozin is attached. Additionally, the chromatographic Condition used in the assay verification report is the same as mentioned in the specification of ertugliflozin L-pyroglutamic acid under assay test. Additionally, we already submitted the assay verification report of ertugliflozin L-pyroglutamic Acid because ertugliflozin occurs as ertugliflozin L-pyroglutamic Acid.
2.	Provide justification for not including LPGA content test in the quality analysis of the Ertugliflozin API by the drug product manufacturer, considering that it is a critical parameter in the quality assessment of Ertugliflozin LPGA	Firm submitted the revised specification and testing method of drug substance of ertugliflozin without the analytical report and their obtained result.
3.	Please justify the following deviations from the USP assay method for Metformin Hydrochloride despite the claim that the API is complied with USP specification both by drug substance manufacturer and drug product manufacturer: · Mobile phase: USP uses phosphate buffer: acetonitrile (95:5, pH 3.0), whereas your method uses water: acetonitrile: TFA in gradient mode. · Diluent: USP uses mobile phase; you used acetonitrile. · Detection wavelength: USP specifies 215 nm; your method uses 250 nm. · Column: USP specifies L9 (4.6 × 250 mm, 10 µm); you used C18 (4.6 × 150 mm, 5 µm). · Flow rate and injection volume: USP uses 1.5 mL/min and 20 µL; your method uses 1.0 mL/min and 10 µL. · Calculation formula: USP uses response ratio; your method uses peak area with weight-based calculations. · System suitability: USP includes tailing and %RSD limits; your method does not specify.	Firm submit the revised assay method without any justification/clarification.
4.	Metformin HCl: Submit the long term stability data of drug substance till the claimed re-test , since you have submitted the data of only 6 months.	The firm has again submitted stability data for the drug substance at long-term storage conditions for only 6 months, instead of providing data covering the complete re-test period as required.

5.	In the drug substance section, it is stated that USP-complied Metformin HCl was procured; however, the composition table in section 3.2.P.1 indicates the use of BP-complied Metformin HCl used in the manufacturing of drug product. Please clarify this inconsistency. Additionally, since Ertugliflozin L-PGA does not have an official monograph in any recognized pharmacopoeia, Justify how it is referred to as USP-complied in section 3.2.P.1 for use in the drug product	Firm submit the revised composition table in the requisite section.
6.	Innovator data classifies Ertugliflozin L-PGA as BCS Class I and Metformin HCl as BCS Class III, both exhibiting high solubility across physiological pH and >85% release within 15 minutes. In contrast, the CDP data for the proposed formulation shows <80% release at 30 minutes in pH 1.2 and 4.5. Justify the observed dissolution behavior of the proposed formulation in light of the solubility and release characteristics reported in the innovator's literature.	Firm replied that , “On Evaluation the discrepancy is found in the CDP valuation process. The error impacted the overall results and has since been corrected. Remediation steps, including correction in the CDP report has been taken and the report is attached. This report clarifies the behavior and release pattern of both active in all mediums with the reference product”.
7.	As per standard analytical practice, assay sample preparation is typically performed using a quantity of powdered tablet equivalent to one tablet, or a specific quantity of powdered tablet in which the amounts of both APIs are known, to ensure accurate and representative concentrations in the final dilution. However, your method involves using 3 intact tablets directly in a 500 mL volumetric flask for sample preparation. Please justify this deviation from standard practice, explain how this approach ensures accurate quantification of both APIs in the final solution, and clarify how the concentrations of both APIs are assessed in the final dilution. Later firm was asked to justify the use of intact tablets over powdered form with reference to relevant guidelines (e.g., ICH Q2(R2), USP <905>). Also clarify how the final concentration of actives is accurately known and representative of the label claim without verifying individual tablet content.	Firm replied that Taking intact tablet for assay sample preparation is more accurate than taking powdered quantity because taking intact tablets contains all amount of active and can easily be transferred into volumetric flask and reduces the chance of error. While taking intact tablets, we consider that all the amount of active, equivalent to 3 tablets have been transferred into volumetric flask and final dilution be prepared as per procedure. In response of second query firm replied that “ On review of our testing method, we revise our testing method of assay in which we change the intact tablet sample preparation method to powdered tablet instead of intact tablet. The Revised Testing method has been attached”
8.	The sample preparation method used during the precision parameter of the assay validation for the drug product differs from the sample preparation method described in the assay procedure given in section 3.2.P.5.2. Please clarify and justify this inconsistency, and explain how the validation data supports the intended routine analytical method. Again Firm was asked that, In your response, you have stated that the same sample	Initially firm replied, The method used during the precision parameter of the assay validation for the drug product is same as used for routine analysis. We calculate the result and mention the result in report as per procedure. Later, firm accept their mistake and replied that “We reviewed both the Assay method verification report of Ertumet 7.5/500 mg tablet and Ertumet 7.5/1000 mg and a discrepancy of typo error was found in the precision parameter, because in the accuracy sample of 100%

	preparation method has been used for both the assay and precision parameters. However, it has been observed that the final sample concentrations differ between the two sections. Specifically, for Ertugliflozin, the concentration is stated as 0.0144 mg/mL in Section 3.2.P.5.2, while it is reported as 0.015 mg/mL in the precision section. Similarly, for Metformin HCl, the concentration is stated as 0.042 mg/mL in the assay method, and 0.0375 mg/mL in the precision section. Justify this discrepancy in sample concentrations, despite the claim that the same sample preparation method was used.	same concentration was used as per the assay method.
9.	Considering that both Ertugliflozin and Metformin HCl are reported in the innovator literature to be highly soluble across the physiological pH range at 37 ± 0.5 °C, and that the tablets exhibit rapid dissolution with >85% release of both APIs within 15 minutes for all strengths, please rationalize the proposed dissolution specification of NLT 80% (Q) in 30 minutes for both Ertugliflozin and Metformin HCl. Justify how this limit is appropriate in light of the known solubility and rapid release characteristics of the APIs. When again asked, "Please specify the international guidelines (e.g., ICH Q6A, FDA, WHO) followed for setting the dissolution acceptance criteria. As the product is non-pharmacopoeial, and if the innovator's literature defines dissolution conditions and limits, the same should be adopted. If an in-house method is used, submit the complete method development data along with justification for the selected parameters and explain any deviation from the innovator's dissolution conditions".	Firm replied that this is a non-Pharmacopeial method, the dissolution test was conducted in accordance with general method guideline. Later, firm replied that, As product is non-pharmacopeial, we performed CDP of the selection of dissolution medium and condition, our product dissolves and innovator both dissolves greater than 85% in 15 minutes, so as per our DRAP guideline in which when 85% dissolves in 15 minutes we take next sampling point for specification which is 20 minutes for routine dissolution process, So, we revised our Specification and supporting data have been attached. However, the innovator literature revealed that the acceptance criteria for dissolution test is Q= % in 15 minutes.

Decision

Approved

Subject to revision of dissolution acceptance in accordance of revision and requisite fee for revision of specifications.

793	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	Maxitech Pharma (Pvt) Ltd. E-178, S.I.T.E., Super Highway Phase-II, Karachi (000851)
	Application Form Dy. No / Tracking ID & date of submission	(SSX-SA9-DU96, 2024-03-18)
	Detail of Fee Submitted	30000.0, 2023-12-21,
	The proposed proprietary name / brand name	ERTUMET 2.5mg+1000mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Ertugliflozin.....2.5mg Metformin HCl...1000mg

Reference to Finished product specifications	Manufacturer Specification
Proposed Pack Size	14's (as per SRO)-As per SRO
Shelf Life (Unit)	2 Year(s)Store at room temperature below 30
For generic drugs (me-too Status)	Ertuvia-M 2.5mg+1000mg Tablet
Pharmacotherapeutic Group of (API)	Anti-Diabetic
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	
Detail of stability batches of drug product	TR-001 1000 Tablets ,TR-002 1000 Tablets , TR-003 1000 Tablets
Documents for the procurement of API with approval from DRAP (in case of Import)	Not submitted
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP performed against the Ertuvia-M 2.5mg +1000mg (2L35 05-2022 05-2024) of M/s. Ferozsans Laboratories Limited.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone iv condition is submitted by the firm.
The status in reference regulatory authorities	Segluromet 2.5mg+1000mg Tablet by Merck Sharp & Dohme B.V
GMP status of the firm	Firm submit the GMP certificate dated 31-08-2022.
Evidence of approval of manufacturing facility	Firm submit the GMP certificate dated 31-08-2022, in which mentioned that firm has tablet (general) section.

Evaluation Remarks

Sr.no.	Shortcomings	Response of the Firm
1.	Ertugliflozin LPGA: Submit the specification and detailed analytical procedure of the drug substance used by the drug product manufacturer for the analysis of the drug substance. The submitted dossier includes only the assay verification report without a complete description of the solution preparation method or chromatographic conditions. Additionally, the assay verification report appears to pertain to Ertugliflozin rather than Ertugliflozin L-pyroglutamic acid (Ertugliflozin LPGA). Therefore, clarification is required regarding the identity and analytical method of the drug substance being used.	Updated Specification of Ertugliflozin is attached. Additionally, the chromatographic Condition used in the assay verification report is the same as mentioned in the specification of ertugliflozin L-pyroglutamic acid under assay test. Additionally, we already submitted the assay verification report of ertugliflozin L-pyroglutamic Acid because ertugliflozin occurs as ertugliflozin L-pyroglutamic Acid.
2.	Provide justification for not including LPGA content test in the quality analysis of the Ertugliflozin API by the drug product manufacturer, considering that it is a critical parameter in the quality assessment of Ertugliflozin LPGA	Firm submitted the revised specification and testing method of drug substance of ertugliflozin without the analytical report and their obtained result.
3.	Please justify the following deviations from the USP assay method for Metformin Hydrochloride despite the claim that the API is complied with USP specification both by drug substance manufacturer and drug product manufacturer: · Mobile phase: USP uses phosphate buffer: acetonitrile (95:5, pH 3.0), whereas your method uses water:	Firm submit the revised assay method without any justification/clarification.

	acetonitrile: TFA in gradient mode. · Diluent: USP uses mobile phase; you used acetonitrile. · Detection wavelength: USP specifies 215 nm; your method uses 250 nm. · Column: USP specifies L9 (4.6 × 250 mm, 10 µm); you used C18 (4.6 × 150 mm, 5 µm). · Flow rate and injection volume: USP uses 1.5 mL/min and 20 µL; your method uses 1.0 mL/min and 10 µL. · Calculation formula: USP uses response ratio; your method uses peak area with weight-based calculations. · System suitability: USP includes tailing and %RSD limits; your method does not specify.	
4.	Metformin HCl: Submit the long term stability data of drug substance till the claimed re-test , since you have submitted the data of only 6 months.	The firm has again submitted stability data for the drug substance at long-term storage conditions for only 6 months, instead of providing data covering the complete re-test period as required.
5.	In the drug substance section, it is stated that USP-complied Metformin HCl was procured; however, the composition table in section 3.2.P.1 indicates the use of BP-complied Metformin HCl used in the manufacturing of drug product. Please clarify this inconsistency. Additionally, since Ertugliflozin L-PGA does not have an official monograph in any recognized pharmacopoeia, Justify how it is referred to as USP-complied in section 3.2.P.1 for use in the drug product	Firm submit the revised composition table in the requisite section.
6.	Innovator data classifies Ertugliflozin L-PGA as BCS Class I and Metformin HCl as BCS Class III, both exhibiting high solubility across physiological pH and >85% release within 15 minutes. In contrast, the CDP data for the proposed formulation shows <80% release at 30 minutes in pH 1.2 and 4.5. Justify the observed dissolution behavior of the proposed formulation in light of the solubility and release characteristics reported in the innovator's literature.	Firm replied that , “On Evaluation the discrepancy is found in the CDP valuation process. The error impacted the overall results and has since been corrected. Remediation steps, including correction in the CDP report has been taken and the report is attached. This report clarifies the behavior and release pattern of both active in all mediums with the reference product”.
7.	As per standard analytical practice, assay sample preparation is typically performed using a quantity of powdered tablet equivalent to one tablet, or a specific quantity of powdered tablet in which the amounts of both APIs are known, to ensure accurate and representative concentrations in the final dilution. However, your method involves using 3 intact tablets directly in a 500 mL volumetric flask for sample preparation. Please justify this deviation from standard practice, explain how this approach ensures accurate quantification of both APIs in the final solution, and clarify how the concentrations of both APIs are assessed in	Firm replied that Taking intact tablet for assay sample preparation is more accurate than taking powdered quantity because taking intact tablets contains all amount of active and can easily be transferred into volumetric flask and reduces the chance of error. While taking intact tablets, we consider that all the amount of active, equivalent to 3 tablets have been transferred into volumetric flask and final dilution be prepared as per procedure. In response of second query firm replied that “ On review of our testing method, we revise our testing method of assay in which we change the intact tablet sample preparation method to powdered tablet instead of intact tablet. The Revised Testing method has been attached”

	the final dilution. Later firm was asked to justify the use of intact tablets over powdered form with reference to relevant guidelines (e.g., ICH Q2(R2), USP <905>). Also clarify how the final concentration of actives is accurately known and representative of the label claim without verifying individual tablet content.	
8.	The sample preparation method used during the precision parameter of the assay validation for the drug product differs from the sample preparation method described in the assay procedure given in section 3.2.P.5.2. Please clarify and justify this inconsistency, and explain how the validation data supports the intended routine analytical method. Again Firm was asked that, In your response, you have stated that the same sample preparation method has been used for both the assay and precision parameters. However, it has been observed that the final sample concentrations differ between the two sections. Specifically, for Ertugliflozin, the concentration is stated as 0.0144 mg/mL in Section 3.2.P.5.2, while it is reported as 0.015 mg/mL in the precision section. Similarly, for Metformin HCl, the concentration is stated as 0.042 mg/mL in the assay method, and 0.0375 mg/mL in the precision section. Justify this discrepancy in sample concentrations, despite the claim that the same sample preparation method was used.	Initially firm replied, The method used during the precision parameter of the assay validation for the drug product is same as used for routine analysis. We calculate the result and mention the result in report as per procedure. Later, firm accept their mistake and replied that “We reviewed both the Assay method verification report of Ertumet 7.5/500 mg tablet and Ertumet 7.5/1000 mg and a discrepancy of typo error was found in the precision parameter, because in the accuracy sample of 100% same concentration was used as per the assay method.
9.	Considering that both Ertugliflozin and Metformin HCl are reported in the innovator literature to be highly soluble across the physiological pH range at 37 ± 0.5 °C, and that the tablets exhibit rapid dissolution with >85% release of both APIs within 15 minutes for all strengths, please rationalize the proposed dissolution specification of NLT 80% (Q) in 30 minutes for both Ertugliflozin and Metformin HCl. Justify how this limit is appropriate in light of the known solubility and rapid release characteristics of the APIs. When again asked, “Please specify the international guidelines (e.g., ICH Q6A, FDA, WHO) followed for setting the dissolution acceptance criteria. As the product is non-pharmacopoeial, and if the innovator’s literature defines dissolution conditions and limits, the same should be adopted. If an in-house method is used, submit the complete method development data along with justification for the selected parameters and	Firm replied that this is a non-Pharmacopeial method, the dissolution test was conducted in accordance with general method guideline. Later, firm replied that, As product is non-pharmacopeial, we performed CDP of the selection of dissolution medium and condition, our product dissolves and innovator both dissolves greater than 85% in 15 minutes, so as per our DRAP guideline in which when 85% dissolves in 15 minutes we take next sampling point for specification which is 20 minutes for routine dissolution process, So, we revised our Specification and supporting data have been attached. However, the innovator literature revealed that the acceptance criteria for dissolution test is Q= % in 15 minutes.

	explain any deviation from the innovator's dissolution conditions".	

Decision

Approved

Subject to revision of dissolution acceptance in accordance of revision and requisite fee for revision of specifications.

794	Case Category	Priority As Per 257-M of RB (Saima Hussain)
	Name, address of Applicant.	Kaizen Pharmaceuticals (Pvt) Ltd Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi (000755)
	Application Form Dy. No / Tracking ID & date of submission	(TJZ-8UX-RZEX, 2025-08-04)
	Detail of Fee Submitted	75000.0, 2025-07-02,
	The proposed proprietary name / brand name	INTONING 420MG TABLET
	Label Claim	Each Film coated Tablet Contains: Ibrutinib 420mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	28's-As per SRO
	Shelf Life (Unit)	2 Yearstore below 30°C in a cool and dry place
	For generic drugs (me-too Status)	Not applicable as it is a new drug product
	Pharmacotherapeutic Group of (API)	protein kinase inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Anhui Haikang Pharmaceutical.Co.,LtdAddress ADDRESS:N0.21 HUANCHENG WEST ROAD, DAGUAN DISTRICT, ANQING CITY, ANHUI PROVINCE, 246000 CHINA
	Detail of stability batches of drug product	Accelerated Stability Study {0, 3 & 6 months (completed)}, Long term / Real time stability study {0,3, 6 & 9) months (completed)}
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	pharmaceutical equivalence and CDP has been provided,
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	provided
	The status in reference regulatory authorities	Medicines and Healthcare products Regulatory Agency (MHRA)
	GMP status of the firm	valid
	Evidence of approval of manufacturing facility	attached

Evaluation Remarks

IMBRUVICA is a kinase inhibitor indicated for the treatment of: • Adult patients with chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) (1.1). • Adult patients with chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) with 17p deletion (1.2). • Adult patients with Waldenström's macroglobulinemia (WM) (1.3). • Adult and pediatric patients age 1 year and older with chronic graft versus host disease (cGVHD) after failure of one or more lines of systemic therapy. CLL/SLL and WM: 420 mg taken orally once daily (2.1). • cGVHD: o Patients 12 years and older: 420 mg taken orally once daily (2.1). o Patients 1 to less than 12 years of age: 240 mg/m2 taken orally once daily (up to a dose of 420 mg) (2.1). Tablets or capsules should be taken orally with a glass of water. Do not open, break, or chew the capsules. Do not cut, crush, or chew the

tablets. See full prescribing information for oral suspension administration instructions (2.1).USFDA Approved strength 140mg,280mg and 420mg Film coated (IMBRUVICA)

Sr.no.	Observations/Shortcomings	Response of the Firm
1.	Justify for not including the test of S-isomer of Ibrutinib and chiral purity test while performing the quality analysis of drug substance by the drug product manufacturer, since the test is part of the specification of drug substance manufacturer.	Firm replied that "We assure your good office that we will perform the required test for our commercial consignment, since the availability of racemic reference standard is committed by API Manufacturer. Commitment letter of API Manufacturer is attached".
2.	Please clarify the sample preparation step equivalent to one tablet content powder weight in the assay procedure, specifically the phrase: 'Accurately weigh to into 100 mL Volumetric flask with diluent' What type of powder is being referred to as equivalent to the weight of one tablet i.e., is it the finely powdered whole tablets, a blend, or another material?"	Firm clarified that "As mentioned in the method 'Accurately weigh to equivalent to one tablet content powder weight into 100 mL Volumetric flask with diluent' refers to the sample to be drawn from blend of 20 crushed tablets. Revised method is submitted.
3.	Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP.	Firm submit the License to import the active ingredient issued by DRAP dated 28/09/2024 along with commercial invoice that has not attested by DRAP and FEdx receipt.

Decision

Deferred

Deferred for on-site inspection of the firm for the authenticity/verification of submitted pharmaceutical development data and stability data. Further, firm shall perform the test of S-isomer of Ibrutinib and chiral purity test on the remaining quantity of drug substance and submit the report accordingly.

795	Case Category	Priority As Per 257-M of RB (Saima Hussain)
	Name, address of Applicant.	Kaizen Pharmaceuticals (Pvt) Ltd Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi (000755)
	Application Form Dy. No / Tracking ID & date of submission	(XN1-D8P-JQY4, 2025-08-04)
	Detail of Fee Submitted	75000.0, 2025-07-02,
	The proposed proprietary name / brand name	INTONING 280MG TABLET
	Label Claim	Each Film coated Tablet Contains: Ibrutinib 280mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	28's-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30°C in a cool and dry place
	For generic drugs (me-too Status)	Not applicable as it is a new drug product
	Pharmacotherapeutic Group of (API)	protein kinase inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Anhui Haikang Pharmaceutical.Co.,LtdAddress ADDRESS:N0.21 HUANCHENG WEST ROAD,

	DAGUAN DISTRICT, ANQING CITY, ANHUI PROVINCE, 246000 CHINA
Detail of stability batches of drug product	Accelerated Stability Study {0, 3 & 6 months (completed)}, Long term / Real time stability study {0,3, 6 & 9) months (completed)}
Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
Pharmaceutical Equivalence and Comparative Dissolution Profile	pharmaceutical equivalence and CDP has been provided,
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	provided
The status in reference regulatory authorities	Medicines and Healthcare products Regulatory Agency (MHRA)
GMP status of the firm	valid
Evidence of approval of manufacturing facility	attached

Evaluation Remarks

IMBRUVICA is a kinase inhibitor indicated for the treatment of: • Adult patients with chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) (1.1). • Adult patients with chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) with 17p deletion (1.2). • Adult patients with Waldenström's macroglobulinemia (WM) (1.3). • Adult and pediatric patients age 1 year and older with chronic graft versus host disease (cGVHD) after failure of one or more lines of systemic therapy. CLL/SLL and WM: 420 mg taken orally once daily (2.1). • cGVHD: o Patients 12 years and older: 420 mg taken orally once daily (2.1). o Patients 1 to less than 12 years of age: 240 mg/m² taken orally once daily (up to a dose of 420 mg) (2.1). Tablets or capsules should be taken orally with a glass of water. Do not open, break, or chew the capsules. Do not cut, crush, or chew the tablets. See full prescribing information for oral suspension administration instructions (2.1). USFDA Approved strength 140mg, 280mg and 420mg Film coated (IMBRUVICA)

Sr.no.	Observations/Shortcomings	Response of the Firm
1.	Justify for not including the test of S-isomer of Ibrutinib and chiral purity test while performing the quality analysis of drug substance by the drug product manufacturer, since the test is part of the specification of drug substance manufacturer.	Firm replied that "We a good office that we will required test for our co consignment, since the of racemic reference s' committed by API Man Commitment letter of A Manufacturer is attach
2.	Please clarify the sample preparation step equivalent to one tablet content powder weight in the assay procedure, specifically the phrase: 'Accurately weigh to into 100 mL Volumetric flask with diluent' What type of powder is being referred to as equivalent to the weight of one tablet i.e., is it the finely powdered whole tablets, a blend, or another material?"	Firm clarified that "As r the method 'Accurately equivalent to one table powder weight into 100 Volumetric flask with di to the sample to be dra blend of 20 crushed ta Revised method is sub
3.	Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP.	Firm submit the Licens the active ingredient is DRAP dated 28/09/202 commercial invoice the

Decision

Deferred

Deferred for on-site inspection of the firm for the authenticity/verification of submitted pharmaceutical development data and stability data. Further, firm shall perform the test of S-isomer of Ibrutinib and chiral purity test on the remaining quantity of drug substance and submit the report accordingly.

796	Case Category	Priority As Per 257-M of RB (Saima Hussain)
	Name, address of Applicant.	Oncogen Pharma (Pvt) Limited WH-26 & 27-A3 , Korangi Creek Industrial Park (KCIP) (000960)
	Application Form Dy. No / Tracking ID & date of submission	(Z3Q-P9E-63LS, 2025-09-08)
	Detail of Fee Submitted	38700.0, 2025-08-11,
	The proposed proprietary name / brand name	Osivant Tablet 80mg
	Label Claim	Each film-coated tablet contains: Osimertinib Mesylate equivalent to Osimertinib 80mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's & 30's-De-Controlled
	Shelf Life (Unit)	2 YearDo not store above 30°C. Protect from sunlight and moisture.
	For generic drugs (me-too Status)	Tagrix Tablet 80mg
	Pharmacotherapeutic Group of (API)	Osimertinib belongs to the pharmacological group of Antineoplastic agents, protein kinase inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Stability study of 03 batches i.e 012NS04-80, 012NS05- 80 & 012NS06-80 is enclosed in module 3
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 and clearance certificate is attached in module 3
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Osimertinib Tablet 80mg is equivalent to the reference product Tagrix Tablet 80mg
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	stability studies of 36 months is enclosed in module 3
	The status in reference regulatory authorities	US-FDA Approved
	GMP status of the firm	Last GMP Inspection was carried on 07th december 2023 and found good
	Evidence of approval of manufacturing facility	Tablet (Oncology) approved on 04th July 2022

Evaluation Remarks

Sr.no.	Observations	Response of the Firm
1.	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.	As per USFDA innovator chemistry review data (208065orig1s000) Tagrisso 80mg tablet by AstraZeneca Pharmaceuticals, Q value is not mentioned in the report only time is given i.e. 30 mins. According to USFDA Dissolution Testing and Acceptance Criteria for Immediate-

Release Solid Oral Dosage Form Drug Products Containing High Solubility Drug Substances in 2018, "If an alternate acceptance criterion is proposed, the sponsor/applicant should provide additional data to support the proposed acceptance criterion." We have performed pharmaceutical equivalence dissolution testing as per USFDA suggested dissolution parameters i.e. dissolution medium, dissolution RPM, dissolution apparatus for innovator as well as test product. On this basis of above data, we set the dissolution acceptance criteria NLT 80% (Q=75%) in 30 min.

2.

The potency adjustment for the dispensing of drug substance per tablet shall be justified against the Assay and LOD value reported in COA.

As per COA of raw material, Potency of Osimertinib Mesylate is 99.14% on as is basis and LOD is 0.35%. Batch size of Osivant tablet 80mg (Osimertinib Mesylate eq. To Osimertinib) 80mg is 1901 tablets. Osimertinib free base 80mg is equivalent to 95.4mg of Osimertinib Mesylate. (Ref. chemistry review data (208065orig1s000) Tagrisso 80mg tablet by AstraZeneca Pharmaceuticals) Quantity required for 1901 tablet $(95.4 \times 1901) = 181.36\text{g}$ Potency (as is basis) = 99.14% API dispensed Quantity = $181.36 \times 100 / 99.14 = 182.9\text{g}$ Same dispensed quantity is mentioned in the BMR for all 3 batches in the dossier.

Decision

Approved

797

Case Category	New License (Saima Hussain)
Name, address of Applicant.	Gelcaps (Pakistan) Limited B 43 Hub Industrial Estate Baluchistan (000980)
Application Form Dy. No / Tracking ID & date of submission	(J26-G2N-VEJ5, 2025-01-01)
Detail of Fee Submitted	30000.0, 7000.0 2024-03-13, 2024-10-01
The proposed proprietary name / brand name	G-ESOMOL 40mg Cpasule
Label Claim	Esomeprazole 22.5% (As Mg.3H ₂ O Enteric coated pellets) eq. to Esomeprazole 40mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	14's-As per SRO

Shelf Life (Unit)	2 Year(s)Store below 30°C ,Protect from sunlight & moisture
For generic drugs (me-too Status)	NEXIUM 40MG CAPSULE
Pharmacotherapeutic Group of (API)	PPI
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Saakh Pharma (Pvt) Ltd
Detail of stability batches of drug product	3 batches of 2500 capsules each
Documents for the procurement of API with approval from DRAP (in case of Import)	Copy of invoice submitted from M/s Saakh pharma
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE & CDP submitted against Nexum capsule of Getz pharma
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
The status in reference regulatory authorities	Approved by MHRA of UK
GMP status of the firm	NEW DML granted dated 25-10-2023 ncluding Capsule general section
Evidence of approval of manufacturing facility	NEW DML granted dated 25-10-2023 ncluding Capsule general section

Evaluation Remarks

Sr.no.	Shortcomings	Response of the Firm
1.	The drug substance manufacturer has specified that not less than 90% of the labeled amount of Esomeprazole Magnesium should be retained after 2 hours in 0.1N HCl, as an acceptance criterion for their dissolution test of gastric resistant stage. However, the dissolution procedure submitted by the applicant indicates that sampling was performed from the medium after 2 hours in 0.1N HCl. In this context, clarify how the applicant evaluated the retained amount of Esomeprazole in the pellets by analyzing the acid medium, and explain how this correlates with the claimed retention criterion.	In reply of the query firm submit revised analytical procedure,
2.	Submit specification and detailed analytical procedure of drug substance by drug product manufacturer.	Firm submit specification and detailed analytical procedure of drug substance by drug product manufacturer.
3.	Submit analytical method verification report of drug substance performed by drug product manufacturer.	Firm submit the assay verification report of drug product.
4.	Submit batch analysis report of drug substance performed by drug product manufacturer.	Firm submit the batch analysis report of drug substance performed by drug product manufacturer.
5.	Perform comparative dissolution profiling of the drug product in accordance with the decision of the 293rd meeting of the Registration Board, and submit the report accordingly.	Firm has performed comparative dissolution profiling against the comparator product in only pH 6.8 medium.
6.	Submit the chromatograms of the standards used during both the assay and dissolution tests conducted as part of the drug product's stability study, along with the raw data sheets for all tests performed during the stability evaluation.	The firm, in their response, submitted the chromatogram provided by the API manufacturer as part of the Certificate of Analysis (CoA) of the working standard, instead of providing the chromatograms of the actual standards used during the assay and

		dissolution tests performed as part of the drug product's stability study.
7.	Justify the proposed quantity of Esomeprazole enteric coated pellets per unit capsule, for the desired label claim, considering the potency of Esomeprazole determined in drug substance analysis.	According to the calculations provided by the firm, the quantity of pellets filled per capsule during the manufacturing of trial batches was 197.42 mg per capsule. However, the theoretical calculation, based on the potency of esomeprazole (as magnesium trihydrate) pellets at 22.5% to deliver a 40 mg dose, is approximately 177.7 mg per capsule.

Decision

Approved

Subject to the submission of CDP at three times points in accordance with 293rd meeting of Registration Board and revised filling weight in line with potency of esomperazole pellets.

798	Case Category	New License (Saima Hussain)
	Name, address of Applicant.	Gelcaps (Pakistan) Limited B 43 Hub Industrial Estate Baluchistan (000980)
	Application Form Dy. No / Tracking ID & date of submission	(2ZT-L6Z-JW4Z, 2025-06-16)
	Detail of Fee Submitted	37000.0, 2025-05-08,
	The proposed proprietary name / brand name	G-Dexlan 60mg Capsule
	Label Claim	Dexlansoprazole 60mg (As DDR Pellets)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3 x 10's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C ,Protect from sunlight & moisture
	For generic drugs (me-too Status)	Dexilant 60mg Capsule
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vision pharmaceutical ltd
	Detail of stability batches of drug product	Attached in Module III
	Documents for the procurement of API with approval from DRAP (in case of Import)	Local (Attached)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached in DMF
	The status in reference regulatory authorities	FDA
	GMP status of the firm	Certified (Attached)
	Evidence of approval of manufacturing facility	000980

Evaluation Remarks

Sr.no.	Shortcomings	Response of the Firm
1.	It is noted from the innovator product literature that the drug product contains two separate types	Firm in their reply stated that "Yes we manufacture 02 differently coated pellets and

	of enteric-coated granules, each designed to release the active substance at different pH levels — one at approximately pH 5.5 and the other at pH 6.75. The innovator clearly describes the preparation of two distinct batches of pellets, each individually coated with a specific enteric polymer to achieve the dual delayed-release profile. However, according to the manufacturing details provided by drug substance manufacturer, a single batch of pH 5.5 enteric-coated granules is prepared, from which 25% is separated, and the remaining 75% is further coated with an additional polymer layer to achieve pH 6.75 release. In view of this difference, drug substance manufacturer required to clarify how API manufacturer's manufacturing approach is considered comparable to that of the innovator, particularly when the innovator has utilized two independently manufactured and coated granule types, whereas your process involves a single granule population subjected to sequential coating.	blend them in about 25: 75 ratio. Drug layering stage of pellets, is combined, further coating is pH dependent (pH 5.5 & 7.0) coating is done separately and then both pellets blended". However, it is clearly written in the pellets manufacturing procedure "After QC approval of the enteric-coated pellets with drug release at pH 5.5, 75% of the yield (Stage IV) is reloaded into the same fluid bed coater/bottom coater, maintaining a temperature of 30–35°C. The remaining 25% of the pellets are packed into appropriately labeled containers for the final blend".
2.	Submit specification and detailed analytical procedure of drug substance by drug product manufacturer.	Firm submit specification and detailed analytical procedure of drug substance by drug product manufacturer.
3.	Submit analytical method verification report of drug substance performed by drug product manufacturer.	Firm submit analytical verification report
4.	The dissolution acceptance limits provided in Sections 3.2.S.4.1 and 3.2.S.7 differ significantly clarify the reason for these discrepancies.	Stability data shared in DMF is of Initial Trial samples, and stability testing is performed at 07 time points, as recommended by FDA dissolution guidelines. After commercial lots these testing points were minimized to 04, at buffer pH 7.0 (Specification and testing method attached). Release limits were kept narrow, for better evaluation of product stability. During this Batches of Dexlansoprazole DDRP 22.5% (From commercial Lots) Kept at stability testing and stability data is attached , Release Limits are also in compliance.
5.	Perform the comparative dissolution profiling of the applied product against the comparator/reference (innovator) product in accordance with the guidelines approved in the 293rd meeting of the Registration Board, and submit a clear, complete, and readable report accordingly.	The firm has repeatedly submitted the same CDP report in which the sampling times remain unclear and unreadable. Furthermore, the CDP was conducted at pH 1.2, 5.5, and 6.8, whereas it is recommended for Dexlansoprazole capsules to also include testing at pH 7 as part of the study requirements.
6.	Provide reference literature which is used for setting the dissolution acceptance limit.	Firm replied that FDA Dissolution guidelines (Dexlansoprazole Capsules) is used as reference for time points, and limits are set from comparative testing with Dexilant capsules.
7.	Submit detailed calculation of dispensed weight of pellets per capsule along with Batch Manufacturing Record (BMR) of all stability batches.	Firm submitted BMR dispensed weight of pellets per capsule is mentioned.

Decision
Approved

799	Case Category	New License (Saima Hussain)
	Name, address of Applicant.	Gelcaps (Pakistan) Limited B 43 Hub Industrial Estate Baluchistan (000980)
	Application Form Dy. No / Tracking ID & date of submission	(57D-WXJ-4HNA, 2025-06-05)
	Detail of Fee Submitted	37000.0, 2025-05-08,
	The proposed proprietary name / brand name	G-Dexlan 30mg Capsule
	Label Claim	Dexlansoprazole 30mg (As DDR Pellets)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3 x 10's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C ,Protect from sunlight & moisture
	For generic drugs (me-too Status)	DEXILANT 30MG CAPSULE
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vision pharmaceutical ltd
	Detail of stability batches of drug product	Attached in Module III
	Documents for the procurement of API with approval from DRAP (in case of Import)	Local (Attached)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP are performed against the comparator product.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone-iv conditions are submitted.
	The status in reference regulatory authorities	FDA
	GMP status of the firm	New DML issue dated 25-10-2023
	Evidence of approval of manufacturing facility	Issuance of DML letter attached dated 25-10-2023 in which mentioned that firm has capsule (general) section

Evaluation Remarks

Sr.no.	Shortcomings	Response of the Firm
1.	It is noted from the innovator product literature that the drug product contains two separate types of enteric-coated granules, each designed to release the active substance at different pH levels — one at approximately pH 5.5 and the other at pH 6.75. The innovator clearly describes the preparation of two distinct batches of pellets, each individually coated with a specific enteric polymer to achieve the dual delayed-release profile. However, according to the manufacturing details provided by drug substance manufacturer, a single batch of pH 5.5 enteric-coated granules is prepared, from which 25% is separated, and the remaining 75% is further coated with an additional polymer layer to achieve pH 6.75 release. In view of this difference, drug substance	Firm in their reply stated that “Yes we manufacture 02 differently coated pellets and blend them in about 25: 75 ratio. Drug layering stage of pellets, is combined, further coating is pH dependent (pH 5.5 & 7.0) coating is done separately and then both pellets blended”. However, it is clearly written in the pellets manufacturing procedure “After QC approval of the enteric-coated pellets with drug release at pH 5.5, 75% of the yield (Stage IV) is reloaded into the same fluid bed coater/bottom coater, maintaining a temperature of 30–35°C. The remaining 25% of the pellets are packed into appropriately labeled containers for the final blend”.

	manufacturer required to clarify how API manufacturer's manufacturing approach is considered comparable to that of the innovator, particularly when the innovator has utilized two independently manufactured and coated granule types, whereas your process involves a single granule population subjected to sequential coating.	
2.	Submit specification and detailed analytical procedure of drug substance by drug product manufacturer.	Firm submit specification and detailed analytical procedure of drug substance by drug product manufacturer.
3.	Submit analytical method verification report of drug substance performed by drug product manufacturer.	Firm submit analytical verification report
4.	The dissolution acceptance limits provided in Sections 3.2.S.4.1 and 3.2.S.7 differ significantly clarify the reason for these discrepancies.	Stability data shared in DMF is of Initial Trial samples, and stability testing is performed at 07 time points, as recommended by FDA dissolution guidelines. After commercial lots these testing points were minimized to 04, at buffer pH 7.0 (Specification and testing method attached). Release limits were kept narrow, for better evaluation of product stability. During this Batches of Dexlansoprazole DDRP 22.5% (From commercial Lots) Kept at stability testing and stability data is attached , Release Limits are also in compliance.
5.	Perform the comparative dissolution profiling of the applied product against the comparator/reference (innovator) product in accordance with the guidelines approved in the 293rd meeting of the Registration Board, and submit a clear, complete, and readable report accordingly.	The firm has repeatedly submitted the same CDP report in which the sampling times remain unclear and unreadable. Furthermore, the CDP was conducted at pH 1.2, 5.5, and 6.8, whereas it is recommended for Dexlansoprazole capsules to also include testing at pH 7 as part of the study requirements.
6.	Provide reference literature which is used for setting the dissolution acceptance limit.	Firm replied that FDA Dissolution guidelines (Dexlansoprazole Capsules) is used as reference for time points, and limits are set from comparative testing with Dexilant capsules.
7.	Submit detailed calculation of dispensed weight of pellets per capsule along with Batch Manufacturing Record (BMR) of all stability batches.	Firm submitted BMR dispensed weight of pellets per capsule is mentioned.

Decision

Approved

800	Case Category	New License (Saima Hussain)
	Name, address of Applicant.	S&K Pharmaceuticals Plot N0. 252, Sunder Industrial Estate (000961)
	Application Form Dy. No / Tracking ID & date of submission	(1NB-PBU-HZB1, 2025-03-10)
	Detail of Fee Submitted	37000.0, 2024-12-12,
	The proposed proprietary name / brand name	SK-ZOL 0.5%

Label Claim	Each 100mL contains: Metronidazole 0.5%w/v
Reference to Finished product specifications	British Pharmacopoeia
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 Year(s)Room temperature
For generic drugs (me-too Status)	Medigyl IV Infusion by Medipak Limited
Pharmacotherapeutic Group of (API)	Antibacterial agents
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Aarti Drugs Limited
Detail of stability batches of drug product	Stability data of batches A,B,C of 100 liter batch sizes each is submitted by the firm.
Documents for the procurement of API with approval from DRAP (in case of Import)	API Loan letter has been submitted on the letter head of Rasco
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE has been performed against Medigyl Infusion of M/s. : Medipak Limited.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone iv condition is submitted by the firm
The status in reference regulatory authorities	MHRA Approved
GMP status of the firm	Copy of DML issue dated 08-11-2022 is submitted by the firm.
Evidence of approval of manufacturing facility	Issuance of DML letter dated 10th November,2022 mentioned that Liquid Infusion(General) section

Evaluation Remarks

Sr.no.	Shortcomings	Response of the Firm
1.	Clarify the rationale for using varying sample weights (148 mg, 149 mg, 150 mg) instead of the specified 0.150 g (150 mg) in the precision study for metronidazole. Justify how this weight variations comply with the method and confirm whether the assay results were normalized based on actual sample weight taken.	Firm replied that Minor variations in sample weights occur due to practical limitations in laboratory weighing. Using slightly varying weights (148–150 mg) reflects real-world conditions and evaluates method robustness. Assay results were normalized based on the actual weight of each sample to ensure accuracy.
2.	Submit the long-term stability data of the drug substance conducted under Zone IV-A conditions, as only the stability data at 25°C/60% RH has been provided.	Long-term stability data conducted under Zone IV-A conditions has been attached for review.
3.	Justify for not including the sterility testing for Metronidazole Intravenous Infusion, while performing the pharmaceutical equivalence study and stability study of applied drug product, considering that it is a parenteral preparation and must comply with sterility requirements as per the General Notices of the British Pharmacopoeia (BP).	Firm replied that, Sterility testing was performed in accordance with BP general notices. It was inadvertently omitted due to a typographical error. Corrected data is now submitted for review.
4.	Justify the selection of 106°C for 1 hour as the sterilization condition for the LDPE container, considering its thermal stability. Provide data or documented evidence demonstrating that this temperature does not cause degradation or leaching of plastic components, ensuring the container's integrity and product safety.	Firm in its reply stated that The 106°C for 1 hour condition is within the thermal stability limits of LDPE. It ensures effective sterilization without causing degradation or leaching. Scientific literature and regulatory guidelines (FDA, USP) confirm that LDPE remains stable under these conditions. Detailed data and references provided in the response. However, firm has not provided any reference material

		along with reply nor submit the COA of the plastic container/ pellets provided by the vendor for the confirmation of thermal stability of plastic packaging material.
5.	The submitted Batch Manufacturing Record (BMR) specifies that the pH of the injectable solution is maintained between 5.0 and 7.0, whereas the British Pharmacopoeia (BP) monograph for Metronidazole Injection defines the pH specification as 4.5 to 6.0. Provide a scientific justification rationale for how the proposed pH range complies with the BP specification.	Firm clarified that The BMR for Metronidazole infusion has been corrected to reflect the BP-specified range of 4.5–6.0. The 5.0–7.0 range applies only to the Water for Injection used in the formulation. Relevant BMR page reference is included for clarity.

Decision

Approved

Firm shall submit fee of Rs. 9,400/- for pre-registration variations as per notification vide No. S.R.O. 1399(I)/2025 dated 01-10-2025 before issuance of registration letter.

801	Case Category	New License (Saima Hussain)
	Name, address of Applicant.	Misaq Pharmaceuticals Pvt Ltd. Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad. (000985)
	Application Form Dy. No / Tracking ID & date of submission	(GEQ-2NL-848Y, 2025-04-23)
	Detail of Fee Submitted	37000.0, 2025-03-14,
	The proposed proprietary name / brand name	Prosrex
	Label Claim	Each Capsule Contains: Tamsulosin HCl as Sustained Release Pellets-----0.4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2x10's/3x10's/10x10'-As per SRO
	Shelf Life (Unit)	2 Year(s)15-30 Degree Centigrade
	For generic drugs (me-too Status)	Tamsolin Capsule By Getz Pharma, Karachi-Pakistan
	Pharmacotherapeutic Group of (API)	Tamsulosin hydrochloride is an alpha1- adrenoceptor blocking agent in Prostate.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vision Pharmaceuticals Pvt. Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad-Pakistan, Tel:+92 (51) 4493587, Email: Contact@visionpharmapk.com, Web: www.visionpharmapk.com.
	Detail of stability batches of drug product	Batch Nos.: 1- TRD-TMS0.4-001, 2- TRD-TMS0.4-002, 3- TRD-TMS0.4-003, Batch Size Each: 2000 Capsules
	Documents for the procurement of API with approval from DRAP (in case of Import)	NA
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PHARMACEUTICAL EQUIVALENCE(ATTACHED IN RELEVANT MODULE): Prosrex(Misaq) & Tamsolin(Getz) are similar or comparable to each other in physical/chemical aspects as per USP. 2-COMPARATIVE DISSOLUTION PROFILE(ATTACHED IN RELEVANT MODULE):

	The dissolution profile of test product is similar to comparator product by factor 99.97 in the acidic medium and 99.23 in the buffer medium.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	1- Long term stability study: Tamsulosin HCl is packed in container similar to commercial pack, kept at storage temperature ($30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / RH 65 % $\pm$ 5 %) It is being tested interval of three months for one year and later on will be tested once in a six month up to one year and then once in a year till the expiry date of product. Thus three batches of Tamsulosin HCl were subjected to stability testing at storage temperature and the results are recorded. The data obtained from the real time studies is for 36 months. 2- Accelerated stability study: The batch of Tamsulosin HCl (TMS205T/TMS206/TMS208) were also subjected to accelerated stability study at $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / RH 75 % $\pm$ 5 %) for 0 month, 3 months, and 6 months. The results were recorded. There is neither significant drop in assay values nor significant increase in values of related compounds.
The status in reference regulatory authorities	US-FDA
GMP status of the firm	Our Firm is Newly Licensed.
Evidence of approval of manufacturing facility	Name: MISAQ PHARMACEUTICALS PVT. LTD. /DML # 000985/ Site Address: 7-B, Woven Garments Zone, Value Addition City, Khurrianwala-Sahianwala Road, Faisalabad-Pakistan.

Evaluation Remarks

Sr.no.	Observations	Response of the firm
1.	Submit the specification and detailed analytical procedure of the drug substance as used by the drug product manufacturer for analysis purposes.	Specification and analytical procedure of the drug substance are submitted by the firm.
2.	Submit the assay verification report of the drug substance, conducted by the drug product manufacturer, to confirm compliance with the applicable pharmacopoeial standards.	The raw material for Tamsulosin Capsules consists of pre-formulated pellets, directly filled into capsules without further modification. Since the manufacturing process does not alter the physical or chemical properties, the same pharmacopoeial assay method applies to both the raw material and the finished product. Hence, the assay verification performed on the raw material also confirms compliance of the drug substance.
3.	The claimed filled weight of 270 mg per capsule for delivering 0.4 mg of Tamsulosin HCl using 0.2% w/w pellets with NMT 5% water content exceeds the theoretical requirement of approximately 208 mg. Rationalize the excess fill weight.	Calculation: • Required pellet weight = $0.4 \text{ mg} \div 0.002 = 200 \text{ mg}$ • Adjusted for maximum 5% water = $200 \times 1.05 = 210 \text{ mg}$ Theoretical minimum fill weight: 208–210 mg Empty hard gelatin capsule shell weight: 60 mg Total weight including shell: 270 mg
4.	Justify the rationale for conducting the CDP using only one time point in	The CDP was conducted as per the USP monograph, which specifies: •

	acidic medium and two time points in buffer stage, instead of multiple time points (at least three) as generally required for sustained-release formulations.	One point in acid stage (limit 13–34%) • First buffer stage point (limit 47–68%) • Final buffer stage point (NLT 80%) Since these three specific time points are clearly defined by USP, additional intermediate time points were not required. The study fully complies with official pharmacopeial requirements.
5.	Justify the verification of the assay method that deviates from the USP-recommended procedure, specifically regarding: • Absence of system suitability data • Use of a sample solution concentration not aligned with the USP monograph.	No deviations were made from the USP-recommended procedure. All system suitability parameters were adopted and verified, including: • Resolution ≥ 12 between Tamsulosin and Propyl Paraben • %RSD $\leq 2.0\%$ for ratios of peak areas (Tamsulosin to internal standard) The sample solution concentration and preparation matched the USP monograph. Complete verification data and chromatograms are attached
6.	Submit raw data sheets of the entire tests performed during the stability studies of the drug product.	Raw analytical sheets are provided for review
7.	Justify the use of 100 μ L injection volume during dissolution testing instead of the USP-recommended 250 μ L. Additionally, label all peaks in the chromatograms, especially those near the principal peak, and clarify their identity	A 100 μ L injection volume was used as it provided well-resolved peak responses without compromising sensitivity, resolution, or overall chromatographic performance. System suitability parameters remained within acceptable limits. Peak Identification: • Total of three peaks observed: – First and last peaks: Internal standard (Propyl Paraben) – Middle peak: Principal peak of Tamsulosin Separate injections of the internal standard confirmed retention time and specificity. Supporting chromatograms attached.

Decision

Approved

802	Case Category	Export Facilitation (Saima Hussain)
	Name, address of Applicant.	AGP Limited B-23-C, S.I.T.E., Karachi (000348)
	Application Form Dy. No / Tracking ID & date of submission	(X27-ZSU-P81H, 2025-02-17)
	Detail of Fee Submitted	30000.0, 2023-09-26,
	The proposed proprietary name / brand name	Pleurobiotic
	Label Claim	Each film coated tablet Contains: Lefamulin as Acetate -- -----600mg.

Reference to Finished product specifications	Manufacturer Specification
Proposed Pack Size	Pleurobiotic 600mg t-As per SRO
Shelf Life (Unit)	2 Year(s)store below 30 degree Centigrade
For generic drugs (me-too Status)	Generic drug product,lefazon by M/s.Horizon healthcare Pvt.Ltd.
Pharmacotherapeutic Group of (API)	Pleuromutilin antibiotic.
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	
Detail of stability batches of drug product	051DS01,051DS02,051DS03
Documents for the procurement of API with approval from DRAP (in case of Import)	Form-6 has been submitted by the firm.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP performed against the comparator product Lefaly 600mg Tablet of M/s. Horizon (Batch no.52724)
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone iv condition is submitted by the firm
The status in reference regulatory authorities	FDA approved,Xanelta 600mg Tablet by Nebriva Therapeutics U.S INC
GMP status of the firm	GMP certificate dated 15-06-2023 is submitted by the firm.
Evidence of approval of manufacturing facility	Renewal of DML letter dated 30-06-2020 is submitted in which mentioned that firm has tablet (general) section.

Evaluation Remarks

Sr.no.	Observations/Shortcoming	Response of the Firm
1.	Justify the rationale for adopting a different assay method for API by the drug product manufacturer compared to the assay method recommended by the drug substance manufacturer, particularly with respect to the differences observed in mobile phase composition (buffering system and organic solvent), gradient program, injection volume, and sample preparation	The submitted API testing procedure was also provided by supplier. However, we have revised the testing procedure as per DMF provided by supplier. The revised testing method has been validated & related record is attached
2.	Submit DRAP attested commercial invoice as an evidence of procurement of API from the country of origin.	Firm has submitted only Form 6
3.	According to the weight variation chart of coated tablets attached in the BMR for the three trial batches, none of the 10 tested tablets at any in-process testing point achieved the target weight of 1025 mg; all tablets consistently showed values on the lower side. Kindly clarify whether there is a specific reason for not targeting the exact weight of the coated tablets, or if a potential systemic error in the process could be responsible for this deviation.	In coating process, the rate of tablet weight increases with time and coating process stops when target weight achieved. In this case, the final in process data is missing.However, we have checked the weight of available coated tablets and after two years the results showing that the target weight was nearly achieved in all the batches.The reference weight slips of all these batches are attached-

Decision

Approved

Registration Board approved the product subject to compliance of current Import Policy for finished drugs. Further, firm shall submit valid, legalized and original CoPP/free sale certificate and letter of authorization prior the issuance of Registration letter.

803	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	Genetics Pharmaceuticals Pvt. Ltd 539-A Sundar Industrial Estate Raiwind Road Lahore (000845)
	Application Form Dy. No / Tracking ID & date of submission	(XZX-3A4-LDH9, 2024-03-11)
	Detail of Fee Submitted	30000.0, 150000.0 2023-12-18, 2024-01-24
	The proposed proprietary name / brand name	Memaxa SR Capsule 14mg
	Label Claim	Each capsule Contains: Memantine hydrochloride SR Pellets 14mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	2 Year(s)Protect from Heat light and moisture
	For generic drugs (me-too Status)	Memura by PharmEvo
	Pharmacotherapeutic Group of (API)	NMDA receptors antagonist (Anti-Alzheimer)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Name and address of API manufacturer: ALPHAMED FORMULATIONS PRIVATE LIMITED Survey No. 225, Sampanbole Village, Shamirpet Mandal, Medchal-Malkajgiri District, Telangana-500078, India.
	Detail of stability batches of drug product	Stability batches (RD-GP-5DMM-23001 2500 CAPSULES, RD-GP-5DMM-23002 2500 capsules, RD-GP-5DMM-23003 2500 capsules)
	Documents for the procurement of API with approval from DRAP (in case of Import)	submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP performed against the Namenda 14mg XR Capsule
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone-iv condition is submitted by the firm.
	The status in reference regulatory authorities	Reference Regulatory Authority: U.S. FDA Manufacturer name: Allergen, AbbVie Brand name: Namend
	GMP status of the firm	GMP certificate dated 06-06-2022 is submitted by the firm.
	Evidence of approval of manufacturing facility	GMP certificate dated 06-06-2022 mentioned that firm has tablet general section.

Evaluation Remarks

Sr.no.	Observations	Response of the Firm
1.	Justify the selection of dissolution sampling time points at 2.5, 6, and 12 hours for the drug product, whereas the innovator product literature specifies sampling time points at 1, 4, 8, and 12 hours. Provide a rationale for the deviation from the dissolution	There is no official method available for Memantine SR Capsules; therefore, the manufacturer's method was adopted for analysis. Dissolution sampling time points at 2.5, 6, and 12 hours were selected based on the manufacturer's method. Additionally, the time points specified in the

	profile recommended for the innovator product.	innovator product literature (1, 4, 8, and 12 hours) were evaluated in the Comparative Dissolution Profile (CDP), and the results complied with the specified requirements).
2.	According to the provided assay method, it is stated that Amantadine HCl was used as an internal standard; however, it has not been specified whether a pharmacopoeial standard or a working standard was used. The applicant is advised to clarify the source and type of standard employed and to provide the Certificate of Analysis (CoA) for the primary or working standard of Amantadine HCl used in the assay.	According to the provided assay method, Memantine HCl was used as the working standard, while Amantadine HCl used as the internal standard. The internal standard, Amantadine HCl, was a USP Pharmacopoeial Reference Standard (USP Lot # R049P0). The Certificate of Analysis (CoA) for the USP primary reference standard used as the internal standard is attached
3.	Please clarify the reason for not procuring the working standard of Memantine HCl from the pellet manufacturer, i.e., Alphamed Formulations, India, from whom the extended-release pellets of Memantine HCl were sourced.	Both the API and the working standard were obtained from Alphamed Formulations, India, the designated pellet manufacturer. The working standard supplied by Alphamed Formulations originates from MSN Pharmachem Pvt Ltd. Certificate of Analysis (CoA) of Memantine working standard received from Alphamed Formulations, India, is also attached.

Decision

Approved

804	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	Genetics Pharmaceuticals Pvt. Ltd 539-A Sundar Industrial Estate Raiwind Road Lahore (000845)
	Application Form Dy. No / Tracking ID & date of submission	(YTW-VH5-G1LY, 2024-03-11)
	Detail of Fee Submitted	30000.0, 150000.0 2023-12-15, 2024-01-19
	The proposed proprietary name / brand name	Memaxa SR Capsule 28mg
	Label Claim	Each capsule Contains: Memantine hydrochloride SR Pellets 28mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	2 Year(s)Protect from Heat light and moisture
	For generic drugs (me-too Status)	Memura by PharmEvo
	Pharmacotherapeutic Group of (API)	NMDA receptors antagonist (Anti-Alzheimer)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Name and address of API manufacturer: ALPHAMED FORMULATIONS PRIVATE LIMITED Survey No. 225, Sampanbole Village, Shamirpet Mandal, Medchal-Malkajgiri District, Telangana-500078, India.

Detail of stability batches of drug product	Stability batches (RD-GP-5DMM-23001 2500 CAPSULES, RD-GP-5DMM-23002 2500 capsules, RD-GP-5DMM-23003 2500 capsules)
Documents for the procurement of API with approval from DRAP (in case of Import)	submitted
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP performed against the Namenda 28mg XR Capsules
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone-iv condition is submitted by the firm.
The status in reference regulatory authorities	Reference Regulatory Authority: U.S. FDA Manufacturer name: Allergen, AbbVie Brand name: Namend
GMP status of the firm	GMP certificate dated 06-06-2022 is submitted by the firm.
Evidence of approval of manufacturing facility	GMP certificate dated 06-06-2022 mentioned that firm has tablet general section.

Evaluation Remarks

Sr.no.	Observations	Response of the Firm
1.	Justify the selection of dissolution sampling time points at 2.5, 6, and 12 hours for the drug product, whereas the innovator product literature specifies sampling time points at 1, 4, 8, and 12 hours. Provide a rationale for the deviation from the dissolution profile recommended for the innovator product.	There is no official method available for Memantine SR Capsules; therefore, the manufacturer's method was adopted for analysis. Dissolution sampling time points at 2.5, 6, and 12 hours were selected based on the manufacturer's method. Additionally, the time points specified in the innovator product literature (1, 4, 8, and 12 hours) were evaluated in the Comparative Dissolution Profile (CDP), and the results complied with the specified requirements).
2.	According to the provided assay method, it is stated that Amantadine HCl was used as an internal standard; however, it has not been specified whether a pharmacopoeial standard or a working standard was used. The applicant	According to the provided assay method, Memantine HCl was used as the working standard, while Amantadine HCl used as the internal standard. The internal standard, Amantadine HCl, was a USP Pharmacopeial Reference

	is advised to clarify the source and type of standard employed and to provide the Certificate of Analysis (CoA) for the primary or working standard of Amantadine HCl used in the assay.	Standard (USP Lot # R049P0). The Certificate of Analysis (CoA) for the USP primary reference standard used as the internal standard is attached
3.	Please clarify the reason for not procuring the working standard of Memantine HCl from the pellet manufacturer, i.e., Alphamed Formulations, India, from whom the extended-release pellets of Memantine HCl were sourced.	Both the API and the working standard were obtained from Alphamed Formulations, India, the designated pellet manufacturer. The working standard supplied by Alphamed Formulations originates from MSN Pharmachem Pvt Ltd. Certificate of Analysis (CoA) of Memantine working standard received from Alphamed Formulations, India, is also attached.

Decision

Approved

805	Case Category	Export Facilitation (Saima Hussain)
	Name, address of Applicant.	CCL Pharmaceuticals (Pvt.) Ltd. 62-Quaid-e-Azam Industrial Estate, Kot Lakhpat (000052)
	Application Form Dy. No / Tracking ID & date of submission	(E2L-BEA-V98J, 2024-10-09)
	Detail of Fee Submitted	75000.0, 2024-05-23,
	The proposed proprietary name / brand name	Mirogab 15 mg
	Label Claim	Each film coated tablet contains Mirogabalin besylate eq to Mirogabalin 15mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,14'-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled,5's-De-Controlled,7's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Not more than 30C
	For generic drugs (me-too Status)	Not available
	Pharmacotherapeutic Group of (API)	Gabapentinoid. ATC Code: N02BF03.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Stability batches (T2-22, T3-22,T4-22) OF 1000 tablets batch size is submitted by the firm.

Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP is performed against the Tarlige 15mg Tablet (YDA 2009)
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone-iv condition is submitted by the firm.
The status in reference regulatory authorities	Tarlige - PMDA Japan Approved
GMP status of the firm	GMP dated 28-03-2023 is submitted by the firm.
Evidence of approval of manufacturing facility	GMP dated 28-03-2023 in which tablet (general) section is submitted by the firm.

Evaluation Remarks

Sr.no.	Shortcomings	Response of the Firm
1.	Please provide a justification for selecting water as the dissolution medium, considering that the drug product demonstrates more than 85% release within 15 minutes across all dissolution media. Submit your response along with a reference document of the innovator product supporting the use of water as the dissolution medium	The dissolution medium and conditions for Mirogabalin tablets have not been disclosed by the innovator, despite regulatory approval by PMDA. No details are available from either FDA or PMDA documentation regarding the dissolution parameters. In accordance with the DRB-293 guidance document titled "Setting Dissolution Specifications for Immediate Release Solid Dosage Forms," a comprehensive comparative dissolution profile (CDP) was performed using pH 1.2, pH 4.5, and pH 6.8 buffer solutions, as well as purified water. Across all media, the formulation demonstrated greater than 85% drug release within 15 minutes. These results indicate that Mirogabalin exhibits pH-independent dissolution behavior. Consequently, the requirement for a buffered medium is minimized, and purified water was selected as the dissolution medium for routine testing of Mirogabalin tablets.
2.	Justify the significant difference in the peak areas of standard and sample solutions observed between: Validation studies (Standard: ~1,409,130; Sample: ~1,283,649 at 100% concentration). Stability studies (Standard: ~1,287; Sample: ~1,307). Clarify why such variation exists despite using the same assay method.	The significant difference in absolute peak areas between the validation studies (Standard: ~1,409,130; Sample: ~1,283,649 at 100% concentration). Stability studies (Standard: ~1,287; Sample: ~1,307) is an expected and acceptable variation resulting from the use of two different HPLC systems. • Validation Studies: Performed on a Shimadzu HPLC system. • Stability Studies: Performed on an Agilent HPLC system. Different HPLC models and manufacturers utilize detectors with varying designs, lamp intensities, and signal amplification electronics. These instrumental differences directly influence the magnitude of the detector's response, leading to different absolute peak area values for the same analyte concentration.
3.	Kindly label the consistently observed peak in all chromatograms attached with the stability report of the drug product. The unlabeled peak elutes at approximately 2 minutes, appearing just before and in close proximity to the principal peak.	The consistently observed peak at ~2 minutes, eluting just before the principal peak, has been labeled as besylate (salt) peak in the 0 Month, 3rd Months and 6 th Month chromatograms. This labeling has been incorporated in chromatograms for clarity and reference
4.	Provide justification from the API manufacturer for specifying such a broad limit of benzenesulfonic acid (42%–46%) in	The drug substance is an acid-addition benzenesulfonate salt. Benzenesulfonic acid functions as the stoichiometric counterion and is part

the API specification, with clarification on whether it is considered an impurity or a residual solvent. Further, submit reference documents from stringent regulatory authorities or other recognized international organizations supporting the presence of benzenesulfonic acid at a level exceeding 40% in a pharmaceutical active ingredient.

of the intended chemical structure. It is therefore neither an impurity (ICH Q3A/B) nor a residual solvent (ICH Q3C), and is controlled as part of the API identity and assay. Theoretical BSA fraction: $0.158.17 \div 367.46 = 0.4305 \rightarrow 43.05\% \text{ w/w}$ (anhydrous, solvent-free basis). • This value anchors the specification range; any justified acceptance criteria should bracket 42.00% - 46.00% considering validated method uncertainty and material attributes. Validation of Benzenesulfonic acid from DMF is also attached for reference.

Decision

Approved

806

Case Category	Export Facilitation (Saima Hussain)
Name, address of Applicant.	CCL Pharmaceuticals (Pvt.) Ltd. 62-Quaid-e-Azam Industrial Estate, Kot Lakhpat (000052)
Application Form Dy. No / Tracking ID & date of submission	(E71-258-GVT6, 2024-10-09)
Detail of Fee Submitted	75000.0, 2024-05-23,
The proposed proprietary name / brand name	Mirogab 2.5 mg
Label Claim	Each film coated tablet contains; Mirogabalin besylate eq to Mirogabalin 2.5 mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled,5's-De-Controlled,7's-De-Controlled
Shelf Life (Unit)	2 Year(s)Not more than 30C
For generic drugs (me-too Status)	Not available
Pharmacotherapeutic Group of (API)	Gabapentinoid. ATC Code: N02BF03.
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	
Detail of stability batches of drug product	Stability batches (T2-23, T3-23,T4-23) OF 1000 tablets batch size is submitted by the firm.
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP is performed against the Tarlige 2.5mg Tablet (YDA 2009)
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone-iv condition is submitted by the firm.
The status in reference regulatory authorities	Tarlige - PMDA Japan Approved
GMP status of the firm	GMP dated 28-03-2023 is submitted by the firm.
Evidence of approval of manufacturing facility	GMP dated 28-03-2023 in which tablet (general) section is submitted by the firm.

Evaluation Remarks

Sr.no.	Shortcomings	Response of the Firm
1.	Please provide a justification for selecting water as the dissolution medium, considering	The dissolution medium and conditions for Mirogabalin tablets have not been disclosed by the

	that the drug product demonstrates more than 85% release within 15 minutes across all dissolution media. Submit your response along with a reference document of the innovator product supporting the use of water as the dissolution medium	innovator, despite regulatory approval by PMDA. No details are available from either FDA or PMDA documentation regarding the dissolution parameters. In accordance with the DRB-293 guidance document titled "Setting Dissolution Specifications for Immediate Release Solid Dosage Forms," a comprehensive comparative dissolution profile (CDP) was performed using pH 1.2, pH 4.5, and pH 6.8 buffer solutions, as well as purified water. Across all media, the formulation demonstrated greater than 85% drug release within 15 minutes. These results indicate that Mirogabalin exhibits pH-independent dissolution behavior. Consequently, the requirement for a buffered medium is minimized, and purified water was selected as the dissolution medium for routine testing of Mirogabalin tablets.
2.	Justify the significant difference in the peak areas of standard and sample solutions observed between: Validation studies (Standard: ~1,409,130; Sample: ~1,283,649 at 100% concentration). Stability studies (Standard: ~1,287; Sample: ~1,307). Clarify why such variation exists despite using the same assay method.	The significant difference in absolute peak areas between the validation studies (Standard: ~1,409,130; Sample: ~1,283,649 at 100% concentration). Stability studies (Standard: ~1,287; Sample: ~1,307) is an expected and acceptable variation resulting from the use of two different HPLC systems. • Validation Studies: Performed on a Shimadzu HPLC system. • Stability Studies: Performed on an Agilent HPLC system. Different HPLC models and manufacturers utilize detectors with varying designs, lamp intensities, and signal amplification electronics. These instrumental differences directly influence the magnitude of the detector's response, leading to different absolute peak area values for the same analyte concentration.
3.	Kindly label the consistently observed peak in all chromatograms attached with the stability report of the drug product. The unlabeled peak elutes at approximately 2 minutes, appearing just before and in close proximity to the principal peak.	The consistently observed peak at ~2 minutes, eluting just before the principal peak, has been labeled as besylate (salt) peak in the 0 Month, 3rd Months and 6 th Month chromatograms. This labeling has been incorporated in chromatograms for clarity and reference
4.	Provide justification from the API manufacturer for specifying such a broad limit of benzenesulfonic acid (42%–46%) in the API specification, with clarification on whether it is considered an impurity or a residual solvent. Further, submit reference documents from stringent regulatory authorities or other recognized international organizations supporting the presence of benzenesulfonic acid at a level exceeding 40% in a pharmaceutical active ingredient.	The drug substance is an acid-addition benzenesulfonate salt. Benzenesulfonic acid functions as the stoichiometric counterion and is part of the intended chemical structure. It is therefore neither an impurity (ICH Q3A/B) nor a residual solvent (ICH Q3C), and is controlled as part of the API identity and assay. Theoretical BSA fraction: $0.158.17 \div 367.46 = 0.4305 \rightarrow 43.05\% \text{ w/w}$ (anhydrous, solvent-free basis). • This value anchors the specification range; any justified acceptance criteria should bracket 42.00% - 46.00% considering validated method uncertainty and material attributes. Validation of Benzenesulfonic acid from DMF is also attached for reference.

Decision

Approved

807

Case Category	Export Facilitation (Saima Hussain)	
Name, address of Applicant.	CCL Pharmaceuticals (Pvt.) Ltd. 62-Quaid-e-Azam Industrial Estate, Kot Lakhpat (000052)	
Application Form Dy. No / Tracking ID & date of submission	(NA9-ZAB-YG7N, 2024-10-09)	
Detail of Fee Submitted	75000.0, 2024-05-23,	
The proposed proprietary name / brand name	Mirogab 10 mg	
Label Claim	Each film coated tablet contains; Mirogabalin besylate eq to Mirogabalin 10 mg	
Reference to Finished product specifications	As per Innovators Specification	
Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled,5's-De-Controlled,7's-De-Controlled	
Shelf Life (Unit)	2 Year(s)Not more than 30C	
For generic drugs (me-too Status)	Not available	
Pharmacotherapeutic Group of (API)	Gabapentinoid. ATC Code: N02BF03.	
Name, address of Manufacturing site:	Self Manufacturing	
Name & address of API manufacturer		
Detail of stability batches of drug product	Stability batches (T2-23, T3-23,T4-23) OF 1000 tablets batch size is submitted by the firm.	
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted by the firm	
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP is performed against the Tarlige 10mg Tablet	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone-iv condition is submitted by the firm.	
The status in reference regulatory authorities	Tarlige - PMDA Japan Approved	
GMP status of the firm	GMP dated 28-03-2023 is submitted by the firm.	
Evidence of approval of manufacturing facility	GMP dated 28-03-2023 in which tablet (general) section is submitted by the firm.	
Evaluation Remarks		
Sr.no.	Shortcomings	Response of the Firm
1.	Please provide a justification for selecting water as the dissolution medium, considering that the drug product demonstrates more than 85% release within 15 minutes across all dissolution media. Submit your response along with a reference document of the innovator product supporting the use of water as the dissolution medium	The dissolution medium and conditions for Mirogabalin tablets have not been disclosed by the innovator, despite regulatory approval by PMDA. No details are available from either FDA or PMDA documentation regarding the dissolution parameters. In accordance with the DRB-293 guidance document titled “Setting Dissolution Specifications for Immediate Release Solid Dosage Forms,” a comprehensive comparative dissolution profile (CDP) was performed using pH 1.2, pH 4.5, and pH 6.8 buffer solutions, as well as purified water. Across all media, the formulation demonstrated greater than 85% drug release within 15 minutes. These results indicate that Mirogabalin exhibits pH-independent dissolution behavior. Consequently, the requirement for a buffered medium is minimized, and purified water was selected as the dissolution medium for routine testing of Mirogabalin tablets.

2.	Justify the significant difference in the peak areas of standard and sample solutions observed between: Validation studies (Standard: ~1,409,130; Sample: ~1,283,649 at 100% concentration). Stability studies (Standard: ~1,287; Sample: ~1,307). Clarify why such variation exists despite using the same assay method.	The significant difference in absolute peak areas between the validation studies (Standard: ~1,409,130; Sample: ~1,283,649 at 100% concentration). Stability studies (Standard: ~1,287; Sample: ~1,307) is an expected and acceptable variation resulting from the use of two different HPLC systems. • Validation Studies: Performed on a Shimadzu HPLC system. • Stability Studies: Performed on an Agilent HPLC system. Different HPLC models and manufacturers utilize detectors with varying designs, lamp intensities, and signal amplification electronics. These instrumental differences directly influence the magnitude of the detector's response, leading to different absolute peak area values for the same analyte concentration.
3.	Kindly label the consistently observed peak in all chromatograms attached with the stability report of the drug product. The unlabeled peak elutes at approximately 2 minutes, appearing just before and in close proximity to the principal peak.	The consistently observed peak at ~2 minutes, eluting just before the principal peak, has been labeled as besylate (salt) peak in the 0 Month, 3rd Months and 6 th Month chromatograms. This labeling has been incorporated in chromatograms for clarity and reference
4.	Provide justification from the API manufacturer for specifying such a broad limit of benzenesulfonic acid (42%–46%) in the API specification, with clarification on whether it is considered an impurity or a residual solvent. Further, submit reference documents from stringent regulatory authorities or other recognized international organizations supporting the presence of benzenesulfonic acid at a level exceeding 40% in a pharmaceutical active ingredient.	The drug substance is an acid-addition benzenesulfonate salt. Benzenesulfonic acid functions as the stoichiometric counterion and is part of the intended chemical structure. It is therefore neither an impurity (ICH Q3A/B) nor a residual solvent (ICH Q3C), and is controlled as part of the API identity and assay. Theoretical BSA fraction: $0.158.17 \div 367.46 = 0.4305 \rightarrow 43.05\% \text{ w/w}$ (anhydrous, solvent-free basis). • This value anchors the specification range; any justified acceptance criteria should bracket 42.00% - 46.00% considering validated method uncertainty and material attributes. Validation of Benzenesulfonic acid from DMF is also attached for reference.

Decision

Approved

808

Case Category	Export Facilitation (Saima Hussain)
Name, address of Applicant.	CCL Pharmaceuticals (Pvt.) Ltd. 62-Quaid-e-Azam Industrial Estate, Kot Lakhpat (000052)
Application Form Dy. No / Tracking ID & date of submission	(L2Q-8WQ-ND28, 2024-10-03)
Detail of Fee Submitted	75000.0, 2024-05-23,
The proposed proprietary name / brand name	Mirogab 5 mg
Label Claim	Each film coated tablet contains; Mirogabalin besylate eq. to Mirogabalin 5 mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled,5's-De-Controlled,7's-De-Controlled

Shelf Life (Unit)	2 Year(s) Not more than 30C
For generic drugs (me-too Status)	Not available
Pharmacotherapeutic Group of (API)	Gabapentinoid. ATC Code: N02BF03.
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	
Detail of stability batches of drug product	Stability batches (T2-23, T3-23, T4-23) OF 1000 tablets batch size is submitted by the firm.
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted by the firm
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP is performed against the Tarlige 5mg Tablet (YBA 2046)
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone-iv condition is submitted by the firm.
The status in reference regulatory authorities	Tarlige - PMDA Japan Approved
GMP status of the firm	GMP dated 28-03-2023 is submitted by the firm.
Evidence of approval of manufacturing facility	GMP dated 28-03-2023 in which tablet (general) section is submitted by the firm.

Evaluation Remarks

Sr.no.	Shortcomings	Response of the Firm
1.	Please provide a justification for selecting water as the dissolution medium, considering that the drug product demonstrates more than 85% release within 15 minutes across all dissolution media. Submit your response along with a reference document of the innovator product supporting the use of water as the dissolution medium	The dissolution medium and conditions for Mirogabalin tablets have not been disclosed by the innovator, despite regulatory approval by PMDA. No details are available from either FDA or PMDA documentation regarding the dissolution parameters. In accordance with the DRB-293 guidance document titled "Setting Dissolution Specifications for Immediate Release Solid Dosage Forms," a comprehensive comparative dissolution profile (CDP) was performed using pH 1.2, pH 4.5, and pH 6.8 buffer solutions, as well as purified water. Across all media, the formulation demonstrated greater than 85% drug release within 15 minutes. These results indicate that Mirogabalin exhibits pH-independent dissolution behavior. Consequently, the requirement for a buffered medium is minimized, and purified water was selected as the dissolution medium for routine testing of Mirogabalin tablets.
2.	Justify the significant difference in the peak areas of standard and sample solutions observed between: Validation studies (Standard: ~1,409,130; Sample: ~1,283,649 at 100% concentration). Stability studies (Standard: ~1,287; Sample: ~1,307). Clarify why such variation exists despite using the same assay method.	The significant difference in absolute peak areas between the validation studies (Standard: ~1,409,130; Sample: ~1,283,649 at 100% concentration). Stability studies (Standard: ~1,287; Sample: ~1,307) is an expected and acceptable variation resulting from the use of two different HPLC systems. • Validation Studies: Performed on a Shimadzu HPLC system. • Stability Studies: Performed on an Agilent HPLC system. Different HPLC models and manufacturers utilize detectors with varying designs, lamp intensities, and signal amplification electronics. These instrumental differences directly influence the magnitude of the detector's response, leading to different absolute peak area values for the same analyte concentration.

3.	Kindly label the consistently observed peak in all chromatograms attached with the stability report of the drug product. The unlabeled peak elutes at approximately 2 minutes, appearing just before and in close proximity to the principal peak.	The consistently observed peak at ~2 minutes, eluting just before the principal peak, has been labeled as besylate (salt) peak in the 0 Month, 3rd Months and 6 th Month chromatograms. This labeling has been incorporated in chromatograms for clarity and reference
4.	Provide justification from the API manufacturer for specifying such a broad limit of benzenesulfonic acid (42%–46%) in the API specification, with clarification on whether it is considered an impurity or a residual solvent. Further, submit reference documents from stringent regulatory authorities or other recognized international organizations supporting the presence of benzenesulfonic acid at a level exceeding 40% in a pharmaceutical active ingredient.	The drug substance is an acid-addition benzenesulfonate salt. Benzenesulfonic acid functions as the stoichiometric counterion and is part of the intended chemical structure. It is therefore neither an impurity (ICH Q3A/B) nor a residual solvent (ICH Q3C), and is controlled as part of the API identity and assay. Theoretical BSA fraction: $158.17 \div 367.46 = 0.4305 \rightarrow 43.05\% \text{ w/w}$ (anhydrous, solvent-free basis). • This value anchors the specification range; any justified acceptance criteria should bracket 42.00% - 46.00% considering validated method uncertainty and material attributes. Validation of Benzenesulfonic acid from DMF is also attached for reference.

Decision

Approved

809	Case Category	Export Facilitation (Saima Hussain)
	Name, address of Applicant.	M/s. Genix Pharma (Pvt) Ltd. Plot No 44-45-B, Korangi Creek Road, Karachi (000351)
	Application Form Dy. No / Tracking ID & date of submission	(8T7-24Y-6ARN, 2024-07-25)
	Detail of Fee Submitted	75000.0, 2024-07-23,
	The proposed proprietary name / brand name	Pitamibe
	Label Claim	Each film-coated tablet contains: Pitavastatin Calcium equivalent to Pitavastatin.....2mg Ezetimibe.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's, 10's, 14's, 20'-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30oC. Protect from heat, light and moisture.
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	HMG-COA reductase Inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Ruyuan HEC Pharm CO., Ltd. Manufacturing Site: Xiaba Development Zone, Ruyuan Country, Shaoguan City, Guangdong Province, P.R. China,Zhejiang Tianyu Pharmaceutical Co., Ltd. Manufacturing Site: No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City
	Detail of stability batches of drug product	23SB-598-01,23SB-599-02,23SB-600-03 1500 tablet batch size.
	Documents for the procurement of API with approval from DRAP	Clearance certificate for Pitavastatin Calcium and DRAP attested commercial invoice for ezetimibe.

(in case of Import)	
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP is performed against the innovator product Livazebe Combination Tablets Ld 2mg/10mg Tablets (B#853370) Kowa Co., Ltd. 3-4--14Nihonbashi Honmachi, Chuo-ku, Tokyo
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone-IV condition is submitted by the firm.
The status in reference regulatory authorities	Livazebe Combination Tablets LD by Kowa Company Ltd, Japan PMDA
GMP status of the firm	GMP certificate dated 13-06-2023 is submitted by the firm.
Evidence of approval of manufacturing facility	GMP certificate dated 13-06-2023 mentioned that firm has Tablet (general).

Evaluation Remarks

Sr.no.	Observations	Response of the Firm
1.	Provide justification for adopting a different assay method for the drug substance by the drug product manufacturer instead of the method specified by the drug substance manufacturer.	Firm replied that they have revised their testing method as per drug substance manufacturer.
2.	Procedure adopted to analyze the calcium content by the drug product manufacturer is different from the method recommended by drug substance manufacture, justification is required in this regard.	Firm replied that they have revised their calcium content testing method as per drug substance manufacturer.
3.	The reference product approved by PMDA Japan, LIVAZEBE Combination Tablets LD, contains pitavastatin calcium hydrate as the active ingredient, whereas your applied formulation contains pitavastatin calcium (anhydrous form), as evident from the submitted drug substance section and the provided procurement documents. Considering that pitavastatin calcium hydrate and pitavastatin calcium (anhydrous) differ in molecular formula, molecular weight, and CAS number, kindly justify how the applied formulation can be claimed as similar to the reference product.	The water molecules in Pitavastatin calcium mainly impact physical properties (crystal form, stability, solubility, flow), not the fundamental chemical structure of the drug. Hence the the active molecule remains the same in both hydrated and anhydrous forms. Pitavastatin calcium anhydrous form with approximately 3.5% moisture (i.e., water content)-as indicated in certificate of analysis (CoA)-matches the water content observed for polymorphic Form K of pitavastatin calcium. Form K, is a newly characterized polymorph noted for superior chemical and physical stability. However, the innovator product approved in PMDA Japan, LIVAZEBE Combination Tablets LD, contains pitavastatin calcium hydrate as the active ingredient along with ezetimibe. Further, Pitavastatin calcium hydrate and pitavastatin calcium (anhydrous) differ in molecular formula, molecular weight, and CAS number. CAS number of pitavastatin calcium: 147526-32-7 CAS number of pitavastatin calcium hydrate: 1852536-33-4
4.	Provide Batch Manufacturing Record (BMR) of all stability batches.	Submitted

Decision

Deferred

Deferred for evidence of approval of applied formulation i.e. Pitavastatin Calcium (anhydrous) with ezetimibe in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting,

since the submitted reference product approved in PMDA Japan, LIVAZEBE Combination Tablets LD, contains pitavastatin calcium hydrate as the active ingredient along with ezetimibe.

810

Case Category	Export Facilitation (Saima Hussain)
Name, address of Applicant.	M/s. Genix Pharma (Pvt) Ltd. Plot No 44-45-B, Korangi Creek Road, Karachi (000351)
Application Form Dy. No / Tracking ID & date of submission	(98H-ZLB-JJJJ, 2024-09-11)
Detail of Fee Submitted	75000.0, 2024-07-23,
The proposed proprietary name / brand name	Pitamibe
Label Claim	Each film-coated tablet contains: Pitavastatin Calcium equivalent to Pitavastatin.....4mg Ezetimibe.....10mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	7's, 10's, 14's, 20'-As per SRO
Shelf Life (Unit)	24 Year(s)Store below 30oC. Protect from heat, light and moisture.
For generic drugs (me-too Status)	Not Applicable
Pharmacotherapeutic Group of (API)	HMG-COA reductase Inhibitors
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Ruyuan HEC Pharm CO., Ltd. Manufacturing Site: Xiaba Development Zone, Ruyuan Country, Shaoguan City, Guangdong Province, P.R. China,Zhejiang Tianyu Pharmaceutical Co., Ltd. Manufacturing Site: No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City
Detail of stability batches of drug product	23SB-601-01,23SB-602-02,23SB-603-03 1500 tablet batch size.
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate for Pitavastatin Calcium and DRAP attested commercial invoice for ezetimibe.
Pharmaceutical Equivalence and Comparative Dissolution Profile	E and CDP is performed against the innovator product Livazebe Combination Tablets Ld 4mg/10mg Tablets (B#853370) Kowa Co., Ltd. 3-4--14Nihonbashi Honmachi, Chuo-ku, Tokyo
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone-IV condition is submitted by the firm.
The status in reference regulatory authorities	Livazebe Combination Tablets LD by Kowa Company Ltd, Japan PMDA
GMP status of the firm	GMP certificate dated 13-06-2023 is submitted by the firm.
Evidence of approval of manufacturing facility	GMP certificate dated 13-06-2023 mentioned that firm has Tablet (general).

Evaluation Remarks

Sr.no.	Observations	Response of the Firm
1.	Provide justification for adopting a different assay method for the drug substance by the drug product manufacturer instead of the method specified by the drug substance manufacturer.	Firm replied that they have revised their testing method as per drug substance manufacturer.

2.	Procedure adopted to analyze the calcium content by the drug product manufacturer is different from the method recommended by drug substance manufacture, justification is required in this regard.	Firm replied that they have revised their calcium content testing method as per drug substance manufacturer.
3.	The reference product approved by PMDA Japan, LIVAZEBE Combination Tablets LD, contains pitavastatin calcium hydrate as the active ingredient, whereas your applied formulation contains pitavastatin calcium (anhydrous form), as evident from the submitted drug substance section and the provided procurement documents. Considering that pitavastatin calcium hydrate and pitavastatin calcium (anhydrous) differ in molecular formula, molecular weight, and CAS number, kindly justify how the applied formulation can be claimed as similar to the reference product.	The water molecules in Pitavastatin calcium mainly impact physical properties (crystal form, stability, solubility, flow), not the fundamental chemical structure of the drug. Hence the the active molecule remains the same in both hydrated and anhydrous forms. Pitavastatin calcium anhydrous form with approximately 3.5% moisture (i.e., water content)-as indicated in certificate of analysis (CoA)-matches the water content observed for polymorphic Form K of pitavastatin calcium. Form K, is a newly characterized polymorph noted for superior chemical and physical stability. However, the innovator product approved in PMDA Japan, LIVAZEBE Combination Tablets LD, contains pitavastatin calcium hydrate as the active ingredient along with ezetimibe. Further, Pitavastatin calcium hydrate and pitavastatin calcium (anhydrous) differ in molecular formula, molecular weight, and CAS number. CAS number of pitavastatin calcium: 147526-32-7 CAS number of pitavastatin calcium hydrate: 1852536-33-4
4.	Provide Batch Manufacturing Record (BMR) of all stability batches.	Submitted

Decision

Deferred

Deferred for evidence of approval of applied formulation i.e. Pitavastatin Calcium (anhydrous) with ezetimibe in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting, since the submitted reference product approved in PMDA Japan, LIVAZEBE Combination Tablets LD, contains pitavastatin calcium hydrate as the active ingredient along with ezetimibe.

811	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	Nabiqasim Industries (Pvt) Ltd., 17/24, Korangi Industrial Area, Karachi. (000105)
	Application Form Dy. No / Tracking ID & date of submission	(D8P-LHW-LUHT, 2024-03-12)
	Detail of Fee Submitted	30000.0, 2024-01-08,
	The proposed proprietary name / brand name	Tapen IR Tablet 50mg
	Label Claim	Each film coated tablet contains; Tapentadol hydrochloride eq. to Tapentadol.... 50mg (Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 14's, 20's,28'-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 Degree Celsius Temperature
	For generic drugs (me-too Status)	Tapcynta tablet 50mg (Hiranis pharmaceutical)
	Pharmacotherapeutic Group of (API)	opioid analgesic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Arene life sciences, Plot No. 48, 49 & 50, 209, 210 & 211 Phase-II, IDA, Pashamylaram Sangareddy

	Telangana, India.
Detail of stability batches of drug product	413DS01,413DS02,413DS03 100 TABLETS BATCH SIZE
Documents for the procurement of API with approval from DRAP (in case of Import)	Form-6 and commercial invoice is submitted
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP is performed against Tapento IR 50mg Tablet (Sami Pharmaceuticals (Pvt.) Ltd.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone-IV condition is submitted by the firm.
The status in reference regulatory authorities	Nucynta tablet 50mg (FDA Approved)
GMP status of the firm	GMP certificate dated 28th may ,2022 is submitted by the firm.
Evidence of approval of manufacturing facility	GMP certificate dated 28th may ,2022 mentioned that firm has tablet(general) section.
Evaluation Remarks	
Decision	
Approved	
The Registration Board has decided to approve Tapentadol Tablet with an age-restricted therapeutic indication, consistent with the innovator product approved by the USFDA, i.e., Tapentadol Tablet is an opioid analgesic indicated for the relief of moderate to severe acute pain in patients 18 years of age and older."	
812	Case Category
	Contract Manufacturing (Saima Hussain)
	Name, address of Applicant.
	Bio-Next Pharmaceuticals plot no 50 street no S-10 RCCI Rawat (000910)
	Application Form Dy. No / Tracking ID & date of submission
	(Q8Q-2Z2-P25G, 2024-02-01)
	Detail of Fee Submitted
	75000.0, 2024-01-05,
	The proposed proprietary name / brand name
	Cetonext
	Label Claim
	Each ml contains: Paracetamol 10mg
	Reference to Finished product specifications
	As per Innovators Specification
	Proposed Pack Size
	100ml-Controlled
	Shelf Life (Unit)
	2 Year(s)Store below 30C
	For generic drugs (me-too Status)
	Provas infusion by sami Pharma.
	Pharmacotherapeutic Group of (API)
	analgesic and antipyretic
	Name, address of Manufacturing site:
	Self Manufacturing
	Name & address of API manufacturer
	Hebei jiheng (Group) Pharmaceutical Co.,Ltd
	Detail of stability batches of drug product
	Submitted (CET 21 -41 CET 21 -42 CET 21 -43) (extract from the minutes of 322nd meeting)
	Documents for the procurement of API with approval from DRAP (in case of Import)
	Submitted (extract from the minutes of 322nd meeting)
	Pharmaceutical Equivalence and Comparative Dissolution Profile
	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator i.e. Provas 100ml infusion.(extract from the minutes of 322nd meeting)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)
	Submitted as per zone iv(extract from the minutes of 322nd meeting)

The status in reference regulatory authorities	USFDA
GMP status of the firm	GMP certificate issued based upon inspection conduct 23-4-2019, valid upto 22-04-2022.(extract from the minutes of 322nd meeting)
Evidence of approval of manufacturing facility	Evidence of Grant of additional section letter dated 23-07-2012 mentioning Infusion (100ml) General section. (extract from the minutes of 322nd meeting)

Evaluation Remarks

Bio-Next Pharmaceuticals, located at Plot No. 50, street No.S-10, RCCI Industrial Estate , Rawat Islamabad applied for contract manufacturing from M/s Bio-Labs (Pvt) Ltd located at Plot No. 145, Industrial Triangle Kahuta Road Islamabad for the product that has already been approved in 322nd meeting with innovator specifications, on the data in which the source of API is Hebei jiheng (Group) Pharmaceutical Co.,Ltd Xijingming Village Donganzhuang Township Shenzhou Country Hengshui City,Hebei Province,053800 China. However, at the time of evaluation of contract manufacturing case, it has been come into notice that the official monograph for Paracetamol Infusion is included in the British Pharmacopoeia (BP)2025. Accordingly, firm was asked to update the finished product specification to comply with the BP monograph and submit revised stability data for the drug product in accordance with the updated specification. In their reply firm submit the stability data of 4 months of batch 25C022(Batch size 2500 pack), in which firm complied BP monograph of Paracetamol infusion for the quality testing of finished product. However, the source of API used in this batch is procured from M/s. Zenith Chemical Industries, Ferozepur Road, Lahore.

Decision

Approved

Subject to requisite fee for change of specification. Contract acceptor M/s. Bio Labs be asked to obtain permission for revised specification as per BP monograph.

813	Case Category	Priority As Per 257-M of RB (Saima Hussain)
	Name, address of Applicant.	HIMMEL PHARMACEUTICALS (PVT.) LTD Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Zazaria e Pakistan Lahore (05-352-0065)
	Application Form Dy. No / Tracking ID & date of submission	(YSJ-68H-6VT4, 2025-05-12)
	Detail of Fee Submitted	300000.0, 2025-03-14,
	The proposed proprietary name / brand name	Abenix 200mg Tablet
	Label Claim	Each film coated tablet contains.....Abemaciclib 200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	60's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C.
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	Anti-neoplastic (Protein kinase inhibitor) ATC Code: L01EF03
	Name, address of Manufacturing site:	Beacon Pharmaceuticals PLC.-Kathali, Bhaluka , Mymensingh, -Bangladesh
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP performed against the innovator product VERZENIO 200 MG TABLETS® (abemaciclib; manufactured by –Eli Lilly USA) & ABENIX 200 TABLET
	Name, address of Marketing Authorization Holder:	Beacon Pharmaceuticals PLC., Kathali, Bhaluka , Mymensingh, , Bangladesh
	Details of Certificates (CoPP/FSC/cGMP):	Firm submit GMP CERTIFICATE NO. DA/6-110/06/ 896 dated 08-Jan-2024 of M/s. Beacon Pharmaceuticals PLC. : Kathali, Bhaluka, Mymensingh, Bangladesh

	certifying authority: Directorate General of Drug Administration. Aushad Bhaban, Mohakhali, Dhaka -1212 val
Details of Authorization Letter :	NA
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data submitted
The status in reference regulatory authorities	Verzenio 200mg Film-coated Tablet (USA)

Evaluation Remarks

Sr.no.	Observations	Response of the Firm
1.	Submit specification and detailed analytical procedure that has actually been for the quality analysis of the drug substance by drug product manufacturer.	Firm submit specification and detailed analytical procedure that has been used for the quality analysis of the drug substance by drug product manufacturer.
2.	Submit analytical method verification report of drug substance performed by drug product manufacturer.	Firm submit analytical method verification report of drug substance performed by drug product manufacturer.
3.	Submit batch analysis report of drug substance performed by drug product manufacturer.	Firm submit batch analysis report of drug substance performed by drug product manufacturer.
4.	Submit the pharmaceutical equivalence report against the innovator/reference product, including all quality tests that are part of the finished product specifications.	Firm submit Pharmaceutical equivalence report.
5.	Justify the omission of the Uniformity of Weight test and Water Content test in the batch analysis of the drug product, since the results of these tests have not been included in the batch analysis report.	Firm submit revised batch analysis report of drug product.
6.	Submit the stability data (three batches) of the drug product manufactured at commercial batch size, as the submitted data pertains only to a batch size of 400 tablets.	The firm has resubmitted the same stability data sheets that were previously provided, with the only change being the batch size, which is now stated as 6666 tablets, whereas the previously submitted data indicated a batch size of 400 tablets.
7.	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.	The firm submitted the unfilled Batch Manufacturing Records (BMR) for all three batches, indicating that 1000 g of active ingredient was dispensed for the manufacturing of a batch size of 6666 tablets. However, the theoretical calculation shows that 1333.2 g of active ingredient is required to manufacture 6666 tablets of 200 mg strength.

Decision

Deferred

Deferred for submission of stability data of commercial batches of the drug product, performed under Zone-IV conditions up to the claimed shelf life.

Name, address of Applicant.	HIMMEL PHARMACEUTICALS (PVT.) LTD Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Zazaria e Pakistan Lahore (05-352-0065)
Application Form Dy. No / Tracking ID & date of submission	(6UM-YEY-JUPT, 2025-06-04)
Detail of Fee Submitted	300000.0, 2025-03-14,
The proposed proprietary name / brand name	Abenix 100mg Tablet
Label Claim	Each film-coated tablet contains.... Abemaciclib 100mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	60's-As per SRO
Shelf Life (Unit)	24 Month(s)Store below 30°C.
For generic drugs (me-too Status)	Not Applicable
Pharmacotherapeutic Group of (API)	Anti-neoplastic (Protein kinase inhibitor) ATC Code: L01EF03
Name, address of Manufacturing site:	Beacon Pharmaceuticals PLC.-Kathali, Bhaluka , Mymensingh, -Bangladesh
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP performed against the innovator product VERZENIO 100 MG TABLETS® (abemaciclib; manufactured by –Eli Lilly USA) & ABENIX 100 TABLET
Name, address of Marketing Authorization Holder:	Beacon Pharmaceuticals PLC., Kathali, Bhaluka , Mymensingh, , Bangladesh
Details of Certificates (CoPP/FSC/cGMP):	Firm submit GMP CERTIFICATE NO. DA/6-110/06/ 896 dated 08-Jan-2024 of M/s. Beacon Pharmaceuticals PLC. : Kathali, Bhaluka, Mymensingh, Bangladesh certifying authority: Directorate General of Drug Administration. Aushad Bhaban, Mohakhali, Dhaka -1212 val
Details of Authorization Letter :	NA
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data submitted
The status in reference regulatory authorities	Verzenio 100mg Film-coated Tablet (USA)

Evaluation Remarks

CoPP of certificate no. DA/6-110 /2016/975 dated 22.01.2025 certifying authority: Directorate General of Drug Administration, Mohakhali, Dhaka-1212, Bangladesh. valid for 2 years from the date of issuance.Letter of Authorization dated 02-October,2024 did not specify the name of products is submitted by the firm.

Sr.no.	Observations	Response of the Firm
1.	Submit specification and detailed analytical procedure that has actually been for the quality analysis of the drug substance by drug product manufacturer.	Firm submit specification and detailed analytical procedure that has been used for the quality analysis of the drug substance by drug product manufacturer.
2.	Submit analytical method verification report of drug substance performed by drug product manufacturer.	Firm submit analytical method verification report of drug substance performed by drug product manufacturer.
3.	Submit batch analysis report of drug substance performed by drug product manufacturer.	Firm submit batch analysis report of drug substance performed by drug product manufacturer.
4.	Submit the pharmaceutical equivalence report against the innovator/reference	Firm submit Pharmaceutical equivalence report.

	product, including all quality tests that are part of the finished product specifications.	
5.	Justify the omission of the Uniformity of Weight test and Water Content test in the batch analysis of the drug product, since the results of these tests have not been included in the batch analysis report.	Firm submit revised batch analysis report of drug product.
6.	Submit the stability data (three batches) of the drug product manufactured at commercial batch size, as the submitted data pertains only to a batch size of 400 tablets.	The firm has resubmitted the same stability data sheets that were previously provided, with the only change being the batch size, which is now stated as 6666 tablets, whereas the previously submitted data indicated a batch size of 400 tablets.
7.	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.	The firm submitted the unfilled Batch Manufacturing Records (BMR) for all three batches, indicating that 1000 g of active ingredient was dispensed for the manufacturing of a batch size of 6666 tablets. However, the theoretical calculation shows that 666.6g of active ingredient is required to manufacture 6666 tablets of 100 mg strength.

Decision

Deferred

Deferred for submission of stability data of commercial batches of the drug product, performed under Zone-IV conditions up to the claimed shelf life.

815	Case Category	Priority As Per 257-M of RB (Saima Hussain)
	Name, address of Applicant.	Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan (01-374-0006)
	Application Form Dy. No / Tracking ID & date of submission	(UZT-9SM-L1VX, 2025-02-17)
	Detail of Fee Submitted	300000.0, 2025-01-17,
	The proposed proprietary name / brand name	GUFISOME
	Label Claim	Each vial contains: Amphotericin B 50mg Excipients (Intercalated in to Liposomal membrane).....q.s
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's (Vial)-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 25°C. Do not freeze. Protect from light and moisture.
	For generic drugs (me-too Status)	Anfotericina FADA 50mg Injection Manufactured by: Medinet Pharmaceuticals, Pakistan
	Pharmacotherapeutic Group of (API)	Antimycotics
	Name, address of Manufacturing site:	Gufic Biosciences Limited -National Highway No. 8, Near Grid, Kabilpore, Navsari - 396424, Gujarat, INDIA-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	.

Name, address of Marketing Authorization Holder:	Gufic Biosciences Limited , National Highway No. 8, Near Grid, Kabilpore, Navsari - 396424, Gujarat, INDIA, India
Details of Certificates (CoPP/FSC/cGMP):	Firm submit the scanned copy of CoPP which was valid till 15-09-2024. GMP certificate of Manufacturer Abroad M/s. Gufic Biosciences Ltd. Unit no.2 Survey no.171 Gujarat State India is submitted which is valid till 15-09- 2027.
Details of Authorization Letter :	NA
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	submitted
The status in reference regulatory authorities	AmBisome 50mg Manufactured by: Gilead Sciences Inc., San Dimas. Marketed by: Astellas Pharma., USFDA Approved

Evaluation Remarks

Sr. No.	Shortcomings	Response of the Firm																				
1.	Submit a valid and legalized Certificate of Pharmaceutical Product (CoPP), duly signed and stamped by the issuing authority, clearly indicating the date of issuance and providing detailed information on all excipients included in the applied formulation.	Firm has not submitted the response of this query.																				
2.	Submit a product-specific, valid, and legalized Sole Agency Agreement or Letter of Authorization between the applicant and the overseas Marketing Authorization Holder (MAH).	Firm has not submitted the response of this query.																				
	The microbial assay of the drug substance provided by the drug product manufacturer indicates an incubation duration of 24 hours, whereas the pharmacopeial recommendation is 18 hours. Provide justification for the extended incubation duration used in the assay. Clarify the final pH of the medium, as it has not been mentioned in the submitted procedure.	Microbial assay is critical quality attribute for drug substance specification. Amphotericin-B API. Extended incubation can be necessary to ensure adequate and consistent microbial growth in the assay, especially if preliminary validation studies or routine observations demonstrate insufficient or inconsistent zone formation or microbial response at the 18-hour mark. For microbial assay of Amphotericin-B as per EP chapter 2.7.2 for growth of test organism <i>Saccharomyces cerevisiae</i> on medium F at 30-37°C ,24 hrs required. Hence, we recommended 24 hours incubation period. Final pH of the medium is pH 6.0 + 0.1																				
	Provide the complete and detailed composition of Medium F used by the drug product manufacturer during the performance of the microbiological assay of the drug substance.	<table><tr><td colspan="2">Please refer below detailed composition of Medium-F</td></tr><tr><td colspan="2">Medium No. F</td></tr><tr><td>Peptone</td><td>9.4 g</td></tr><tr><td>Yeast extract</td><td>4.7 g</td></tr><tr><td>Beef extract</td><td>2.4 g</td></tr><tr><td>Sodium Chloride</td><td>10.0 g</td></tr><tr><td>Glucose monohydrate</td><td>10.0 g</td></tr><tr><td>Agar</td><td>23.5 g</td></tr><tr><td>Water</td><td>To 1000 ml</td></tr><tr><td>pH after sterilization</td><td>6.1 ± 0.1</td></tr></table>	Please refer below detailed composition of Medium-F		Medium No. F		Peptone	9.4 g	Yeast extract	4.7 g	Beef extract	2.4 g	Sodium Chloride	10.0 g	Glucose monohydrate	10.0 g	Agar	23.5 g	Water	To 1000 ml	pH after sterilization	6.1 ± 0.1
Please refer below detailed composition of Medium-F																						
Medium No. F																						
Peptone	9.4 g																					
Yeast extract	4.7 g																					
Beef extract	2.4 g																					
Sodium Chloride	10.0 g																					
Glucose monohydrate	10.0 g																					
Agar	23.5 g																					
Water	To 1000 ml																					
pH after sterilization	6.1 ± 0.1																					

	Since the drug substance manufacturer claims compliance with European Pharmacopoeia (Eur. Ph.) specifications, then justify the use of a USP reference standard for testing of drug substance instead of an Eur. Ph. Reference standard.	As per various regulatory agencies guidance's we can use alternative standards material if it is found equivalence hence, we used USP reference standard because it is equivalent with Ph.EUR standards. We use alternative standards only when there is shortage of availability of Ph.EUR standards. As amphotericin-B is used for critical care and life supporting medicine hence we adopted policy to use alternative pharmacopeial reference standard to complete product analysis on time.
	Submit stability data of the drug substance performed under both accelerated and long-term conditions, conducted in accordance with ICH guidelines, covering the claimed re-test period.	Please find attached the updated stability data of the drug substance performed under both accelerated and long-term conditions, in compliance with ICH guidelines.
7.05	As per the innovator literature, "Liposomal encapsulation or incorporation into a lipid complex can substantially affect a drug's functional properties relative to those of the unencapsulated drug or non-lipid-associated drug. "Justify for not including a specific test to analyze the entrapped/encapsulated drug, considering that it is neither part of the finished product specifications nor monitored as a critical process control parameter during manufacturing of finished product.	We confirm that the assay of Amphotericin-B is monitored during in-process controls, confirming the presence of the active substance. Additionally, for the finished product, both Assay and Free Drug Content are tested, which collectively ensure control of drug encapsulation in liposomes. Therefore, a separate test for entrapped drug is not required
	Justify for not including particle size determination test of the lyophilized liposomal amphotericin B Injection prior to reconstitution in the finished product specification. Since the current specification includes only the particle size test after reconstitution, with limits set between NLT 75 nm and NMT 150 nm. Furthermore, provide a scientific rationale for the adopted particle size limits, in light of the innovator's statement that "AmBisome contains true liposomes that are less than 100 nm in diameter.	The final formulation is liposomal in nature, and particle size is a critical quality attribute. Particle size determination is performed after reconstitution, as this reflects the actual size of liposomes in the final preparation. The specification range of NLT 75 nm to NMT 150 nm has been established based on our product trend data and comparative evaluation with the RLD. Hence, the current specification is scientifically justified. However, the innovator claimed that "AmBisome contains true liposomes that are less than 100 nm in diameter" . Further, the size of liposomes is a common key property in the optimization of pharmacokinetic factors, and a suitable liposome size is likely to be around 100 nm or less. This size range is concluded to be important in designing of a more effective liposomal antitumor preparation
	Submit in-use stability data of drug product along with proposed in-use storage statement and in-use shelf-life	In-use stability data from representative batches is available and has been provided in the attachment, along with the proposed in-use storage conditions and shelf-life.
	Provide details of type and quantity of diluents used for reconstitution and further dilution of applied product.	Reconstitution and diluent study data from representative batches is available and has been provided in the attachment.

	Decision	
	Deferred	
	Deferred to explain the scientific basis for adopting the particle size specification of NLT 75 nm and NMT 150 nm, whereas the innovator has stated that AmBisome contains liposomes of less than 100 nm. As the batch results of the particle size test are all above 100 nm, and considering that liposome size is a critical determinant of pharmacokinetic performance, the applicant is required to justify the proposed limit.	
816	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Pharmonix Pharmaceuticals Plot 28, Street SS-2, National Industrial Zone, Rawat (000990)
	Application Form Dy. No / Tracking ID & date of submission	(1WB-8LR-UJL5, 2025-01-21)
	Detail of Fee Submitted	37000.0, 2025-01-21,
	The proposed proprietary name / brand name	E.C Mol Oral Powder
	Label Claim	Each 100g contains: Paracetamol USP..... 20gm Vitamin C USP..... 5.0gm Potassium carbonate USP..... 12.5gm Sodium Bicarbonate USP..... 12.5gm Vitamin E USP.....12.5gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50gm, 100 gm, 250 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)store below 30
	For generic drugs (me-too Status)	PARA CE Oral Powder (Reg. # (063812)Biogen PHarma 8-KM, Chak Beli Road, Rawat,
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
817	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	POULVET PHARMACEUTICAL (PVT) LTD 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN (000970)
	Application Form Dy. No / Tracking ID & date of submission	(DJ2-L19-97BN, 2025-01-21)
	Detail of Fee Submitted	37000.0, 2025-01-15,
	The proposed proprietary name / brand name	Poul Mectin Oral Drench
	Label Claim	Each ml contains:-Ivermectin BP - 10mg (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100ml, 150ml, 250ml,-De-Controlled
	Shelf Life (Unit)	2 Year(s)AT ROOM TEMPERATURE
	For generic drugs (me-too Status)	Micrise Oral Drench of Biorise Pharma (Reg#125623)

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR, DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG, DRAP, LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
818	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Pharmonix Pharmaceuticals Plot 28, Street SS-2, National Industrial Zone, Rawat (000990)
	Application Form Dy. No / Tracking ID & date of submission	(WQ9-52B-RVXZ, 2025-01-21)
	Detail of Fee Submitted	37000.0, 2025-01-21,
	The proposed proprietary name / brand name	Toltril Oral Liquid
	Label Claim	Each ml contains: Toltrazuril..... 2.5 mg.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml, 100 ml, 120ml,-De-Controlled
	Shelf Life (Unit)	2 Year(s)store below 30
	For generic drugs (me-too Status)	TOLRA Oral Liquid (Reg. #116873)BIORIFIC Pharmaceuticals Islamabad
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
819	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Pharmonix Pharmaceuticals Plot 28, Street SS-2, National Industrial Zone, Rawat (000990)
	Application Form Dy. No / Tracking ID & date of submission	(YLG-ZTW-L5AD, 2025-01-21)
	Detail of Fee Submitted	37000.0, 2025-01-21,
	The proposed proprietary name / brand name	Amsovit Oral Powder
	Label Claim	Each 100gm powder contains: Ammonium chloride 70 gm Methionine BP.....10gm Vitamin A BP.. 150000 IU Sorbitol BP..... 5 gm Vitamin C BP..... 10 gm
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	50gm, 100 gm, 250 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)store below 30
	For generic drugs (me-too Status)	Gumbo Rex Water Soluble Powder (Reg. # 039977)Bio-Labs (Pvt) Ltd Model town islamabad
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
820	Approved	
	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Pharmonix Pharmaceuticals Plot 28, Street SS-2, National Industrial Zone, Rawat (000990)
	Application Form Dy. No / Tracking ID & date of submission	(7BZ-7UN-7RD6, 2025-01-21)
	Detail of Fee Submitted	37000.0, 2025-01-21,
	The proposed proprietary name / brand name	Neoflix Oral Powder
	Label Claim	Each gram contains: Oxytetracycline HCl BP..... 300mg Florfenicol 100mg Neomycin Sulphate USP 150mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50gm, 100 gm, 250 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)store below 30
821	For generic drugs (me-too Status)	Bio-Floximycin Oral Powder (Reg. # 106668)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	MEDPHARM RESEARCH LAB 28 KM FEROZPUR ROAD LAHORE (000878)
	Application Form Dy. No / Tracking ID & date of submission	(RUS-EHA-YY3J, 2025-01-17)
	Detail of Fee Submitted	37000.0, 2024-12-19,
	The proposed proprietary name / brand name	AR MEDJEST ORAL POWDER
	Label Claim	Each Kg Contains: Propionic Acid Calcium USP..... 250g Propionic Acid Sodium USP..... 400mg

		Acetanilide..... 150g Magnesium Oxide USP..... 125g Iron II Sulphate USP..... 400mg Zinc Sulphate USP..... 100mg Magnesium Sulphate USP..... 200mg Copper Sulphate BP..... 450mg Cobalt Sulphate..... 400mg USP Sodium Molybdate 100mg Sodium Chloride USP..... 20g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1kg, 5kg or as Per S-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature below 30
	For generic drugs (me-too Status)	LITHARGEX ORAL POWDER (097956) BY M/S. RAS PHARMACEUTICALS (PVT) LTD., 25-KM LAHORE ROAD, MULTAN.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel approved the plant for GMP Injection
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
822	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(T5Q-TJE-JLZW, 2025-07-20)
	Detail of Fee Submitted	37000.0, 2025-06-26,
	The proposed proprietary name / brand name	Synoxy Cure-50 Oral Powder
	Label Claim	Each 100gm contains: Oxytetracycline HCl USP.....50gm(USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100gm, 250gm, 500gm, 1kg, 2kg, 5kg, 10kg, 20kg, 25-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at Room Temperature
	For generic drugs (me-too Status)	Nobitet 50% Powder (Reg. No. 063643) by Noble Pharma, Mirpur, Azad Kashmir
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
823	Case Category	Routine (Sara Mehreen)

Name, address of Applicant.	MEDPHARM RESEARCH LAB 28 KM FEROPUR ROAD LAHORE (000878)
Application Form Dy. No / Tracking ID & date of submission	(VAS-3ZG-9WA8, 2025-01-23)
Detail of Fee Submitted	37000.0, 2024-12-18,
The proposed proprietary name / brand name	AR Med ADEK Oral Solution
Label Claim	Each Liter Contains: Vitamin A USP.....10,000,000 IU Vitamin D3 USP.....2,000,000 IU Vitamin E USP.....4000mg Vitamin K3 USP.....2000mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1Liter or 5Lietr and-De-Controlled
Shelf Life (Unit)	2 Year(s)Store at room temperature below 30
For generic drugs (me-too Status)	ADEK Excel (058985) of M/s Nawan Laboratoies
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	Panel approved the plant for GMP Injection
Evidence of approval of manufacturing facility	

Evaluation Remarks

Decision

Approved

824

Case Category	Routine (Sara Mehreen)
Name, address of Applicant.	MEDPHARM RESEARCH LAB 28 KM FEROPUR ROAD LAHORE (000878)
Application Form Dy. No / Tracking ID & date of submission	(674-HS7-M4D7, 2025-04-04)
Detail of Fee Submitted	37000.0, 2025-03-20,
The proposed proprietary name / brand name	AR MED SHELL ORAL SOLUTION
Label Claim	Each 1000ml Contains: Tylosin Tartrate USP.....50g Sulfamethoxypyridazine Sodium.....50g Trimethoprim USP.....10g Bromhexine HCl BP.....5g
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	500ml, 01 Liter-De-Controlled
Shelf Life (Unit)	2 Year(s)Store at room temperature below 30
For generic drugs (me-too Status)	Compli Shell Liquid of M/s Inshal Pharma Rawat Islamabad (Reg No. 063882)
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	Panel approved the plant for GMP Injection
Evidence of approval of manufacturing facility	

Evaluation Remarks

Decision

Approved

825	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	MEDPHARM RESEARCH LAB 28 KM FEROZPUR ROAD LAHORE (000878)
	Application Form Dy. No / Tracking ID & date of submission	(DN2-44X-RWT4, 2025-01-23)
	Detail of Fee Submitted	37000.0, 2024-12-19,
	The proposed proprietary name / brand name	AR Medrox Oral Solution
	Label Claim	Each ml Contains: Sulphadiazine USP.....35.50mg Sulphadimidine EP..... 28.40mg Neomycine Sulphate USP..... 18.00mg Hyoscine Methyl bromide 0.040mg Pectin USP..... 7.10mg Kaolin USP.....103.3mg Vitamin B1 USP..... 0.150mg Vitamin B2 USP..... 0.220mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml & 500ml as Per-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature below 30
	For generic drugs (me-too Status)	Ever-X Oral Solution of M/s Evergreen Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel approved the plant for GMP Injection
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
826	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	MEDPHARM RESEARCH LAB 28 KM FEROZPUR ROAD LAHORE (000878)
	Application Form Dy. No / Tracking ID & date of submission	(RQQ-VB3-7HXA, 2025-04-14)
	Detail of Fee Submitted	37000.0, 2025-04-09,
	The proposed proprietary name / brand name	AR MEDOX PLUS DRENCH
	Label Claim	Each ml Contains: Oxytoclozanide BP (VET).....62.5mg Oxfendazole USP.....22.65mg Cobalt Sulphate BP (VET).....1.67mg Sodium Selenite BP.....0.500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	500ml, 01 Liter-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature below 30
	For generic drugs (me-too Status)	Deviser Plus Drench of M/s Evergreen Pharmaceutical

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel approved the plant for GMP Injection
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
827	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Kohinoor Industries 159-160/B Small Industrial Estate, Sahiwal (000197)
	Application Form Dy. No / Tracking ID & date of submission	(5J9-DB6-X9YD, 2025-01-05)
	Detail of Fee Submitted	37000.0, 2024-11-30,
	The proposed proprietary name / brand name	Para Plus Oral W/S Powder
	Label Claim	Each 1000 gm contains:Paracetamol B.P. 200 gmPotassium Carbonate B.P. 125 gmSodium Bicarbonate B.P. 125 gmVitamin E B.P. 125 gmVitamin C B.P. 50 gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm, 250gm, 500gm,-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30 CG
	For generic drugs (me-too Status)	PARA CE Powder
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
828	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Majestic Pharma plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad (000873)
	Application Form Dy. No / Tracking ID & date of submission	(H7P-HA5-M46Y, 2025-01-27)
	Detail of Fee Submitted	37000.0, 2025-01-25,
	The proposed proprietary name / brand name	REHYDROMIN-M ORAL LIQUID
	Label Claim	Each ml contains:Calcium Chloride Hexahydrate BP----- ----- 2 mg Magnesium Chloride Hexahydrate BP----- ----- 4 mg Potassium Chloride BP----- 8 mg Sodium Chloride BP----- 120 mg Cyanocobalamin BP----- 0.025 mg Sodium Lactate BP----- - 42.7 mg

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 Lit-De-Controlled,1000ml-De-Controlled,100ml-De-Controlled,250ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature and avoid from heat and sunlight.
	For generic drugs (me-too Status)	Supplitol Oral Solution (099367)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
829	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Pharmonix Pharmaceuticals Plot 28, Street SS-2, National Industrial Zone, Rawat (000990)
	Application Form Dy. No / Tracking ID & date of submission	(RD5-LTP-35H2, 2025-01-21)
	Detail of Fee Submitted	37000.0, 2025-01-21,
	The proposed proprietary name / brand name	ACO NIX 4.4 Oral Powder
	Label Claim	Each 1000 gram contains: Lincomycin as HCl (USP) 440 gm
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50gm, 100 gm, 250 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)store below 30
	For generic drugs (me-too Status)	LINCOS-P POWDER (Reg. # (049667)M/S A&K Pharma Faisalabad.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
830	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	POULVET PHARMACEUTICAL (PVT) LTD 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN (000970)
	Application Form Dy. No / Tracking ID & date of submission	(4GY-PNQ-BAJ6, 2025-01-14)

	Detail of Fee Submitted	37000.0, 2024-12-17,
	The proposed proprietary name / brand name	Poul Fon Powder
	Label Claim	Each gm contains Trichlorfon - 980mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10gm, 100gm, 250gm, -De-Controlled
	Shelf Life (Unit)	2 Year(s)AT ROOM TEMPERATURE
	For generic drugs (me-too Status)	Trichlovet 98.0% (080768) of Vetz Pharmaceuticals (Reg#080768)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR,DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG,DRAP,LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
831	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	POULVET PHARMACEUTICAL (PVT) LTD 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN (000970)
	Application Form Dy. No / Tracking ID & date of submission	(61Z-YZ2-SBW7, 2025-01-14)
	Detail of Fee Submitted	37000.0, 2024-12-17,
	The proposed proprietary name / brand name	Poul Triverzole Oral Drench
	Label Claim	Triclabendazole BP- 12.0gm/100ml Albendazole BP- 10.0gm/100ml Ivermectin BP- 0.20gm/100ml
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 150ml, 250ml,-De-Controlled
	Shelf Life (Unit)	2 Year(s)AT ROOM TEMPERATURE
	For generic drugs (me-too Status)	Thunder Drench of Star Labs (Reg#058941)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR,DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG,DRAP,LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT)
	Evidence of approval of manufacturing facility	

	Evaluation Remarks	
	Decision	
832	Approved	
	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	POULVET PHARMACEUTICAL (PVT) LTD 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN (000970)
	Application Form Dy. No / Tracking ID & date of submission	(A5D-HAZ-ELNY, 2025-01-14)
	Detail of Fee Submitted	37000.0, 2024-12-17,
	The proposed proprietary name / brand name	Poul Zesal-29 Solution
	Label Claim	Each 1000ml contains Vit. E - 200,000mg Selenium BP - 2000mg Zinc USP - 9000mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 250ml, 500ml,-De-Controlled
	Shelf Life (Unit)	2 Year(s)AT ROOM TEMPERATURE
	For generic drugs (me-too Status)	Baxsel E Solution (072636) of Baxter Pharmaceuticals (Reg#072636)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR,DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG,DRAP,LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
833	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	POULVET PHARMACEUTICAL (PVT) LTD 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN (000970)
	Application Form Dy. No / Tracking ID & date of submission	(B8E-6ZN-SWG1, 2025-01-14)
	Detail of Fee Submitted	37000.0, 2024-12-17,
	The proposed proprietary name / brand name	Necox-55 WSP
	Label Claim	Each 100gm contains Oxytetracycline HCl BP- 30gm Neomycin Sulphate BP- 25gm Colistin Sulphate BP - 50MIU

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10gm, 100gm, 250gm, -De-Controlled
	Shelf Life (Unit)	2 Year(s)AT ROOM TEMPERATURE
	For generic drugs (me-too Status)	Necloxy-55 WSP (111217) of Biorise Pharmaceuticals (Reg#111217)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR,DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG,DRAP,LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
834	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	POULVET PHARMACEUTICAL (PVT) LTD 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN (000970)
	Application Form Dy. No / Tracking ID & date of submission	(DPW-Y44-E8GB, 2025-01-13)
	Detail of Fee Submitted	37000.0, 2024-12-17,
	The proposed proprietary name / brand name	Poul Sali-C Powder
	Label Claim	Each 100gm Contains Acetylsalicylic Acid BP- 6.70 gm Vitamin C BP - 20gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm, 250gm, 500gm,-De-Controlled
	Shelf Life (Unit)	2 Year(s)AT ROOM TEMPERATURE
	For generic drugs (me-too Status)	Sali-C Powder (043537) of Selmore Pharmaceuticals (Reg#043537)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR,DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG,DRAP,LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

Approved

835	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	POULVET PHARMACEUTICAL (PVT) LTD 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN (000970)
	Application Form Dy. No / Tracking ID & date of submission	(ENV-N8G-AQZR, 2025-01-14)
	Detail of Fee Submitted	37000.0, 2024-12-17,
	The proposed proprietary name / brand name	Poul Cox-2.5 Oral Solution
	Label Claim	Each ml contains Toltrazuril 25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml,, 250ml, 450ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)AT ROOM TEMPERATURE
	For generic drugs (me-too Status)	Nocox 2.5% Oral Solution of Hilton Pharma (Reg#032203)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR,DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG,DRAP,LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
836	Decision	
	Approved	
	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	POULVET PHARMACEUTICAL (PVT) LTD 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN (000970)
	Application Form Dy. No / Tracking ID & date of submission	(LP7-7W8-RAPT, 2025-01-13)
	Detail of Fee Submitted	37000.0, 2024-12-17,
	The proposed proprietary name / brand name	Lincos BR Oral Powder
	Label Claim	Each gm contains Lincomycin HCl BP- 50mg Spectinomycin HCl - 75mg Spiramycin Adipate - 25mg Bromhexine HCl BP- 5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm, 250gm, 500gm,-De-Controlled
	Shelf Life (Unit)	2 Year(s)AT ROOM TEMPERATURE
	For generic drugs (me-too Status)	Brolin-S Oral Powder of Leads Pharma (Reg#102027)
	Minutes of 351st Meeting of Registration Board (23rd – 24th September, 2025)	
	650	

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR, DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG, DRAP, LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
837	Approved	
	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	POULVET PHARMACEUTICAL (PVT) LTD 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN (000970)
	Application Form Dy. No / Tracking ID & date of submission	(N8R-7QN-MAWP, 2025-01-14)
	Detail of Fee Submitted	37000.0, 2024-12-17,
	The proposed proprietary name / brand name	Veto Micine Powder
	Label Claim	Each 1000gm contains Choline Chloride BP- 80gm L- Lysine BP- 35gm DL-Methionine BP- 55gm Zinc Bacitracin (10%) vet BP- 15gm Vitamin E - 3000mg Nicotinic Acid - 3000mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm, 250gm, 500gm,-De-Controlled
	Shelf Life (Unit)	2 Year(s) AT ROOM TEMPERATURE
	For generic drugs (me-too Status)	Cholimine Powder (096831) of RAS Pharmaceuticals (Reg#096831)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR, DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG, DRAP, LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	

838	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	POULVET PHARMACEUTICAL (PVT) LTD 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN (000970)
	Application Form Dy. No / Tracking ID & date of submission	(NTH-YLQ-RS9X, 2025-01-13)
	Detail of Fee Submitted	37000.0, 2024-12-17,
	The proposed proprietary name / brand name	Poul Daek-18 Oral Solution
	Label Claim	Each ml contains Vitamin A BP..... 10,000IU Vitamin D3 BP..... 2000 IU Vitamin E BP..... 4 mg Vitamin K3 BP..... 2mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 250ml, 500ml,-De-Controlled
	Shelf Life (Unit)	2 Year(s)AT ROOM TEMPERATURE
	For generic drugs (me-too Status)	Adek Excel Oral Solution Of Nawan Pharma (Reg#058985)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR,DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG,DRAP,LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT)
	Evidence of approval of manufacturing facility	
839	Evaluation Remarks	
	Decision	
	Approved	
	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	POULVET PHARMACEUTICAL (PVT) LTD 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN (000970)
	Application Form Dy. No / Tracking ID & date of submission	(QGP-79V-QPS8, 2025-01-14)
	Detail of Fee Submitted	37000.0, 2024-12-17,
	The proposed proprietary name / brand name	Leva Poul Powder
	Label Claim	Each 100gm contains Levamisole HCl BP 50gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 250ml, 450ml,-De-Controlled
	Shelf Life (Unit)	2 Year(s)AT ROOM TEMPERATURE
	For generic drugs (me-too Status)	Levosin Powder (058946) of A&K Pharmaceuticals (Reg#058946)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--

	GMP status of the firm	INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR, DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG, DRAP, LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
840	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	POULVET PHARMACEUTICAL (PVT) LTD 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN (000970)
	Application Form Dy. No / Tracking ID & date of submission	(QJ2-6JH-BVA6, 2025-01-13)
	Detail of Fee Submitted	37000.0, 2024-12-17,
	The proposed proprietary name / brand name	Poul Linco Water Soluble Powder
	Label Claim	Each gram Contains: Lincomycin HCl BP 100mg Colistin Sulphate BP 800,000 IU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm, 250gm, 500gm,-De-Controlled
	Shelf Life (Unit)	2 Year(s) AT ROOM TEMPERATURE
	For generic drugs (me-too Status)	Mylinco Water Soluble Powder (087138) of Baariq Pharmaceuticals (Reg#087138)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR, DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG, DRAP, LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
841	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	POULVET PHARMACEUTICAL (PVT) LTD 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN (000970)

Application Form Dy. No / Tracking ID & date of submission	(R8N-B4S-9EMU, 2025-01-14)
Detail of Fee Submitted	37000.0, 2024-12-17,
The proposed proprietary name / brand name	Poul Meth WSP
Label Claim	Each 100gm contains Methenamine USP - 95gm Vitamin B1 BP - 0.80gm Vitamin B2 BP - 0.92gm Vitamin K3 BP - 0.2gm
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	100gm, 250gm, 500gm,-De-Controlled
Shelf Life (Unit)	2 Year(s)AT ROOM TEMPERATURE
For generic drugs (me-too Status)	Diuriq WSP (080735) Pharmaceuticals of Baariq Pharmaceuticals (Reg#080735)
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR,DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG,DRAP,LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT)
Evidence of approval of manufacturing facility	

Evaluation Remarks

Decision

Approved

842	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	POULVET PHARMACEUTICAL (PVT) LTD 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN (000970)
	Application Form Dy. No / Tracking ID & date of submission	(SX8-7MV-6EEH, 2025-01-14)
	Detail of Fee Submitted	37000.0, 2024-12-17,
	The proposed proprietary name / brand name	Poulvet C-30 WSP
	Label Claim	Each gm contains Vitamin C BP- 300mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm, 250gm, 500gm,-De-Controlled
	Shelf Life (Unit)	2 Year(s)AT ROOM TEMPERATURE
	For generic drugs (me-too Status)	Ceprix 300 (043287) of Prix Pharmaceuticals (Reg#043287)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR,DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH

		FEDERAL INSPECTOR OF DRUG, DRAP, LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
843	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	POULVET PHARMACEUTICAL (PVT) LTD 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN (000970)
	Application Form Dy. No / Tracking ID & date of submission	(USR-2L7-7VZT, 2025-01-14)
	Detail of Fee Submitted	37000.0, 2024-12-17,
	The proposed proprietary name / brand name	Poul AGE-24 Oral Liquid
	Label Claim	Each 100ml contains Enrofloxacin BP- 10gm Aminophylline - 4gm Guaiphenesin - 10gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 250ml, 500ml, -De-Controlled
	Shelf Life (Unit)	2 Year(s) AT ROOM TEMPERATURE
	For generic drugs (me-too Status)	Enrophylin Oral Liquid (080730) of Baariq Pharmaceuticals (Reg#080730)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR, DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG, DRAP, LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
844	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	POULVET PHARMACEUTICAL (PVT) LTD 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN (000970)
	Application Form Dy. No / Tracking ID & date of submission	(ZLL-4Y1-PEUL, 2025-01-13)
	Detail of Fee Submitted	37000.0, 2024-12-17,

The proposed proprietary name / brand name	Paramol Super WSP
Label Claim	Each 100gm contains Paracetamol BP- 2g Vitamin C BP - 20g Calcium Carbonate BP - 4.5g Magnesium Sulphate BP- 3.5g Potassium Chloride BP- 4g
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	100gm, 250gm, 500gm,-De-Controlled
Shelf Life (Unit)	2 Year(s)AT ROOM TEMPERATURE
For generic drugs (me-too Status)	Bimrol-C WSP (of 102232) D Haanse Pharma (Reg#102232)
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR,DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG,DRAP,LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT)
Evidence of approval of manufacturing facility	
Evaluation Remarks	
Decision	
Approved	
845 Case Category	Routine (Sara Mehreen)
Name, address of Applicant.	POULVET PHARMACEUTICAL (PVT) LTD 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN (000970)
Application Form Dy. No / Tracking ID & date of submission	(235-SW7-TQYS, 2025-01-14)
Detail of Fee Submitted	37000.0, 2024-12-17,
The proposed proprietary name / brand name	Poul Punch Extra Oral Drench
Label Claim	Each ml contains: Oxfendazol BP- 22.65mg Oxyclozanide BP- 62.50mg Cobalt Sulphate BP- 3.82mg Sodium Selenite BP- 0.35mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	100ml, 150ml, 250ml,-De-Controlled
Shelf Life (Unit)	2 Year(s)AT ROOM TEMPERATURE
For generic drugs (me-too Status)	Galied Oral Drench (063615) of IPL Pharmaceuticals (Reg#063615)
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR,DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG,DRAP,LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT)

	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
846	Approved	
	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	POULVET PHARMACEUTICAL (PVT) LTD 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN (000970)
	Application Form Dy. No / Tracking ID & date of submission	(QYJ-XGB-QPDX, 2025-01-13)
	Detail of Fee Submitted	37000.0, 2024-12-17,
	The proposed proprietary name / brand name	Poul Zesel-25 Oral Liquid
	Label Claim	Each 1000ml contains Vitamin E - 150,000mg Selenium (as sodium selenite BP)- 2300mg Zinc Sulphate USP- 8000mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 150ml, 250ml,-De-Controlled
	Shelf Life (Unit)	2 Year(s)AT ROOM TEMPERATURE
	For generic drugs (me-too Status)	Sel-EZ Oral Liquid of Baariq Pharmaceuticals (Reg#073949)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR,DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG,DRAP,LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
847	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	POULVET PHARMACEUTICAL (PVT) LTD 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN (000970)
	Application Form Dy. No / Tracking ID & date of submission	(SLA-Y53-Y2DE, 2025-01-14)
	Detail of Fee Submitted	37000.0, 2024-12-17,
	The proposed proprietary name / brand name	Poul Tonic E Oral Solution

Label Claim	Each ml contains: Vitamin E 200mg Sorbitol 50mg Choline Chloride 50mg Selenium (As Sodium Selenite) 2.3mg Zinc (as Zinc Sulphate) 4mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	100ml, 500ml, 1Lite-De-Controlled
Shelf Life (Unit)	2 Year(s)AT ROOM TEMPERATURE
For generic drugs (me-too Status)	LIVEROSE-5 Oral Solution (063647) of M/S. Noble Pharma Azad Kashmir (Reg#063647)
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR,DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG,DRAP,LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT)
Evidence of approval of manufacturing facility	
Evaluation Remarks	
Decision	
Approved	

848	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	POULVET PHARMACEUTICAL (PVT) LTD 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN (000970)
	Application Form Dy. No / Tracking ID & date of submission	(TTU-HX7-G7PN, 2025-01-10)
	Detail of Fee Submitted	37000.0, 2024-12-17,
	The proposed proprietary name / brand name	POUL ZAN ORAL DRENCH
	Label Claim	Each 100 ml contains: LEVAMISOLE HCL BP 3.0gm OXYCLOZANIDE BP 6.0gm COBALT SULPHATE..... 0.764gm SODIUM SELENITE BP..... 0.076gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 150ml, 250ml,-De-Controlled
	Shelf Life (Unit)	2 Year(s)AT ROOM TERMPERATURE
	For generic drugs (me-too Status)	DE-WORM SURE ORAL DRENCH (063694) OF PRIX PHARMA(REG#063694)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR,DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG,DRAP,LAHORE

		THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
849	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Pharmonix Pharmaceuticals Plot 28, Street SS-2, National Industrial Zone, Rawat (000990)
	Application Form Dy. No / Tracking ID & date of submission	(XAT-QBA-HN21, 2025-01-21)
	Detail of Fee Submitted	37000.0, 2025-01-21,
	The proposed proprietary name / brand name	Acospec Oral Powder
	Label Claim	Each 150 gram contains: Lincomycin as HCl BP.....33.3g Spectinomycin as sulphate USP.....66.7g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50gm, 100 gm, 250 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)store below 30
	For generic drugs (me-too Status)	Bio-spin powder (Reg. # (112171)Bio Lab Pvt Ltd., model Town Islamabad
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
850	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	POULVET PHARMACEUTICAL (PVT) LTD 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN (000970)
	Application Form Dy. No / Tracking ID & date of submission	(GBN-2G9-Q9X9, 2025-01-14)
	Detail of Fee Submitted	37000.0, 2024-12-17,
	The proposed proprietary name / brand name	POUL SCOUR Oral Suspension

Label Claim	Each 100ml contains Sulphadiazine BP..... 3.550gm Sulphadimidine 2.840gm Neomycin Sulphate 0.180gm Hyoscine Methylbromide 0.004gm Pectin -..... 0.710gm Kaolin BP.....10.330gm Vitamin B-1 BP..... 0.015gm Vitamin B-2 0.022gm
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	100ml, 150ml, 250ml,-De-Controlled
Shelf Life (Unit)	2 Year(s)AT ROOM TEMPERATURE
For generic drugs (me-too Status)	Boviscour Liquid (079110) by M/s Hawk Bio Pharma (Pvt.) Ltd., Islamabad
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	INSPECTION WAS CONDUCTED ON DATED 09-09- 2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR,DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG,DRAP,LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT)
Evidence of approval of manufacturing facility	
Evaluation Remarks	
Decision	
Approved	
Case Category	Routine (Sara Mehreen)
Name, address of Applicant.	ACME PHARMACEUTICALS Plot No. 29, Street SS-2, RCCI Industrial Estate Rawat (000967)
Application Form Dy. No / Tracking ID & date of submission	(WWB-XP9-SNQX, 2025-01-16)
Detail of Fee Submitted	37000.0, 2025-01-13,
The proposed proprietary name / brand name	Reanl-10 WSP
Label Claim	Each gram contains: Hexamethylene Tetramine 955mg, Riboflavin . BP,,,,. 10mg, Calcium Pantothenae BP.....5mg, Nicotinamide 25mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	100gm,200gm,250gm,50-De-Controlled
Shelf Life (Unit)	2 Year(s)storage at room temperature
For generic drugs (me-too Status)	TOLORENAL WATER SOLUBLE POWDER. 035175 by M/s MEDIEXCEL PHARMACEUTICALS, ISLAMABAD.
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	Good Level
Evidence of approval of manufacturing facility	
Evaluation Remarks	

	Decision	
	Approved	
852	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	ACME PHARMACEUTICALS Plot No. 29, Street SS-2, RCCI Industrial Estate Rawat (000967)
	Application Form Dy. No / Tracking ID & date of submission	(XMB-SSM-2PGG, 2025-01-16)
	Detail of Fee Submitted	37000.0, 2025-01-13,
	The proposed proprietary name / brand name	Neocol-C
	Label Claim	Each gram contains: Chlortetracycline HCL BP 80 mg Neomycin Sulphate BP..... 70mg, Colistin Sulphate BP..... 4mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gm, 250 gm, 500 -De-Controlled
	Shelf Life (Unit)	2 Year(s)storage at room temperature
	For generic drugs (me-too Status)	CCN-154 POWDER. 044940 by M/s GUYTON PHARMACEUTICALS, LAHORE.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Good Level
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
853	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	POULVET PHARMACEUTICAL (PVT) LTD 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN (000970)
	Application Form Dy. No / Tracking ID & date of submission	(224-VYG-QQY4, 2025-01-10)
	Detail of Fee Submitted	37000.0, 2024-12-17,
	The proposed proprietary name / brand name	POUL ZYME E ORAL POWDER
	Label Claim	EACH 100GM CONTAINS.....LYSOZYME=22.0gm VITAMIN E=0.50gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm, 250gm, 500gm,-De-Controlled
	Shelf Life (Unit)	2 Year(s)AT ROOM TEMPERATURE
	For generic drugs (me-too Status)	MILIZYME E ORAL POWDER OF MILIVET PHARMACEUTICALS (REG#112206)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--

	GMP status of the firm	INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR, DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG, DRAP, LAHORE
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
854	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Kohinoor Industries 159-160/B Small Industrial Estate, Sahiwal (000197)
	Application Form Dy. No / Tracking ID & date of submission	(TXT-5BJ-PNS1, 2025-01-21)
	Detail of Fee Submitted	37000.0, 2024-11-30,
	The proposed proprietary name / brand name	EZYME Oral W/S Powder
	Label Claim	Each gm contains: Lysozyme 220mg Vitamin E 50 5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	20gm, 50gm, 100gm, 250g-De-Controlled
	Shelf Life (Unit)	2 Year(s) Below 30 Celsius
	For generic drugs (me-too Status)	LISO 10 Powder (049566) by Mallard Pharmaceutical
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
855	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	DMAARSON PHARMACTUICALS PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD (000744)
	Application Form Dy. No / Tracking ID & date of submission	(4W4-3E1-U2T5, 2025-02-20)
	Detail of Fee Submitted	37000.0, 2024-10-23,
	The proposed proprietary name / brand name	FENOCIN POWDER
	Label Claim	Each g contains (As Per Innovator Spec.)- Oxytetracycline HCl BP 300mg Florfenicol 100mg Neomycin sulphate BP 150mg
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	1000g-De-Controlled,100g-De-Controlled,250g-De-Controlled,500g-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	STONIS POWDER (097977) NAWAL PHARMACEUTICALS TAXILLA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was found operating at good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
856	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	DMAARSON PHARMACTUICALS PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD (000744)
	Application Form Dy. No / Tracking ID & date of submission	(XN7-H7X-MSG3, 2025-02-20)
	Detail of Fee Submitted	37000.0, 2024-10-23,
	The proposed proprietary name / brand name	FLORAMEC INJECTION
	Label Claim	Each ml contains (BP) Ivermectin BP..... 20mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	SELMEC INJECTION (071087) SELMORE PHARMA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was found operating at good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
857	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	DMAARSON PHARMACTUICALS PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD (000744)
	Application Form Dy. No / Tracking ID & date of submission	(UVX-EP8-T8HT, 2025-02-20)
	Detail of Fee Submitted	37000.0, 2024-10-23,

The proposed proprietary name / brand name	MAXMECTIN 3.15% INJECTION
Label Claim	Each ml contains (BP) Ivermectin BP..... 31.5 mg
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	50ml-De-Controlled
Shelf Life (Unit)	2 Year(s)Store Below 30°C
For generic drugs (me-too Status)	ELVOMEK STAR INJECTION 3.15% (063728) ELKO ORGANIZATION
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	At the time of inspection firm was operating according to GMP
Evidence of approval of manufacturing facility	

Evaluation Remarks

Decision

Deferred

Deferred for review of sub-committee on veterinary drugs regarding therapeutic requirements & dose keeping in view safety efficacy & quality parameters.

858	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	DMAARSON PHARMACTUICALS PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD (000744)
	Application Form Dy. No / Tracking ID & date of submission	(74W-A9Z-BRHN, 2025-02-20)
	Detail of Fee Submitted	37000.0, 2024-10-23,
	The proposed proprietary name / brand name	MAXMECTIN 3.15% INJECTION
	Label Claim	Each ml contains (BP) Ivermectin BP..... 31.5 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	ELVOMEK STAR INJECTION 3.15% (063728) ELKO ORGANIZATION
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	At the time of inspection firm was operating according to GMP
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Deferred	
	Deferred for review of sub-committee on veterinary drugs regarding therapeutic requirements & dose keeping in view safety efficacy & quality parameters.	
859	Case Category	Routine (Sara Mehreen)

Name, address of Applicant.	DMAARSON PHARMACTUICALS PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD (000744)
Application Form Dy. No / Tracking ID & date of submission	(A9U-Z5T-MPQ7, 2025-02-20)
Detail of Fee Submitted	37000.0, 2024-10-23,
The proposed proprietary name / brand name	FOSFO MAARS POWDER
Label Claim	Each g contains (As Per Innovators Spec.) Fosfomycin Calcium BP..... 200mg Tylosin as tartrate BP 100mg Fructose 1,6 Diphosphate BP..... 180mg Sodium Phosphate BP 150mg Magnesium Sulphate BP..... 100mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1000g-De-Controlled,100g-De-Controlled,250g-De-Controlled,500g-De-Controlled
Shelf Life (Unit)	2 Year(s)Store Below 30°C
For generic drugs (me-too Status)	WAL-FOS W/S Powder (120736) NAWAL PHARMACEUTICALS TAXILLA
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	Firm was found operating at good level of GMP Compliance
Evidence of approval of manufacturing facility	
Evaluation Remarks	
Decision	
Approved	
860	Case Category
Name, address of Applicant.	DMAARSON PHARMACTUICALS PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD (000744)
Application Form Dy. No / Tracking ID & date of submission	(BTU-UNN-87PN, 2025-02-20)
Detail of Fee Submitted	37000.0, 2024-10-23,
The proposed proprietary name / brand name	IVA GN INJECTION
Label Claim	Each 100ml contains (BP) Ivermectin BP..... 1g
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	10ml-De-Controlled
Shelf Life (Unit)	2 Year(s)Store Below 30°C
For generic drugs (me-too Status)	ACTIMEC INJECTION (034595) SELMORE PHARMA
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	At the time of inspection firm was operating according to GMP

	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
861	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	DMAARSON PHARMACTUICALS PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD (000744)
	Application Form Dy. No / Tracking ID & date of submission	(D95-4RL-ZZR5, 2025-02-20)
	Detail of Fee Submitted	37000.0, 2024-10-23,
	The proposed proprietary name / brand name	MAXMECTIN 3.15% INJECTION
	Label Claim	Each ml contains (BP) Ivermectin BP..... 31.5 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	ELVOMEK STAR INJECTION 3.15% (063728) ELKO ORGANIZATION
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	At the time of inspection firm was operating according to GMP
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Deferred	
	Deferred for review of sub-committee on veterinary drugs regarding therapeutic requirements & dose keeping in view safety efficacy & quality parameters.	
862	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	DMAARSON PHARMACTUICALS PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD (000744)
	Application Form Dy. No / Tracking ID & date of submission	(MTS-TBE-4HPR, 2025-02-19)
	Detail of Fee Submitted	37000.0, 2024-10-23,
	The proposed proprietary name / brand name	DM ROLIUM POWDER
	Label Claim	Each 100g contains (USP) Amprolium HCl USP.....50g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100g-De-Controlled,250g-De-Controlled,500g-De-Controlled,Kg-De-Controlled

Shelf Life (Unit)	2 Year(s)Store Below 30°C
For generic drugs (me-too Status)	AMPROCON POWDER (049758) LEXICON PHARMA KARACHI
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	At the time of inspection firm was operating according to GMP
Evidence of approval of manufacturing facility	

Evaluation Remarks

Decision

Approved

863	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	DMAARSON PHARMACTUICALS PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD (000744)
	Application Form Dy. No / Tracking ID & date of submission	(P29-LXM-3V5Y, 2025-02-20)
	Detail of Fee Submitted	37000.0, 2024-10-23,
	The proposed proprietary name / brand name	THOMAN LIQUID
	Label Claim	Each ml contains (As Per Innovatorr Spec.) Bromhexine HCl BP 50mg Menthol BP 40mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled,250ml-De-Controlled,500ml-De-Controlled,Lit-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	HEXTHOL LIQUID (097984) NAWAL PHARMACEUTICALS TAXILLA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	At the time of inspection firm was operating according to GMP
	Evidence of approval of manufacturing facility	

Evaluation Remarks

Decision

Approved

864	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	DMAARSON PHARMACTUICALS PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD (000744)
	Application Form Dy. No / Tracking ID & date of submission	(T64-XDS-VNS5, 2025-02-20)
	Detail of Fee Submitted	37000.0, 2024-10-23,

	The proposed proprietary name / brand name	IVA GN INJECTION
	Label Claim	Each 100ml contains (BP) Ivermectin BP..... 1g
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	ACTIMEC INJECTION (034595) SELMORE PHARMA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	At the time of inspection firm was operating according to GMP
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
865	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	DMAARSON PHARMACTUICALS PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD (000744)
	Application Form Dy. No / Tracking ID & date of submission	(UD2-YQ3-4SYR, 2025-02-20)
	Detail of Fee Submitted	37000.0, 2024-10-23,
	The proposed proprietary name / brand name	FLORAMEC INJECTION
	Label Claim	Each ml contains (BP) Ivermectin BP..... 20mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	SELMEC INJECTION (071087) SELMORE PHARMA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was found operating at good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
866	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(ZXH-H5B-XWSP, 2024-04-22)

Detail of Fee Submitted	30000.0, 2024-03-19,
The proposed proprietary name / brand name	ASP 200mg Tablet
Label Claim	Each Tablet contains: Amisulpride.....200mg
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
Shelf Life (Unit)	2 Year(s)Store at cool &dry place below 30
For generic drugs (me-too Status)	Amiride200mg Tablet M/s Shrooq Pharmaceuticals
Pharmacotherapeutic Group of (API)	Dopamine receptor antagonist; neuroleptic
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Atlas Life Sciences Private Limited. Address C-1/360-361, G.I.D.C. Estate, Ahmedabad – 382415, Gujarat
Detail of stability batches of drug product	930 tablets 3 batches
Documents for the procurement of API with approval from DRAP (in case of Import)	Loan from M/s Medisure letter ref No. ML/03/2022 and clearance certificate from Loan giver E-2670562245736 13.sep.22
Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparator drug Product (Solian 200mg Tablets)
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
The status in reference regulatory authorities	Solian 50mg Tablets M/sSanofi-Winthrop Industrie, United Kingdom(HPRA Approved)
GMP status of the firm	188/2023-DRAP(AD-3489860170) 14.11.23
Evidence of approval of manufacturing facility	No. F.1-51/2004-LIC dated 7th -02-2014 mentioning tablet section

Evaluation Remarks

Sr. No	Observation	Response
1	1.3.4 Valid Drug Manufacturing License of Manufacturer required	Provided
2	3.2.P.5.2 ANALYTICAL PROCEDURE: Firm has adopted analytical procedure specifications according to B.P with Inj volume 20ul and detection wavelength as 240nm however in chromatogram provided analytical procedure was changed P WITH INJ volume 10ul and detection wavelength as 225nm. Justification required for change.	Firm has briefed that the chromatograms showing Inj volume 10 µL and wavelength 225 nm was the result of a typographical error in the chromatogram printout and does not reflect the actual test parameters used during analysis
3	3.2. P.8.3 API Loan intimation letter to DRAP required.	We have not intimated for loan as we were not aware about it and unfortunately it was overlooked

Decision

Approved

Registration Board Approved the said case subject to verification of loan letter of API & the authenticity of the submitted stability data by the panel constituted by the Chairman, Registration Board.

867	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(44H-A4P-86J5, 2024-04-22)

Detail of Fee Submitted	30000.0, 2024-03-19,
The proposed proprietary name / brand name	ASP 50mg Tablet
Label Claim	Each Tablet contains Amisulpride.....50mg
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
Shelf Life (Unit)	2 Year(s)Store at cool &dry place below 30
For generic drugs (me-too Status)	Aisul 50mg Tablet M/s Siam Pharmaceuticals Registration #106988
Pharmacotherapeutic Group of (API)	Dopamine receptor antagonist; neuroleptic
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Atlas Life Sciences Private Limited. Address C-1/360-361, G.I.D.C. Estate, Ahmedabad – 382415, Gujarat
Detail of stability batches of drug product	930 tablets 3 batches
Documents for the procurement of API with approval from DRAP (in case of Import)	Loan from M/s Medisure letter ref No. ML/03/2022 and clearance certificate from Loan giver E-2670562245736 13.sep.22
Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparator drug Product (Solian 50mg Tablets)
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
The status in reference regulatory authorities	Solian 50mg Tablets M/s Sanofi-Winthrop Industrie, United Kingdom (HPRA Approved)
GMP status of the firm	188/2023-DRAP(AD-3489860170) 14.11.23
Evidence of approval of manufacturing facility	No. F.1-51/2004-LIC dated 7th -02-2014 mentioning tablet section

Evaluation Remarks

Sr. No	Observation	Response
1	1.3.4 Valid Drug Manufacturing License of Manufacturer required	Provided
2	3.2.P.5.2 ANALYTICAL PROCEDURE: Firm has adopted analytical procedure specifications according to B.P with Inj volume 20ul and detection wavelength as 240nm however in chromatogram provided analytical procedure was changed P WITH INJ volume 10ul and detection wavelength as 225nm. Justification required for change.	Firm has briefed that the chromatograms showing Inj volume 10 µL and wavelength 225 nm was the result of a typographical error in the chromatogram printout and does not reflect the actual test parameters used during analysis
3	3.2. P.8.3 API Loan intimation letter to DRAP required.	We have not intimated for loan as we were not aware about it and unfortunately it was overlooked

Decision

Approved

Registration Board Approved the said case subject to verification of verification of loan letter of API & the authenticity of the submitted stability data by the panel constituted by the Chairman, Registration Board.

868	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(5T6-U9X-U5G4, 2024-04-24)

Detail of Fee Submitted	30000.0, 2024-03-19,
The proposed proprietary name / brand name	ASP 100mg Tablet
Label Claim	Each Tablet contains Amisulpride.....100mg
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
Shelf Life (Unit)	2 Year(s)Store at cool &dry place below 30
For generic drugs (me-too Status)	Aisul 100mg Tablet M/s Siam Pharmaceuticals Registration #105654
Pharmacotherapeutic Group of (API)	Dopamine receptor antagonist; neuroleptic
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Atlas Life Sciences Private Limited. Address C-1/360-361, G.I.D.C. Estate, Ahmedabad – 382415, Gujarat
Detail of stability batches of drug product	930 tablets 3 batches
Documents for the procurement of API with approval from DRAP (in case of Import)	Loan from M/s Medisure letter ref No. ML/03/2022 and clearance certificate from Loan giver E-2670562245736 13.sep.22
Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparator drug Product (Solian 100mg Tablets)
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
The status in reference regulatory authorities	Solian 100mg Tablets M/sSanofi-Winthrop Industrie, United Kingdom(HPRA Approved)
GMP status of the firm	188/2023-DRAP(AD-3489860170) 14.11.23
Evidence of approval of manufacturing facility	No. F.1-51/2004-LIC dated 7th -02-2014 mentioning tablet section

Evaluation Remarks

Sr. No	Observation	Response
1	1.3.4 Valid Drug Manufacturing License of Manufacturer required	Provided
2	3.2.P.5.2 ANALYTICAL PROCEDURE: Firm has adopted analytical procedure specifications according to B.P with Inj volume 20ul and detection wavelength as 240nm however in chromatogram provided analytical procedure was changed P WITH INJ volume 10ul and detection wavelength as 225nm. Justification required for change.	Firm has briefed that the chromatograms showing Inj volume 10 µL and wavelength 225 nm was the result of a typographical error in the chromatogram printout and does not reflect the actual test parameters used during analysis
3	3.2. P.8.3 API Loan intimation letter to DRAP required.	We have not intimated for loan as we were not aware about it and unfortunately it was overlooked

Decision

Approved

Registration Board Approved the said case subject to verification of loan letter of API & the authenticity of the submitted stability data by the panel constituted by the Chairman, Registration Board.

869	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	Axis Pharmaceuticals (Pvt) Ltd 3-B, vale Addition City, 1.5Km Khurrianwala- Sahianwala Road Faisalabad (000667)

Application Form Dy. No / Tracking ID & date of submission	(1H8-WBR-5QYV, 2025-06-17)
Detail of Fee Submitted	37000.0, 2025-02-27,
The proposed proprietary name / brand name	Cefposalbix Injection 2g (IV/IM)
Label Claim	Each vial Contains: Cefoperazone (as sodium)....1g+Sulbactam(as sodium)...1g
Reference to Finished product specifications	Any Other
Proposed Pack Size	1's-As per SRO
Shelf Life (Unit)	24 Year(s)Store below 30°C
For generic drugs (me-too Status)	2Sum 2g Injection
Pharmacotherapeutic Group of (API)	Antiinfective for systemic use
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Zhuhai United Laboratories Co., Ltd.
Detail of stability batches of drug product	3 Batch manufactured each having 2000 vials batch sizes
Documents for the procurement of API with approval from DRAP (in case of Import)	loan from medisave E-8177464883561 Clearance certificate of API Import dated 02 February 2024
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies are conducted against 2 Sum 2g Injection (IV/IM)of Sami Pharmaceuticals / Healthtek (pvt.) Limited, Karachi –Pakistan
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 Batches of API As per Zone IV-A
The status in reference regulatory authorities	Sulcef Injection (Approved in Bulgaria,Luithania,Slovakia)
GMP status of the firm	New section
Evidence of approval of manufacturing facility	letter for issurance of Cephalosporins section approval dated 23-08-2024

Evaluation Remarks

3.2. S.4.1. Drug Substance specifications of the Drug Substance &Product manufacturer: Drug substance specifications are not as per finished product specifications'. As per inhouse method adopted limit for water contents are 4% however as per JP specifications' adopted for finished product limit for water content is 1% which makes API substandard for finish product.	1.5.6. Pharmacopoeial Reference/Status of applied formulation: Firm has opted for Manufacturer specs and submitted validation studies along with fee for revision .
3.2.S.4.4. BATCH ANALYSES: Batch analysis shows assay of 1g injection (cefoperazone (as sodium) 500mg+Sulbactam (as sodium) ...500mg however the applied product is different.	Firm claimed that they have used Drug substance in same ratio. 1:1
3.2.S.7.1. STABILITY SUMMARY AND CONCLUSIONS: Drug substance has provided Storage Condition at 2 - 8°C in airtight container. 5°C ± 3°C Long-Term Stability study & 25°C ± 2°C / 60% ± 5% Accelerated Stability study, and provided stability study data however firm has claimed storage conditions of room temperature clarification required Assay results shows the stability data provided is for cefoperazone& Sulbactam combined 1g however the applied product is 250mg each.	Firm submitted additional data as per zone IV-A
3.2.P.2.2.1 Formulation Development Pharmaceutical Equivalence: Pharmaceutical Equivalence data shows Minutes of 351st Meeting of Registration Board	Firm has opted for Manufacturer specs and submitted validation studies along with fee for revision . (23rd – 24th September, 2025)

	that the test product is out of specs in water content as per JP specs.	
	3.2.P.5.1. SPECIFICATION(S): Firm has adopted JP specification however Water Content specifications' are not in line to JP (NMT 4.0 %) instead of NMT 1%. Justification required for choosing other specification's from JP and water content specifications' from manufacturer inhouse method. Potency adjustment has been made based on water contents. Justification required along with complete sheets of adjustment calculations	3.2.P.5.1. SPECIFICATION(S): Firm has opted for Manufacturer specs and submitted validation studies along with fee for revision. Firm submitted revised calculations
	3.2.P.8 Stability: Chromatograms for each time interval for both accelerated and real time shall be submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted. Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted	3.2.P.8 Stability:
	R&I for submission of intimation to DRAP regarding loan of API..	Submitted
	1.5.6. Pharmacopoeial Reference/Status of applied formulation: Firm has opted for Japanese Pharmacopoeia (JP) in said section and attached monograph as reference however water content limits were not followed. Firm is now claiming innovator specs. Firm is advised to provide Manufacturer specs and validation studies accordingly along with fee for revision .	Firm has opted for Manufacturer specs and submitted validation studies along with fee for revision.
	3.2.S.2. Manufacture: Firm is advised to submit complete manufacturing process whether it is through Dissolution Crystallization Method or Unit Lyophilization	Flow diagram submitted : Crystallization Method
	3.2.P.5.1. SPECIFICATION(S): revised innovator specs required as the previous specs opted are JP specs except water content.	Firm has opted for Manufacturer specs and submitted validation studies along with fee for revision.
Decision		
Approved		
Registration letter will be issued after verification of loan letter of API		
870	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	Axis Pharmaceuticals (Pvt) Ltd 3-B, vale Addition City, 1.5Km Khurrianwala- Sahianwala Road Faisalabad (000667)
	Application Form Dy. No / Tracking ID & date of submission	(R24-W8A-LDA2, 2025-07-18)
	Detail of Fee Submitted	37000.0, 2025-02-27,
	The proposed proprietary name / brand name	Cefposalbix Injection 1g (IV/IM)
	Label Claim	Each vial Contains: Cefoperazone (as sodium)....500mg+Sulbactam(as sodium)...500mg
	Reference to Finished product specifications	Any Other

Proposed Pack Size	1's-As per SRO
Shelf Life (Unit)	24 Year(s)Store below 30°C
For generic drugs (me-too Status)	2Sum 1g Injection
Pharmacotherapeutic Group of (API)	Antiinfective for systemic use
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Zhuhai United Laboratories Co., Ltd.
Detail of stability batches of drug product	3 Batch manufactured each having 2000 vials batch sizes
Documents for the procurement of API with approval from DRAP (in case of Import)	loan from medisave E-8177464883561 Clearance certificate of API Import dated 02 February 2024
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies are conducted against 2 Sum 1g Injection (IV/IM)of Sami Pharmaceuticals / Healthtek (pvt.) Limited, Karachi –Pakistan
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 Batches of API As per Zone IV-A
The status in reference regulatory authorities	Pmda
GMP status of the firm	new license
Evidence of approval of manufacturing facility	letter for issuance of Cephalosporins section approval dated 23-08-2024

Evaluation Remarks

3.2. S.4.1. Drug Substance specifications of the Drug Substance &Product manufacturer: Drug substance specifications are not as per finished product specifications'. As per inhouse method adopted limit for water contents are 4% however as per JP specifications' adopted for finished product limit for water content is 1% which makes API substandard for finish product.	1.5.6. Pharmacopoeial Reference/Status of applied formulation: Firm has opted for Manufacturer specs and submitted validation studies along with fee for revision .
3.2.S.4.4. BATCH ANALYSES: Batch analysis shows assay of 1g injection (cefoperazone (as sodium) 500mg+Sulbactam (as sodium) ...500mg however the applied product is different.	Firm claimed that they have used Drug substance in same ratio. 1:1
3.2.S.7.1. STABILITY SUMMARY AND CONCLUSIONS: Drug substance has provided Storage Condition at 2 - 8°C in airtight container. 5°C ± 3°C Long-Term Stability study & 25°C ± 2°C / 60% ± 5% Accelerated Stability study, and provided stability study data however firm has claimed storage conditions of room temperature clarification required Assay results shows the stability data provided is for cefoperazone& Sulbactam combined 1g however the applied product is 250mg each.	Firm submitted additional data as per zone IV-A
3.2.P.2.2.1 Formulation Development Pharmaceutical Equivalence: Pharmaceutical Equivalence data shows that the test product is out of specs in water content as per JP specs.	Firm has opted for Manufacturer specs and submitted validation studies along with fee for revision .
3.2.P.5.1. SPECIFICATION(S): Firm has adopted JP specification however Water Content specifications' are not in line to JP (NMT 4.0 %) instead of NMT 1%. Justification required for choosing other specification's from JP and water content specifications' from manufacturer inhouse method. Potency adjustment has been made based on water contents. Justification	3.2.P.5.1. SPECIFICATION(S): Firm has opted for Manufacturer specs and submitted validation studies along with fee for revision. Firm submitted revised calculations

required along with complete sheets of adjustment calculations	
3.2.P.8 Stability: Chromatograms for each time interval for both accelerated and real time shall be submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted. Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted	3.2.P.8 Stability:
R&I for submission of intimation to DRAP regarding loan of API..	Submitted
1.5.6. Pharmacopoeial Reference/Status of applied formulation: Firm has opted for Japanese Pharmacopoeia (JP) in said section and attached monograph as reference however water content limits were not followed. Firm is now claiming innovator specs. Firm is advised to provide Manufacturer specs and validation studies accordingly along with fee for revision .	Firm has opted for Manufacturer specs and submitted validation studies along with fee for revision.
3.2.S.2. Manufacture: Firm is advised to submit complete manufacturing process whether it is through Dissolution Crystallization Method or Unit Lyophilization	Flow diagram submitted : Crystallization Method
3.2.P.5.1. SPECIFICATION(S): revised innovator specs required as the previous specs opted are JP specs except water content.	Firm has opted for Manufacturer specs and submitted validation studies along with fee for revision.

Decision

Approved

Registration letter will be issued after verification of loan letter of API

871	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	Axis Pharmaceuticals (Pvt) Ltd 3-B, vale Addition City, 1.5Km Khurrianwala- Sahianwala Road Faisalabad (000667)
	Application Form Dy. No / Tracking ID & date of submission	(VBG-49G-YJXL, 2025-07-18)
	Detail of Fee Submitted	37000.0, 2025-02-27,
	The proposed proprietary name / brand name	Cefposalbix Injection 500mg (IV/IM)
	Label Claim	Each vial Contains: Cefoperazone (as sodium)....250mg+Sulbactam(as sodium)...250mg
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C
	For generic drugs (me-too Status)	2Sum 500mg Injection
	Pharmacotherapeutic Group of (API)	Antiinfective for systemic use
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhuhai United Laboratories Co., Ltd.
	Detail of stability batches of drug product	3 Batch manufactured each having 2000 vials batch sizes

Documents for the procurement of API with approval from DRAP (in case of Import)	E-8177464883561 Clearance certificate of API Import dated 02 February 2024 loan from medisave
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies are conducted against 2 Sum 500mg Injection (IV/IM) of Sami Pharmaceuticals
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IV-A
The status in reference regulatory authorities	Pmda
GMP status of the firm	New section
Evidence of approval of manufacturing facility	letter for issuance of Cephalosporins section approval dated 23-08-2024

Evaluation Remarks

3.2. S.4.1. Drug Substance specifications of the Drug Substance & Product manufacturer: Drug substance specifications are not as per finished product specifications'. As per inhouse method adopted limit for water contents are 4% however as per JP specifications' adopted for finished product limit for water content is 1% which makes API substandard for finish product.	1.5.6. Pharmacopoeial Reference/Status of applied formulation: Firm has opted for Manufacturer specs and submitted validation studies along with fee for revision .
3.2.S.4.4. BATCH ANALYSES: Batch analysis shows assay of 1g injection (cefoperazone (as sodium) 500mg+Sulbactam (as sodium) ...500mg however the applied product is different.	Firm claimed that they have used Drug substance in same ratio. 1:1
3.2.S.7.1. STABILITY SUMMARY AND CONCLUSIONS: Drug substance has provided Storage Condition at 2 - 8°C in airtight container. 5°C ± 3°C Long-Term Stability study & 25°C ± 2°C / 60% ± 5% Accelerated Stability study, and provided stability study data however firm has claimed storage conditions of room temperature clarification required Assay results shows the stability data provided is for cefoperazone& Sulbactam combined 1g however the applied product is 250mg each.	Firm submitted additional data as per zone IV-A
3.2.P.2.2.1 Formulation Development Pharmaceutical Equivalence: Pharmaceutical Equivalence data shows that the test product is out of specs in water content as per JP specs.	Firm has opted for Manufacturer specs and submitted validation studies along with fee for revision .
3.2.P.5.1. SPECIFICATION(S): Firm has adopted JP specification however Water Content specifications' are not in line to JP (NMT 4.0 %) instead of NMT 1%. Justification required for choosing other specification's from JP and water content specifications' from manufacturer inhouse method. Potency adjustment has been made based on water contents. Justification required along with complete sheets of adjustment calculations	3.2.P.5.1. SPECIFICATION(S): Firm has opted for Manufacturer specs and submitted validation studies along with fee for revision. Firm submitted revised calculations
3.2.P.8 Stability: Chromatograms for each time interval for both accelerated and real time shall be submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted. Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted	3.2.P.8 Stability:

R&I for submission of intimation to DRAP regarding loan of API..	Submitted
1.5.6. Pharmacopoeial Reference/Status of applied formulation: Firm has opted for Japanese Pharmacopoeia (JP) in said section and attached monograph as reference however water content limits were not followed. Firm is now claiming innovator specs. Firm is advised to provide Manufacturer specs and validation studies accordingly along with fee for revision .	Firm has opted for Manufacturer specs and submitted validation studies along with fee for revision.
3.2.S.2. Manufacture: Firm is advised to submit complete manufacturing process whether it is through Dissolution Crystallization Method or Unit Lyophilization	Flow diagram submitted : Crystallization Method
3.2.P.5.1. SPECIFICATION(S): revised innovator specs required as the previous specs opted are JP specs except water content.	Firm has opted for Manufacturer specs and submitted validation studies along with fee for revision.

Decision

Approved

Registration letter will be issued after verification of loan letter of API

872	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	Axis Pharmaceuticals (Pvt) Ltd 3-B, vale Addition City, 1.5Km Khurrianwala- Sahianwala Road Faisalabad (000667)
	Application Form Dy. No / Tracking ID & date of submission	(YMR-BQD-Z4BM, 2025-07-18)
	Detail of Fee Submitted	37000.0, 2025-04-08,
	The proposed proprietary name / brand name	Cefotax Injection 1g (IV/IM)
	Label Claim	Each vial contains cefotaxime (as sodium) 1g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Claforan 1g Injection
	Pharmacotherapeutic Group of (API)	Antiinfective for systemic use (3rd generation cephalosporins)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Henan Kangda Pharmaceuticals co.,Ltd
	Detail of stability batches of drug product	3 Batch manufactured each having 2000 vials batch sizes
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate of API Import dated 09th February 2024
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies are conducted against Claforan 1g Injection of Sanofi-aventis Pakistan Ltd
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 Batches of API As per Zone IV-A
	The status in reference regulatory authorities	MHRA
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 3-7-2024

Evidence of approval of manufacturing facility	letter for issuance of Cephalosporins section approval dated 23-08-2024

Evaluation Remarks

3.2..S.4.2. Analytical procedure: Analytical method of Drug Substance by Drug Product manufacturer & Drug substance manufacturer lacks system suitability as provided in assay by USP monograph. Justification required for omitting system suitability as per USP monograph.	Firm has submitted Analytical procedure for system suitability.
3.2. S.4.4 Analytical method verification report lacks resolution	Submitted
3.2. P.5.2. Analytical procedures: Assay procedure are not in line to USP monograph, lacks system suitability as provided in assay by USP monograph. Justification required for omitting system suitability as per USP monograph	Submitted
3.2.P.8 Stability: System suitability is not performed as per USP monograph	Submitted
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted	Submitted
Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted	Submitted
R&I for submission of intimation to DRAP regarding loan of API	Submitted

Decision

Approved

Registration letter will be issued after verification of loan letter of API

873	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	Medifine Laboratories (Pvt) Ltd. Plot No A-11, New Industrial Area, Mirpur, Azad Kashmir (000672)
	Application Form Dy. No / Tracking ID & date of submission	(96H-9M5-V6N1, 2024-03-01)
	Detail of Fee Submitted	30000.0, 2024-01-24,
	The proposed proprietary name / brand name	Alerkast
	Label Claim	Each sachet contains: Montelukast Sodium eq. to Montelukast. 4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14's -As per SRO
	Shelf Life (Unit)	2 Year(s) Store below 30C at cool and dry place
	For generic drugs (me-too Status)	Lucast ® 4mg Sachet
	Pharmacotherapeutic Group of (API)	Leukotriene Receptor Antagonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Morepen Laboratories Limited.
	Detail of stability batches of drug product	5000 Sachets
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan : E 169080022836 28.02.22 M/s Seraph Pharmaceutical
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Singulair ® 4mg Sachet Marketing Authorization holder: Merck Research Laboratories
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Singulair ® 4mg Sachet by Merck Research Laboratories
	GMP status of the firm	No F.3-97/2022-Add.dir (Qa-Lt-1) dated 22-August-2022 mentioning sachet section

Evidence of approval of manufacturing facility	No F.5-1/2025-Lic (Vol-1)dated 15-february-2021 mentioning Sachet section

Evaluation Remarks

1.6.5: Valid copy of GMP certificate of the drug product manufacturer & issued by concerned/relevant regulatory authority shall be submitted.	Firm has submitted last inspection report conducted 15.2.21 for grant of additional section.
Valid copy of DML required	Not submitted
3.2.P.2.2.1 Formulation Development Pharmaceutical Equivalence: Batch details and pictorial evidence from google images is attached. Justification required. Assay results are not quantified. https://www.medicalbazar.co/products/singulair-powder-4mg-28s	Firm claims that the picture from net was taken for excipient details and No evidence for reference product is submitted
3.2.P.5 Specification's: Assay specs are not in line to USP monograph, Chromatographic system Injection volume: 15µL instead of 20 µL, Run time: 1.5 times the retention time of montelukast System suitability instead of 2 times.	Firm has submitted that According to USP Chapter "chromatography" (USP), the following chromatographic parameters fall under the "allowable adjustment parameters": · Column dimension · Column temperature · Injection volume · Flowrate
Dissolution specs are not in line to USP monograph Flow rate: 0.9 mL/min instead of 0.8 mL/min	In case of "Dissolution" the following parameters. The flow rate is adjusted slightly as it falls under "modification allowable parameters".
3.2.P.8 Stability: Why system suitability is not performed as per USP monograph. Submitted chromatograms have no wavelength. Clarification shall be submitted. Injection volume for dissolution sheets is not as per USP monograph R&I for submission of intimation to DRAP regarding loan of API	The resolution was not calculated. However we commit to calculate the resolution at upcoming stability time point and shall submit to relevant department. The chromatograms shows the details, which were selected while integrating the chromatograms i.e .while integrating the wavelength option was mistakenly not selected, Due to unawareness, we failed to intimate to DRAP about loan. We commit to intimate DRAP about loan

Decision

Deferred

Registration Board deferred the application for submission of dissolution testing & system suitability as per USP monograph, for all the trial batches at the next time point of long term stability studies

874

Case Category	Routine (Shahrukh Ali)
Name, address of Applicant.	Bio-Labs(Pvt) Ltd Plot 145, Industrial Triangle, Kahuta Road (000296)
Application Form Dy. No / Tracking ID & date of submission	(TWV-QY1-7U1Y, 2024-04-18)
Detail of Fee Submitted	30000.0, 2024-03-13,
The proposed proprietary name / brand name	Rivonew 2.5mg tablet
Label Claim	Each film coated Tablet Contains: Rivaroxaban 2.5mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	10's, 20's,-As per SRO
Shelf Life (Unit)	2 Year(s)Store Below 30
For generic drugs (me-too Status)	Rivaroxaban 2.5mg Tablet
Pharmacotherapeutic Group of (API)	Anti –coagulant B0IAF01
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Nantong Chanyoo Pharmatech Co., Ltd

Detail of stability batches of drug product	Three batches having 1500 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate E-2768755572536 20.08.22
Pharmaceutical Equivalence and Comparative Dissolution Profile	Xcept tablet 2.5mg PharmEvo (Pvt.) Ltd
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
The status in reference regulatory authorities	RIVAROXABAN 2.5mg Tablets FDA Approved (ANDA): 208557
GMP status of the firm	F.3-1912019-Addl. Dir. (QA & LT-I)77 28 December,2023
Evidence of approval of manufacturing facility	No. F.1-12/98-LIC dated 24 -03-2007 mentioning Tablet section

Evaluation Remarks

1.3.5 Valid copy of DML	Renewal application tracking number of the application is SVJ-7MW-8ZLL.
1.6.5: Valid copy of GMP certificate of the drug product & Substance manufacturer issued by concerned/relevant regulatory authority shall be submitted.	Submitted
3.2. P.8.3 •Documents for procurement of API with approval from DRAP shall be submitted.	Submitted

Decision

Approved

875	Case Category	Export Facilitation (Shahrukh Ali)
	Name, address of Applicant.	Helix Pharma (Pvt)., Ltd. Hakimsons House, A-56, S.I.T.E, Manghopir Road, Karachi-75700 (000030)
	Application Form Dy. No / Tracking ID & date of submission	(YM7-US3-2HNV, 2025-02-13)
	Detail of Fee Submitted	37000.0, 2025-01-16,
	The proposed proprietary name / brand name	Onso Injection 8mg/4ml
	Label Claim	Each 4ml contains: Ondansetron hydrochloride dihydrate eq. to Ondansetron 8mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's ; 5's-Controlled
	Shelf Life (Unit)	24 Year(s)Store below 30C.
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	5-HT3 Receptor Antagonists. ATC code A04AA01
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Anugraha Chemicals, India
	Detail of stability batches of drug product	952 Ampoules 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	FORM 6 3000919845876 Valid Upto: 11-Feb-2026 & invoice attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Onset Injection 8mg/4ml by Pharmedic Laboratories (Pvt.) Ltd.

Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
The status in reference regulatory authorities	USFDA Approved
GMP status of the firm	Certificate No. 102 /2024-DRAP (K) Karachi the, 24TH July, 2024
Evidence of approval of manufacturing facility	No. F.2-20/84-Lic (Vol-V)dated 28 December, 2020 Liquid Injectable (General)

Evaluation Remarks

1.3.5 Valid copy of DML	Submitted
1.6.5: Valid copy of GMP certificate of the drug Substance manufacturer issued by concerned/relevant regulatory authority shall be submitted	Submitted

Decision

Approved

876	Case Category	Export Facilitation (Shahrukh Ali)
	Name, address of Applicant.	Helix Pharma (Pvt)., Ltd. Hakimsons House, A-56, S.I.T.E, Manghopir Road, Karachi-75700 (000030)
	Application Form Dy. No / Tracking ID & date of submission	(Y5H-JHP-X4U5, 2025-02-13)
	Detail of Fee Submitted	37000.0, 2025-01-16,
	The proposed proprietary name / brand name	Onso Injection 4mg/2ml
	Label Claim	Each 2ml contains: Ondansetron hydrochloride dihydrate eq. to Ondansetron 4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's ; 5's-Controlled
	Shelf Life (Unit)	24 Year(s)Store below 30C.
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	5-HT3 Receptor Antagonists. ATC code A04AA01
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Anugraha Chemicals, India
	Detail of stability batches of drug product	952 Ampoules 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	FORM 6 3000919845876 Valid Upto: 11-Feb-2026 & invoice attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Onset Injection 4mg/2ml OOJP32
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	Certificate No. 102 /2024-DRAP (K) Karachi the, 24TH July, 2024
	Evidence of approval of manufacturing facility	No. F.2-20/84-Lic (Vol-V)dated 28 December, 2020 mentioning Tablet (General), Liquid Injectable (General)
	Evaluation Remarks	
	1.3.5 Valid copy of DML	Submitted
	1.6.5: Valid copy of GMP certificate of the drug Substance manufacturer issued by concerned/relevant	Submitted

	regulatory authority shall be submitted	
	Decision	
	Approved	
877	Case Category	Export Facilitation (Shahrukh Ali)
	Name, address of Applicant.	Helix Pharma (Pvt)., Ltd. Hakimsons House, A-56, S.I.T.E, Manghopir Road, Karachi-75700 (000030)
	Application Form Dy. No / Tracking ID & date of submission	(P6L-ZUH-HG5E, 2025-05-06)
	Detail of Fee Submitted	37000.0, 2025-01-16,
	The proposed proprietary name / brand name	Onso Oral Solution 4mg/5ml
	Label Claim	Each 5ml contains: Ondansetron HCl (dihydrate) eq. to Ondansetron 4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	15ml; 25ml; 30ml; 50-Controlled
	Shelf Life (Unit)	24 Year(s)Store below 30C.
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	5-HT3 Receptor Antagonists. ATC code A04AA01
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Anugraha Chemicals, India
	Detail of stability batches of drug product	2500ml / 50 Bottles
	Documents for the procurement of API with approval from DRAP (in case of Import)	FORM 6 3000919845876 Valid Upto: 11-Feb-2026 & invoice attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	onseron oral syrup 4mg/5ml M/s indus pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	Certificate No. 102 /2024-DRAP (K) Karachi the, 24TH July, 2024
	Evidence of approval of manufacturing facility	No. F.2-20/84-Lic (Vol-V)dated 28 December, 2020 mentioning Tablet (General), Liquid Injectable (General)
	Evaluation Remarks	
	1.3.5 Valid copy of DML	Submitted
	1.6.5: Valid copy of GMP certificate of the drug Substance manufacturer issued by concerned/relevant regulatory authority shall be submitted	Submitted
	Decision	
	Approved	
878	Case Category	Export Facilitation (Shahrukh Ali)
	Name, address of Applicant.	Helix Pharma (Pvt)., Ltd. Hakimsons House, A-56, S.I.T.E, Manghopir Road, Karachi-75700 (000030)
	Application Form Dy. No / Tracking ID & date of submission	(1LR-TPL-GAX2, 2025-04-11)
	Detail of Fee Submitted	37000.0, 2025-01-16,

The proposed proprietary name / brand name	Onso Tablets 8mg
Label Claim	Each Film coated tablet contains: Ondansetron HCl dihydrate eq. to Ondansetron 8mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	10's; 20's; 30's; 7'-Controlled
Shelf Life (Unit)	24 Year(s)Store below 30C.
For generic drugs (me-too Status)	Available
Pharmacotherapeutic Group of (API)	5-HT3 Receptor Antagonists. ATC code A04AA01
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	M/s Anugraha Chemicals, India
Detail of stability batches of drug product	2000 tablets 3 batches
Documents for the procurement of API with approval from DRAP (in case of Import)	FORM 6 3000919845876 Valid Upto: 11-Feb-2026 & invoice attached
Pharmaceutical Equivalence and Comparative Dissolution Profile	Onset tablet 8mg by Pharmedic Laboratories (Pvt.) Ltd.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
The status in reference regulatory authorities	USFDA Approved
GMP status of the firm	Certificate No. 102 /2024-DRAP (K) Karachi the, 24TH July, 2024
Evidence of approval of manufacturing facility	No. F.2-20/84-Lic (Vol-V)dated 28 December, 2020 mentioning Tablet (General)
Evaluation Remarks	
1.3.5 Valid copy of DML	Submitted
1.6.5: Valid copy of GMP certificate of the drug Substance manufacturer issued by concerned/relevant regulatory authority shall be submitted	Submitted
Decision	
Approved	
879	Case Category
Name, address of Applicant.	Helix Pharma (Pvt)., Ltd. Hakimsons House, A-56, S.I.T.E, Manghopir Road, Karachi-75700 (000030)
Application Form Dy. No / Tracking ID & date of submission	(A1Y-ZQR-E8Y4, 2025-05-06)
Detail of Fee Submitted	37000.0, 2025-01-16,
The proposed proprietary name / brand name	Onso Tablets 4mg
Label Claim	Each Film coated tablet contains: Ondansetron HCl dihydrate eq. to Ondansetron 4mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	10's; 20's; 30's; 7'-Controlled
Shelf Life (Unit)	24 Year(s)Store below 30C.
For generic drugs (me-too Status)	Available
Pharmacotherapeutic Group of (API)	5-HT3 Receptor Antagonists. ATC code A04AA01
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	M/s Anugraha Chemicals, India

	Detail of stability batches of drug product	2000 tablets 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	FORM 6 3000919845876 Valid Upto: 11-Feb-2026 & invoice attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Onset tablet 4mg pharmedic laboratories
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	Certificate No. 102 /2024-DRAP (K) Karachi the, 24TH July, 2024
	Evidence of approval of manufacturing facility	No. F.2-20/84-Lic (Vol-V)dated 28 December, 2020 mentioning Tablet (General)
	Evaluation Remarks	
	1.3.5 Valid copy of DML	Submitted
	1.6.5: Valid copy of GMP certificate of the drug Substance manufacturer issued by concerned/relevant regulatory authority shall be submitted	Submitted
	Decision	
	Approved	
880	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	M/s Daneen Pharma (Pvt) Ltd Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, (000688)
	Application Form Dy. No / Tracking ID & date of submission	(1LU-WLW-ZA8P, 2024-03-14)
	Detail of Fee Submitted	75000.0, 2024-02-21,
	The proposed proprietary name / brand name	Xineen Dry Powder for Oral Suspension 500mg/5ml
	Label Claim	Each 5ml Contains: Cefixime as trihydrate 500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	20ml-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C. Protect from heat, light and moisture.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	antiinfective
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Pharmagen Ltd., Kot Nabi Baksh Wala, 34 KM, Ferozepur Road, Lahore - Pakistan
	Detail of stability batches of drug product	214 bottles 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	locally purchased
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Suprax 500mg/5ml (Manufactured by Lupin pharma).
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A

The status in reference regulatory authorities	Suprax for Oral Suspension 500mg/5ml Mfg. by Lupin Pharma, India
GMP status of the firm	No F.10/2022-DRAP (AD-2702139294)dated 2-2-2022
Evidence of approval of manufacturing facility	No F.1-12/2006-Lic (Vol-I)dated 12-January-2022 mentioning dry powder suspension cephalosporin section

Evaluation Remarks

1.6.5: Valid copy of GMP certificate of the drug product & Substance manufacturer issued by concerned/relevant regulatory authority shall be submitted.	Submitted
Valid copy of DML required	Submitted

Decision

Deferred

For opinion of renowned Pediatricians.

881	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	Max Pharmaceuticals Plot #12, Street # N-7, National Industrial Zone, Rawat, Islamabad. 44000 (000671)
	Application Form Dy. No / Tracking ID & date of submission	(7ZQ-MPQ-PP5N, 2024-04-17)
	Detail of Fee Submitted	30000.0, 2023-09-13,
	The proposed proprietary name / brand name	Welbac 2g Injection
	Label Claim	Each vial contains:Cefoperazone as Sodium 1000mgSulbactam as Sodium... 1000mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 vial per pack-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25 degree centigrade
	For generic drugs (me-too Status)	Cebac Injection 2g, Bosch Pharmaceuticals (Pvt)Ltd, 037631
	Pharmacotherapeutic Group of (API)	J01DD62 cefoperazone and beta-lactamase inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Qilu Antibiotics Pharmaceutical Co, Ltd. No. 849, Dongjia Town, Licheng District , Jinan City.
	Detail of stability batches of drug product	3 batches of 600 vials each
	Documents for the procurement of API with approval from DRAP (in case of Import)	R&I no 1672 dated 21.05.21
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Cebac 2g injection
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Sulperazone for intravenous injection 1g / 1g Pfizer Japan Inc PMDA Japan
	GMP status of the firm	No F.1-106/2023-Add.Dir (QA-LT-1)-44 valid till 13-june-2025
	Evidence of approval of manufacturing facility	No F.1-103/2005-Lic(Vol-II) dated 7-july-2021 mentioning dry powder for injection cephalosporin
	Evaluation Remarks	
	1.6.5: Valid copy of GMP certificate of the drug product & Substance manufacturer issued by	Submitted No F.1-106/2023-Add.Dir (QA-LT-1)-44 valid till 13-june-2025

concerned/relevant regulatory authority shall be submitted.	
Valid copy of DML required	Application for renewal submitted
3.2.S.4.2 ANALYTICAL PROCEDURE OF DRUG PRODUCT MANUFACTURER: HPLC test method and procedure not submitted for assay of cefaperazone, sodium and salbactam	Submitted
3.2. S.4.3 Validation of Analytical Procedures: only a summary chart is provided complete calculations are required	Submitted
3.2. S.4.4 Batch analysis of Drug Product Manufacturer is not provided. COA of drug substance manufacturer is attached in this section	Submitted
3.2.S.7.3 Stability Data provided Signed and stamped required from drug substance manufacturer Pharmaceutical equivalence study provided has no pictorial evidence or batch number of comparator product.	Submitted Submitted
3.2.P.5.3 Validation of Analytical Procedures not provided	Submitted
2.3.P.5.4 Batch Analysis provided is not signed and stamped	Submitted

Decision

Approved

882	Case Category	Export Facilitation (Shahrukh Ali)
	Name, address of Applicant.	NovaMed Pharmaceuticals(Pvt.)Ltd 28-KM Ferozepur Road Lahore (000590)
	Application Form Dy. No / Tracking ID & date of submission	(9GJ-LLE-6HP1, 2024-10-21)
	Detail of Fee Submitted	37000.0, 2024-10-02,
	The proposed proprietary name / brand name	Finero Tablet 20mg
	Label Claim	Each Film Coated Tablet contains: Finerenone.....20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 20°C to 25°C; excursions are permitted from 15°C to 30°C
	For generic drugs (me-too Status)	FINERON 20mg Tablet
	Pharmacotherapeutic Group of (API)	Mineralocorticoid receptor (MR) antagonists
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Gansu Haotian PharmaTech Co.,Ltd.
	Detail of stability batches of drug product	2,000 Tablet 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate E-6208124802648 DOI: 13-Aug-2023
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Kerendia Tablet 20mg Bayer zaydus pharma

Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
The status in reference regulatory authorities	Kerendia Tablet 20mg by FDA
GMP status of the firm	Certificate No. 68 /2021-DRAP the, 6.9.21
Evidence of approval of manufacturing facility	No. F.1-9/2003-Lic (Vol-II)dated 14 September, 2021 mentioning Tablet (General),

Evaluation Remarks

1.6.5: Valid copy of GMP certificate of the drug product & substance manufacturer issued by concerned/relevant regulatory authority shall be submitted	Submitted

Decision

Approved

883

Case Category	Export Facilitation (Shahrukh Ali)
Name, address of Applicant.	NovaMed Pharmaceuticals(Pvt.)Ltd 28-KM Ferozepur Road Lahore (000590)
Application Form Dy. No / Tracking ID & date of submission	(SRG-VYH-SMN8, 2024-10-10)
Detail of Fee Submitted	37000.0, 2024-10-02,
The proposed proprietary name / brand name	Finero Tablet 10mg
Label Claim	Each Film Coated Tablet Contains: Finerenone.....10mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled
Shelf Life (Unit)	2 Year(s)Store at 20°C to 25°C; excursions are permitted from 15°C to 30°C
For generic drugs (me-too Status)	FINERON 10mg Tablet
Pharmacotherapeutic Group of (API)	Mineralocorticoid receptor (MR) antagonists.
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Gansu Haotian PharmaTech Co.,Ltd.
Detail of stability batches of drug product	2,000 Tablet
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate E-6208124802648 DOI: 13-Aug-2023
Pharmaceutical Equivalence and Comparative Dissolution Profile	Kerendia Tablet 10mg Bayer zaydus pharma
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
The status in reference regulatory authorities	Kerendia Tablet 10mg by FDA
GMP status of the firm	Certificate No. 5 /2024-DRAP AD-957949223 dated 9.1.24
Evidence of approval of manufacturing facility	No. F.1-9/2003-Lic (Vol-II)dated 14 September, 2021 mentioning Tablet (General),

Evaluation Remarks

1.6.5: Valid copy of GMP certificate of the drug product & substance manufacturer issued by	Submitted

	concerned/relevant regulatory authority shall be submitted	
	Decision	
	Approved	
884	Case Category	New Section (Shahrukh Ali)
	Name, address of Applicant.	Axis Pharmaceuticals (Pvt) Ltd 3-B, vale Addition City, 1.5Km Khurrianwala- Sahianwala Road Faisalabad (000667)
	Application Form Dy. No / Tracking ID & date of submission	(QB3-H7E-4AXJ, 2025-04-25)
	Detail of Fee Submitted	37000.0, 2025-01-17,
	The proposed proprietary name / brand name	Ceftriaxis Injection 250mg(IM)
	Label Claim	Each vial contains Ceftriaxone(as sodium).....250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Oxidil 250mg IM Injection
	Pharmacotherapeutic Group of (API)	Antiinfective for systemic use (3rd generation cephalosporins)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Sinopharm Weiqida Pharmaceutical Co,Ltd
	Detail of stability batches of drug product	3 Batch manufactured each having 1000 vials batch sizes
	Documents for the procurement of API with approval from DRAP (in case of Import)	E-8177464883561 Clearance certificate of API Import dated 02 February 2024 loan from medisave
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies are conducted against Oxidil 250mg IV Injection (IV/IM)of Sami Pharmaceuticals Limited, Karachi –Pakistan
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	MHRA
	GMP status of the firm	New Section
	Evidence of approval of manufacturing facility	letter for issurance of Cephalosporins section approval dated 23-08-2024
	Evaluation Remarks	
	3.2. S.4.2. ANALYTICAL PROCEDURE: Analytical method of Drug Substance lacks system suitability as provided in assay by USP monograph. Justification required	System suitability Submitted
	3.2. S.4.4 Analytical method verification report lacks resolution	Submitted
	3.2 S.7 Stability studies provided by drug substance manufacturer are not as per Zone IV-A conditions	Submitted
	3.2.P.1.2. COMPOSITION OF DRUG PRODUCT: Quantity (mg/Vial) is 2624.12mg/vial subjected to potency adjustment calculations required	Submitted
	3.2. P.5.2. ANALYTICAL PROCEDURES: Assay procedure are not in line to USP monograph, lacks system suitability as provided in assay by USP monograph. Justification required. System	Submitted as per USP

	suitability for ceftriaxone and ceftriaxone E-isomer has not been performed	
	3.2.P.8 Stability: System suitability is not performed as per USP monograph. • Raw data sheets are not attached •Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be 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 verification of loan letter of API		
885	Case Category	New Section (Shahrukh Ali)
	Name, address of Applicant.	Axis Pharmaceuticals (Pvt) Ltd 3-B, vale Addition City, 1.5Km Khurrianwala- Sahianwala Road Faisalabad (000667)
	Application Form Dy. No / Tracking ID & date of submission	(PS5-A4U-4SYS, 2025-04-25)
	Detail of Fee Submitted	37000.0, 2025-01-17,
	The proposed proprietary name / brand name	Ceftriaxis Injection 250mg(IV)
	Label Claim	Each vial contains Ceftriaxone (as sodium).....250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Oxidil 250mg IV Injection
	Pharmacotherapeutic Group of (API)	Antiinfective for systemic use (3rd generation cephalosporins)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Sinopharm Weiqida Pharmaceutical Co,Ltd
	Detail of stability batches of drug product	3 Batch manufactured each having 1000 vials batch sizes
	Documents for the procurement of API with approval from DRAP (in case of Import)	E-8177464883561 Clearance certificate of API Import dated 02 February 2024 loan from medisave
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies are conducted against Oxidil 250mg IV Injection (IV/IM)of Sami Pharmaceuticals Limited, Karachi –Pakistan
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	MHRA
	GMP status of the firm	New Section
	Evidence of approval of manufacturing facility	letter for issurance of Cephalosporins section approval dated 23-08-2024
Evaluation Remarks		
	3.2. S.4.2. ANALYTICAL PROCEDURE: Analytical method of Drug Substance lacks system suitability as provided in assay by USP monograph. Justification required	System suitability Submitted
	3.2. S.4.4 Analytical method verification report lacks resolution	Submitted
	3.2 S.7 Stability studies provided by drug substance manufacturer are not as per Zone IV-A conditions	Submitted

3.2.P.1.2. COMPOSITION OF DRUG PRODUCT: Quantity (mg/Vial) is 2624.12mg/vial subjected to potency adjustment calculations required	Submitted
3.2. P.5.2. ANALYTICAL PROCEDURES: Assay procedure are not in line to USP monograph, lacks system suitability as provided in assay by USP monograph. Justification required. System suitability for ceftriaxone and ceftriaxone E-isomer has not been performed	Submitted as per USP
3.2.P.8 Stability: System suitability is not performed as per USP monograph. • Raw data sheets are not attached •Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be 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 verification of loan letter of API

886	Case Category	New Section (Shahrukh Ali)
	Name, address of Applicant.	Axis Pharmaceuticals (Pvt) Ltd 3-B, vale Addition City, 1.5Km Khurrianwala- Sahianwala Road Faisalabad (000667)
	Application Form Dy. No / Tracking ID & date of submission	(M8Q-JVA-3LLY, 2025-04-25)
	Detail of Fee Submitted	37000.0, 2025-01-17,
	The proposed proprietary name / brand name	Ceftriaxis injection 1g (IV)
	Label Claim	Each vial contains Ceftriaxone (as sodium).....1g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Oxidil 1g IV Injection
	Pharmacotherapeutic Group of (API)	Antiinfective for systemic use (3rd generation cephalosporins)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Sinopharm Weiqida Pharmaceutical Co,Ltd
	Detail of stability batches of drug product	3 Batch manufactured each having 1000 vials batch sizes
	Documents for the procurement of API with approval from DRAP (in case of Import)	E-8177464883561 Clearance certificate of API Import dated 02 February 2024 loan from medisave
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies are conducted against Oxidil 1g IV Injection (IV/IM)of Sami Pharmaceuticals Limited, Karachi – Pakistan
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	MHRA
	GMP status of the firm	New Section
	Evidence of approval of manufacturing facility	letter for issuance of Cephalosporins section approval dated 23-08-2024
	Evaluation Remarks	

3.2. S.4.2. ANALYTICAL PROCEDURE: Analytical method of Drug Substance lacks system suitability as provided in assay by USP monograph. Justification required	System suitability Submitted
3.2. S.4.4 Analytical method verification report lacks resolution	Submitted
3.2 S.7 Stability studies provided by drug substance manufacturer are not as per Zone IV-A conditions	Submitted
3.2.P.1.2. COMPOSITION OF DRUG PRODUCT: Quantity (mg/Vial) is 2624.12mg/vial subjected to potency adjustment calculations required	Submitted
3.2. P.5.2. ANALYTICAL PROCEDURES: Assay procedure are not in line to USP monograph, lacks system suitability as provided in assay by USP monograph. Justification required. System suitability for ceftriaxone and ceftriaxone E-isomer has not been performed	Submitted as per USP
3.2.P.8 Stability: System suitability is not performed as per USP monograph. • Raw data sheets are not attached •Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted	Submitted

Decision

Approved

887	Case Category	New Section (Shahrukh Ali)
	Name, address of Applicant.	Axis Pharmaceuticals (Pvt) Ltd 3-B, vale Addition City, 1.5Km Khurrianwala- Sahianwala Road Faisalabad (000667)
	Application Form Dy. No / Tracking ID & date of submission	(DRE-3WH-3B48, 2025-04-25)
	Detail of Fee Submitted	37000.0, 2025-01-17,
	The proposed proprietary name / brand name	Ceftriaxis Injection 2g (IV)
	Label Claim	Each vial contains Ceftriaxone (as sodium).....2g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Oxidil 2g IV Injection
	Pharmacotherapeutic Group of (API)	Antiinfective for systemic use (3rd generation cephalosporins)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Sinopharm Weiqida Pharmaceutical Co,Ltd
	Detail of stability batches of drug product	3 Batch manufactured each having 1000 vials batch sizes
	Documents for the procurement of API with approval from DRAP (in case of Import)	E-8177464883561 Clearance certificate of API Import dated 02 February 2024 loan from medisave
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies are conducted against Oxidil 2g IV Injection B.No MCM004 (IV/IM)of Sami Pharmaceuticals / Healthtek (pvt.) Limited, Karachi –Pakistan
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A

The status in reference regulatory authorities	MHRA
GMP status of the firm	New Section
Evidence of approval of manufacturing facility	letter for issuance of Cephalosporins section approval dated 23-08-2024
Evaluation Remarks	
3.2. S.4.2. ANALYTICAL PROCEDURE: Analytical method of Drug Substance lacks system suitability as provided in assay by USP monograph. Justification required	System suitability Submitted
3.2. S.4.4 Analytical method verification report lacks resolution	Submitted
3.2 S.7 Stability studies provided by drug substance manufacturer are not as per Zone IV-A conditions	Submitted
3.2.P.1.2. COMPOSITION OF DRUG PRODUCT: Quantity (mg/Vial) is 2624.12mg/vial subjected to potency adjustment calculations required	Submitted
3.2. P.5.2. ANALYTICAL PROCEDURES: Assay procedure are not in line to USP monograph, lacks system suitability as provided in assay by USP monograph. Justification required. System suitability for ceftriaxone and ceftriaxone E-isomer has not been performed	Submitted as per USP
3.2.P.8 Stability: System suitability is not performed as per USP monograph. • Raw data sheets are not attached •Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be 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 verification of loan letter of API	
888	
Case Category	New Section (Shahrukh Ali)
Name, address of Applicant.	Axis Pharmaceuticals (Pvt) Ltd 3-B, vale Addition City, 1.5Km Khurrianwala- Sahianwala Road Faisalabad (000667)
Application Form Dy. No / Tracking ID & date of submission	(NX5-8JH-BJXN, 2025-04-25)
Detail of Fee Submitted	37000.0, 2025-01-17,
The proposed proprietary name / brand name	Ceftriaxis injection 500mg (IM)
Label Claim	Each vial contains Ceftriaxone (as sodium).....500mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	1's-As per SRO
Shelf Life (Unit)	24 Year(s)Store below 30°C
For generic drugs (me-too Status)	Oxidil 500mg IM Injection
Pharmacotherapeutic Group of (API)	Antiinfective for systemic use (3rd generation cephalosporins)
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Sinopharm Weiqida Pharmaceutical Co,Ltd
Detail of stability batches of drug product	3 Batch manufactured each having 1000 vials batch sizes
Documents for the procurement of API with approval from DRAP (in case of Import)	E-8177464883561 Clearance certificate of API Import dated 02 February 2024 loan from medisave

Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies are conducted against Oxidil 500mg IV Injection (IV/IM) of Sami Pharmaceuticals / Healthtek (pvt.) Limited, Karachi –Pakistan
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
The status in reference regulatory authorities	MHRA
GMP status of the firm	New Section
Evidence of approval of manufacturing facility	letter for issuance of Cephalosporins section approval dated 23-08-2024

Evaluation Remarks

3.2. S.4.2. ANALYTICAL PROCEDURE: Analytical method of Drug Substance lacks system suitability as provided in assay by USP monograph. Justification required	System suitability Submitted
3.2. S.4.4 Analytical method verification report lacks resolution	Submitted
3.2 S.7 Stability studies provided by drug substance manufacturer are not as per Zone IV-A conditions	Submitted
3.2.P.1.2. COMPOSITION OF DRUG PRODUCT: Quantity (mg/Vial) is 2624.12mg/vial subjected to potency adjustment calculations required	Submitted
3.2. P.5.2. ANALYTICAL PROCEDURES: Assay procedure are not in line to USP monograph, lacks system suitability as provided in assay by USP monograph. Justification required. System suitability for ceftriaxone and ceftriaxone E-isomer has not been performed	Submitted as per USP
3.2.P.8 Stability: System suitability is not performed as per USP monograph. • Raw data sheets are not attached •Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be 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 verification of loan letter of API

889	Case Category	New Section (Shahrukh Ali)
	Name, address of Applicant.	Axis Pharmaceuticals (Pvt) Ltd 3-B, vale Addition City, 1.5Km Khurrianwala- Sahianwala Road Faisalabad (000667)
	Application Form Dy. No / Tracking ID & date of submission	(BXD-E46-PJ83, 2025-04-25)
	Detail of Fee Submitted	37000.0, 2025-01-17,
	The proposed proprietary name / brand name	Ceftriaxis Injection 500mg(IV)
	Label Claim	Each vial contains Ceftriaxone (as sodium).....500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Oxidil 500mg IV Injection
	Pharmacotherapeutic Group of (API)	Antiinfective for systemic use (3rd generation cephalosporins)
	Name, address of Manufacturing site:	Self Manufacturing

Name & address of API manufacturer	Sinopharm Weiqida Pharmaceutical Co,Ltd
Detail of stability batches of drug product	3 Batch manufactured each having 1000 vials batch sizes
Documents for the procurement of API with approval from DRAP (in case of Import)	E-8177464883561 Clearance certificate of API Import dated 02 February 2024 loan from medisave
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies are conducted against Oxidil 500mg IV Injection of Sami Pharmaceuticals / Healthtek (pvt.) Limited, Karachi –Pakistan
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
The status in reference regulatory authorities	MHRA
GMP status of the firm	New Section
Evidence of approval of manufacturing facility	letter for insurance of Cephalosporins section approval dated 23-08-2024

Evaluation Remarks

3.2. S.4.2. ANALYTICAL PROCEDURE: Analytical method of Drug Substance lacks system suitability as provided in assay by USP monograph. Justification required	System suitability Submitted
3.2. S.4.4 Analytical method verification report lacks resolution	Submitted
3.2 S.7 Stability studies provided by drug substance manufacturer are not as per Zone IV-A conditions	Submitted
3.2.P.1.2. COMPOSITION OF DRUG PRODUCT: Quantity (mg/Vial) is 2624.12mg/vial subjected to potency adjustment calculations required	Submitted
3.2. P.5.2. ANALYTICAL PROCEDURES: Assay procedure are not in line to USP monograph, lacks system suitability as provided in assay by USP monograph. Justification required. System suitability for ceftriaxone and ceftriaxone E-isomer has not been performed	Submitted as per USP
3.2.P.8 Stability: System suitability is not performed as per USP monograph. • Raw data sheets are not attached •Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be 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 verification of loan letter of API

890	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	Pharmedic Laboratories (Pvt.) Ltd Lahore 16-Km Multan Road, Lahore (000228)
	Application Form Dy. No / Tracking ID & date of submission	(UET-L3H-8DDA, 2024-01-29)
	Detail of Fee Submitted	30000.0, 2023-12-27,
	The proposed proprietary name / brand name	Twymed Tablet
	Label Claim	Each film coated tablet contains: Imeglimin Hydrochloride. 500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO

Shelf Life (Unit)	2 Year(s) Do not store above 30 C
For generic drugs (me-too Status)	Imeglu Tablet 500mg
Pharmacotherapeutic Group of (API)	Blood Glucose Lowering Drugs, Excl. Insulin ATC code: A10BX15
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	
Detail of stability batches of drug product	1000 tablets
Documents for the procurement of API with approval from DRAP (in case of Import)	E-4801448488176 dated 29.3.23
Pharmaceutical Equivalence and Comparative Dissolution Profile	Twymeeg 500mg (Sumitomo Dainippon Pharma Co., Ltd, Japan.) was performed.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
The status in reference regulatory authorities	Twymeeg Tablet 500mg approved by (Sumitomo Dainippon Pharma Co., Ltd PMDA Japan)
GMP status of the firm	93-2020-DRAP 9.6.20
Evidence of approval of manufacturing facility	DmL Renewal No. 1-40/84-Lic, 16 June, 2023

Evaluation Remarks

Deferred in 340 meeting of Registration Board

1. Submit details of concentrations in mg/ml applied for the performance of several parameters of Analytical method verification studies of drug substance by M/s Pharmedic laboratories.	Submitted
2. As evident from the submitted analytical record the performance of dissolution test has been done at different wavelength from that specified in the submitted analytical procedure. Clarification shall be submitted in this regard.	Revised analytical procedure submitted
Documents confirming import of documents attested by I&E office, DRAP Lahore shall be submitted.	Submitted
Audit trail report for the stability studies performed on HPLC systems shall be submitted	Submitted

Decision

Approved

Registration letter will be issued after submission of fee for revision of specifications

891	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	Platinum Pharmaceuticals A-20, North Western Industrial Zone Bin Qasim, Karachi (000415)
	Application Form Dy. No / Tracking ID & date of submission	(VSN-NQ7-P9EW, 2024-04-30)
	Detail of Fee Submitted	30000.0, 9400.0 2024-01-02, 2025-08-22
	The proposed proprietary name / brand name	Empagliflozin 25mg Tablet
	Label Claim	Each Film-Coated Tablet contains: Empagliflozin 25mg Each Film-Coated Tablet contains: Empagliflozin 25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10s-As per SRO, 14s-As per SRO, 20s-As per SRO, 30s-As per SRO

Shelf Life (Unit)	2 Year(s)store below 30C in a dry place and protect from sunlight
For generic drugs (me-too Status)	Truglif Tablets 25mg, M/s AGP Limited, Reg. No. 104200.
Pharmacotherapeutic Group of (API)	Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03.
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Jiangsu Yungan Pharmaceutical Co., Ltd.,
Detail of stability batches of drug product	03 batches of 1200 tablets each.
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of form 6 No. K-1106820087862 mentioning 650 grams of Empagliflozin from M/s JIANGSU YONGAN PHARMACEUTICAL CO., LTD, China. Form 6 is issued by DRAP Karachi, dated 25-10-2022.
Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP & PE studies are performed against comparator product i.e. Diampa 25mg Tablet, B. No. 069FB6, Mfg. date 12-2022 manufactured by M/s Getz Pharma and both comparator and applied formulation have shown similar release pattern and valueCDP & PE studies are performed against comparator product i.e. Diampa 25mg Tablet, B. No. 069FB6, Mfg. date 12-2022 manufactured by M/s Getz Pharma and both comparator and applied formulation have shown similar release pattern and values of F2 is in acceptable range in all the three mediums of CDP i.e. 0.1N HCl, Acetate buffer and Phosphate buffer.s of F2 is in acceptable range in all the three mediums of CDP i.e. 0.1N HCl, Acetate buffer and Phosphate buffer.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of 3 batches of drug substance as per Zone IV-A is submitted. Accelerated 06 months and real time for 36 months.
The status in reference regulatory authorities	Jardiance 10mg & 25mg Tablets, USFDA approved.
GMP status of the firm	Firm has submitted copy of GMP Certificate No. 46/2023-DRAP (K) dated 16-06-2023 issued on the basis of inspection conducted on 14-06-2023.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-3/94-Lic (Vol-III) dated 16-11-2022 mentioning Tablet (General) section.
Evaluation Remarks	
Specifications and analytical procedures of the drug substance from drug product manufacturer shall be submitted	Revised Spec. & procedure submitted as per innovator [Fee for revision (deposit slip # 72783163524)] .
3.2.P.5.1 & 3.2.P.5.2 has mentioned dissolution specifications of 45 minutes, while the innovator product has mentioned 15 minutes. Clarification shall be submitted	Justification submitted: Dissolution specification was updated on 07-May-2024 to align with the innovator's specification, i.e., not less than 85% drug release within 15 minutes. Stability studies conducted from the 12th month onwards were performed using this updated specification, and the results were found to be satisfactory i. Revised specifications as per innovator; attached in point -1. ii. Result of stability studies after revising specs. iii. Fee for revision of specification as per deposit slip # 72783163524
Clearance certificate shall be submitted.	Form-6 & invoice submitted
Copies of executed BMR's shall be submitted, Minutes of 351st Meeting of Registration Board	Attached (23rd – 24th September, 2025)

	Decision
	Approved

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Registration-I Section

CASE NO. 01: NON-AVAILABILITY OF GENERIC OF PRODUCT APPROVED IN 272ND MEETING OF REGISTRATION BOARD

Registration Board in its 272nd meeting approved following product of M/s Ophth Pharma Karachi as per below mentioned details. However, registration letter was pending for MRP fixation/confirmation.

S. #	Name of Manufacturer	Brand name, composition and demanded specifications	Demand MRP, Pack Size	Approved MRP, Pack size with Reference of meeting	Decision	Current remarks
1.	M/s Ophth Pharma Karachi	Limus Ophthalmic Drops Each ml contains: Tacrolimus 1mg (Manufacturer's Specifications)	5ml Rs.500/-	As per S.R.O. 228(I)/2024 dated 19-02-2024	Approved. Manufacturer shall take protective measures for safety of personnel involved in manufacturing of immunosuppressant products as decided by Registration Board in 271st meeting.	Brand name has been changed to "Lymys" as it is already registered brand name of M/s Ophth for same molecule (R#118272) <u>DOV-G8Q-4MJJ</u> <u>XM5-X47-123L</u> The firm has submitted a fresh fee of Rs.75000/- (Slip#99123036) for standardization of label claim / Composition as under: <i>Each ml contains: Tacrolimus hydrate 1.02 mg eq. to Tacrolimus 1mg</i> Applied formulation is not found available in the accessible editions of pharmacopoeias. FPP specifications may be corrected

						to “As per innovator’s specifications”.

While evaluating the case, the Me-too status / generic of the above-mentioned drug could not be found. The firm upon enquiry has submitted that Tacrolimus 0.1% Eye Drops are not currently available in the local market; however, the Tacrolimus Eye Drops has been approved for Export Registration.

Decision:

Registration Board decided that the firm shall submit the application on Form 5D along with stability data of 6 months. The applicant shall follow the requirements for submission of stability data as per decision of Registration Board taken in its 293rd meeting.

CASE NO. 02: LIQUID INJECTION AMPOULE PSYCHOTROPIC SECTION WITHDRAWAL OF M/S TRIGON PHARMACEUTICALS:

The Registration Board in its 326th meeting approved following psychotropic drug in the name of M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore, However, now the firm has informed that they have replaced their “Liquid Injection Ampoule Psychotropic Section” with “Liquid Injection Vial (LVP) (General) Section”.

M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore	Diazepam Injection 10mg/2ml Each 2ml ampoule Contains: Diazepam...10mg USP Specifications	Approved

The case is placed before the Registration Board since the firm now doesn’t possess the “Liquid Injection Ampoule Psychotropic Section” for cancellation of registration / approval of all approved / registered products pertaining to “Liquid Injection Ampoule Psychotropic Section”.

Decision:

Registration Board decided to cancel all “Psychotropic injectable products” registered / approved in the name of M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore since the firm no longer possesses the “Liquid Injection Ampoule Psychotropic Section”.

CASE NO. 03: CHANGE OF ADDRESS OF M/S MEDISYNTH PHARMACEUTICALS FOR APPROVED PRODUCTS (REGISTRATION LETTER NOT ISSUED)

Registration Board in its 323rd meeting approved the following product(s) in the name of **M/s Medisynth Pharmaceuticals, Plot No.55, Street No.S-5, National Industrial Zone, Rawat, Islamabad**. Registration letter was pending due to brand name resemblance / submission of data / documents as per decision of Board. The firm has submitted requisite documents / data vide Dy.No, 28419 dated 08-12-2023, 120 dated 02-01-2024 and tracking ID: 3ZN-G9E-V47E on 13-08-2025. However, now the address of the DML holder has been changed i.e. **M/s Medisynth Pharmaceuticals, Khasra no 1028/1029 Mouza Jellyari Gujri Tehsil Gujranwala Rawalpindi**.

S/ N	Brand name with composition and	Demande d MRP, Pack Size	Decision/Remarks

	Applied FPP specifications		
1.	SYNPRID 25mg Tablets Each tablet contains: Levosulpiride 25mg Manufacturer's specifications	As per SRO	Approved with Innovator's specifications. • Registration letter shall be issued upon submission of latest GMP inspection report conducted within last three years alongwith fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, manufacturing outlines, pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. • Revised master formulation and manufacturing outlines as per applied label claim/composition which is of "uncoated tablet". In-line with above mentioned decision the firm has submitted: Fee of Rs. 7500/- on 07-12-2023 (Slip # 881768833), verified from https://fee.dra.gov.pk GMP certificate of new address issued on 2nd February 2024 based on inspection dated 06-12-2023 Revised master formulation and manufacturing outlines as per applied label claim/composition which is of "uncoated tablet". Brand name has been changed to "Q-Bin" due to resemblance. Applied pack size: 2x10's
2.	SYNPRID 50mg Tablets Each tablet contains: - Levosulpiride 50mg Manufacturer's specifications	As per SRO	Approved with Innovator's specifications. Registration letter shall be issued upon submission of following: • Latest GMP inspection report conducted within last three years alongwith revised master formulation and manufacturing outlines as per applied label claim/composition which is of "uncoated tablet". • Fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, manufacturing outlines, pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. In-line with above mentioned decision the firm has submitted: Fee of Rs. 7500/- on 07-12-2023 (Slip # 5550606057), verified from https://fee.dra.gov.pk GMP certificate of new address issued on 2nd February 2024 based on inspection dated 06-12-2023 Revised master formulation and manufacturing outlines as per applied label claim/composition which is of "uncoated tablet".

			Brand name has been changed to “Q-Bin” due to resemblance. Applied pack size: 2x10’s
3.	SYNPRID 100mg Tablets Each tablet contains: - Levosulpiride 100mg Manufacturer’s specifications	As per SRO	Approved with Innovator’s specifications. Registration letter shall be issued upon submission of following: • Latest GMP inspection report conducted within last three years alongwith revised master formulation and manufacturing outlines as per applied label claim/composition which is of “uncoated tablet”. • Fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, manufacturing outlines, pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. In-line with above mentioned decision the firm has submitted: Fee of Rs. 7500/- on 07-12-2023 (Slip # 40617418701), verified from https://fee.dra.gov.pk GMP certificate of new address issued on 2nd February 2024 based on inspection dated 06-12-2023 Revised master formulation and manufacturing outlines as per applied label claim/composition which is of “uncoated tablet”. Brand name has been changed to “Q-Bin” due to resemblance. Applied pack size: 2x10’s
4.	DICLO-S SR 100mg capsule Each capsule contains: - Diclofenac Sodium 100mg Manufacturer’s specifications Source of pellets: M/s Vision Pharma	As per SRO	Approved with BP specifications and revised label claim as: Each Sustained Release capsule contains: Diclofenac sodium (as Diclofenac sodium SR Pellets) 100mg Registration letter shall be issued upon submission of latest GMP inspection report conducted within last three years • Revised master formulation as per approved label claim for sustained release capsules. • Sustained released pellets source, CoA, stability study data of three batches of pellets and GMP certificate of pellets manufacturer • The firm shall submit applicable fee for pellets source approval/fixation as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021 In-line with above mentioned decision the firm has submitted: Fee of Rs. 9400/- on 20-08-2025 (Slip # 475235334), verified from https://fee.dra.gov.pk

			GMP certificate issued on 2nd February 2024 based on inspection dated 06-12-2023. Revised master formulation as per approved label claim for sustained release capsules. Sustained released pellets source, CoA, stability study data of three batches of pellets and GMP certificate of pellets manufacturer i.e. M/s Vision issued on 17-04-2025. Brand name has been changed to “Necor SR” which is already registered in the name of firm for same molecule Applied pack size: 2x10’s Label claim is standardized as under: <i>Each capsule contains:</i> <i>Diclofenac Sodium Sustained Release Pellets Eq. to</i> <i>Diclofenac Sodium.....100mg</i> <i>(BP Specifications)</i> Add Condition of boxed warning (NSAID drug)
5.	ORAZOLE Capsule Each capsule contains: - Omeprazole 20mg Sodium bicarbonate.....1100mg g Manufacturer’s specifications	As per SRO	Approved with Innovator’s specifications. Registration letter shall be issued upon submission of following: •Revised master formulation and manufacturing outlines as per label claim. •Latest GMP inspection report conducted within last three years. •Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. In-line with above mentioned decision the firm has submitted: Fee of Rs. 7500/- on 07-12-2023 (Slip # 04263289875), verified from https://fee.dra.gov.pk Revised master formulation and manufacturing outlines as per label claim. GMP certificate of new address issued on 2nd February 2024 based on inspection dated 06-12-2023 Brand name has been changed to “Synzole Plus” which is already registered in the name of firm for Omeprazole. Pack size: 1x10’s, 2x7’s, 4x7’s, 3x10’s
6.	ORAZOLE Capsule Each capsule contains: - Omeprazole 40mg Sodium bicarbonate...1100mg	As per SRO	Approved with Innovator’s specifications. Registration letter shall be issued upon submission of following: •Revised master formulation and manufacturing outlines as per label claim. •Latest GMP inspection report conducted within last three years.

	Manufacturer's specifications		•Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021 In-line with above mentioned decision the firm has submitted: Fee of Rs. 7500/- on 07-12-2023 (Slip # 548071851061), verified from https://fee.dra.gov.pk Revised master formulation and manufacturing outlines as per label claim. GMP certificate of new address issued on 2nd February 2024 based on inspection dated 06-12-2023. Brand name has been changed to "Synzole Plus" which is already registered in the name of firm for Omeprazole. Pack size: 1x10's, 2x7's, 4x7's, 3x10's

Decision:

Registration Board decided that the applicant shall submit new registration applications on CTD format for abovementioned products along with applicable fee of registration. These applications shall be considered out of queue.

CASE NO. 04: CORRECTION OF DOSAGE FORM OF THE APPROVED PRODUCTS

Following products of M/s Fortune Pharma Private Ltd Karachi, Plot No K/201 S.I.T.E. Super Highway, Phase II, Karachi were approved by the Registration Board in its **321st meeting**, however, evidence of approval of "Lornoxicam film-coated controlled release tablets (4 & 8 mg)" in reference regulatory authorities and their me-too status could not be confirmed. The product approved by the Austrian regulatory authority is "Xefo 4 mg and 8mg - film-coated tablets" which is not controlled release tablet. Me-too available (Loxibar Tablets by Barrett Hodgson) is also of film coated tablets. The firm was asked to provide the evidence of approval in the RRAs, now the firm vide tracking ID 548-V46-PPM4 has submitted the **complete / full fee of registration i.e. Rs.38700/-** for each product vide challans No. 240130866 and 3108006526 for correction of label claim in line with the products approved by the Reference Regulatory Authorities.

Accordingly registration letter has been issued with the correct dosage form as mentioned in below mentioned table:

S. No	Name of the firm	Details of product as approved in 321 st meeting of Registration Board	Correct / standardized Label claim as per RRA:
1.	M/s Fortune Pharmaceutica l Private Ltd Karachi Plot No K/201 S.I.T.E.	FLOXICAM 4mg tablet Each Film coated controlled released tablet contains: Lornoxicam 8mg Manufacturer's Spec	Each Film coated tablet contains: Lornoxicam.....4mg As per Innovator's specifications

2.	(SHW) Phase II, Karachi,	FLOXICAM 8mg tablet Each Film coated controlled released tablet contains: Lornoxicam 8mg Manufacturer's Spec	Each Film coated tablet contains: Lornoxicam.....8mg As per Innovator's specifications

Decision:

Registration Board noted the information.

CASE NO. 05: WITHDRAWAL OF REGISTRATION OF THE PRODUCT REGISTERED IN THE NAME OF M/S KARACHI CHEMICAL INDUSTRIES PVT. LTD. F/25, ESTATE AVENUE, S.I.T.E KARACHI

Registration letter of product tramadol 100mg/2ml Injection approved by the RB in its 323rd meeting in the name of M/s Karachi Chemical Industries Pvt. Ltd. F/25, Estate Avenue, S.I.T.E Karachi, was issued vide letter No. F.No.3-6/2022-Reg-I (M-323) dated 25-07-2025 with following details:

Reg. No.	Name of Drug(s) & Composition	Packing	MRP	Approved Shelf Life
128245	Temodol 100mg/2ml Injection Each 2ml contains: Tramadol hydrochloride.....100mg (BP Specifications)	2mlx5's	As per S.R.O. 228(I)/2024 dated 19-02-2024	Two years

However, it has been noted that the firm does not possess the Liquid injectable section. Therefore, the firm vide tracking ID WJU-Q1M-29AL has submitted the request for withdrawal of registration of above-mentioned product from their name.

Decision:

Registration Board acceded to the request of the firm and cancelled the registration of Temodol 100mg/2ml Injection (Tramadol hydrochloride) from the name of M/s Karachi Chemical Industries Pvt. Ltd. F/25, Estate Avenue, S.I.T.E Karachi.

Case No. 01: 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 Incyte 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 of 343rd Meeting:

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.

Proceedings of 344th meeting

Registration Board deliberated the matter in detail. There are other companies including M/s CCL pharma who also filed the applications for registration of the same molecule before Board. However, M/s Incyte Holdings and M/s Eli Lilly filed suits before Intellectual Property Tribunal, Lahore against all said companies/firm & DRAP and obtained ad-interim injunctions. As stated above, The Lahore High Court, Lahore while vacating ad-interim order against DRAP, directed DRAP to proceed with pending application of respondent No. 4 i.e M/s. CCL Pharma. It is pertinent to mention here that the ad-interim injunction orders against other companies are not vacated so far by the IPT, Lahore or Lahore High Court, Lahore till date.

Decision of 344th Meeting of the Board:

In view of the above, the Registration Board decided to proceed with the pending Registration Letter of M/s CCL Pharma regarding Baricitinib with additional condition of registration that 'the registration letter shall not be construed as permitting M/s CCL Pharmaceuticals to advertise, market or deal with Baricitinib in any manners till final adjudication of FAO No. 22665 of 2024 filed by the Company."

Moreover, The Board also directed PE&R Division to place all pending applications of Baricitinib of all companies/firms in next meeting. Further, the Board also directed Deputy Director (Legal Affairs) of DRAP to give a comprehensive presentation in next meeting on latest status of court orders by IPT, Lahore or Lahore high court.

Legal affair's Division has now prepared a presentation.

Decision of 345th Meeting of RB:

Registration Board deferred the case for further deliberation in forthcoming meeting.

Proceedings and Decision: Legal Affair's Division has presented the following;

SUMMARY OF THE CASES FILED BY INCYTE HOLDINGS AND THEIR STATUS

Background of the matter is that Incyte Holdings claims to be the patent holder of 'Baricitinib' registered under the Patent No. 142331 and 142333. Eli Lilly Pakistan Pvt. Ltd. claims to have Minutes of 351st Meeting of Registration Board (23rd – 24th September, 2025)

obtained drug registration of this product on behalf of Incyte Corporation under the brand name 'OLUMIANT'. It filed several Suits before the Intellectual Property Tribunal, Lahore, claiming patent-linkage for its aforementioned Patent and for restraining the grant of drug registration for 'Baricitnib' containing products to generic manufacturers. The details of the pending is as under:

1. **Incyte Holdings Vs. Himmel Pharma and others:** Ad-Interim Injunction has been granted on the first date on [REDACTED] (Annexure 'A') restraining Himmel Pharma from proceedings with the application for drug registration and also restraining DRAP from issuing Drug Registration. DRAP has filed its Reply but Himmel Pharma has continuously not appeared for arguments and the matter is pending due to its continuous requests for adjournments.
2. **Incyte Holdings Vs. Jenner Pharma and others:** Ad-Interim Injunction has been granted on the first date on 01-06-2022 (Annexure 'B') restraining Jenner Pharma from proceedings with the application for drug registration and also restraining DRAP from issuing Drug Registration. DRAP has filed its Reply but Jenner Pharma has continuously not appeared for arguments and the matter is pending due to its continuous requests for adjournments.
3. **Incyte Holdings Vs. McOLSON Pharma and others:** Ad-Interim Injunction has been granted on the first date on 30-05-2022 (Annexure 'C') restraining McOLSON Pharma from proceedings with the application for drug registration and also restraining DRAP from issuing Drug Registration. DRAP has filed its Reply but McOLSON Pharma has continuously not appeared for arguments and the matter is pending due to its continuous requests for adjournments.
4. **Incyte Holdings Vs. CCL Pharma and others:** The Honorable Lahore High Court through Order dated 27-05-2024 (Annexure 'D') directed DRAP to proceed with its application. The learned Intellectual Property Tribunal has since framed issued through Order dated 29-01-2025 (Annexure 'E') and also heard final arguments by DRAP and CCL Pharma regarding maintainability of the case. The matter is fixed for final arguments by Incyte Holdings on 01-03-2025.
5. **Incyte Holdings Vs. Dyson Research Laboratories Pvt. Ltd. and others:** Ad-Interim Injunction has been granted on the first date on 03-03-2023 (Annexure 'F') restraining Dyson Research Laboratories from proceedings with the application for drug registration and also restraining DRAP from issuing Drug Registration. DRAP has filed its Reply but Dyson Research Laboratories has continuously not appeared for arguments and the matter is pending due to its continuous requests for adjournments.
6. **Incyte Holdings Vs. Hiranis Pharmaceuticals Pvt. Ltd. and others:** Ad-Interim Injunction has been granted on the first date on 04-03-2023 (Annexure 'G') restraining Dyson Research Laboratories from proceedings with the application for drug registration and also restraining DRAP from issuing Drug Registration. DRAP has filed its Reply but Hiranis Pharma has continuously not appeared for arguments and the matter is pending. Hiranis Pharma challenged the ad-interim injunction before the Honorable Lahore High Court through W.P. No. 22632/ 2023 (Annexure 'H'), in which the injunction granted by the Intellectual Property Tribunal was suspended through ad-interim order. Since then, Hiranis Pharma has been seeking continuous adjournments. Learned Tribunal through its Order dated 04-03-2023 had restrained DRAP from processing the application of Hiranis Pharma. Therefore, unless and until the Honorable High Court sets aside the learned Tribunal's both aforementioned direction to the extent of DRAP completely in relation to Hiranis Pharma, DRAP cannot issue Drug Registration Certificate to it.
7. **Incyte Holdings Vs. ATCO and others:** Ad-Interim Injunction has been granted on the first date on 04-03-2023 (Annexure 'I') restraining ATCO from proceedings with the

application for drug registration and also restraining DRAP from issuing Drug Registration. The application for interim injunction was decided against DRAP and ATCO through Order dated 12-07-2023.

DRAP challenged it through FAO No. 48677/ 2023 in which stay order was granted to DRAP through Order dated (Annexure 'J'). ATCO did not appear in the said case and has since been held ex-parte through Order dated 20-11-2023 (Annexure 'K'), due to which it cannot seek benefit of the said stay order. No application for restoration has been filed by ATCO even after more than a year.

ATCO filed FAO No. 51729/ 2023 in which Notices were issued through Order dated 18-08-2023 (Annexure 'L') but no stay order has been granted to ATCO. Its maintainability has yet to be decided.

Since then ATCO has filed W.P. No. 56941/ 2024 seeking issuance of drug registration, in which notices have not yet been issued to DRAP. Till decision of the matters before the Honorable High Court, drug registration cannot be issued to it.

8. **Incyte Holdings Vs. Novamed and others:** Ad-Interim Injunction has been granted on the first date on 31-07-2024 (Annexure 'M') restraining Novamed from proceedings with the application for drug registration and also restraining DRAP from issuing Drug Registration. DRAP has filed its Reply but Novamed has continuously not appeared for arguments and the matter is pending due to its continuous requests for adjournments.
9. **Incyte Holdings Vs. Horizon Pharma and others:** Ad-Interim Injunction has been granted on the first date on 25-09-2024 (Annexure 'N'). DRAP is contesting the matter however, Horizon Pharma has given an undertaking in its Written Statement (Annexure 'O') as under:

“That Defendant No. 1 undertakes to refrain from any activities, including importing, exporting, manufacturing, formulating, stocking, advertising or selling, that may infringe upon Patent No. 142331 and 142333 related to Baricitnib.”

Due to admission by Horizon Pharma, the drug registration cannot be granted till decision by the learned Tribunal.

10. **Incyte Holdings Vs. High-Q Pharma and others:** By the time that this Suit was filed, DRAP had successfully pleaded its case in the CCL Pharma Case whereby it had sensitized the learned Intellectual Property Tribunal about the lack and want of jurisdiction against DRAP. The learned Tribunal while granting ad-interim injunction dated 25-09-2024 (Annexure 'P') has not granted any order restraining the grant of drug registration. Therefore, there is no bar in the grant of drug registration to High-Q Pharma.
11. **Incyte Holdings Vs. AGP Ltd. and others:** By the time that this Suit was filed, DRAP had successfully pleaded its case in the CCL Pharma Case whereby it had sensitized the learned Intellectual Property Tribunal about the lack and want of jurisdiction against DRAP. The learned Tribunal while granting ad-interim injunction dated 19-10-2024 (Annexure 'Q') has not granted any order restraining the grant of drug registration. Therefore, there is no bar in the grant of drug registration to AGP Ltd.

Decision of 348th Meeting:

After thorough deliberation, the Registration Board concluded that apparently there are no restraining orders on DRAP to grant registration letters to M/s. AGP, M/s. High-Q, and M/s. CCL. However, for better understanding of the Court order and related proceeding, the Board decided to refer complete case to seek guidance from Member Law & Justice Division on whether the Registration letters to aforesaid companies be issued unconditionally or otherwise in light of Court and IPT orders.

In compliance of above decision of the Board, case was referred to Mr. Jam Muhammad Aslam Member Law & Justice Division and his opinion is as under;

“The subject case was discussed with Hafiz Bilal Bin Akber (Deputy Director Legal) and Hafiz Muhammad Ali Tayyab (Additional Director, PE&R) DRAP in the office of the undersigned. During the discussion it is submitted that the basic criteria for issuance of Drug Registration Certificate for Drug product is to fulfill all codal formalities contained in the Drugs (Licensing, Registering and Advertisement) Rules, 1976. The Lahore High Court, Lahore vide order dated 27.05.2024 in FAO No. 22656/2024 against the order dated 03.04.2024 passed by the Intellectual Property Tribunal, Lahore vacated the stay order to the extent of DRAP and directed to proceed with pending application of M/S CCL Pharmaceutical in accordance with Drug Act, 1976 and rules made thereunder.

In conclusion, DRAP may proceed in the subject case and all other pending applications on similar product containing baricitinib for approval by Registration Board in accordance with said Act and rules made thereunder, however, Registration Board may not issue registration certificate to any company till the vacation of stay order against companies/parties by any competent Court on said product.”

Decision: Registration Board deliberated the case in detail and in light of opinion of Member Law & justice Division decided to process all pending cases for consideration by the Registration Board. However, registration certificate of Baricitinib 2mg and 4mg Tablets will be issued simultaneously to all companies, if their product is approved, after final decision of cases by the Courts in order to provide equal opportunities to all applicant. It was also decided that M/s. Eli Lilly be directed to provide the details of their imports and distribution of Baricitinib in Pakistan since its registration.

Case No. 02: M/s. Horizon Healthcare (Pvt.) Ltd., Plot No. 35-A, Small Industrial Estate – Taxila.

Registration Board in its 344th meeting approved various products in the name of M/s. Horizon Healthcare (Pvt) Lt., Taxila and further decided that registration letter will be issued after revision of title of the section of "Solution for Inhalation" from Licensing Division.

Firm vide tracking ID: HRA-R5G-GT7Y has submitted a request for Retention of Section Name "Solution for Inhalation" and Release of Product Registration Letters and stated as under:

“With due respect, we wish to submit that in 344th meeting of DRB decision for our products (Solutions for inhalation) approval, board had decided that registration letters will be issued after revision of title of our section “Solution for Inhalation”. So, we have applied for section name change to CLB but CLB is asking about RRA reference for section name. We would like to clarify that our applied product for solution for inhalation fall in this category by nomenclature, as clearly indicated in reference monograph of these products and this name is used by international regulatory bodies such as the U.S. FDA, and is clearly referenced in FDA guidelines (Reference link <https://www.fda.gov/media/70857/download>)

We also wish to highlight that our products under this section have already been approved; in 344th meeting of DRB however, the registration letters for these products are still pending issuance.

In light of the above, we respectfully request that DRAP allow us to retain the current section name “Solution for Inhalation” and facilitate the release of the registration letters for our previously approved products. A list of these products is enclosed herewith for your kind consideration.

We also wish to highlight that our products by name of Glycohale 25mcg/ml inhalation solution (Reg#121623) and Bpules Nebulizer Suspension 1mg/2ml (Reg#124318) are already registered under same section name in DRB meetings in 335th and 339th meetings respectively.

We remain committed to ensuring full compliance with DRAP regulations and appreciate your continued support. Thanking you in anticipation.”

Detail of products is as under:

Sr. No.	Product Name	Decision of 344th Meeting of DRB
1.	Levapule Each 3 mL unit-dose LDPE ampoule contains: 0.31 mg of levalbuterol (as 0.36 mg of levalbuterol HCl)	Approved Registration Board noted the fact that current title of the section i.e., "Solution for Inhalation" has been granted for the manufacturing facilities intended for the production of anaesthetic solutions while the instant formulation is not intended for anaesthesia purpose, hence Board decided that registration letter will be issued after revision of title of the section of "Solution for Inhalation" from Licensing Division.
2.	Levapule Each 3 mL unit-dose LDPE ampoule contains: 0.63 mg of levalbuterol (as 0.73 mg of levalbuterol HCl) (As per USP Specifications.)	Approved Registration Board noted the fact that current title of the section i.e., "Solution for Inhalation" has been granted for the manufacturing facilities intended for the production of anaesthetic solutions while the instant formulation is not intended for anaesthesia purpose, hence Board decided that registration letter will be issued after revision of title of the section of "Solution for Inhalation" from Licensing Division.
3.	Levapule Each 3 mL unit-dose LDPE ampoule contains: 1.25 mg of levalbuterol (as 1.44 mg of levalbuterol HCl)	Approved Registration Board noted the fact that current title of the section i.e., "Solution for Inhalation" has been granted for the manufacturing facilities intended for the production of anaesthetic solutions while the instant formulation is not intended for anaesthesia purpose, hence Board decided that registration letter will be issued after revision of title of the section of "Solution for Inhalation" from Licensing Division.
4.	Bepule Each 2mL LDPE ampoule contains: Beclometasone Dipropionate.....800mcg	Approved Registration Board noted the fact that current title of the section i.e., "Solution for Inhalation" has been granted for the

		manufacturing facilities intended for the production of anaesthetic solutions while the instant formulation is not intended for anaesthesia purpose, hence Board decided that registration letter will be issued after revision of title of the section of "Solution for Inhalation" from Licensing Division.
5.	Bepule Each 1mL ampoule contains: Beclometasone Dipropionate.....400mcg (As per Innovator's Specifications.)	Approved Registration Board noted the fact that current title of the section i.e., "Solution for Inhalation" has been granted for the manufacturing facilities intended for the production of anaesthetic solutions while the instant formulation is not intended for anaesthesia purpose, hence Board decided that registration letter will be issued after revision of title of the section of "Solution for Inhalation" from Licensing Division.
6.	Ipranox Each single 2.5mL unit-dose LDPE vial contains: Ipratropium bromide monohydrate..... 0.5218 mg (equivalent to Ipratropium bromide 0.5 mg) British Pharmacopeia	Approved Registration Board noted the fact that current title of the section i.e., "Solution for Inhalation" has been granted for the manufacturing facilities intended for the production of anaesthetic solutions while the instant formulation is not intended for anaesthesia purpose, hence Board decided that registration letter will be issued after revision of title of the section of "Solution for Inhalation" from Licensing Division.
7.	Ipranox-S Each 2.5ml single dose unit LDPE Vial contains: 500 micrograms Ipratropium bromide (as 520 micrograms Ipratropium bromide monohydrate) 3 mg Albuterol sulfate (corresponds to 2.5mg Albuterol base)	Approved Registration letter will be issued after revision of title of the section of "Solution for Inhalation" from Licensing Division.

Decision: Registration Board acceded to request of the firm and decided to allow the firm to manufacture above mentioned products in Solution for Inhalation Section. However, registration of Anesthetic Inhalation Solution i.e. Isoflurane and Sevoflurane shall be granted in this Section to the firm.

Case No.10. INVALID OF DRUG MANUFACTURING LICENSES BY CENTRAL LICENSING BOARD.

The Central Licensing Board has invalid Drug Manufacturing Licenses of following firms. Details are as under:

Sr. No.	Name of Firm	DML No.	Letter Dated	Remarks
1.	M/s A.Z Pharmaceuticals Co. Ltd, 4-KM, Manga Road, Raiwind District Kasur.	DML No. 000762 (Formulation). Invalid from 17-07-2024	11-08-2025	Renewal application for the duration of 17-07-2024 to 16-07-2029 has not been received.

Decision: Keeping in view the decisions taken by the Central Licensing Board regarding cancellation of DMLs of above-mentioned firms, Registration Board decided to cancel all the registered drugs w.e.f. date of cancellation of DML of M/s A.Z Pharmaceuticals Co. Ltd, 4-KM, Manga Road, Raiwind District Kasur alongwith registration applications which are under process at any level.

Registration-I&V-I Section (Vet)

1. COMPREHENSIVE CLARIFICATION ON OXYTETRACYCLINE INJECTION LABELING, STRENGTH, AND APPLICABILITY OF USP MONOGRAPHS.

The case was received for drug testing laboratory Rawalpindi, where in they have informed that the laboratory has been engaged in detailed correspondence with the United State Pharmacopeia (USP) regarding the correct interpretation of Oxytetracycline injection monographs. During this process, certain ambiguities have identified which require authoritative regulatory guidance for DRAP to ensure uniformity avoid misbranding, and align national registration practices with international standard.

In connection with the pretext it is put forwarded that USP monographs (2025) define separately:

- Oxytetracycline injection a sterile solution containing Oxytetracycline (base), with or without suitable excipients, and assaying between 90.0% -120.0% of the labeled Oxytetracycline.
 - Oxytetracycline for injection: a preparation containing Oxytetracycline hydrochloride equivalent to 90.0% -115.0% of the labeled Oxytetracycline.
1. Moreover the USP experts have indicated through official communications (case No.00776484, 00793392) that:
- Where the monograph specifies Oxytetracycline (base), the products must be formulated with that specific form
 - In cases such as tablets, where the monograph does not specify either free base or hydrochloride may be used.
 - Determination of applicability of USP standards rests with the regulatory authority, as USP does not approve or disallow specific formulations.

Now keeping view the antecedent contents and merit of the cases concerned, as significant regulatory concerns have raised with are narrated as under:

- If marked product contain Oxytetracycline Hydrochloride but claims compliance with USP Oxytetracycline injection (base) monograph, should it be considered misbranded?
- If labeling claims “ Oxytetracycline injection USP” While the formulation uses Oxytetracycline HCl equivalent to Oxytetracycline, does this constitute a violation of compendial compliance?
- Whether registration of Oxytetracycline injection in Pakistan Should clearly differentiate between base and hydrochloride salt forms to prevent ambiguity, similar to the precedent

set in DRAP's clarification on Ciprofloxacin Hydrochloride suspension (Vide Letter No.F.14-1/2022-PEC dated 22nd July 2024)

In light of the above we seek comprehensive written guidance from DRAP on the following Points

- a) Correct labeling requirements for Oxytetracycline injection formulations in Pakistan (base vs. hydrochloride).
- b) Applicability of USP monograph when hydrochloride salt is used instead of base.
- c) Criteria for determining misbranding under the Drugs Act/ Rules if labeling and formulation do not correspond with compendial specifications.
- d) Whether DRAP intends to issue a general policy/ notification harmonizing Oxytetracycline injection registration requirement in line with international pharmacopeial standards.

Same case also received from Director Bahawalpur wherein he has submitted same observations along with correspondence with USP. USP has also shared same status as mentioned above.

Decision: The Board decided that DRAP will issue an advisory to comply strictly with the relevant pharmacopeial monographs for Oxytetracycline Injectable preparations within 06 months of issuance of this advisory. DRAP will also forward a copy of the advisory to PQCB, with the request to allow 06 months time to align their specifications with pharmacopeial standards.

1.	Name and address of Applicant	M/s U.M. Enterprises, Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan
	Detail of Drug Sale License	Name: M/s U.M. Enterprises, Address: Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan Validity: 23-02-2028. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Qilu Animal Health Products Co. Ltd.
		No. 10688, Wenliang Road, Dongjia Town, Licheng District, Jinan, Shandong, China.
	Name and address of marketing authorization holder	M/s Qilu Animal Health Products Co. Ltd. No. 10688, Wenliang Road, Dongjia Town, Licheng District, Jinan, Shandong, China.
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R&I	Dy.No 24500 Dated 06-10-2023
	Fee including differential fee	Rs : 150,000 Dated 27-06-2023
	Brand Name + Dosage Form + Strength	Umedox Water Soluble Powder
	Composition	Each gram contains: Doxycycline as Doxycycline Hyclate...500mg
	Finished Product Specification	CVP specifications
	Pharmacological Group	Antibiotic
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	200gm, 1000gm

International availability	China
Me-too status	Hydrodoxx 500mg/gm powder for use in drinking water of M/s Saadat International, Lahore. (Reg. No. 119765)
Detail of certificates attached	➤ Original legalized COPP No. Vet. Drug No. 150252845 dated 06-05-2023 issued by Shandong Provincial Animal Husbandry & Veterinary Bureau, China confirms GMP status of the manufacturer as well as free sale status of the product in the exporting country. ➤ Scanned copy of legalized LOA dated 20-08-2022 from M/s Qilu Animal Health Products Co. Ltd. China valid for 03 years. (original submitted with Gamicure Injection dossier)
Remarks of the Evaluator ^{xxv}	Firm has provided 06-month accelerated ($40\pm 2^{\circ}\text{C}/75\pm 5\% \text{ RH}$) and 24-month real time ($30\pm 2^{\circ}\text{C}/65\pm 5\% \text{ RH}$) stability studies data of three batches as per zone IV-A conditions. Target species: Chicken (broilers) Shortcomings: • Clarification regarding address of the manufacturer since two different addresses are mentioned on Form-5A, LoA, GMP certificate and CoPP. • 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. • 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 TheDrugs (Labeling and Packing) Rules, 1986.
Decision 340: Deferred for submission of following: • Clarification regarding address of the manufacturer since two different addresses is mentioned on Form-5A, LoA, GMP certificate and CoPP. • Fee Rs. 9000/- for pre-approval correction in FPP specifications as per SRO 1324(I)/2024 dated 30-08-2024. Remarks: 1. Firm has submitted clarification and inform that correct address is same as per CoPP and LOA I.e No. 10688, Wenliang Road, Dongjia Town, Licheng District, Jinan, Shandong, China. 2. Fee is submitted vide challan no. 198373804.	
• Label in accordance with The Drugs (Labeling and Packing) Rules, 1986.	
Decision: Approved as per current policy for inspection of manufacturers abroad. The firm shall submit the fee for specification correction before issuance of letter.	

2.	Name and address of Applicant	M/s U.M. Enterprises, Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan
	Detail of Drug Sale License	Name: M/s U.M. Enterprises, Address: Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan Validity: 23-02-2028. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Qilu Animal Health Products Co. Ltd. No. 10688, Wenliang Road, Dongjia Town, Licheng District, Jinan, Shandong, China.
	Name and address of marketing authorization holder	M/s Qilu Animal Health Products Co. Ltd. No. 10688, Wenliang Road, Dongjia Town, Licheng District, Jinan, Shandong, China.
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 24498 Dated 06-10-2023
	Fee including differential fee	Rs : 150,000 Dated 27-06-2023
	Brand Name + Dosage Form + Strength	Tylo Tic Water Soluble Powder
	Composition	Each gram contains: Tylosin as tartrate...500mg
	Finished Product Specification	CVP specifications
	Pharmacological Group	Antibiotic
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	200gm, 1000gm
	International availability	China
	Me-too status	Grand Tysin 50 Powder of M/s Grand Pharma, Rawat. (Reg. No. 121937)
	Detail of certificates attached	➤ Original legalized COPP No. Vet. Drug No. 150252733 dated 06-05-2023 issued by Shandong Provincial Animal Husbandry & Veterinary Bureau, China confirms GMP status of the manufacturer as well as free sale status of the product in the exporting country. ➤ Scanned copy of legalized LOA dated 20-08-2022 from M/s Qilu Animal Health Products Co. Ltd. China valid for 03 years. (original submitted with Gamicure Injection dossier)

	Remarks of the Evaluator ^{XXV}	Firm has provided 06-month accelerated (40±2°C/ 75±5% RH) and 24-month real time (30±2°C/ 65±5% RH) stability studies data of three batches as per zone IV-A conditions. Target species: Chicken Shortcomings: - Clarification regarding address of the manufacturer since two different addresses are mentioned on Form-5A, LoA, GMP certificate and CoPP. - 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. - 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 340: Deferred for submission of following: - Clarification regarding address of the manufacturer since two different addresses are mentioned on Form-5A, LoA, GMP certificate and CoPP. - 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. - label in accordance with The Drugs (Labeling and Packing) Rules, 1986. Remarks: - Firm has submitted clarification and inform that correct address is same as per CoPP and LOA i.e. No. 10688, Wenliang Road, Dongjia Town, Licheng District, Jinan, Shandong, China. - Fee is submitted vide challan no. 5880587961.	
Decision: Approved as per current policy for inspection of manufacturers abroad. The firm shall submit the fee for specification correction before issuance of letter.		
3.	Name and address of manufacturer / Applicant Brand Name + Dosage Form + Strength Composition	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacy, 30-km Multan Road, Lahore. Pri Calphos Injection 300ml 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 M-343 : Deferred for confirmation of relevant manufacturing facility, i.e. LVP Remarks: Firm has submitted requisite manufacturing facility, i.e. LVP equipment's detail. Submitted for consideration of the Board.	
Decision: Approved. The firm shall submit the fee for specification correction before issuance of letter.		
4.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacy, 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 M-343: Deferred for confirmation of relevant manufacturing facility, i.e. LVP Remarks: Firm has submitted requisite manufacturing facility, i.e. LVP equipment's detail.	
Decision: Approved. The firm shall submit the fee for specification correction before issuance of letter.		
5.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacy, 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 Remarks: Firm has submitted requisite manufacturing facility, i.e. LVP equipment's detail.	
	Decision: Approved. The firm shall submit the fee for specification correction before issuance of letter.	
6.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacy, 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 M-343: Deferred for confirmation of relevant manufacturing facility, i.e. LVP. Remarks: Firm has submitted requisite manufacturing facility, i.e. LVP equipment’s detail.	
Decision: Approved. The firm shall submit the fee for specification correction before issuance of letter.		
7.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacy, 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. Remarks: Firm has submitted requisite manufacturing facility, i.e. LVP equipment’s detail.	
Decision: Approved. The firm shall submit the fee for specification correction and Standardization of salt form as per USP before issuance of letter.		
8.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacy, 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 M-343: Deferred for confirmation of relevant manufacturing facility, i.e. LVP.		
Remarks: Firm has submitted requisite manufacturing facility, i.e. LVP equipment’s detail.		
Decision: Approved. The firm shall submit the fee for specification correction before issuance of letter.		
9.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacy, 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 M- 343: Deferred for confirmation of relevant manufacturing facility, i.e. LVP. Remarks: Firm has submitted requisite manufacturing facility, i.e. LVP equipment’s detail.		
Decision: Approved.		
10.	Name and address of manufacturer / Applicant	M/s Nawal Pharmaceuticals, Plot No. 11-A, Punjab Small Industrial Estate, Taxilla.
	Brand Name +Dosage Form + Strength	Wal Cetamol Powder
	Composition	Each gram contains: Vitamin C...50mg Paracetamol...200mg Potassium Carbonate...125mg Sodium Bicarbonate...125mg Vitamin E...125mg
	Diary No. Date of R& I & fee	Dy.No 19758 dated 14-07-2021 Rs.30,000/- dated 13-07-2021 (slip No. 091565212)
	Pharmacological Group	Analgesic, Antipyretic, Antioxidant
	Type of Form	Form 5

	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 25000gm ; Decontrolled
	Me-too status	Paracet Water Soluble Powder of M/s Decent Pharma, Rawat, Islamabad (Reg. No. 079826)
	GMP status	The firm was inspected on 29-10-2018 with the following conclusion: Firm is compliant to Current Good Manufacturing requirements with need of some improvements which have been discussed and agreed with the management.
	Remarks of the Evaluator X	Oral dry powder (General) (Veterinary) Section confirmed from GMP compliance inspection report conducted on 29-10-2018. Shortcomings: Latest GMP inspection report conducted within the period of last three years.
Decision M-330: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters. Remarks: Sub-committee on veterinary drugs recommended such formulations.		
Decision: Approved. The firm shall submit the fee for specification correction before issuance of letter.		
11.	Name and address of manufacturer / Applicant	M/s Nawal Pharmaceuticals, Plot No. 11-A, Punjab Small Industrial Estate, Taxilla.
	Brand Name +Dosage Form + Strength	Ammar Wal 1% Powder
	Composition	Each gram contains: Amantadine HCl...10mg
	Diary No. Date of R& I & fee	Dy.No 19757 dated 14-07-2021 Rs.30,000/- dated 13-07-2021 (slip No. 68477338)
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 25000gm ; Decontrolled
	Me-too status	Amantabak 10% Powder of M/s Attabak Pharmaceuticals, Islamabad (Reg. No.075697)
	GMP status	The firm was inspected on 29-10-2018 with the following conclusion: Firm is compliant to Current Good Manufacturing requirements with need of some improvements which have been discussed and agreed with the management.
	Remarks of the Evaluator X	Oral dry powder (General) (Veterinary) Section confirmed from GMP compliance inspection report conducted on 29-10-2018. Shortcomings: Latest GMP inspection report conducted within the period of last three years.

	Decision: Registration Board deferred the case for further deliberation and directed PE&R Division to present working paper on international regulatory status of “Amantadine Drug for Veterinary use”, in upcoming Board meeting. Remarks: Sub-committee on veterinary drugs recommended such formulations upto 100gm.	
Decision: Approved upto pack size of 100gm.		
12.	Name and address of Applicant	M/s Prix Pharmaceutica, 26 Abbot Road, Lahore, 54000, Pakistan
	Detail of Drug Sale License	Name: M/s Prix Pharmaceutica, Address: 26 Abbot Road, Lahore Validity: 12-06-2027. Status: License to sell drugs as Distributor (Form No.11).
	Name and address of manufacturer	M/s Eurovet Animal Health B.V., Handelsweg 25, PO Box 179, 5530 AD Bladel, The Netherlands
	Name and address of marketing authorization holder	M/s Eurovet Animal Health B.V., Handelsweg 25, PO Box 179, 5530 AD Bladel, The Netherlands
	Name of exporting country	The Netherlands
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 33720 Dated 18-12-2020
	Fee including differential fee	Rs : 50,000 Dated 18-12-2020
	Brand Name +Dosage Form + Strength	Revozyn RTU 400mg/ml Suspension for Injection
	Composition	Each ml Contains: Penethamate Hydroiodide...400mg
	Finished Product Specification	In house
	Pharmacological Group	Penicillin Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	50ml
	International availability	Netherlands approved
	Me-too status	N/A
	Detail of certificates attached	➤ Photocopy of Legalized COPP No. 253161 dated 09-03-2020 issued by Ministry of Agriculture, Nature and Food Quality of the Netherlands confirms the GMP status of the manufacturer as well as free sale status of the applied product in country of origin. ➤ Copy of distribution agreement/ letter of authorization not provided
	Remarks of the Evaluator x	6 months accelerated and 24 months long term stability studies data has been submitted as per zone-IV-A conditions.

		Shortcomings: • The already submitted COPP is photocopy, Provide legalized valid original COPP. • Provide legalized valid original letter of Authorization (LOA) • Confirmation of dedicated penicillin injectable section. • Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision of 326th meeting: Deferred for following • legalized valid original COPP • legalized valid original letter of Authorization (LOA) • Confirmation of dedicated penicillin injectable section • Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.	
	The firm has submitted the following: ➤ Scanned copy of legalized COPP No. 259737 dated 16-06-2023 issued by Ministry of Agriculture, Nature and Food Quality of the Netherlands confirms the GMP status of the manufacturer as well as free sale status of the applied product in country of origin. ➤ copy of LOA dated 30-09-2020 (not notarized/ legalized). ➤ label in accordance with The Drugs (Labeling and Packing) Rules, 1986	
	Decision 330: Deferred for following: • Consideration of case after the decision of the Authority regarding the manufacturing of Beta-lactum antibiotics and general products as per the International practices • Notarized Valid copy of Letter of Authorization. Firm has submitted: • Statement from manufacturer along with EudraGMDP certificate showing they have dedicated section for penicillin injectable section. • Copy of Letter of Authorization.	
	DecisionM-350: Deferred the case till the decision of the Authority regarding the manufacturing of Beta-lactum antibiotics and general products as per the International practices. Remarks: Statement from manufacturer along with Eudra GMDP certificate showing they have dedicated section for penicillin injectable section.	
	Decision: Approved as per current import policy. The firm shall submit the fee for specification correction before issuance of letter.	
13.	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±2°C/ 75±5%) and 36-month real time (30±2°C/ 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 M-343: 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. Firm reply: With reference to the 343rd DRB meeting of DRAP held from December 3rd to 5th, 2024, we wish to inform you that the relevant documents were already submitted in response to the 340th DRB meeting dated November 12th, 2024. Kindly find the reference attached. We would like to clarify that our company is solely engaged in the manufacturing of penicillin-based formulations. No Cephalosporin products are produced within our manufacturing premises. While GMP already submitted.		
Decision: Approved as per current policy for inspection of manufacturers abroad. The firm shall submit the fee for specification correction before issuance of letter.		
14.	Name and address of Applicant	M/s U.M. Enterprises, Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan
	Detail of Drug Sale License	Name: M/s U.M. Enterprises, Address: Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan Date of issuance: 01-09-2021. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Qilu Animal Health Products Co. Ltd. No. 243, Gongye North Road, Jinan, Shandong, China
	Name and address of marketing authorization holder	M/s Qilu Animal Health Products Co. Ltd. No. 243, Gongye North Road, Jinan, Shandong, China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R&I	Dy.No 26418 Dated 07-10-2020
	Fee including differential fee	Rs : 1,00,000 Dated 07-10-2020
	Brand Name + Dosage Form + Strength	Bovicef 25mg/ml Injectable Suspension
	Composition	Each ml Contains: Cefquinome as Cefquinome Sulphate...25mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Cephalosporin antibiotic
	Shelf life	24 months
	Demanded Price	N/A
	Pack size	50ml

International availability	N/A
Me-too status	Cefanil Injection (50ml) of M/s Nawan Laboratories (Pvt.) Ltd, Karachi. (Reg. No. 081319)
Detail of certificates attached	Originally legalized COPP No. (2014)150252297 dated 03/03/2020 certified by Bureau of Animal Husbandry & Veterinary of Shandong Province, China confirms the GMP status of the manufacturer as well as free sale status of the product in exporting country. Copy of Authorization Letter dated 11-12-2017 Validity: 3 years
Remarks of the Evaluator x	Shortcomings: - The submitted photocopy of letter of Authorization (LOA) is expired now, but valid upon submission, Provide legalized valid original LOA - Provide both accelerated and real time stability studies data of three batches as per zone IV-A conditions upto claimed shelf life. - Confirmation of dedicated manufacturing facility.
Decision of 326th meeting: Deferred for following - legalized valid original LOA - both accelerated and real time stability studies data of three batches as per zone IV-A conditions upto claimed shelf life. - Confirmation of dedicated manufacturing facility	
Updated status: The firm has submitted the following: - Bovicef injection is stable below 25°C comes under the condition for refrigerator (2- 8°C), the firm has submitted 06 month accelerated (25°C ± 2°C/ 60%RH ± 5%RH) and 24-month real time (2-8°C) stability studies data of three batches. - Original legalized LOA dated 20-08-2022 from M/s Qilu Animal Health Products Co.Ltd. China valid for 03 years. - Statement from M/s Qilu Animal Health Products Co. Ltd. China that Cefquinome Sulfate Injectable Suspension (Bovicef) is manufactured in our company by means of dedicated manufacturing facilities for β-lactam veterinary medicinal products, which can comply with the requirements of current GMP for preventing cross-contamination with other products. Shortcomings: - clarification of the manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise.	
M-333 Decision: Deferred for clarification of the manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise. Remarks: Firm reply we confirm that we have dedicated manufacturing area for cephalosporin product and don't produce penicillin product at above sites.	
Decision: Approved as per current policy for inspection of manufacturers abroad. The firm shall submit the fee for specification correction before issuance of letter.	

15.	Name and address of Applicant	M/s U.M. Enterprises, Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan
	Detail of Drug Sale License	Name: M/s U.M. Enterprises, Address: Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan Date of issuance: 21-03-2023. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Qilu Animal Health Products Co. Ltd. No. 10688, Wenliang Road, Dongjia Town, Licheng District, Jinan, Shandong, China.
	Name and address of marketing authorization holder	M/s Qilu Animal Health Products Co. Ltd. No. 10688, Wenliang Road, Dongjia Town, Licheng District, Jinan, Shandong, China.
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R&I	Dy.No 33420 Dated 21-11-2022
	Fee including differential fee	Rs : 75,000 Dated 02-11-2022 (slip No. 71955365481)
	Brand Name +Dosage Form + Strength	Sealer Intra-mammary Infusion
	Composition	Each gram contains: Bismuth Subnitrate...650mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Drug for intra-mammary use
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	4gram powder
	International availability	China
	Me-too status	Could not be confirmed
	Detail of certificates attached	➤ Original legalized COPP No. Vet. Drug No. 150257074 dated 21-07-2022 issued by Shandong Provincial Animal Husbandry & Veterinary Bureau, China confirms GMP status of the manufacturer as well as free sale status of the product in the exporting country. ➤ Scanned copy of legalized LOA dated 20-08-2022 from M/s Qilu Animal Health Products Co. Ltd. China valid for 03 years. (original submitted with Gamicure Injection dossier)
	Remarks of the Evaluator ^{XXV}	Firm has provided 06-month accelerated (40±2°C/ 75±5% RH) and 36-month real time (30±2°C/ 65±5%RH) stability studies data of three batches as per zone IV-A conditions. Shortcomings: evidence of applied formulation/drug already approved by DRAP (generic / me-too status), or approval status of product

		in different Reference Regulatory Authorities, WHO Maturity Level-4 (ML-4) Authorities and PICs member countries
	Decision M-336: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status), or approval status of product in different Reference Regulatory Authorities, WHO Maturity Level-4 (ML-4) Authorities and PICs member countries. Remarks: Firm has submitted International reference of Ireland	
Decision: Approved as per current policy for inspection of manufacturers abroad. The firm shall submit the fee for specification correction before issuance of letter.		

16. CORRECTION IN FORMULATION M/S. SELMORE PHARMACEUTICALS (PVT) LIMITED, 36 KM, MULTAN ROAD, LAHORE

M/s. Selmore Pharmaceuticals (Pvt.) Ltd, Lahore has requested for correction in formulation as per RRA i.e United Kingdom for following already registered product:

S.No	Reg. No.	Name of drug(s) & Composition.	Correction required as per RRA
1.	071083	Colisel Solution. Each ml contains:- Colistine Sulphate.....20 MIU.	Colisel Solution. Each ml contains:- Colistine Sulphate.....2MIU.

Firm has submitted following Documents:

1. Copy of previous requested letter
2. Copy of Registration Letter
3. International Reference
4. Evidence of registration of local me-too products having the same composition
5. Copy of cGMP Certificate

Decision: Registration Board acceded to the request of firm for correction in formulation as per following details:

Reg. No.	Previous formulation	Corrected formulation
071083	Colisel Solution. Each ml contains :- Colistine Sulphate.....20 MIU.	Colisel Solution. Each ml contains: - Colistine Sulphate.....2MIU.

17. Formulations Containing Four Antibiotics in Veterinary Drug Products

- Evaluation of rationality of combination
- Potential concerns regarding antimicrobial resistance (AMR)
- International guidelines and best practices

Diaban Oral Liquid Vetz Pakistan		Scourban Suspension Bayer Australia Ltd	
Each ml contains:-		Public Chemical Registration Information System Search - portal.apvma.gov.au Each ml contains:-	
Sulphadimidine:	35mg	Sulfadimidine	35.5mg
Sulphadiazine:	36mg	Sulfadiazine	35.5mg
Streptomycin Sulphate:	7.6mg	Streptomycin (as sulfate)	6.06mg
Neomycin Sulphate:	1.8mg	Neomycin sulfate	1.80mg
Sodium Chloride:	11	Hyoscine (as hydrobromide)	0.03mg
Calcium Gluconate:	33	Sodium (as chloride)	4.43mg
Magnesium Sulphate:	0.6mg		
Potassium Chloride:	3.6mg		
Kaolin:	103.3mg		
Pectin:	7.1mg		
Glycine:	20.90mg		



Australian Pesticides &
Veterinary Medicines Authority

36026 – SCOURBAN ORAL ANTI-DIARRHOEAL SUSPENSION

Signal heading:	PRESCRIPTION ANIMAL REMEDY KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS BEFORE OPENING OR USING FOR ANIMAL TREATMENT ONLY
Product name:	SCOURBAN ORAL ANTI-DIARRHOEAL SUSPENSION
Constituent statement:	1065 mg/30 mL SULFADIMIDINE 1065 mg/30 mL SULFADIAZINE 182 mg/30 mL STREPTOMYCIN (AS STREPTOMYCIN SULFATE) 159.6 mg/30 mL PECTIN 133 mg/30 mL SODIUM (AS SODIUM CHLORIDE) 57 mg/30 mL POTASSIUM (AS POTASSIUM CHLORIDE) 36.5 mg/30 mL NEOMYCIN (AS NEOMYCIN SULFATE) 5.9 mg/30 mL CALCIUM (AS CALCIUM GLUCONATE) 1.77 mg/30 mL MAGNESIUM (AS MAGNESIUM SULFATE) 0.95 mg/30 mL HYOSCINE (AS HYOSCINE HYDROBROMIDE) Also Contains: 627 mg/30 mL GLYCINE 3.1 g/30 mL KAOLIN CLAY

Recommendation of Sub-committee:

After deliberation, the Sub-committee on Veterinary Drugs recommended that the above formulation, which contains four antibiotics, be used as an antidiarrheal in accordance with international practices. The Committee further recommended the use of similar combinations containing four antibiotics as antidiarrheal.

Decision:

The Board endorsed the recommendation of the Sub-committee on Veterinary Drugs. It was decided that formulations containing similar four antibiotics having indications for use as antidiarrheal preparation will be allowed for registration in compliance with international guidelines and best practices. Other four-antibiotic combinations will be evaluated on a case-by-case basis with regard to potential antimicrobial resistance (AMR) concerns.

Registration-I&V-II Section (Human Import)

Case.No.01: REQUEST OF M/S GLAXOSMITHKLINE PAKISTAN LIMITED, KARACHI FOR DE-REGISTRATION OF REGISTERED PRODUCT.

M/s GlaxoSmithKline Pakistan Limited, F-268, S.I.T.E., Karachi has submitted request for de-registration of following registered imported product as per details mentioned alongside.

S. No	Product(s) Name	Reg. No.	Reason for De-Reg. (stated by firm)	Alternative Registered Product
1.	Anoro Ellipta Dry Powder Inhaler Each pre-dispensed dose contains: Umeclidinium bromide...74.2mcg (eq. To umeclidinium...62.5mcg) Vilanterol (as trifenate)...25mcg (As Per Innovator's Specification)	088874	Suitable therapeutic alternatives and advance therapies are available in the market. Better / new molecules to cater the same portfolio are also available in the market. Virtually there is no demand of this product in local market.	Ipneb solution of M/s Atco. Mucolator Sachet M/s Abbott Ultivair Rotocaps M/s Highnoon. Tiocap Capsule M/s Pharmevo. Easehale Respules Nebulization Solution M/s Hudson. Foster Inhaler M/s Chiesi Tioget Dry Powder Inhaler Capsule M/s Getz. Formiget Dry Powder Inhaler Capsule M/s Getz.

Firm has submitted following supporting documents:

- Registration letter issued on 13-04-2018.
- Last renewal submitted on 22-03-2023.
- Fee of Rs.10,000/- for above product.
- List of alternative brands as mentioned above.
- Justification as mentioned above.
- An Undertaking.

Decision: Registration Board acceded the firm's request for de-registration of following imported product:

Product(s) Name	Reg. No.
Anoro Ellipta Dry Powder Inhaler Each pre-dispensed dose contains: Umeclidinium bromide...74.2mcg (eq. To umeclidinium...62.5mcg) Vilanterol (as trifenate)...25mcg (As Per Innovator's Specification)	088874

Case No: 02: REQUEST OF M/S SEARLE PAKISTAN LIMITED, KARACHI FOR GRANT OF INNOVATOR SPECIFICATIONS OF JANUVIA TABLETS.

M/s Searle Pakistan Limited, Section E, 2nd Floor, One IBL Centre, Plot No. 1, Block 7&8, D.M.C.H.S., Tipu Sultan Road, Off Shahrah-e-Faisal, Karachi has requested for grant of Innovator specifications of already registered drug with a fee of Rs.10,000/- as per following details;

059077 Januvia Tablets.

Each tablet contains:-

Sitagliptin phosphate monohydrate, equivalent to 100mg sitagliptin

Sr.#	Test Parameters	USP specifications	Manufacturer Specifications
1.	Identification by NIR		The presence of Sitagliptin Phosphate is confirmed if the sample spectrum passes the criterion set forth in the library validation.
2.	Identification by UV	The UV spectrum of the major peak of the Sample solution corresponds to that of the Standard solution as obtained in the Assay	
3.	Identification by RT (HPLC)	The retention time of the major peak of the sample solution corresponds to that of standard solution, as obtained in the Assay	
4.	Assay by NIR[†] at release and HPLC at shelf-life	95.0%–105.0% of label amount	95.0%–105.0% of label claim
5.	Impurities by HPLC	Sitagliptin acid – NMT 0.2% Fumarate adduct (if present) – NMT 0.2% Sitagliptin triazecine analog – NMT 0.2% Sitagliptin styrylacetyl analog – NMT 0.2% Sitagliptin phenyl-crotonyl analog– NMT 0.2%	
		Any other individual impurity– NMT 0.2% Total impurities– NMT 0.6%	Single Unspecified ≤ 0.2% (Shelf- life) Total Degradates ≤ 0.2% (Shelf-life)

6.	Uniformity of Dosage Units <905>	Meet <905> requirement	85.0-115.0% of label claim with $\leq c$ tablets outside criteria† ($N \geq 100$ samples, $c = f\{N\}$)
7.	Disintegration <701>	≤ 5 minutes	≤ 5 minutes

Decision 117th PRVC:

Chairman Registration Board on recommendation of committee refer the case to Registration Board.

Decision M-336: Registration Board deferred the case for submission of approved specifications in its country of origin.

Decision M-347: Registration Board decided to ask the firm to submit the complete method validation study along with Chromatograms.

Reply of the firm: Firm has submitted the requisite information/documents via e-application TI:
X8T-W4Q-ALUR

Decision: Registration Board acceded & approved the firm's request for approval of Innovator's Specification for the following product:

059077 Januvia Tablets.

Each tablet contains:-

Sitagliptin phosphate monohydrate, equivalent to 100mg sitagliptin

Case No.3. INVALID OF DRUG MANUFACTURING LICENSES BY CENTRAL LICENSING BOARD.

The Central Licensing Board has invalid Drug Manufacturing Licenses of following firm. Details are as under:

Sr. No.	Name of Firm	DML No.	Letter Dated	Remarks
2.	M/s Attabak Pharmaceuticals Industries, 5-C, I-10/3, Industrial Area, Islamabad	DML#000552 (Formulation)	31-01-2025	Renewal due on 29-10-2024. application received on 03-01-2025 after 60 days of the period of validity of DML, Hence apparently DML stands invalid.

Decision: Keeping in view the decisions taken by the Central Licensing Board regarding cancellation of DMLs of above-mentioned firms, Registration Board decided to cancel all the registered drugs w.e.f. date of cancellation of DML of M/s Attabak Pharmaceuticals Industries, 5-C, I-10/3, Industrial Area, Islamabad along with registration applications which are under process at any level.

Case No: 04: REGISTRATION OF MENORIN VAGINAL CREAM (CONJUGATED ESTROGEN) OF M/S EXCEL HEALTHCARE LABORATORIES PRIVATE LIMITED, KARACHI.

Registration Board in its 290th meeting considered and approved the following product of M/s Excel healthcare Laboratories (Pvt) Ltd, Karachi:

Name of Importer/Manufacturer	Name of Product and Composition	Demanded Price & Pack size
M/s Excel Healthcare Laboratories Pvt Ltd. House. D#122, Block 4 F.B Area Karachi. Product License Holder & Manufacturer: M/s Xinjiang Nuziline Bio Pharmaceuticals Co, Ltd. 252 km, 218 State Raod Xinjiang China	Menorin Vaginal Cream Conjugated Estrogen Cream Each gram cream contains: Conjugated Estrogen.... 0.639gram Manufacturer's Specifications 36 months	1 tube (14gm): Rs:1500/-
Decision: Approved with Innovator's Specifications & as per policy of inspection of manufacturer abroad.		

Virtual inspection of manufacturer abroad was conducted on 13th & 14th May 2025 by nominate panel Dr. Muhammad Haseeb Tariq Deputy Director DRAP, Islamabad & Mr. Shahid Nawaz Deputy Director DRAP, Islamabad. Conclusion of the panel of experts is as under:

Keeping in view the current policy of virtual inspection and the virtual inspection conducted, people interviewed, area observed, and record seen, the panel is of the view to recommend Menorin (Conjugated Estrogens) Vaginal Cream for grant of marketing authorization applied by M/s Excel Healthcare Laboratories Pvt Ltd, Karachi to be manufactured by M/s Xinjiang Nuziline Bio Pharmaceuticals Co, Ltd, China.

Moreover, the applied product contains a natural hormone derived from natural source and product containing Conjugated Estrogens has already been considered by the Registration Board as a Biological drug product.

Decision: The Registration Board approved the case subject to submission of complete data as per biological application requirements. The Board further authorized its Chairman to issue the letter upon fulfillment of the requisite data and referred the case to the Biological Division for further processing.

Case.No.05: REQUEST OF M/S AMGOMED, ISLAMABAD FOR DE-REGISTRATION OF REGISTERED PRODUCTS.

M/s Amgommed, Office No.5, 1st Floor, Rose-I Plaza, I-8 Markaz, Islamabad has submitted request for de-registration of following registered imported product as per details mentioned alongside.

S. No	Product(s) Name	Reg. No.	Reason for De-Reg. (stated by firm)	Alternative Registered Product

1.	Oxaliplatin Medac 100mg Injectable. Each ml reconstituted solution for infusion contains:- Oxaliplatin... 5mg	045746	Due to economic reasons regarding medac's portfolio development and renewed business strategy, we would like to withdraw the marketing authorization.	Debenzole 100mg&50mg of M/s Atco. Eloxatin 100mg&50mg of M/s Hoechst. Kebir 100mg&50mg of M/s Oncogene. Oxaliplatin Aqvida 100mg&50mg of M/s Himmel.
2.	Oxaliplatin Medac 50mg Injectable. Each ml reconstituted solution for infusion contains:- Oxaliplatin.....5mg	045747	-do-	Oxalisol 150mg&50mg of M/s Pharmasol. Oxalitin 100mg&50mg of M/s Sitech. Oxol 100mg&50mg of M/s Helix. Debenzole 100mg&50mg of M/s CCL.
3.	Oxaliplatin Medac 150mg Injection Each vial contains: - Oxaliplatin.....150mg	080400	-do-	
4.	Medac Disodium Pamidronate 30mg Injection. 3mg of Disodium Pamidronate equivalent to 2.527mg of Pamidronic Acid.	047531	-do-	Aminomux 30mg & 90mg of M/s Searle. Dronopam 30mg of M/s Zafa Pamidria 30mg, 60mg & 90mg of M/s AJ Mirza

Firm has submitted following supporting documents:

- Copies of Registration letters issued.
- Copies of last renewal status.
- Fee of Rs.12,500/- for each product..
- List of alternative brands as mentioned above.
- Justification as mentioned above.
- An Undertaking.

Decision: Registration Board acceded the firm's request for de-registration of following imported product:

S.No.	Product(s) Name	Reg. No.
1.	Oxaliplatin Medac 100mg Injectable. Each ml reconstituted solution for infusion contains:- Oxaliplatin... 5mg	045746

2.	Oxaliplatin Medac 50mg Injectable. Each ml reconstituted solution for infusion contains:- Oxaliplatin.....5mg	045747
3.	Oxaliplatin Medac 150mg Injection Each vial contains: - Oxaliplatin.....150mg	080400
4.	Medac Disodium Pamidronate 30mg Injection. 3mg of Disodium Pamidronate equivalent to 2.527mg of Pamidronic Acid.	047531

Case.No.06: REQUEST OF M/S ABBOTT LABORATORIES (PAKISTAN) LTD, KARACHI FOR DE-REGISTRATION OF REGISTERED PRODUCTS.

M/s Abbott Laboratories (Pakistan) Ltd, 8th Floor, Faysal House St-02, Sharah-e-Faisal, Karachi has submitted request for de-registration of following registered imported product as per details mentioned alongside.

S. No	Product(s) Name	Reg. No.	Reason for De-Reg. (stated by firm)	Alternative Registered Product
1.	Protium 40mg Tablets Each enteric coated tablet contains:- Panteprazole sodium sesquihydrate 45.1mg (Coresp. To 40mg Pantoprazole)	021039	Dear Sir, We would like to inform you that the manufacturer of Protium 40mg & 20mg tablets i.e. Takeda GmbH has terminated its commercial agreement with Abbott Laboratories (Pakistan) Limited.	Zopent 20mg & 40mg by M/s Hilton Pharma. Neege 20mg & 40mg by M/s Sami Pharma. Zentro 20mg & 40mg by M/s Bosch. Pantaz 20mg & 40mg by M/s Scilife. Panizox 20mg & 40mg by M/s S.J.&Fazul Ellahi.
2.	Protium 20mg Tablets Each tablet contains:- Panteprazole 20mg	028432	-do-	Baropent 20mg & 40mg by M/s Barret Hodgson

Firm has submitted following supporting documents:

- Copies of Registration letters issued.
- Copies of last renewal status.
- Fee of Rs.12,500/- for each product..
- List of alternative brands as mentioned above.
- Justification as mentioned above.
- An Undertaking.

Decision: Registration Board acceded the firm's request for de-registration of following imported product:

S.No.	Product(s) Name	Reg. No.
1.	Protium 40mg Tablets Each enteric coated tablet contains:- Panteprazole sodium sesquihydrate 45.1mg (Coresp. To 40mg Pantoprazole)	021039
2.	Protium 20mg Tablets Each tablet contains:- Panteprazole 20mg	028432

Case.No.07: COMPLIANCE WITH PHARMACOPEIAL SPECIFICATION STANDARDIZATION OF FORMULATION (SEPTANEST WITH ADRENALINE 1/200000) (REG. NO. 114233)

M/s Universal Dental (Pvt) Ltd, Opp. KE.Medical College Hostel, 17-Macleod Road, Lahore has submitted request for change of specification to Manufacturer's Specification with a fee of Rs.10,000/- for the following registered product: -

Reg. No.	Name of Drug
114233	Articaine Hydrochloride....40mg Adrenaline (as adrenaline tartrate)....0.00mg

1.	Test parameters	IN-HOUSE Specifications	USP Specifications''
2.	Description visual pH Sub-visible particles Diameter $\geq 10 \mu\text{m}$ Diameter $\geq 25 \mu\text{m}$	Clear and colourless solution practically free from particles 2.8 to 5.2 ≤ 6000 per cartridge ≤ 600 per cartridge	NA 2.7 to 5.2 ≤ 6000 per cartridge ≤ 600 per cartridge
3.	IDENTIFICATIONS		
	Articaine hydrochloride		
	A. Thin Layer Chromatography	Complies	NA
	B. HPLC: retention time	Complies	The retention times of the articaine peak from the Sample solution correspond to that of the Standard solution, as obtained in the Assays for Articaine Hydrochloride

	Adrenaline tartrate (Epinephrine)		
	A. HPLC: retention time	Complies	The retention times of the epinephrine peak from the Sample solution correspond to that of the Standard solution, as obtained in the Assays for Epinephrine
	B. HPLC: redox potential	Complies	NA
	Sodium metabisulfite	Positive	NA
	Disodium edetate	Positive	NA
4.	ASSAYS		
	Articaine hydrochloride	3.80 to 4.20 g / 100 ml (95 – 105%)	95.0 % - 105.0 %
	Adrenaline tartrate (epinephrine) (expressed as	0.50 to 0.55 mg / 100 ml (100 – 110%)	90% - 115%
	Sodium chloride*	0.144 to 0.176 g / 100 ml	NA(b)
	Sodium metabisulfite Expressed in SO ₂	35 to 50 mg / 100 ml 24 to 34 mg / 100 ml	NA(b)
	Disodium edetate	22 to 27 mg / 100 ml	NA(b)
5.	DEGRADATION PRODUCTS		
	Degradation products of Articaine Hydrochloride Articainic acid (Articaine related compound B) at RRT 0.6		
	. (reported if > 0.02 %)	≤ 0.5 %	≤ 0.5 %
	. Any other individual impurity (reported if > 0.03 %)	≤ 0.1 %	≤ 0.2 %
	. Total impurities (reported if > 0.05 %)	≤ 0.2 %	≤ 0.5 %
6.	Degradation products of Adrenaline tartrate		
	Adrenaline sulfonic acids at RRT 0.46 (Epinephrine Sulfonate) (reported if > 5.0 %)	≤ 7.4%	≤ 7.5 %

Sulfosulfanyl impurity (specified impurity) (reported if > 1.1 %)	≤ 8 %	≤ 8 %
Total Adrenaline sulfonic acids and Sulfosulfanyl impurities	≤ 18 %	
Any other individual impurity (reported if > 0.5 %)	≤ %	≤ 1 %
Total impurities	≤ 2 %	≤ 10 %
ENANTIOMERIC PURITY · (S)-Adrenaline	≤ 5 %	Not provided in USP
BIOLOGICAL TESTS Sterility Bacterial endotoxins	Sterile < 0.7 IU/mg of Articaine HCl	Sterile ≤ 0.7 USP endotoxin Unit/mg of Articaine HCl

Decision 117th PRVC:

Chairman Registration Board on recommendation of committee decided to refer the case to Registration Board.

Decision M-336: Registration Board deferred the case for submission of approved specifications in its country of origin.

Decision M-347: Registration Board decided to ask the firm to submit the following documents for further evaluation:

1. Scientific justification for the use of the UV method over HPLC.
2. Complete method validation study along with Chromatograms.

Firm's reply:

The manufacturer Septodont has clarified that they are using HPLC method for testing and the term UV is only limited to a UV detector used as a part of HPLC system used for analysis of the assay of articaine hydrochloride.

Firm has submitted the requisite information/documents via e-application TI: [BV6-5D6-685B](#)

Decision: Registration Board considered & approved the Manufacturer Specification for the following registered product:-

Reg. No.	Name of Drug
114233	Articaine Hydrochloride....40mg Adrenaline (as adrenaline tartrate)....0.00mg

Case No: 08. REGISTRATION OF ZUVIDOX-50 OF M/S LAB DIAGNOSTIC SYSTEMS (SMC) PVT. LTD. 36-A, PSIC, SIE, TAXILA.

Registration Board in its 345th meeting considered and approved the following product of M/s Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila:

Name of Importer/Manufacturer	Name of Product and Composition	Demanded Price & Pack size
M/s Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan Product License Holder & Manufacturer: Zuvius Lifesciences Pvt. Ltd., At-Kharuni-Lodhimajra Road, Vill. Nandpur, Baddi, Distt. Solan (H.P.)173205 India,	Zuvidox-50 Each vial contains: Doxorubicin Hydrochloride USP..... 50mg Mannitol USNF.....250mg United States Pharmacopeia.	1 Vial Packing - As per SRO Essential
Decision: Approved. Registration letter will be issued upon submission of analytical record including chromatograms and raw data sheets for the drug product stability studies.		

Inspection exemption abroad granted on the basis of manufacturing facility GMP certificate issued by ANVISA Brazil. Further, M/s Zuvius Lifesciences Pvt Ltd has a loan license in India. Loan License is a license issued to a company that does not own its manufacturing facility but intends to manufacture drugs at another licensed manufacturer's premises. Details as under:

Manufacturer address as per CoPP	Manufacturer address as per ANVISA Brazil Official website
M/s Zuvius Life Sciences Pvt. Ltd, at-Kharuni Lodhimajra Road, Vill. Nandpur Baddi, Distt. Solan, (HP) India	M/s Beta Drugs Limited, Kharuni-Lodhimajra Road, VIII Nandpur, Baddi, Distt. Solan, Himachal Pradesh, India

Decision: Registration Board considered & decided to referred the case to Legal Affair Division for their opinion on such cases.

Case.No.9: REQUEST OF M/S ALLIED DISTRIBUTORS, KARACHI FOR DE-REGISTRATION OF TRACUR INJECTION.

M/s Allied Distributors, 1st Floor, 103-K, Block-2, P.E.C.H.S., Shahra-e-Quaideen, Karachi has submitted request for de-registration of following registered imported product as per details mentioned alongside.

Product(s) Name	Reg. No.	Reason for De-Reg. (stated by firm)	Alternative Registered Product
Tracur Injection Each mL ampoule contains: Atracurium Besylate....10mg.	027350	product is no longer commercially viable in Pakistan as an imported finished product; therefore, its importation has been suspended since 2009. Furthermore, the product under this brand name	A-Care 25mg Injection of M/s Caraway Pharmaceuticals. Relaxtron Injection of M/s Zafa Pharmaceuticals. Novtrium Injection M/s Akhai. Tardax Inj of M/s Pharmasol. Ipracurium Inj of M/s Ipram.

		is no longer being marketed by us, as the current market demand is adequately met by a wide range of locally available generics.	Relocurium Inj of M/s Bajwa. Riumbes Injection of M/s Ameer & Adnan Pharma.

Firm has submitted following supporting documents:

- Copy of Registration letter issued on 13-04-2002.
- Post Registration Variation approval on 01-04-2004
- Last renewal submitted on 13-02-2024.
- List of alternative brands as mentioned above.
- Justification as mentioned above.
- An Undertaking.

Decision: Registration Board acceded the firm's request for de-registration of following imported product:

S.No.	Product(s) Name	Reg. No.
1.	Tracur Injection Each mL ampoule contains: Atracurium Besylate....10mg.	027350

Case No.10. REQUEST FOR AMENDMENT OF FREE FATTY ACIDS (FFA) IN SPECIFICATION OF FREEFOL MCT 1% INJECTION (REG. NO. 115768).

M/s Ghani Brothers, 2nd Floor, Karmiji Building, North Napier Road, Karachi has submitted request to approve the amendment in the FFA Specification at the earliest for the following already approved product.

Reg. No.	Name of Drug(s) & Composition	Existing Specifications	Proposed Specifications
115768	Freefol MCT 1% Injection Each ml contains: Propofol.....10mg	Less than 7mmol/L	NMT 12meq/L As per Korea (country of origin approval), and reference regulatory Authority Austria

Firm has submitted following supporting documents:

- Fee of Rs.12000/- dated 02-07-2025.
- Copy of Registration letter issued on 27-05-2024.
- Post Registration Variation approval on 28-01-2025
- Justification letter.
- Certificate of analysis.
- Country of origin approved specifications.

Decision: Registration Board acceded & approved the firm's request for amendment in the Free Fatty Acids (FFA) Specification as per following details:

Reg. No.	Name of Drug(s) & Composition	Previous Specifications	New approved Specifications
115768	Freefol MCT 1% Injection Each ml contains: Propofol.....10mg	Less than 7mmol/L	NMT 12meq/L

Case No: 11. CANCELLATION OF REGISTRATION OF IMPORTED DRUGS REGISTERED IN NAME FROM PRODUCT LICENSE HOLDER M/S BIOMIN HOLDING GMBH ERBER CAMPUS AUSTRIA.

M/s Biomin Holding GmbH, Erber Campus 1,3131 Getzersdorf, Austria Terminated the distribution agreement with Importer M/s Naseem Traders international Flat No.12, 1st Floor, Satellite Shopping Centre, 6th Road, Rawalpindi for the following veterinary products

S. No.	Reg. No.	Name of Product and Composition
1.	019910	MYCOFIX PLUS Contains: Inactivated yeast (specific types of saccharomycas) 31% specially treated diatomaceous earth 55.2% zeolite....13.0% emulsifier....0.8%
2.	021460	MYCOFIX (R) FEED PREMIX POWDER Contains: diatomaceous earth 18.2%, emulsifier....1.12%
3.	022171	Lisovit R Powder Contains: Lysozyme 22.0%, vitamin E50, SD 0.5%

2. In view of above, a Show Cause Notice was served to the firm dated 2nd July, 2025 and advise to submit reply within seven days, but no reply received from firm. On dated 22nd August, 2025 a reminder was issued to the firm, which returned back with fail delivery.

Decision: Registration Board considered and decided to cancel the following veterinary products from the name of Importer M/s Naseem Traders International, Flat No.12, 1st Floor, Satellite Shopping Centre, 6th Road, Rawalpindi:

S. No.	Reg. No.	Name of Product and Composition
1.	019910	MYCOFIX PLUS Contains: Inactivated yeast (specific types of saccharomycas) 31% specially treated diatomaceous earth 55.2% zeolite....13.0% emulsifier....0.8%
2.	021460	MYCOFIX (R) FEED PREMIX POWDER Contains: diatomaceous earth 18.2%, emulsifier....1.12%
3.	022171	Lisovit R Powder Contains: Lysozyme 22.0%, vitamin E50, SD 0.5%

Case.No.12: REQUEST OF M/S HOECHST PAKISTAN LIMITED, KARACHI FOR DE-REGISTRATION OF REGISTERED PRODUCT.

M/s Hoechst Pakistan Limited, Karachi has submitted request for de-registration of following registered imported product as per details mentioned alongside.

S. No	Product(s) Name	Reg. No.	Reason for De-Reg. (stated by firm)
1.	Fludara 50mg Powder for Solution for Injection/Infusion Each vial contains: Fludarabine phosphate ... 50mg	088890	Product applied for de-registration is not in demand and better molecules are now available for patients' use

Firm has submitted following supporting documents:

- Copy of Registration letter.
- Copy of Last renewal submitted.
- Fee of Rs.12,500/- for above product.
- List of alternative brands as mentioned above.
- Justification as mentioned above.
- An Undertaking.

Decision: Registration Board considered and decided to deferred the case for submission of reasons for de-registration of "Fludara 50mg Powder for Solution for Injection/Infusion" from firm.

Post-Registration Variation-I

Case No. 1. CHANGE OF REGISTRATION STATUS FROM BULK IMPORT / LOCAL REPACKING TO LOCAL CONTRACT MANUFACTURE OF REGISTERED PRODUCT NAMELY ROCEPHIN INJECTION IV OF M/S MARTIN DOW LIMITED KARACHI		
Sr.#	Feature	CHANGE OF REGISTRATION STATUS [FROM BULK IMPORT/ LOCAL REPACKING TO LOCAL MANUFACTURE ON CONTRACT BASIS]
1.	Applicant / MAH Title	M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi
2	Registered Product	Rocephin (Ceftriaxone) 250mg IV Injection Registration No. 008433

3.	Bulk Import From	F. Hoffman La Rosche, Basle Switzerland
4.	Proposed Manufacturing Site	M/s GSK Pakistan Limited, Plot No. 5, Sector 21, Korangi Industrial Area, Karachi
6.	NOC from previous MAH Holder	Provided Dated: 14-03-2024
7.	Dosage Form	Injection
8.	Valid DML & Section Approval letter of new proposed Manufacturer	Provided
9.	API Source	Ceftriaxone : ACS DOBFAR S.P.A. VIALE ADDETTA 2A/12-3/5-20067 TRIBIANO (MI) AIFA GMP Certificate : Provided Accelerated Stability Studies (06 Months) & Real Time Stability Studies (36 Months) test reports are submitted .
10.	Reference product for PE/CDP	Firm has submitted pharmaceutical equivalence product against Traxon 250mg Injection of M/s GSK Pakistan (Pvt) Ltd, Karachi
11.	Procurement documents / Clearance from DRAP Office	Provided
12.	Stability Studies	Accelerated Stability studies (06 Months) & Real time Stability studies (06 months) are conducted on following three batches : Trial Batch No. 01, 02, & Batch No. 03 Date of Manufacture : 11-2024, Expiry date : 11-2026 Batch Size : 2000 injection Date of Initiation 11-2024
13.	BMR, HPLC Raw data sheets	Submitted

Decision : **Registration Board approved the application:-**

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

b) Manufacturer will perform process validation of first three batches.

Case No. 2. CHANGE OF REGISTRATION STATUS FROM BULK IMPORT / LOCAL REPACKING TO LOCAL CONTRACT MANUFACTURE OF REGISTERED PRODUCT NAMELY ROCEPHIN INJECTION IM OF M/S MARTIN DOW LIMITED KARACHI

Sr.#	Feature	CHANGE OF REGISTRATION STATUS

		[FROM BULK IMPORT/ LOCAL REPACKING TO LOCAL MANUFACTURE ON CONTRACT BASIS]
1.	Applicant / MAH Title	M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi
2	Registered Product	Rocephin (Ceftriaxone) 250mg IM Injection Registration No. 008432
3.	Bulk Import From	F. Hoffman La Rosche, Basle Switzerland
4.	Proposed Manufacturing Site	M/s GSK Pakistan Limited, Plot No. 5, Sector 21, Korangi Industrial Area, Karachi DML NO. 000248 (FORMULATION)
6.	NOC from previous MAH Holder	Provided Dated: 14-03-2024
7.	Dosage Form	Injection
8.	Valid DML & Section Approval letter of new proposed Manufacturer	Provided
9.	API Source	Ceftriaxone : ACS DOBFAR S.P.A. VIALE ADDETTA 2A/12-3/5-20067 TRIBIANO (MI) AIFA GMP Certificate : Provided Accelerated Stability Studies (06 Months) & Real Time Stability Studies (36 Months) test reports are submitted .
10.	Reference product for PE/CDP	Firm has submitted pharmaceutical equivalence product against Traxon 250mg Injection of M/s GSK Pakistan (Pvt) Ltd, Karachi
11.	Procurement documents / Clearance from DRAP Office	Provided
12.	Stability Studies	Accelerated Stability studies (06 Months) & Real time Stability studies (06 months) are conducted on following three batches : Trial Batch No. 01, 02, & Batch No. 03 Date of Manufacture : 11-2024, Expiry date : 11-2026 Batch Size : 2000 injection Date of Initiation 11-2024
13.	BMR, HPLC Raw data sheets	Submitted
Decision : Registration Board approved the application:-		

- a) Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.
b) Manufacturer will perform process validation of first three batches.

Case No. 3. CHANGE OF REGISTRATION STATUS FROM FINISHED IMPORT TO LOCAL MANUFACTURE OF REGISTERED PRODUCT NAMELY ZOLDOX 60MG CAPSULE OF M/S AGP LIMITED KARACHI

Sr.#	Feature	CHANGE OF REGISTRATION STATUS [FROM FINISHED IMPORT TO LOCAL MANUFACTURE]
1.	Applicant	M/s AGP Limited, B-23-C, S.I.T.E., Karachi
2.	Registered Product	Zeldox 60mg Capsule (Ziprasidone hydrochloride monohydrate) Registration No. 045682
3.	Current MAH Holder and Manufacturing Site	MAH Holder: M/s Pfizer Pakistan Limited, 12-Dockyard Road, West Wharf, Karachi Manufacturing Site: M/s Pfizer Ireland Pharmaceuticals, Republic of Ireland Packaging, Testing and Batch Release Site: M/s Pfizer Manufacturing Deutschland GmbH Betriebsstatte Germany
4.	Proposed Manufacturing Site and MAH Holder	M/s AGP Limited, B-23-C, S.I.T.E., Karachi
6.	NOC from previous MAH Holder	Provided Dated: 11-9-2024
7.	Dosage Form	Capsule
8.	Valid DML & Section Approval letter of new proposed Manufacturer	Provided
9.	API Source	Ziprasidone hydrochloride: M/s CHROMO LABORATORIES INDIA PVT LTD, PLOT 43 & 44, IDA, PHASE-II, PASHAMYLARAM, PATANCHERU, SANGAREDDY, PASHAMYLARAM VILLAGE, PATANCHERU MANDAL, SANGAREDDY DISTRICT, PINCODE 502307, TELANGANA STATE, INDIA Telangana State, India GMP Certificate : Provided

		Accelerated Stability Studies (06 Months) & Real Time Stability Studies (24 Months) test reports are submitted .
10.	Reference product for PE/CDP	Firm has submitted pharmaceutical equivalence and CDP of product against Zeldox 60mg Capsule of M/s Pfizer Pakistan Limited
11.	Procurement documents / Clearance from DRAP Office	Provided (DIL-C-1E1BDD dated 24/10/2024)
12.	Stability Studies	Accelerated Stability studies (06 Months) & Real time Stability studies (06 months) are conducted on following three batches : Trial Batch No. 205DS01, 205DS02, & Batch No. 205DS03 Date of Manufacture : 10-2024, Expiry date : 10-2026 Batch Size : 3000 Capsule Date of Initiation 30-10-2024
13.	BMR, HPLC Raw data sheets	Submitted
Decision : Registration Board approved the application:- a) Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months. b) Manufacturer will perform process validation of first three batches.		
Case No. 4. CHANGE OF REGISTRATION STATUS FROM FINISHED IMPORT TO LOCAL MANUFACTURE OF REGISTERED PRODUCT NAMELY ZOLDOX 40MG CAPSULE OF M/S AGP LIMITED KARACHI		
Sr.#	Feature	CHANGE OF REGISTRATION STATUS [FROM FINISHED IMPORT TO LOCAL MANUFACTURE]
1.	Applicant	M/s AGP Limited, B-23-C, S.I.T.E., Karachi
2	Registered Product	Zeldox 40mg Capsule (Ziprasidone hydrochloride monohydrate) Registration No. 041196
3.	Current MAH Holder and Manufacturing Site	MAH Holder: M/s Pfizer Pakistan Limited, 12-Dockyard Road, West Wharf, Karachi Manufacturing Site:

		M/s Pfizer Ireland Pharmaceuticals, Republic of Ireland Packaging, Testing and Batch Release Site: M/s Pfizer Manufacturing Deutschland GmbH Betriebsstatte Germany
4.	Proposed Manufacturing Site and MAH Holder	M/s AGP Limited, B-23-C, S.I.T.E., Karachi
6.	NOC from previous MAH Holder	Provided Dated: 11-9-2024
7.	Dosage Form	Capsule
8.	Valid DML & Section Approval letter of new proposed Manufacturer	Provided
9.	API Source	Ziprasidone hydrochloride: M/s CHROMO LABORATORIES INDIA PVT LTD, PLOT 43 & 44, IDA, PHASE-II, PASHAMYLARAM, PATANCHERU, SANGAREDDY, PASHAMYLARAM VILLAGE, PATANCHERU MANDAL, SANGAREDDY DISTRICT, PINCODE 502307, TELANGANA STATE, INDIA Telangana State, India GMP Certificate : Provided Accelerated Stability Studies (06 Months) & Real Time Stability Studies (24 Months) test reports are submitted .
10.	Reference product for PE/CDP	Firm has submitted pharmaceutical equivalence and CDP of product against Zeldox 40mg Capsule of M/s Pfizer Ireland Pharmaceuticals, Ireland
11.	Procurement documents / Clearance from DRAP Office	Provided (DIL-C-1E1BDD dated 24/10/2024)
12.	Stability Studies	Accelerated Stability studies (06 Months) & Real time Stability studies (06 months) are conducted on following three batches : Trial Batch No. 204DS01, 204DS02, & Batch No. 204DS03 Date of Manufacture : 10-2024, Expiry date : 10-2026 Batch Size : 4000 Capsule Date of Initiation 13-11-2024
13.	BMR, HPLC Raw data sheets	Submitted

Decision : Registration Board approved the application:-

- a) Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.**
- b) Manufacturer will perform process validation of first three batches.**

Case No. 5. CHANGE OF REGISTRATION STATUS FROM FINISHED IMPORT TO LOCAL MANUFACTURE ON CONTRACT BASIS OF REGISTERED PRODUCT NAMELY TROPAN 30MG INJECTION OF M/S AL-HAMEED AGENCIES

Sr.#	Feature	CHANGE OF REGISTRATION STATUS [FROM FINISHED IMPORT TO LOCAL MANUFACTURE ON CONTRACT BASIS]
1.	Applicant	M/s Al-Hameed Agencies 20, Opp Ayub National Park, Jhelum Road Rawalpindi
2	Registered Product	Torapan 30mg Injection Each 1 ml ampoule contains: Ketoralac Tromethamine USP.....30mg Registration No. 025295
3.	Current MAH Holder and Manufacturing Site	MAH Holder: M/s Al-Hameed Agencies 20, Opp Ayub National Park, Jhelum Road Rawalpindi Manufacturing Site: M/s Duopharma (M) Sdn. Bhd. Malaysia
4.	Proposed Manufacturing Site	M/s Biogen Life Sciences, 8-KM Chakbeli Road, Rawat, Rawalpindi.
5.	Dosage Form	Injection
6.	Valid DML & Section Approval letter of new proposed Manufacturer	Provided
7.	Drug substance and Drug P	Submitted on Module-I The firm has submitted evidence of approved formulation with similar composition Biorolac 30mg/ml injection at proposed manufacturing site, approved on CTD format in the 336 th meeting of the Registration Board

Decision : Registration Board approved the application:.

- a) Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.**
- b) Manufacturer will perform process validation of first three batches.**

Case No.5. STANDARDIZATION OF LABEL CLAIM OF REGISTERED PRODUCT AMPICILLIN ORAL SUSPENSION 125MG/5ML BY M/S PLIVA PAKISTAN (PVT) LTD, BALOCHISTAN

M/s Pliva Pakistan (Pvt) Ltd, Balochistan has submitted request on E-App vide TID : V54-BDE-43R1 for revised label claim / Standardization of registered product as under :

Sr. No.	Reg. No.	Existing Name of Drug & Composition	Correct Name of Drug & Composition
1.	007665	Ampicillin Syrup 125mg/5ml Each 5ml contains:- Ampicillin (as trihydrate).....125mg	Ampicillin Oral Suspension 125mg/5ml Each 5ml contains:- Ampicillin (as trihydrate).....125mg

The firm has claimed that Ampicillin oral suspension is registered as brand name Ampicillin Syrup 125mg/5ml (Registration No. 007665) since 1989 and has requested that since the said product is only available as Dry Powder for suspension therefore, the label claim be revised accordingly.

Decision of the Registration Board :

The Registration Board considered the case and approved the standardization/ label claim of registered product.

Case No. 6. RESEMBLANCE OF PACKAGING DESIGN AND COLOUR SCHEME OF REGISTERED PRODUCT PANADOL TABLET BY M/S HALEON PAKSITAN LIMITED PETARO ROAD JAMSHORO

M/s. Haleon Pakistan Limited, **Petaro Road, Jamshoro** has submitted request on e-app regarding similarity of packaging design and color scheme of Tab. Cekamol (Reg. No. 004268) of M/s CKD Pharmaceuticals Pakistan (Pvt) Ltd, 50/28, Korangi Industrial Area, Karachi with the registered product i.e. Panadol Tablet (Reg. No. 000817) of M/s. Haleon Pakistan Limited, Petaro Road, Jamshoro along with documents.

Since the registration of the Panadol Tablet (Reg. No. 000817) was granted prior to the Tab. Cekamol (Reg. No. 004268) therefore, letter dated : 21st July, 2025 and later on final Reminder dated : 2nd September 2025 was issued to the firm M/s CKD Pharmaceuticals Pakistan (Pvt) Ltd, 50/28, Korangi Industrial Area, Karachi to revise the packaging design and color scheme of its registered product.

In reply, the firm has submitted that through comparison of product reveals no resemblance or similarity. Our Product's name, packaging, labelling and overall presentation are distinct and do not bear any likeness to product of M/s Haleon Pakistan Limited.

In this respect a Legal notice dated 30-7-2025 was served upon this company on behalf of M/s Haleon Pakistan Limited which has been duly responded vide reply dated August 12, 2025 to the Legal notice.

Considering the above, we once again respectfully request this esteemed authority to provide an opportunity to present our case through personal hearing.

The firm is called for personal hearing accordingly.

Decision of the Registration Board:

No person on behalf of the firm appeared before the board. The Registration Board deliberated the matter and decided that the firm M/s CKD Pharmaceuticals Pakistan (Pvt) Ltd, 50/28, Korangi Industrial Area, Karachi shall be directed to immediately change the color and packaging design of Cekamol Tablet due to resemblance with previously registered product i.e. Panadol Tablet (Reg. No. 000817) to avoid regulatory action under Section 3(f) read with Section 23 (1) (ii) & 27 (2) (a) of the Drugs Act, 1976.

CASE NO 7: 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 Zancok 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, Sheikhpura. (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, Sheikhpura. (DML No. 000108)	Wondseptic Solution	030073	No	No	No	No	No resemblance
14.	M/s ISIS Pharmaceuticals & Chemical works, Karachi (DML No.	ISIS Povidone Iodine Solution	110071	No	No	Yes	Yes	Only label

	000126)							
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.**

3. In the light of the decision of the Registration Board, letter no. F-12/2025 (PR-I) E-App dated 15th January, 2025 was forwarded to the respective firms regarding change of brand name. label claim or both within 07 days for further necessary action.

4. The brand name resemble letter communicate to the firm vide letter no. F-12/2025 (PR-I) E-App vide 15th January, 2025 (Annex-I). However seven firms have submitted reply and the same are reproduced as below:

M/s Kohinoor industries Sahiwal submitted a reply against our letter of even number in which they stated that:-

- Why brookes Pharma used the door of honorable high court, this act is showing de-interest on respectable government institute DRAP for lable claim & similar brand name. Even this brand name allotted us from respectable institute DRAP in 1996, because we have owned the name **prodine Solution** despite of this Brookes Pharma has owned the Name of

Pyodine Solution. These brand names cannot match from each other & this brand name was registered after the approval of DRAP.

- Our registered brand also does not fall under the category of counterfeit drugs. Accordingly section 3 clause (F) of The Drug Act 1976, Counterfeit Drug” means a drugs the label or outer packing of which is an imitation of or resembles or so nearly resembles as to be calculated to deceived the label or outer packing of a drug of another manufacturer. We deny any intention to deceive the public with our product label or banding.
- With reference to letter no. 14280/2020DRAP (L-IV) we have already changed the label of this brand name through legal process. That time same competitor filed letter to your respective institute & we fully complied your letter & immediately change the label of this registered brand name **Prodine Solution**.
- The department has proceeded without giving us a fair opportunity to plead or differentiate the differences, which is in contradiction with Article-10 of constitution of Pakistan 1973. We hereby agitate the same as our fundamental right of fair trial has been breached.
- Moreover, the subject letter is based on the facts. Based on the missing facts which area necessary to be incorporated as following
- **Label differences:**
- We have already changed the label of this brand through legal process. “Prodine’s” label is brown & Peach in long rectangular shape. While the label color of Brookes products “Pyodine Solution” is red and orange in color and it is in oval shape.
- **Font Style:**
- The font style of both solution is totally different from each other. Prodine Solution is written in Arial Style on bottle, while pyodine solution is pasted in Times New Roman Style on bottle
- **Pronunciation:**
- Here is vital difference in pronunciation of both words between prodine solution & pyodine solution. The Oval sound getting no break in word of prodine solution but this sound gets a break when we speak the word Pyodine Solution.
- Here are some actual facts that we area oppressed under the hand of Brookes Pharma, this firm has attached us several time by different ways.
 1. This firm filed a f=grievance in every government institute for the purpose to sale their expensive brand and trying to damage the popularity of our product.
 2. In KPK the DG health KPK rejected this firm due to quoted high rates in this institute.
 3. This firm approaching the government health officers to stop the sale in government semi-government institutes and also in market and finally this firm is declared with low handed thugs in every field. After this the firm has approached at your door.
 4. We are supplying this item in Reputable institute throughout Pakistan and not a single batch is declared substandard.
 5. The firm M/s Brookes Pharma refused to give the supplies in different government institute but the institues approached to us and we given immediate supply o no profit no loss.
 6. Our import raw material is FDA approved, our stability reports on long terms showing the excellent result. Under all the aspects this pharma use those weapon which are just open for to attain illegal means and to establish its monarchy but remain failed every time.

We humbly request your good office to withdraw the letter keeping in view all the facts narrated above. We also hereby our right to file an appeal against this arbitrary order, if our consideration are not taken into account by your esteemed authority.

Reply of M/s. Pharmawise Lab.

- The matters of Drug & Medicine area highly technical nature which other than a Pharmacist all cannot understand. For the subject matter it is consoling that whole of the DRAP at executive level comprises of pharmacist.
- A minute study of brand names of drug and medicine reveals that the same are extracted from the Generic name of the same drug or from leading proprietary / brand name. Whole of the world market of drugs / medicine is flooded with such names. The Drug and Medicine market of we the Pakistan is no exception. For your ease and ready reference following are Symbolic examples. Not to antagonize the learned Drug Registration Board but to appreciate that now realistically the learned board has adopted it as short of such practices the system will get stuck up.
 - a) Tablets / suspension Ponsac of M/s. Brookes Pharma, Karachi. This name was extract from the leading proprietary / brand name Postan of M/s Pfizer. Other name are Phontan of M/s. Pharmwise Lab Protan of Proressive, Nobstan of M/s. Nawabson Lahore. Kindly appreciate that where all the above names, with many other partly qualify to be counterfeit drug as defined in drug act 1976, yet the same are helpful for the prescribed as well the patient as their phonetic sounds ensure all that the same are what the leading propiatory / brand name ponstant is
 - b) The same is the case with every other leading Trade Name of every Generic Name of Medicine.
- Now coming to our name Povine Solution Registration no. 037527 alleged to be counterfeit the name Pyodine Solution Registration No. 009528 of our friend M/s. Brookes Pharma Karachi it is to respectfully explain that.
 - The Generic name of both the above drug i.e. Povidine solution and pyodine is povidone iodine.
 - Only a pharmacist can appreciate who each worthy member of registration board is, that phonetic sound the above name guides that both have been extracted from the generic name Povidone Iodine.
 - It is requested to appreciate what while pronouncing loudly both the names each distinguished it from the other being different
 - Every manufacturer has equal right to extract his brand / proprietary name of Drug from it generic name the way our friend M/s. Brookes Pharma Karachi Invented their name Pyodine.
 - It seems the present management of M/s. Brookes Pharma Karachi particularly my friend learned D. Arif Hussain Siddiqui Advisor on Regulatory & Marketing Affair is not well conversant with legalities recorded as above he being not a Pharmacist.
 - In view of the submission tendered as above it is respectfully stated that we need not to tender to worthy Registration Board alternate 3 names.

Reply of M/s. Hoover Pharmaceuticals Pvt Ltd.

It is submitted that DRB in its 339th meeting has announced their decision without taking our point of view or issuing show cause notice to us.

It is incorrect to say that hoover Pharmaceuticals Pvt Ltd is involved to manufacturer any counterfeit product in particular to the alleged drug poviderm solution. The product poviderm having reg. no. 094559 has been properly registered with DRAP and the concerned department of DRAP has given us the name products after thorough and careful consideration.

Complainant Products Pyodine

Our Product Poviderm

You can find that there is a differences in 7 figure regarding sesquences / spelling of alphabet in the name of both brands. Furthermore our product Poviderm is logically based on two terms

Povi from Povidone

Derm from Skin

So there is no question that we have copied / followed that name of the product of complainant. As far as label of primary packaging is concerned it's designed and graphics are totally different from the product of complainant.

In the circumstances stated above as our product is not a counterfeit product, it is requested that initiation of any proceeding may kindly be dropped against us and the said letter may be withdrawn in the interest of justice.

Reply of M/s. ISIS Pharmaceuticals & Chemical Works.

The firm has submitted reply which say that, A close perusal of the minutes of the meeting 339th Pages 397-398 indicate that our particular case, the requirement was to change only in the text, and graphics and as only complainant was present in the meeting with the allegation of labeling, so we request you as follow before forward with change to be made in our labeling.

- a) Provide us with a clear copy of the complaint with it legal grounds.
- b) Text of label is a regulatory requirement and is already approved by the registration Board. So please clarify what change has to be made.
- c) Same in graphic please clarify what extract has to be change.

As per regulations in place after making changes without violating, we shall follow the procedure as laid down by DRAP, in its guideline on PR variations.

Reply of M/s. Lahore Pharma

M/s. Lahore Pharma products registered as brand name Plasodine Liquid 7.5% with under the Drug Act 1976 Plasodine Liquid 7.5% Registration no. 014228. And colour scheme of labels is not resemble to any other product.

But M/s. Brookes Pharma Karachi registered product with brand name Pyodine Solution 10% brand name & Products of color of label scheme is not resemble to M/s. Lahore Pharma labels.

Kindly accept the letter if any query about for registration of registered product plasodine liquid 7.5% we have fulfilled all requirement of registration of Plasodine liquid 7.5% according to Drug Act 1976.

Reply of M/s. Oval Pharmaceuticals

The firm mentioned that it is not manufacturing counterfeit drug. Our product septodine Antiseptic Solution 049925 packing do not resemble with Pyodine Solution 009528 of M/s. Brookes Pharma Pvt Ltd, Karachi

It is stated m/s. oval pharmaceuticals is a well know and well reputed company. We do not believe in unethical marketing practices. Label design of Septodine Antiseptic Solution is of orange color and have different segment in design which do not resemble with pyodine. Furthermore if you are not satisfied with packing we will change our label designed and color.

Reply of M/s. Zantok Pharmaceuticals Laboratories

With reference to letter of even number dated 15-01-2025 the firm submit following point which is as under:-

- It is to put forth on record that we granted registration of the products "Zyodine " by the Registration Board after thorough review and analysis , approving the stated brand name vide Registration letter dated 09-07-2007 and later in 2009 also received approval for additional pack size 50ml &400ml with the same brand name
- That we had been successfully manufacturing and marketing the said product for the past 17s without having received any complaint regarding drug quality packaging branding etc or any instance of medicine error on account of similarity of the product brand or appearance.

- The due to established high quality efficacy and safety of our products we had obtained considerable market share and good reput among health care professional and patient both. That our brand commercial is well perceived in the market such that the name itself has wide acceptability and patient association.
- That subsequently the federal inspector of drug, Karachi referred the complaint to central drug laboratories Karachi with a sample of Zyodine 7.5% w/v Solution. For their necessary analysis. The CDL vide their test report No. KQ-4-24-000092 dated 09th May 2024 cleared our product of any such violation an excerpt of the report finding is reproduced hereunder:

“The sample Zyodine 7.5% w/v solution has been compared with brand leader i.e. Pyodine Solution registration number 009528, manufactured by M/s. Brookes Pharmam, Karachi. The colour scheme of the label and outer packing font size font style and graphic of the sample are different as compared with the brand leader. Therefore the sample cannot be declared as imitation product”

- That the Federal Laboratory CDL Test Report has clearly stated that our product cannot be declared as an imitation product which is to be considered as a conclusive report. The under such circumstances, where a verdict has been given on the matter filling of this suit is just another weak attempt of M/s. Brookes to create nuisance of us.
- That our brand has attained good market reput and acceptability among users over past 17 years such that requiring us to change the brand name will negatively impact our business as well as patient compliance.

In the above mentioned argument and supporting evidence it is request to withdraw the case of change of brand name and label claim. If not an opportunity for personal hearing may be given to appear before the registration board in its forth coming meeting to defend our case.

No reply is received from following firms:

1. M/s Cortex Pharmaceuticals, Rawalpindi.
2. M/s N.B.S. Pharma, Lahore.
3. M/s Jawa Pharmaceuticals (Pvt) Ltd, Lahore.
4. M/s Trigon Pharmaceuticals, Lahore.
5. M/s Perfect Pharma, Label.

Decision of the 345th meeting of the Registration Board:-
The Registration Board decided to give an opportunity of Personal Hearing to the respective firms.

M/s Perfect Pharma, Lahore has submitted that the firm will revised the label claim once it is finalized but no request regarding revised label claim is received

In the light of the decision of the Registration Board, all the firms have been called for personal hearing .

In light of above decision of the Board, firms have been called for personal hearing.

Proceedings of 346th meeting of the Registration Board:

Proceedings of Meeting:

Nine firms appeared for person hearing before the Registration Board, the detail is as under:-

S.No.	Name of the Firm	Name of Representative.	Designation.

1.	M/s. Lawrance Pharma.	Naveed Iqbal	Production Manager.
2.	M/s. Kohinoor Industries	Haroon Rashid	Director
3.	M/s. Havoor Pharma	Anjum Ishaq	Chief Executive.
4.	M/s. Pharwise	Ch. Nadir Nuaman Nadir	CEO
5.	M/s. Perfect Pharma	Nasir Hussain	Manager.
6.	M/s. Oval Pharmaceuticals	Wasim Haider	Quality Control Manager.
7.	M/s. Jawa Pharma	Ahmed Ali	Quality Control Incharge.
8.	M/s. Cortex Pharmaceutical	Muhammad Nazir	CEO
9.	M/s. Zantok Pharmaceutical	Advocate Rashid Mureed Mr. Feroz Lasi Mr. Faisal	Council. Managing Partner. -do-

Majority of the firms contended that their products has no resemblance with the brand name and label of M/s. Brookes Pharma. The firm added that M/s. Brookes Pharma is using these tactics to get the commercial benefits in tender business for which the procurement is made after pre-qualification of the manufacturer. Representatives from M/s. Kohinoor Industries and M/s. Cortex Pharmaceuticals also presented the notice of the Registrar, Intellectual Property Tribunal, Lahore, for Case No. 98/IPT/28, filed by M/s Brookes Pharma. Date of hearing of the case is 10-05-2025.

Decision:

The Registration Board thoroughly discussed the matter and decided as under:

i. The order dated 03.07.2024 passed by the Islamabad High Court in Writ Petition No. 2073 of 2024 filed by M/s Brookes Pharma against DRAP reveals that the contention raised by the petitioner (Brookes Pharma) was of sale of counterfeit versions of PYODINE Solution (see, paragraph 2). Section 3(f) of the Drugs Act, 1976 defines “counterfeit drug” as a drug the label or outer packing of which is an imitation of, or resembles or so nearly resembles as to be calculated to deceive the label or outer-packing of a drug of another manufacture. Section 3(o) provides a definition of “label” as a display of written, printed or graphic matter upon the immediate container, or the outside container or wrapper of a drug package. Neither the Writ Petition No. 2073 of 2024 nor the representations filed by Brookes Pharma alleged the trademark infringement rather they alleged availability of counterfeit versions of PYODINE Solution in the market.

ii. It is not the prerogative of Registration Board to decide the matter of infringement of trademarks which is an exclusive domain of Intellectual Property Tribunals under section 18 of the Intellectual Property Organization of Pakistan Act, 2012. The aforesaid Act read with the Trade Marks Ordinance, 2001 have adequate provisions and remedies to which an owner or right holder of a registered trademark may resort in case of being aggrieved.

iii. Recently, in Writ Petition No. 3227/2022 titled M/s Vifor International AG Vs Drugs Appellate Board, etc, the Islamabad High Court has held that the Intellectual Property Tribunal has competent jurisdiction over the matter.

iv. Infringement of a trademark (if any) has to be established in a court of law (IP Tribunal) under the provisions of the Trade Marks Ordinance, 2001.

v. Notwithstanding anything stated hereinabove, pharmaceutical trademarks are usually coined from the drug’s treatment, indication, salt composition, or any other associated

medical word. Therefore, there is more degree of acceptance of resemblance between pharmaceutical trademarks around the world. Like PYODINE, other alleged marks are arbitrary word marks coined from the generic name of the product i.e. POVIDONE IODINE. No one can be allowed exclusive rights to use of generic name of the product POVIDONE IODINE.

vi. The Registration Board considers it appropriate to confine itself to the regulatory jurisdiction of the DRAP Act, 2012 and the Drugs Act, 1976 and not to encroach upon the matter to be dealt under the provisions of the Trade Marks Ordinance, 2001 by specialized IP courts.

vii. Foregoing in view, M/s Brookes Pharma may approach the IP Tribunal for any alleged infringement of its trademark 'PYODINE' (like it has already filed a Suit No, 95/IPT/28 against M/s Kohinoor Industries in the IP Tribunal, Lahore) and this Board will act accordingly in light of the determination(s) made by the Tribunal. The representation of M/s Brookes Pharma is disposed of in above terms.

M/s. Brookes has submitted an appeal against above decision of the Registration Board before the Appellate Board. Decision of 172nd meeting of the Appellate Board is as under:

1. Brookes Pharma Pvt. Ltd. (the 'Appellant') has challenged the Decision passed by the Registration Board in its 346th Meeting held on 22.04.2025 ('Impugned Decision'), whereby its complaint against the manufacture and sale of counterfeits of 'PYODINE' has been disposed of.
2. Mr. Umer Hameed Khan, Advocate appearing on behalf of the Appellant argued in brief that the impugned order is passed without granting an opportunity hearing to the appellant. The drug regulatory framework provides a comprehensive and self-contained mechanism for the identification and determination of a "counterfeit drug," which being 'criminal' in nature, is distinct and independent from the procedures and standards set out under intellectual property laws, which protect the civil property rights.
3. At the very outset, the Board took note of the fact that the Appellant had submitted an Affidavit affirming that no appeal or other proceedings pertaining to the matter in hand are pending before any court of law or forum. However, it was brought to the Board's attention that the Appellant has instituted four separate civil suits before the learned Intellectual Property Tribunal, Lahore, against four different companies for alleged infringement of its intellectual property rights. Upon query, learned Counsel for the Appellant clarified that the subject matter of the said suits is not the Impugned Order passed by the Registration Board in its 346th meeting. Rather, they pertain strictly to the claims of trademark infringement under the Trade Marks Ordinance, 2001. The learned Counsel further contended that the Appellant has approached the DRAP for action under the Drugs Act, 1976 and DRAP Act, 2012 for alleged commission of offence of 'counterfeiting', which is independent of the trademark infringement claims.
4. Be that as it may, the matter is remanded back to the Registration Board to decide afresh after affording an opportunity of hearing to the appellant and all other companies having registration of povidone-iodine solution whose label (i.e. display of written, printed or graphic matter upon the immediate container, or the outside container or wrapper of drug

package) or outer packing is imitating or resembling or so nearly resembling as to be calculated to deceive the label or outer packing of the appellant's drug.

5. The appeal is disposed of in above terms.

Decision of the 351st meeting of the Registration Board:

The Registration board deliberated the matter and decided that the firms due to resemblance with previously registered product i.e. **Pyodine Solution” (Reg No. 009528)**, will change the brand name, color and packaging design of registered products (as per following details to avoid regulatory action under Section 3(f) read with Section 23 (1) (ii) & 27 (2) (a) of the Drugs Act, 1976:

Sr. No.	Name of the Manufacturer	Brand name	Reg. No	Resemblance
1.	M/s Cortex Pharmaceuticals, Rawalpindi. (DML No. 000826)	Pyidine Solution	080824	Brand name
2.	M/s Zanclok Pharmaceutical Laboratories, Sindh (DML No. 000251)	Zyodine Solution	045451	Both label and Brand name
3.	M/s Lahore Pharma, Sheikhpura. (DML No. 000084)	Plasodine liquid	014228	Only label
4.	M/s Kohinoor Industries, Sahiwal. (DML No. 000197)	Prodine Solution	037440	Only Brand name
5.	M/s Hoover Pharmaceuticals, Lahore. (DML No. 000676)	Povidern Solution	094559	Only label revision
6.	M/s N.B.S. Pharma, Lahore. (DML No. 000467)	Povidone-I Solution	025552	Only label
7.	M/s Jawa Pharmaceuticals (Pvt.) Ltd, Lahore. (DML No. 000150)	Japodon Solution	096512	Only Label
8.	M/s Trigon Pharmaceuticals, Lahore. (DML No. 000342)	Halodine Solution	057302	Only Label
9.	M/s Perfect Pharma (Pvt.) Ltd. Lahore. (DML No.	Povidone Iodine Solution	026935	Only Label

	000469)			
10.	M/s ISIS Pharmaceuticals & Chemical works, Karachi (DML No. 000126)	ISIS Povidone Iodine Solution	110071	Only Label

Case No. 8. IMPLEMENTATION OF MULTIBATCHING APPROACH IN PRODUCTION OF REGISTERED PRODUCT CAC 1000 PLUS EFFERVESCENT TABLETS BY M/s HALEON PAKSITAN LIMITED, PETARO ROAD, JAMSHORO

M/s Haleon Paksitan Limited , Jamshoro has submitted applications on E-APP vide TID(s) : NLU-DHE-6H9P, WAB-7VT-2PPE & LP2-D45-WNPN wherein the company has requested for approval to implement a packaging process optimization in production system known as “Multibatching”.

The packaging process optimization will bring a continuous process that allows several bulk batches, that were **dispensed and manufactured separately, to be packed into a single and continuous packaging process** via a single Packaging Process Order (PO). This will allow improvement in efficiency of the production packaging lines, line clearance and batch release process. The resulting packaged Finished Product is assigned a single Finished Product Batch No. for traceability.

The provision of Multi-batching is given in the Rule 2(e) of the Drugs Licensing, registration and Advertising Rules, 1976 that defines a batch as:

2(e) "batch (or lot)" means a defined quantity of starting material, packaging material, or finish product processed in a single process or series of processes so that it could be expected to be homogeneous in the case of continuous manufacture the batch must correspond to a defined fraction of the production, characterized by its intended homogeneity, and to complete certain stages of manufacture it may sometimes be necessary to divide a batch into a number of sub-batches, which are later brought together to form a final homogeneous batch;

Decision of the 351st meeting of the Registration Board:

The Registration Board deliberated the matter and did not accede to the request/ interpretation of the firm.

Case No.01: M/s. Safina Pharmaceuticals (Pvt) Limited 17-km Lahore Sheikhpura Road, Sheikhpura

01.	Brand Name + Dosage Form and Strength	Ofloxy tablet 200mg
	Composition	Each film coated tablet contains Ofloxacin 200mg
	Dairy No. date of R &I fee	Tracking ID: 6NW-41G-1YNE Rs.37,000/-dated: 30.04.2025, (5535224114)
	Type of form	Fom-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO, 1x10's
	GMP Status	DML inspection report dated 16.02.2021
	RRA status	Ofloxacin 200mg tablet by TEVA USFDA (USA) Approved
	Remark of the Renewal section	Registration of Ofloxy tablet 200mg (071317) is applied a fresh due to cancellation of DML due to non- submission of renewal. Updated GMP status to be provided
	Decision: Approved	
02.	Brand Name + Dosage Form and Strength	Parad Extra Tablet
	Composition	Each tablet contains Paracetamol 500mg Caffeine.....65mg
	Dairy No. date of R &I fee	Tracking ID: RXU-X4E-G5TQ Rs.37,000/-dated: 30.04.2025, (135346479048)
	Type of form	Fom-5
	Finished product specifications	BP
	Pack size and Demand Price	As per SRO, 10x10, 1's
	GMP Status	DML inspection report dated 16.02.2021
	RRA Status	Panadol Extra Tablets of MHRA approved
	Remark of the Renewal section	Registration of Parad Extra Tablet (071314) is applied a fresh due to cancellation of DML due to non- submission of renewal. Updated GMP status to be provided Label claim to be standardized in line with RRA as "film coated tablet"
	Decision: Approved. Label claim to be standardized along with fee (as per SRO).	
03.	Brand Name + Dosage Form and Strength	Safiquin tablet 250mg

	Composition	Each film coated tablet contains Ciprofloxacin as HCl 250mg
	Dairy No. date of R &I fee	Tracking ID: WE5-7MQ-H91Z Rs.37,000/-dated: 30.04.2025, (8570308481)
	Type of form	Fom-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO, 1x10's
	GMP Status	DML inspection report dated 16.02.2021
	RRA status	Ciprofloxacin tablets 500mg of M/s Special Concept Development (UK MHRA Approved)
	Remark of the Renewal section	Registration of Safiquin tablet 250mg (071581) is applied a fresh due to cancellation of DML due to non- submission of renewal. Updated GMP status to be provided
	Decision: Approved	
04.	Brand Name + Dosage Form and Strength	Levofina Tablet 250mg
	Composition	Each film coated tablet contains Levofloxacin as hemihydrate 250mg
	Dairy No. date of R &I fee	Tracking ID: UJE-1MP-T7T2 Rs.37,000/-dated: 30.04.2025, (1794308449)
	Type of form	Fom-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO, 1x10's
	GMP Status	DML inspection report dated 16.02.2021
	RRA status	Evoxil 250 mg film-coated tablets by M/s Beacon Pharm (MHRA approved)
	Remark of the Renewal section	Registration of Levofina Tablet 250mg (071586) is applied a fresh due to cancellation of DML due to non- submission of renewal. Updated GMP status to be provided
	Decision: Approved	
05.	Brand Name + Dosage Form and Strength	Sepilex Capsule 100mg
	Composition	Each hard gelatin capsule contains Cefpodoxime (as Proxetil) 100mg
	Dairy No. date of R &I fee	Tracking ID: XLD-89Q-BPMQ Rs.37,000/-dated: 30.04.2025, (1194605735)
	Type of form	Fom-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO, 1 x 12's
	GMP Status	DML inspection report dated 16.02.2021
	RRA status	Not found

	Remark of the Renewal section	Registration of Sepilex Capsule 100mg (057600) is applied a fresh due to cancellation of DML due to non- submission of renewal. RRA approval status not found Applied formulation is not available in USP
	Decision: Deferred for above mentioned shortcomings.	
06.	Brand Name + Dosage Form and Strength	Saflaw Capsule 250mg
	Composition	Each hard gelatin capsule contains Cefaclor (as monohydrate) 250mg
	Dairy No. date of R &I fee	Tracking ID: 5R8-HWY-AY6Y Rs.37,000/-dated: 30.04.2025, (2250177858)
	Type of form	Fom-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO, 1 x 12's
	GMP Status	DML inspection report dated 16.02.2021
	RRA status	Approved by USFDA
	Remark of the Renewal section	Registration of Saflaw Capsule 250mg (057595) is applied a fresh due to cancellation of DML due to non- submission of renewal. Updated GMP status to be provided
	Decision: Approved	
07.	Brand Name + Dosage Form and Strength	Diclofenac Gel
	Composition	Each 100gm contains: Diclofenac diethyl ammonium salt eq. to Diclofenac sodium.....2gm
	Dairy No. date of R &I fee	Tracking ID: 7LN-LXH-USTD Rs.37,000/-dated: 16.04.2025, (973521395596)
	Type of form	Fom-5
	Finished product specifications	BP Specs
	Pack size and Demand Price	As per SRO, 20g
	GMP Status	DML inspection report dated 18.02.2021
	RRA status	Volstarol 12 Hour Emulgel 2.32% Gel (MHRA Approved)
	Remark of the Renewal section	Registration of Diclofenac Gel (071321) is applied a fresh due to cancellation of DML due to non-submission of renewal. Updated GMP status to be provided
	Decision: Approved	
08.	Brand Name + Dosage Form and Strength	Lignocain Gel

	Composition	Each tube contains: Lignocaine HCl.....2%w/v
	Dairy No. date of R &I fee	Tracking ID: J1T-QJA-NXNV Rs.37,000/-dated: 16.04.2025 , (9246212)
	Type of form	Fom-5
	Finished product specifications	BP
	Pack size and Demand Price	15g As per SRO,
	GMP Status	DML inspection report dated 16.02.2021
	RRA status	Lignocaine 2% of TGA Australia approved
	Remark of the Renewal section	Registration of Lignocain Gel (071322) is applied a fresh due to cancellation of DML due to non-submission of renewal. Updated GMP status to be provided
	Decision: Approved	
09.	Brand Name + Dosage Form and Strength	Isotri Gel
	Composition	Each 10gm contains: Isotretinoin..... 0.05%w/w Erythromycin.....2%w/w
	Dairy No. date of R &I fee	Tracking ID: SD7-15T-6D76 Rs.37,000/-dated: 16.04.2025, (118720261085)
	Type of form	Fom-5
	Finished product specifications	Innovator's Specification
	Pack size and Demand Price	As per SRO, 10gm
	GMP Status	DML inspection report dated 18.02.2021
	RRA status	Isotrexin Gel MHRA Approved
	Remark of the Renewal section	Registration of Isotri Gel (071323) is applied a fresh due to cancellation of DML due to non-submission of renewal. Updated GMP status to be provided.
	Decision: Approved	
10.	Brand Name + Dosage Form and Strength	Fenpro Gel
	Composition	Each 100gm contains: Flurbiprofen.....5gm
	Dairy No. date of R &I fee	Tracking ID: AZ4-8PM-2G4X Rs.37,000/-dated: 16.04.2025, (037807999754)
	Type of form	Fom-5
	Finished product specifications	Innovator's Specifications
	Pack size and Demand Price	As per SRO, 20gm
	GMP Status	DML inspection report dated 16.02.2021
	RRA status	Brugel 5% (Abbot)
	Remark of the Renewal section	Registration of Fenpro Gel (071324) is applied a fresh due to cancellation of DML due to non-submission of renewal.

		Updated GMP status to be provided
	Decision: Approved	
11.	Brand Name + Dosage Form and Strength	Clotrimazole Cream
	Composition	Each gram contains: Clotrimazole.....10mg
	Dairy No. date of R &I fee	Tracking ID: QEM-YDR-BQ1J Rs.37,000/-dated: 16.04.2025, (6534039088)
	Type of form	Fom-5
	Finished product specifications	BP
	Pack size and Demand Price	As per SRO, 10gm
	GMP Status	DML inspection report dated 16.02.2021
	RRA status	USFDA (USA) Approved
	Remark of the Renewal section	Registration of Clotrimazole Cream (071325) is applied a fresh due to cancellation of DML due to non- submission of renewal.
	Updated GMP status to be provided	
	Decision: Approved	
12.	Brand Name + Dosage Form and Strength	Clindasafe Gel
	Composition	Each gram contains: Clindamycin phosphate..... 1.29% w/w Eq to clindamycin 1% w/w (10mg/gm)
	Dairy No. date of R &I fee	Tracking ID: LDE-4MM-S7BX Rs.37,000/-dated: 16.04.2025, (39629394907)
	Type of form	Fom-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO, 10gm
	GMP Status	DML inspection report dated 16.02.2021
	RRA status	USFDA Approved by ZYDUS LIFESCIENCES
	Remark of the Renewal section	Registration of Clindasafe Gel (071587)) is applied a fresh due to cancellation of DML due to non-submission of renewal.
	Updated GMP status to be provided	
	Decision: Approved	

Case No.2: M/s. Uni-Tiech Pharmaceuticals Pvt Ltd., Plot. No. 4/116, Sector 21, Korangi Industrial Area, Karachi-74900.

13.	Brand Name + Dosage Form and Strength	Likzone 1gm Injection
	Composition	Each Vial contains: Ceftriaxone Sodium eq. to Ceftriaxone 1gm
	Dairy No. date of R &I fee	Rs.38700/- (Tracking ID: EJW-DDB-7LGQ)

	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	1's (Vial) , As per SRO
	Me-too status	Getofin Injection of M/s Getz Pharma (Reg.No. 019876)
	RRA Status	USFDA approved
	GMP Status	DML renewal inspection was conducted on 31 st May 2023 Dry powder (Cephalosporin) section is approved.
	Remark of the Renewal section	Registration of Likzone 1gm Injection (039668) is applied afresh due to unavailability of a proper renewal trail record, unable to proceed under the usual renewal process Route of administration (IV/IM) to be provided
	Decision: Approved subject to Route of administration (IV/IM) to be provided by the applicant.	
14.	Brand Name + Dosage Form and Strength	Likzone 500mg Injection
	Composition	Each Vial contains: Ceftriaxone Sodium eq. to Ceftriaxone 500mg
	Dairy No. date of R &I fee	Rs.38700/- (Tracking ID: NYT-B32-UWMG)
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	1's (Vial), As per SRO
	Me-too status	Getofin Injection of M/s Getz Pharma (Reg.No. 019875)
	RRA Status	Sandoz Ceftriaxone For Injection (Sandoz Canada Inc.)
	GMP Status	DML renewal inspection was conducted on 31 st May 2023 Dry powder (Cephalosporin) section is approved
	Remark of the Renewal section	Registration of Likzone 500mg Injection (039667) due to unavailability of a proper renewal trail record, unable to proceed under the usual renewal process Route of administration (IV/IM) to be provided
	Decision: Approved subject to Route of administration (IV/IM) to be provided by the applicant.	
15.	Brand Name + Dosage Form and Strength	Likzone 250mg Injection
	Composition	Each Vial contains: Ceftriaxone Sodium eq. to Ceftriaxone 250mg
	Dairy No. date of R &I fee	Rs.38700/- (Tracking ID: HRA-W89-GRHW)
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	1's (Vial),

		As per SRO
	Me-too status	Getofin Injection of M/s Getz Pharma (Reg.No. 024629)
	RRA Status	Ceftriaxone 250mg Powder for solution for Injection (Bowmed Ibisqus Limited UK)
	GMP Status	DML renewal inspection was conducted on 31 st May 2023 Dry powder (Cephalsporin) section is approved
	Remark of the Renewal section	Registration of Likzone 250mg Injection (039666) is applied afresh due to unavailability of a proper renewal trail record, unable to proceed under the usual renewal process Route of administration (IV/IM) to be provided
	Decision: Approved subject to Route of administration (IV/IM) to be provided by the applicant.	
16.	Brand Name + Dosage Form and Strength	Diclolac 75mg Injection
	Composition	Each 3ml contains: Diclofenac Sodium 75mg
	Dairy No. date of R &I fee	Rs.38700/- (Tracking ID: P2V-TRM-448X)
	Type of form	Fom-5
	Finished product specifications	Innovator's Specifications
	Pack size and Demand Price	3mlx5's, As per SRO
	Me-too status	Artifen Injection of M/s. Abbott Pharmaceuticals (Reg. No. 017278)
	RRA Status	MHRA approved
	GMP Status	DML renewal inspection was conducted on 31 st May 2023 Sterile liquid injection (ampoule) is approved
	Remark of the Renewal section	Registration of Diclolac 75mg Injection (042220) is applied afresh due to unavailability of a proper renewal trail record, unable to proceed under the usual renewal process
	Decision: Approved	
17.	Brand Name + Dosage Form and Strength	Unizo 250mg Injection
	Composition	Each Vial contains: Cefotaxime Sodium eq. to Cefotaxime 250mg
	Dairy No. date of R &I fee	Rs.38700/- (Tracking ID: Y5M-538-MT7V)
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	1's (Vial), As per SRO

	Me-too status	Yorker Injection of M/s Sami Pharmaceuticals (Reg. No. 047004)
	RRA Status	Cefotaxime Sodium for Injection (Hospira Healthcare Corporation)
	GMP Status	DML renewal inspection was conducted on 31 st May 2023 Dry powder (Cephalsporin) section is approved
	Remark of the Renewal section	Registration of Unizo 250mg Injection (039663) due to unavailability of a proper renewal trail record, unable to proceed under the usual renewal process
	Decision: Approved	
18.	Brand Name + Dosage Form and Strength	Unizo 500mg Injection
	Composition	Each Vial contains: Cefotaxime Sodium eq. to Cefotaxime 500mg
	Dairy No. date of R &I fee	Rs.38700/- (Tracking ID: NZQ-6JP-2M44)
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	1's (Vial), As per SRO
	Me-too status	Yorker Injection of M/s Sami Pharmaceuticals (Reg. No. 047005)
	RRA Status	Claforan (Cefotaxime for Injection) Baxter Healthcare Corporation (USA).
	GMP Status	DML renewal inspection was conducted on 31 st May 2023 Dry powder (Cephalsporin) section is approved
	Remark of the Renewal section	Registration of Unizo 500mg Injection (039664) due to unavailability of a proper renewal trail record, unable to proceed under the usual renewal process
	Decision: Approved	
19.	Brand Name + Dosage Form and Strength	Unizo 1gm Injection
	Composition	Each Vial contains: Cefotaxime Sodium eq. to Cefotaxime 1gm
	Dairy No. date of R &I fee	Rs.38700/- (Tracking ID: S1R-141-PBAN)
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	1's (Vial), As per Last CPI (2023) Rs. 244.32 /-
	Me-too status	Yorker Injection of M/s Sami Pharmaceuticals (Reg. No. 047006)
	RRA Status	Claforan (Cefotaxime for Injection) Baxter Healthcare Corporation (USA).

	GMP Status	DML renewal inspection was conducted on 31 st May 2023 Dry powder (Cephalsporin) section is approved
	Remark of the Renewal section	Registration of Unizo 1gm Injection (039665) due to unavailability of a proper renewal trail record, unable to proceed under the usual renewal process
	Decision: Approved	
20.	Brand Name + Dosage Form and Strength	Utime 20mg Tablet
	Composition	Each Film coated Tablet contains: Ebastine 20mg
	Dairy No. date of R &I fee	Rs.38700/- (Tracking ID: GTX-5HY-1S8V)
	Type of form	Fom-5
	Finished product specifications	JP Specifications
	Pack size and Demand Price	10's, As per SRO
	Me-too status	Kestine 10 mg Tablets of M/s. Highnoon Laboratories Ltd. (Reg. No.025432)
	RRA Status	Ebastine 20 mg film-coated tablets (Lindopharm GmbH)
	GMP Status	DML renewal inspection was conducted on 31 st May 2023 Tablet (General)section is approved
	Remark of the Renewal section	Registration of Utime 20mg Tablet (067311) due to unavailability of a proper renewal trail record, unable to proceed under the usual renewal process
Decision: Approved		

Case No.03 M/s. Crown Pharmaceuticals Pvt Ltd., Plot. No. 286, Industrial Triangle Kahuta Road, Islamabad.

21	Brand Name + Dosage Form and Strength	Crompara Capsule 40mg
	Composition	Each capsule contains: Omeprazole (enteric coated pellets) 40mg Source of pellets: M/s Surge Laboratories (Pvt) Ltd.
	Dairy No. date of R &I fee	Rs.37000/ (Tracking ID: RNU-YUH-4WT8)
	Type of form	Fom-5
	Finished product specifications	USP Specification
	Pack size and Demand Price	2x7's , As per SRO
	Me-too status	Risek 40mg capsule of M/s Getz Pharma (Reg.No. 019876)
	RRA Status	Losec 40mg capsule UK

GMP Status	DML renewal inspection was conducted on 14 th May 2024 Capsule (General) section is approved
Remark of the Renewal section	Registration of Crompara Capsule (031004) is applied a fresh due to non- submission of renewal (in the light of 180 th Authority decision).
Decision: Approved	

Case No.04 M/s. PDH Pharmaceuticals Pvt Ltd., 19-Km Ferozpur Road, Lahore Pakistan.

22.	Brand Name + Dosage Form and Strength	Omecer Capsule 20mg
	Composition	Each capsule contains: Omeprazole...20 mg Source of pellets: M/s Vision Pharmaceuticals (Pvt) Ltd. Islamabad
	Dairy No. date of R &I fee	Rs.37000/-: (Tracking ID: P5D-8X9-JHJ8)
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	14's , As per SRO
	Me-too status	Risek 20mg capsule of M/s Getz Pharma (Reg.No. 019364)
	RRA Status	Losec 20mg capsule UK
	GMP Status	GMP inspection dated 04-12-2023
	Remark of the Renewal section	Registration of Omecer Capsule 20mg (018610) is applied afresh due to non- submission of renewal (in the light of 180 th Authority decision). Formulation to be standardized in line with RRA.
	Decision: Approved. Formulation to be standardized in line with RRA along with fee (as per SRO)	

Case No.05 M/s Aventek Pharmaceuticals (Pvt.) Ltd., located at Plot No. 44-C, Sundar Industrial Estate, Lahore.

23.	Brand Name + Dosage Form and Strength	Avexil Capsules 500mg
	Composition	Each capsule contains: Cefadroxil Monohydrate eq. to Cefadroxil.....500mg
	Dairy No. date of R &I fee	Rs.37000/- (Tracking ID: 4WX-8LR-BYV7)

	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	5's , 7's, 10's , 14's, 20's, 30's, 100's (As per SRO)
	Me-too status	Sundox Capsule 500mg
	RRA Status	Sandrox 500mg Capsule (USFDA Approved)
	GMP Status	Cephalosporin capsule is approved by CLB. As per DML renewal approval letter dated 09-04-2025
	Remark of the Renewal section	Registration of Avexil Capsules 500mg (059604) is applied a fresh due to cancellation of DML due to non- submission of renewal.
Decision: Approved.		
24.	Brand Name + Dosage Form and Strength	Avemrol Dry Susp.250mg
	Composition	Each 5ml contains: Cefprozil as Monohydrate....250mg
	Dairy No. date of R &I fee	Rs.37000/- (Tracking ID: NH4-JBL-JEL4)
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	50ml , As per SRO
	Me-too status	Cefzil 250mg Suspension by GSK
	RRA Status	Cefzil Suspension 250mg (USFDA Approved)
	GMP Status	Cephalosporin Dry Powder Suspension section is approved by CLB as per DML renewal approval letter dated 09-04-2025
	Remark of the Renewal section	Registration of Avemrol Dry Susp.250mg (059589) is applied a fresh due to cancellation of DML due to non- submission of renewal.
Decision: Approved		
25.	Brand Name + Dosage Form and Strength	A-Glip Tab. 50mg
	Composition	Each film coated Tablet contains: Vildagliptin 50mg
	Dairy No. date of R &I fee	Rs.37000/- (Tracking ID: NJX-Y48-G143)
	Type of form	Fom-5
	Finished product specifications	Manufacturer Specification
	Pack size and Demand Price	1x10's , As per SRO
	Me-too status	Galvus 50mg Tablet by Novartis
	RRA Status	Galvus 50mg Tablet (USFDA)
	GMP Status	New DML dated 09-04-2025
	Remark of the Renewal section	Registration of A-Glip Tab. 50mg (080071) is applied a fresh due to cancellation of DML due to non- submission of renewal.

	Formulation approved in RRA is “uncoated” while applied formulation is film coated as verified from Master formula.
Decision: Approved	

Deferred cases of 349th meeting of Registration Board:

26.	Brand Name + Dosage Form and Strength	Aveteose – F Tablet
	Composition	Each Tablet contains: Iron Polymaltose Complex 100mg Folic Acid.....0.35mg (Innovator’s Specifications).
	Tracking ID and fee details	M6R-M75-A4S1 Rs.37,000/-dated: 21.04.2025, (2197278414)
	Type of form	Fom-5
	Finished product specifications	Innovator’s ’s Specs.
	Pack size and Demand Price	As per SRO, 10’s
	GMP Status	Re-grant DML issuance date 09-04-2025.
	Remark of the Renewal section	Generic versions already registered in Pakistan are available in chewable form Tablet (General) section is approved by CLB. As per last inspection report dated 16-01-2025
	Remarks:	Aveteose – F Tablet (080072) by M/s Aventek Pharmaceuticals (Pvt.) Ltd, address Plot No. 44-C, Sundar Industrial Estate, Lahore (DML No. 000660), was declared invalid letter No. F.1-70/2022-Lic (Vol-I) dated 11 November 2024, due to the late submission of the application for DML renewal.
	Decision 349th meeting: Deferred for confirmation of applied formulation (whether chewable or to be swallowed) along with relevant reference (generic version/RRA)	
	Reply (Tracking ID 963-P69-651U):	
	Applied formulation is as Chewable tablet as under: Each Chewable tablet contains: Iron (III) Hydroxide Polymaltose Complex eq to Iron.....100mg Folic acid.....0.35mg	
	Remarks of Renewal section: Fee (as per SRO) to be submitted for standardization of label claim in line with RRA.	
	Decision: Approved subject to submission of fee for standardization of label claim as per SRO.	

27.	Brand Name + Dosage Form and Strength	Aveome Capsule. 20mg
	Composition	Each capsule contains: Omeprazole enteric coated pellets eq. to Omeprazole.....20mg
	Tracking ID and fee details	SZZ-BR7-H93E Rs.37,000/-dated: 21-04-2025 (336681484838)
	Type of form	Fom-5
	Finished product specifications	BP Specifications
	Pack size and Demand Price	As per SRO, 10', 14's, 100's
	GMP Status	DML Regrant Issuance Date 09-04-2025
	RRA status	PRILOSEC Capsule (USFDA Approved)
	Remark of the Renewal section	Source of pellets to be provided along with relevant documents. Capsule (General) section is approved by CLB. As per last inspection report dated 16-01-2025
	Remarks:	Aveome Capsule. 20mg (080994) by M/s Aventek Pharmaceuticals (Pvt.) Ltd, address Plot No. 44-C, Sundar Industrial Estate, Lahore (DML No. 000660), was declared invalid vide letter No. F.1-70/2022-Lic (Vol-I) dated 11 November 2024, due to the late submission of the application for DML renewal.
	Decision 349th meeting: Deferred for submission of source of pellets along with relevant documents.	
	Reply (Tracking ID 963-P69-651U): Source of Pellets: M/s Vision Pharmaceuticals (Pvt) Ltd. Following documents are provided as under: 1. Certificate of analysis 2. Stability studies 3. Valid GMP Certificate (dated 27-02-2025)	
28.	Decision: Approved	
	Brand Name + Dosage Form and Strength	Aveome Capsule. 40mg
	Composition	Each capsule contains: Omeprazole enteric coated pellets eq. to Omeprazole.....40mg
	Tracking ID and fee details	X5E-J1V-NM7J Rs.37,000/-dated: 21-04-2025 (32552806164)
	Type of form	Fom-5
	Finished product specifications	BP Specifications
	Pack size and Demand Price	As per SRO, 10', 14's, 100's
	GMP Status	DML Re-grant Issuance Date 09-04-2025
	RRA status	USFDA Approved
	Remark of the Renewal section	Source of pellets to be provided along with relevant documents.

		Capsule (General) section is approved by CLB. As per last inspection report dated 16-01-2025
	Remarks:	Aveome Cap. 40mg (080995) M/s Aventek Pharmaceuticals (Pvt.) Ltd, address Plot No. 44-C, Sundar Industrial Estate, Lahore (DML No. 000660), was declared invalid vide letter No. F.1-70/2022-Lic (Vol-I) dated 11 November 2024, due to the late submission of the application for DML renewal.
	Decision 349th meeting : Deferred for submission of source of pellets along with relevant documents.	
	Reply (Tracking ID 963-P69-651U): Source of Pellets: M/s Vision Pharmaceuticals (Pvt) Ltd. Following documents are provided as under: 1. Certificate of analysis 2. Stability studies 3. Valid GMP Certificate (dated 27-02-2025)	
	Decision: Approved	

29.	Brand Name + Dosage Form and Strength	A-Lenso Capsule 30mg
	Composition	Each Capsule contains: Enteric coated pellets of Lansoprazole equivalent to Lansoprazole 30mg
	Tracking ID and fee details	E7V-QN3-WAHE Rs.37,000/-dated: 21-04-2025 (895397954904)
	Type of form	Fom-5
	Finished product specifications	Innovator's Specifications
	Pack size and Demand Price	As per SRO, 10', 14's, 100's
	GMP Status	DML Re-grant Issuance Date 09-04-2025
	RRA status	USFDA Approved
	Remark of the Renewal section	Applied formulation is available in official monographs. Hence firm is advised to apply for change of specifications along with fee. Source of pellets to be provided along with required documents. Capsule (General) section is approved by CLB. As per last inspection report dated 16-01-2025
	Remarks:	A-Lenso Capsule 30mg (080996) by M/s Aventek Pharmaceuticals (Pvt.) Ltd, address Plot No. 44-C, Sundar Industrial Estate, Lahore (DML No. 000660), was declared invalid vide letter No. F.1-70/2022-Lic (Vol-I) dated 11 November 2024, due to the late submission of the application for DML renewal.
	Decision 349th meeting : Deferred for submission of source of pellets along with relevant documents.	
	Reply (Tracking ID 963-P69-651U):	

Source of Pellets: M/s Vision Pharmaceuticals (Pvt) Ltd. Following documents are provided as under: 1. Certificate of analysis 2. Stability studies 3. Valid GMP Certificate (dated 27-02-2025)
Decision: Approved

30.	Brand Name + Dosage Form and Strength	Esdor Capsule 20mg
	Composition	Each Capsule contains: Delayed release pellets of Esomeprazole Magnesium Trihydrate equivalent to Esomeprazole.....20mg
	Tracking ID and fee details	ES2-8MS-WDG4 Rs.37,000/-dated: 21-04-2025 (2037641054)
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO, 10', 14's, 100's
	GMP Status	DML Re-grant Issuance Date 09-04-2025
	RRA status	USFDA Approved
	Remark of the Renewal section	Source of pellets to be provided along with required documents. Capsule (General) section is approved by CLB. As per last inspection report dated 16-01-2025
	Remarks:	Esdor Capsule 20mg (080998) by M/s Aventek Pharmaceuticals (Pvt.) Ltd, address Plot No. 44-C, Sundar Industrial Estate, Lahore (DML No. 000660), was declared invalid vide letter No. F.1-70/2022-Lic (Vol-I) dated 11 November 2024, due to the late submission of the application for DML renewal.
Decision 349th meeting: Deferred for submission of source of pellets along with relevant documents.		
Reply (Tracking ID 963-P69-651U): Source of Pellets: M/s Vision Pharmaceuticals (Pvt) Ltd. Following documents are provided as under: 1. Certificate of analysis 2. Stability studies 3. Valid GMP Certificate (dated 27-02-2025)		
Decision: Approved		

31.	Brand Name + Dosage Form and Strength	Esdor Capsule 40mg
	Composition	Each Capsule contains: Delayed release pellets of Esomeprazole Magnesium Trihydrate equivalent to Esomeprazole.....40mg
	Tracking ID and fee details	HQN-VJ4-UXS7 Rs.37,000/-dated: 21-04-2025 (4121270322)
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO,

	10', 14's, 100's
GMP Status	DML Re-grant Issuance Date 09-04-2025
RRA status	USFDA Approved
Remark of the Renewal section	Source of pellets to be provided along with required documents. Capsule (General) section is approved by CLB. As per last inspection report dated 16-01-2025
Remarks:	Esdor Capsule 40mg (080997) by M/s Aventek Pharmaceuticals (Pvt.) Ltd, address Plot No. 44-C, Sundar Industrial Estate, Lahore (DML No. 000660), was declared invalid vide letter No. F.1-70/2022-Lic (Vol-I) dated 11 November 2024, due to the late submission of the application for DML renewal.
Decision 349th meeting: Deferred for submission of source of pellets along with relevant documents. Reply (Tracking ID 963-P69-651U): Source of Pellets: M/s Vision Pharmaceuticals (Pvt) Ltd. Following documents are provided as under: 1. Certificate of analysis 2. Stability studies 3. Valid GMP Certificate (dated 27-02-2025)	
Decision: Approved	

Case No. 06: M/s Regal Pharmaceuticals Plot No. 2-A, Street No. S-5 National Industrial Zone RCCI Rawat Islamabad.

32.	Brand Name + Dosage Form and Strength	Refnox 550mg Tablet
	Composition	Each film coated tablet contains: Rifaximin.....550mg
	Dairy No. date of R &I fee	Rupees 38700/- (Tracking ID: 7M1-WT6-9T8L)
	Type of form	Fom-5
	Finished product specifications	As per innovator's Specifications
	Pack size and Demand Price	1x10's As per SRO
	Me-too status	Rifixa 550mg Tab Ferozsos
	RRA Status	Targaxan 550mg tablets (Norgine Pharmaceuticals Ltd)
	GMP Status	Not provided
	Remark of the Renewal section	Registration of Refnox 550mg Tablet (095335) is applied afresh due to non-submission of renewal. - Applied formulation is available in BP monograph. Fee to be submitted for change of specification accordingly - Updated GMP status to be provided.
Decision: Approved . Finished product specification to be changed along with fee (as per		

	SRO)

Case No. 07: M/S FRONTIER DEXTROSE LIMITED PLOT NO. 18/3 PHASE-1 INDUSTRIAL ESTATE HATTAR

33.	Brand Name + Dosage Form and Strength	Sterifluid N/3 500ml & 1000ml (Reg# 064077)
	Composition	Each 100ml contains: Dextrose anhydrous.....3.3g Sodium chloride.....0.30g Water for injection (q.s)
	Dairy No. date of R &I fee	Rupees 30,000/- (Tracking ID: L7D-UY5-3L6D)
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	500ml and 1000ml As per SRO
	Me-too status	Medisol Sodium Chloride 0.3% w/v & Glucose 3.3% w/v Solution for Infusion BP by Medipak
	RRA Status	Sodium Chloride 0.3% w/v & Glucose 3.3% w/v Solution for Infusion BP By Baxter Healthcare Ltd.
	GMP Status	Not provided
	Remark of the Renewal section	Registration of Sterifluid N/3 (Reg# 064077) is applied afresh due to non-submission of renewal. Differential fee of Rs 7000/- to be submitted as per SRO. Firm is required to specify 1 volume (either 500ml or 1000ml) as per existing practice. Separate application to be submitted against other volume which shall be treated as New application. Updated GMP status to be provided.
	Decision: Approved with single pack size (either 500ml or 1000ml) to be determined by the applicant. The firm shall be apply for new registration for other pack size which shall be considered out of queue.	

Item No. III Division of Quality Assurance & Laboratory Testing

S. No.	CASE TITLE
1.	Substandard SN Zor Powder For Oral Suspension Batch No. 342, Manufactured By M/s. S.N.B Pharma (Pvt) Ltd. Peshawar.
2.	Manufacturing & Sale Of Sub-Standard Dexyken 300 Mg Tablets Manufactured By M/S Kanel Pharma, Rawat
3.	Substandard Fungo Tablet, Reg. No. 052506 Batch No # 8520 Manufactured By M/S Alfalah Pharma (Pvt) Ltd, Lahore
4.	Substandard Medi-Lox Tablet (Reg. No. 056133) Manufactured by M/s. Medicon Pharmaceutical Industries (Pvt) Ltd, Peshawar.
5.	Permission For Extension In Order Not To Dispose Of Under Section 18 (1)(I) Of The Drugs Act, 1976.
6.	Resemblance Of Colour Scheme, Design And Artistic Work And Packaging
7.	Recall Of Pharmix Products Due To Presence Of Impurities
8.	Manufacture And Sale Of Substandard Manadol Suspension (Paracetamol) Batch No. 4md-005 Manufactured By M/S Masfa Industries (Pvt.) Ltd Lahore.

Case No.1: SUBSTANDARD SN ZOR POWDER FOR ORAL SUSPENSION BATCH NO. 342, MANUFACTURED BY M/S. S.N.B PHARMA (PVT) LTD. PESHAWAR.

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	08-2023	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.*

9. Division of QA&LT issued Show Cause notice vide office F. No. 03-2/2025-QALT (343-RB) dated 13th January, 2025 under Section 42 of the Drugs Act 1976.

10. In response to said show cause, M/s. S.N.B Pharma (PVT) LTD. Peshawar. vide letter SN/DRP-QALT/1601/2025 dated 17th January, 2025 replied as under:

Reference to your letter F. No. 03-2/2025-QALT (343-RB), dated 13th January 2025 regarding subjected product.

We M/s SNB Pharma (Pvt) Ltd., Plot #142, Industrial Estate, Hayatabad Peshawar-Pakistan has great respect with highest possible level of compliance to all the prevailing law regulating Pharmaceutical industry and has always worked within the legal framework of the DRAP Act 2012/ Drug Act 1976 and Rules framed there-under in order to ensure delivery of high quality effective and safe drugs to the patients at National level.

That the Govt. Analyst Central Drug Testing Laboratory Karachi has determined 88.33% of the active ingredient (Azithromycin) against the prescribed limit of 90-110%, which showed that there, might be some technical errors that can affect the potency of test results resulting in lower than expected values & potentially out of specification (OOS).

That DTL report (Test Report No. KQ-11-23-000154 dated 22-02-2024) is time barred report as issued on 22-02-2024 by the Govt. Analyst Central Drug Testing Laboratory Karachi after the laps sixty (60) days under section 22(2) of the Drugs Act, 1976 and how can be justified & could be possible that sample present to lab for test which might be mishandled & not stored at proper ware house conditions. While, it is the property of suspension that after reconstitution, bubble formation & sedimentation can occur. Therefore, for an analyst it is mandatory to prepare the sample correctly before start of analysis. Without proper shaking of the sample, the content of active ingredient can vary in different portions within the same pack. From the assay results it seems that the suspension has not been uniformly distributed. This may result in varying concentration of active Ingredients in different portions of sample. During analysis correct volume of the sample by pipette is played important role and a minor careless will alter the result and can lead to OOS results. So, it is clear that he has ignored the mentioned law, It is well settled law that when initial order or act relating to initialization of proceedings is contrary to law. Subsequent proceedings and actions taken thereon would have no basis at would fall. Reliance 2009 SCMR 339.

That we submitted the retesting request within stipulated time under section 22(4) of the Drugs Act, 1976 and adduced the evidence under section 22(5) of the Drugs Act, 1976.

That the Govt. Analyst failed to issue the conclusive test analysis report which is stating to be under specification of USP, without the raw data and details of the test and calculations, inspires no confidence and is contrary to the mandates of law. It is a statutory requirement of Section 24A of the General Clauses Act, 1897, that all the particulars, details and documents, based on which a Show Cause Notice is issued, be provided to the respondent for properly defending any allegation.

It is pertinent to mention that we have initiated the recall of the aforesaid batch from the market & almost 924 packs (Copy of Letters attached) recovered from market & stock in hand.

That thus no further proceedings or action of any nature is required or justified against us in the admitted and acknowledged facts and circumstances of the case.

Accordingly, for breach of such mandatory provisions of the law and denial of our rights to challenge the DTL report under the same, the entire matter stands vitiated and rendered void ab initio, where upon the case stands foreclosed, abated and a futility.

In view of above-mentioned facts, the present case based upon Disputed, Non-Conclusive Test/Analysis Report No. KQ-11-23-000154 dated 22-02-2024 and no legal proceedings may kindly be initiated against the Firm under the Drug Act, 1976/DRAP Act, 2012 and Rules framed there under. Therefore, it is requested that the case may kindly be considered as dropped case as there is no contravention of the Drug Act 1976 or any other law prevailing in Pakistan,

11. Accordingly, the firm has been issued notice of personal hearing to appear before the Board, under Section 42 of the Drug Act 1976.

12. **Proceedings and Decision of 345th Meeting of Registration Board**

In Compliance to personal Hearing letter from Division of QA&LT Mr. Liaqat Ali Q.C Manager and Mr. Dawood Kamal, Legal advisor of M/s. S.N.B Pharma (PVT) LTD. Peshawar appeared before the Board. They said that they have applied for appellate testing within time and also submitted copy of letter submitted in R&I of DRAP dated 29th March, 2024.

The Board decided to verify authenticity of the letter of firm for appellate testing dated 29th March, 2024 by the R&I Section and to place the case on the agenda for the next Registration Board meeting.

13. Copy of letter for request of Appellate testing, verified from R&I Section. As per R&I Section letter was received on 29th March, 2024 vide Diary No.4200.

14. **Proceedings and Decision of 347th Meeting of Registration Board**

QA & LT Division presented the case before the Registration Board. The Board after considering the facts of the case and thorough deliberations decided to accede request of firm for appellate testing, of SN Zor powder for oral suspension (074547), Batch No. 342 manufactured by M/s S.N.B. Pharma, Peshawar, under Section 22 (5) of the Drugs Act, 1976, Registration Board further directed that the said sample be forwarded for appellate testing at the earliest, in view of its near expiry, without waiting for the formal approval of the meeting minutes.

15. 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.F.03-10/2024-QC dated 13-05-2025.

16. The appellate laboratory declared the sample as “**Standard**” quality vide report No. F. 1-20/01-M/2025-DC&TMD dated 28th July, 2025. (Assay of Azithromycin (as dehydrate): 94.32%, Limit: 90-110%)

Proceeding and Decision of 351st meeting of Registration Board

The Board, after considering facts of the case and keeping in view the report of the Appellate Lab, NIH, Islamabad vide letter No. F. 1-20/01-M/2025-DC&TMD dated 28th July, 2025,

wherein the Lab has declared the sample of “SN Zor powder for oral suspension, Batch No 342” as of “Standard Quality” has decided to dispose of the case.

Case No.2: MANUFACTURING & SALE OF SUB-STANDARD DEXYKEN 300 MG TABLETS MANUFACTURED BY M/S KANEL PHARMA, RAWAT

The Federal Inspector of Drugs, DRAP, Quetta Mr., Kirshan during inspection of M/s Sirajud din & Sons, M.A Jinnah road, Quetta dated 10th September, 2024 took samples of the Dxyken Tablets 300mg 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.9-24-000142 dated 15th November, 2024, declared the batch KF23006 of product Dxyken Tablets 300mg manufactured by M/s. Kanel Pharma, Rawat, Islamabad 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
Dxyken 300mg Tablet	M/s. Kanel Pharma, Rawat	075234	KF23006	06-2023	06-2025	Sub-Standard On the Basis of “ <i>Chipping and peeling off tablets observed</i> ” <i>Does not comply</i> Limit: A white colored ,Oval shaped, biconvex, bisected core tablets

3. Complete Case was received from FID vide letter No. DK-24-28/2024-FID-QTA dated 4th February 2025 wherein he mentioned that M/s Kanel Pharma, Rawat vide their letter dated 02nd January 2025 (received on 03rd February 2025) requested for appellate testing from NIH, Islamabad. under Section 22(4) of the Drugs Act, 1976.

4. After evaluation of firm’s reply following observations are made:

FID communicated report to Firm vide letter dated 16 th December 2024	Firm received letter on 31 st December 2024
Firm applied for appellate testing vide letter dated 02 nd January 2025	Letter received in DRAP Quetta on 03 rd February 2025

As per Section 22(4) of Drugs Act 1976, firm should request of Appellate testing within 30 days of communication of CDL report by FID while as per **Diary Date of R&I Section of DRAP Quetta, firm applied after 30 days.**

5. **Proceedings and Decision of 347th Meeting of Registration Board.**

QA & LT Division presented the case before the Registration Board. The board after threadbare deliberation decided to accede request of firm for appellate testing, under Section 22 (5) of the Drugs Act, 1976, of Dexyken 300mg Tablets (075234), Batch No. KF23006 manufactured by M/s Kanel Pharma, Rawat..

6. The Registration Board portion was sent to the Appellate laboratory for resting under Section 22(5) of the Drug Act 1976

7. The Appellate laboratory, vide test report No F 1-20/06-M/2025-DC&TMD dated 27th June, 2025, as declared sample of “Dexyken Tablet 300mg Batch no. KF23006 manufactured by M/s. Kanel Pharma, Islamabad, as of “Substandard” quality. (*Does not comply with manufacturer specification which states that white color, round, biconvex film coated Tablet, Results: White, oblong shaped, biconvex tablets having bisectational line on one side contained in aluminum packing further packed in outer carton*)

8. In the light of Appellate Report Division of QA&LT issued Show Cause notice vide office F. No. 03-53/2024-ADQC-V dated 14th July, 2025 under Section 42 of the Drugs Act 1976.

9. In response to said show cause, M/s. Kanel Pharma, Islamabad replied as under:

“With reference to your letter No. F.03-53/2024-ADOC-V, this is to certify that the coating variation observed in one batch of Dexyken 300 mg Tablets, as reported by CDL Karachi. This case was considered in 347th Meeting of Registration Board which was held on 28th April to 30 April 2025

A review of the matter indicated that the variation was related to the product's sensitivity to elevated temperature and humidity, which can influence coating appearance. The investigation, conducted through FMEA (Failure Modes and Effects Analysis), confirmed that the variation was cosmetic in nature and had no impact on product safety, potency, or therapeutic performance.

Corrective and Preventive Actions were implemented, including:

- Enhancement of coating formulation and sealing.*
- Adoption of high-barrier Alu-Alu packaging.*
- Improved environmental controls during packing.*

Validation studies confirmed effectiveness:

- Accelerated and long-term stability testing showed no recurrence of coating variation.*

The product continues to comply with all relevant quality standards, and ongoing stability monitoring remains in place as part of our quality management system.

We remain committed to ensuring consistent product quality and regulatory compliance.

10. Accordingly, the firm has been issued notice of personal hearing to appear before the Board, under Section 42 of the Drug Act 1976.

Proceeding and Decision of 351st meeting of Registration Board

In compliance to the show cause notice and personal hearing letter issued, Mr. Asad Khan, Quality Control Manager of M/s. Kanel Pharma, Rawat, Islamabad appeared before Board. He said that corrective action has been taken to prevent chipping and peeling.

The Board after considering the facts of the case and after thorough deliberations decided:

- i. Submission of RCA and CAPA by the firm.*
- ii. Product Specific Inspection including verification of RCA and CAPA by panel of inspectors/experts to be nominated by Director QA/LT.*
- iii. Suspension of the Registration of Dexyken 300 mg Tablet, Registration No. 075234 manufactured by M/s. Kanel Pharma, Rawat, Islamabad 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 constituted by the Director (QA&LT) with satisfactory report; whichever is earlier.*

Case No.3: SUBSTANDARD FUNGO TABLET, REG. NO. 052506 BATCH NO # 8520 MANUFACTURED BY M/S ALFALAH PHARMA (PVT) LTD, LAHORE

The Federal Inspector of Drugs, DRAP, Lahore during inspection of M/s Alfalah Pharma (Pvt) Ltd, Lahore dated 25th September, 2024 took samples of the FunGo Tablet 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 LHR-10-24-000006 dated 17th December, 2024, declared the batch KF23006 of product M/s Alfalah Pharma (Pvt) Ltd, Lahore as of “Substandard Quality”. Details of CDL test report are as under.

Product Name	Manufactured by	Reg. No	Batch No.	Mfg. Date	Exp. Date	Test Results
FunGo Tablet Reg. No. 052506 Terbinafine HCl	M/s Alfalah Pharma (Pvt) Ltd, Lahore	052506	8520	07-2024	07-2026	Sample has been declared as “ <i>Substandard</i> ” on the basis of Dissolution Does not Comply Limit: Each unite is not less than 80%(Q)

3. Federal Inspector of Drugs Lahore was directed to investigate the matter and submit a comprehensive report in the matter.

4. Federal Inspector of Drugs, DRAP, Lahore, submitted the company's request of Appellate testing vide letter No. AP/DRAP/24002 dated 17th January, 2025, after receiving letter along with CDL report from FID, Lahore (which was sent on 11th December, 2024).

5. 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.*
- iv. *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.”*

6. In the light of above-mentioned decision of the Board, the division of QA&LT vide letter F.No.03-58/2024-AD(QALT-IV) dated 3rd March, 2025 requested the Federal Government Analyst CDL Karachi and M/s. Aries Pharmaceuticals (Pvt.) Ltd., Peshawar for the submission of Out of specification (OOS) investigation as directed by the Registration Board.

7. Firm submitted recall log, the percentage of recall is **30.19%**.

8. Summary of evaluation of Out of specification (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 wherein it is informed that the sample is tested in accordance with the test/analysis method provided in the USP 2023 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 Alfalah Pharma (Pvt) Ltd, Lahore

M/s Alfalah Pharma (Pvt) Ltd, Lahore in their reply has provided OOS investigation at laboratory and manufacturing level along with relevant evidences and has also ruled out any chance of error in the manufacturing or testing of the product in question.

Technical Evaluation of OOS Investigation:

- i. The product was declared by CDL as sub-standard on the basis of Dissolution
- ii. CDL and manufacturer both performed the test as per USP
- iii. There may be issues during formulation development, manufacturing processes, quality of API, and instability of product.

Proceeding and Decision of 351st meeting of Registration Board

Minutes of 351st Meeting of Registration Board (23rd – 24th September, 2025)

The Board after considering the facts of the case and thorough deliberations decided to accede to the request of firm for appellate testing of product FunGo Tablet (052506), Batch No. 8520 Manufactured by M/s Alfalah Pharma (Pvt) Ltd, Lahore, under Section 22 (5) of the Drugs Act, 1976.

Case No.4: SUBSTANDARD MEDI-LOX TABLET (REG. NO. 056133)
MANUFACTURED BY M/S. MEDICON PHARMACEUTICAL
INDUSTRIES (PVT) LTD, PESHAWAR.

Federal Inspector of DRAP, Peshawar, inspected Premises of M/s Medicon Pharmaceutical Industries (Pvt) Ltd., Peshawar, on 5th December, 2024, wherein sample of Medi-Lox Tablet was taken for the purpose of test/analysis on prescribed Form-3. and sent to the Federal Government Analyst, CDL Karachi for test/analysis on Form-4. Federal Government Analyst, CDL Karachi vide test report No. IP-12-24-000103 dated 13th January, 2025 declared the batch 425 of product Medi-Lox Tablets manufactured by M/s. Medicon Pharmaceutical Industries (Pvt.) Ltd., Peshawar as of '**Substandard Quality**'. Details of CDL test report are as under.

Product Name	Manufactured by	Reg. No.	Batch No.	Mfg. Date	Exp. Date	Test Results
Medi-Lox Tablet Ciprofloxacin (250mg/tablet)	M/s. Medicon Pharmaceutical Industries (Pvt.) Ltd., Peshawar.	056133	425	08-2024	07-2027	Sample has been declared as "Substandard" on the basis of Dissolution Dissolution (S₁) = 61.90% Does not comply. Dissolution (S₂) = 63.28% Does not comply Dissolution S₃ = 64.96% Does not comply

2. Federal Inspector of Drugs Peshawar was directed to investigate the matter and submit a comprehensive report in the matter.

3. Federal Inspector of Drugs, DRAP, Peshawar, Mr. Atiq ul Bari submitted that the firm has informed that their Chief Executive Officer (Dr. Maqbool Khan) has sadly passed away, creating a temporary leadership transition within the organization. Currently they are in the process of appointing a new CEO in accordance with the company's internal governance procedures and regulatory requirements. Moreover, the firm has requested for extension for the submission of the documents requested by this office.

4. Meanwhile the firm submitted reconciliation report of recalled stocks indicating that a total of 5,500 packs of the product were manufactured and distributed in the market. Of these, 1030 packs have been recalled. In this regard, the permission for the destruction of stocks recalled by the manufacturer may be granted so that destruction of the recalled stocks be carried out in accordance with implemented guidelines. Moreover, it is further requested that the power to approve destruction of recalled stock be delegated to Chairman Registration Board, please.

5. Proceedings and Decision of 348th Meeting of Registration Board.

Division of QA & LT presented the case before The Registration Board. The board was appraised about firm's reply. The board after thorough deliberation and reviewing firm's request for extension for the submission of documents due to demise of their Chief Executive Officer (Dr. Maqbool Khan) decided as following:

- i. *To issue show cause notice to M/s. Medicon Pharmaceutical Industries (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.*
- ii. *The Board delegated the following function / power to the Chairman, Registration Board.*

Functions / Powers	Functions / Powers Delegated to
<i>Grant of permission of destruction of recalled stock of out of specifications products</i>	<i>Chairman, Registration Board.</i>

6. Division of QA&LT issued Show Cause notice vide office F. No. 5-5/2025-ADQA-V(348-RB) dated 5th August, 2025 under Section 42 of the Drugs Act 1976.

7. In response to said show cause, M/s. Medicon Pharmaceuticals Industries (Pvt) Ltd., Islamabad replied as under:

"The test report from CDL Karachi declared the sample of Medi-Lox Tablet as "Sub-Standard," which is a matter of serious concern for us. However, we respectfully submit that, according to our in-house Quality Control testing, the concerned batch was within acceptable specifications at the time of release.

This discrepancy drew our immediate attention, and we initiated an internal investigation to identify any potential cause. While our results differed from those of the Federal Government Analyst, we fully respect the test report and are cooperating closely to address the matter in a responsible manner.

Corrective and Preventive Measures:

The concerned batch was voluntarily recalled from the market as a precaution. Our Internal Standard Operating Procedures (SOPs) have been thoroughly reviewed and improved.

Leadership Transition:

As previously communicated, our CEO, Dr. Maqbool Khan, sadly passed away in December 2024, causing a temporary disruption in our management structure.

We are currently finalizing the appointment of a new CEO, and leadership stability is being fully restored.

Humble Request:

In light of the circumstances, we respectfully request the esteemed Board to consider our position sympathetically and avoid harsh penalties such as suspension or cancellation of product registration.

We remain committed to continuous improvement and full compliance with all regulatory requirements.

Request for Personal Hearing:

We also request the opportunity to appear for a personal hearing before the Registration Board in its upcoming meeting, so we may present our case in detail.

We look forward to your kind understanding and remain available to provide any further documents or clarification you may require."

8. Accordingly, the firm has been issued notice of personal hearing to appear before the Board, under Section 42 of the Drug Act 1976.

Proceeding and Decision of 351st meeting of Registration Board

In compliance to the show cause notice and personal hearing letter issued, Mr. Rasul Muhammad Production in charge and Mr. Arbas. M- Dainsh, Quality Control Manager of M/s. Medicon Pharmaceutical Industries (Pvt.) Ltd., Peshawar appeared before Board. They stated that according to in-house Quality Control testing, the concerned batch was within acceptable specifications. In response to the Board's query regarding the number of Medi-Lox Tablet batches manufactured after Batch No. 425, it was informed that only one batch was manufactured.

The Board after considering the facts of the case and after thorough deliberations decided:

- i. Submission of RCA and CAPA by the firm.**
- ii. Product Specific Inspection including verification of RCA and CAPA by panel of inspectors/experts to be nominated by Director QA/LT.**
- iii. Directed the Area FID for fresh sampling of batches manufactured by the firm (if any) after manufacturing of Medi-Lox Tablet Batch No. 425.**
- iv. Suspension of the Registration of Medi-Lox Tablet, Registration No. 056133 manufactured by M/s. Medicon Pharmaceutical Industries (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 constituted by the Director QA/LT with satisfactory report; whichever is earlier.**

Case No. 5: PERMISSION FOR EXTENSION IN ORDER NOT TO DISPOSE OF UNDER SECTION 18 (1)(i) OF THE DRUGS ACT, 1976.

A complaint was received in DRAP from Afzal corporation that M/s United International have been importing Metronidazole Injection 100ml in Glass bottle, but suddenly they have recently imported Metronidazole Injection 100ml in PP bottle under same Registration Number, while M.R.P of both Packing's i.e Glass bottle and PP bottle are different.

Deputy Director, DRAP, Karachi, Mr. Asfandiyar Ajab Khan, visited M/s Qasim Traders, Katchi Gali, Karachi, on 1st August 2025. During the visit, he collected a sample of **Metronidazole Injection 0.5% (500mg/100ml)** and forwarded it to the Federal Government Analyst for testing and analysis on the prescribed Form-3. Furthermore, an Order "Not to Dispose Of" was issued on the prescribed Form-I, dated 1st August 2025, initially for a period of 28 days, directing that the following stock must not be disposed off.

Name of Product	Manufacturer	Reg. NO	Batch No.	Mfg. date	Expiry date	Qty.
Metronidazole Injection 0.5% 500mg/100ml	M/s Wuhan Grand Pharmaceuticals Group Co. Ltd, China Imported by M/s Qasim Traders, Katchi Gali, Karachi	044855	2503104	03/2025	02/2028	100ml X 1 bottle X 100 X 1050

2. He requested permission to retain the specified stock of the drug, which had been ordered "Not to be disposed of", for an extended period under Section 18(1)(i) of the Drugs Act, 1976.

Sub-paragraph (i) of paragraph (1) of Schedule-V of the DRAP Act 2012 read with the Drugs Act 1976 states that "*forbid for a reasonable period, not exceeding four weeks or such further period, which shall not be more than three months, as the Inspector may, with the approval of the Provincial Quality Control Board, the Licensing Board, the Registration Board, as the case may be, specify, any person in charge of any premises from removing or dispensing of any therapeutic good, article or other thing likely to be used in evidence of the commission of an offence under this Act or the rules; and*"

3. The request for grant of permission for keeping the above mentioned stock Ordered not to dispose of for further three months under sub-paragraph (i) of paragraph (1) of Schedule-V of DRAP Act 2012 read with Section 18(1)(i) of the Drug Act, 1976 was acceded by Chairman Registration Board and submitted for ratification.

4. Moreover, the said stock was imported by M/s Qasim Traders in plastic containers, whereas M/s United International (Address: Plot No. MR-1/122, Madina Centre, 3rd floor, Kutchi Gali No. 2, Marriot Road) PRV-approved letter dated 22-08-2025, primary packaging material for Metronidazole Injection 500mg/100ml Reg No. 044855 is glass vials.

Proceeding and Decision of 351st meeting of Registration Board

Minutes of 351st Meeting of Registration Board (23rd – 24th September, 2025)

The Board after reviewing the facts and noting that M/s United International, Karachi had been importing Metronidazole Injection 0.5% simultaneously in both glass and plastic containers under the same registration number, decided as under:”

- i. *To issue show cause notice to M/s United International Karachi for import of product in different container closure system without any regulatory approval and not printing the name of importer/registration holdersr, under Section 42 of the Drugs Act, 1976 and*
- ii. *To call the representatives of the firm for personal hearing before Registration Board in its forthcoming meeting.”*

Case No.6: RESEMBLANCE OF COLOUR SCHEME, DESIGN AND ARTISTIC WORK AND PACKAGING

M/s GlaxoSmithKline Pakistan Limited (Company) Submitted an application dated 01-01-2025 Wherein they stated that they have been marketing and selling “Septran DS” in Pakistan which has been registered in DRAP holding Registration No. 008752 and with the trademarks Registry at the intellectual Property of Pakistan.

2. They further stated that Rasco Pharma, Lahore has been manufacturing and marketing a product under the brand name “Rascotran DS”. The Packaging, design, artistic work and colour scheme of the product is visually identical and deceptively similar to their product.

3. As Rascotran DS packaging is in violation of the provisions of the Trade Marks Ordinance 2001 and the Drugs Act 1976, we have enforced this before the Intellectual Property Tribunal, Lahore in suit no. 264/IPT/2024 wherein the Presiding Officer, IPT Lahore has been pleased to restrain Rasco Pharma from manufacturing, advertising, marketing, offering for sale in the market and participating/offering tenders in the public and private procurement using the color scheme infringing to that of the Product and the two lions devices for Rascotran DS suspension in any manner whatsoever.

4. In light of the above, they requested to support to restrain Rasco Pharma from packing, distributing, selling or offering for sale the product "Rascotran DS" and request the recall of the Infringing Product from the market.

5. Legal Division of DRAP said that *“The subject case is a classic example of counterfeit drugs as defined under the Drugs Act, 1976. The alleged counterfeiter may be asked to change his label design. A show cause may be issued for suspension or cancellation of registration under section 7(11) of the Drugs Act ready with section 42 thereof.”*

Proceeding and Decision of 351st meeting of Registration Board

The Board, after deliberations, observed resemblance in the colour and design pattern of the primary and secondary labels and packaging of Septran DS (Reg. No. 008752) manufactured by M/s GlaxoSmithKline Pakistan Limited, and Rascotran DS (Reg. No. 057202) manufactured by M/s Rasco Pharma, Lahore, which may attracts provision of Section 3(f) read with Section 23(1)(ii) of the Drugs Act, 1976 .Therefore, the Board decided to direct the firm M/s Rasco Pharma, 5.5 KM, Raiwind Road, Lahore to immediately change the colour scheme of their product's packaging Rascotran DS (Reg. No. 057202) and submit their request for Post Registration Variation (PRV) in PE&R Division of DRAP .

Case No. 7: RECALL OF PHARMIX PRODUCTS DUE TO PRESENCE OF IMPURITIES

Incidents and Substandard/Falsified Medical Products (ISF), Regulation and Safety unit, World Health Organization informed regarding the identification of DEG/EG (via TLC testing) by Maldives Food and Drug Authority, Ministry of Health, Republic of Maldives (the sample was forwarded to TGA Australia for detailed testing via GC-FID analysis) in product namely Alergo Syrup Batch No. B220 (Mfg. Date: 16-02-2022 Exp. Date: 15-02-2024) manufactured and exported to Maldives by M/s. Pharmix Laboratories Lahore.

2. Subsequently, a panel of inspectors from DRAP Lahore office comprising of Mr. Abdul Rashid Shaikh, FID Lahore and Mr. Ishtiaq Shafiq Assistant Director, Lahore inspected the premises of M/s. Pharmix Laboratories Lahore on 10-11-2023.

3. Summary of the said report is given as under:

- In response to the information received from WHO, the panel inspected the firm on 10-11-2023. The panel has informed that M/s. Pharmix Laboratories Lahore had manufacturer batch No. B220 (Batch size 600L) of their product Alergo Syrup on 16-02-2022. The said batch contained sorbitol solution 70%, glycerin, and propylene glycol in its master formulation.
- The firm distributed the batch in Maldives (3000 packs), Laos (5000 packs), Belize (200 packs) Fiji (300 packs) and 400 packs locally in Pakistan. Firm has provided the details of NOC obtained from DRAP Lahore as Annex-A.
- Firm has provided details of the source of suspected excipients as under and has provided COAs of same:

S. No.	Name of Material	Name of Manufacturer
01	Sorbitol Solution 70%	PT Sorini As a Corporindo, Indonesia
02	Glycerin	PT Musim Mas Indonesia
03	Propylene Glycol	Dow chemical Pacific(Singapore)

- During inspection it was observed by the panel that in certificate of analysis, principle manufacturer has performed the impurity testing in the purported raw material of glycerin and propylene glycol. However, impurity testing was missing in the COA of the Sorbitol. Moreover, firm has not performed the impurities testing in-house or through a third party. It was also revealed that firm has same source of propylene glycol and glycerin (firm provided the report of third- party impurities testing conducted in 2023). However, firm has changed the source of sorbitol in December 2022

- Panel directed the firm to recall the batches of products containing the suspected excipients and took following samples as a part of risk-based approach for the purpose of test/analysis and directed the firm to stop the production of all oral liquid dosage forms and also hold available products and raw material in their warehouse till the finalization of results. In compliance to the directions firm has submitted an undertaking.
4. The panel further informed that M/s. Pharmix Laboratories Lahore has manufactured following products from the suspected contaminated batches:

S#	Product Name	Batch No.	Mfg. by
01.	Mucorid Syrup	A230, B201, B224, B225, C210, C227, L111, L121, A210, A211, A212, A230, B201	M/s. Pharmix Laboratories (Pvt.) Ltd., 21-Km Ferozpur Road, Lahore.
02.	Ulcofin Suspension	B209, C223	-do-
03.	Alergo syrup	B220, L126	-do-
04.	Emidone Suspension	B227	-do-
05.	Zincell Syrup	C218	-do-

5. In the light of above-mentioned inspection report, the division of QA&LT issued directions to M/s. Pharmix Laboratories Lahore to recall the products from both National and International Markets, issued Public notice on DRAP's website and informed the Regulatory Agencies of importing countries to recall the suspected products from their markets as well. Moreover, DRAP Karachi was also directed to inspect the suppliers of raw materials. DRAP Karachi team visited premises of M/s. United Chemicals Karachi (Supplier of Sorbitol) and M/s. Brother Enterprises Karachi (supplier of Propylene Glycol and Glycerin) and took samples of available raw materials from the later and forwarded the samples to CDL Karachi for the purpose of test/analysis. CDL Karachi vide report RM-11-23-000230 dated 21-12-2023 and RM-11-23-000231 dated 19-12-2023. Details of reports are as under:

S#	Raw material	B. No.	Mfg. by	Test	Result
01	Propylene Glycol	C815N4HR41		Ethylene Glycol	Not detected
			M/s. Dow Chemicals, Thailand.	Diethylene Glycol	Not detected
02	Glycerin 99.7% USP	000243IMD3C5L	M/s. PT Musim Mas Indonesia	Ethylene Glycol	Not detected
				Diethylene Glycol	Not detected

6. Details of CDL test/analysis reports of samples sent by the inspection panel of Lahore office from the premises of M/s. Pharmix Laboratories Lahore are given as under:

S#	Product name	Mfg. by	B. No.	CDL Report No.	Results
01	Allergo Syrup 120ml	M/s. Pharmix Laboratories (Pvt.) Ltd., Pakistan	L210	LHR-11-23000038	EG content: 1.1116% DEG content: 0.1584%

02	-do-	-do-	B220	LHR-11-23000026	EG content: 0.8874 % DEG content: 0.1087%
03	-do-	-do-	H231	LHR-11-23000053	EG content: 1.4282%
04	-do-	-do-	C231	LHR-11-23000054	EG content: 1.2158%
05	-do-	-do-	J242	LHR-11-23000039	EG content: 1.2366%
06	-do-	-do-	D224	LHR-11-23000041	EG content: 1.3484%
07	-do-	-do-	G204	LHR-11-23000037	EG content: 1.6828%
08	Allergo Syrup 60ml	-do-	L210	LHR-11-23000040	EG content: 1.4933%
09	Mucorid syrup	-do-	C227	LHR-11-23000029	EG content: 9.8709%
10	-do-	-do-	B224	LHR-11-23000028	EG content: 14.9891%
11	-do-	-do-	B201	LHR-11-23000030	EG content: 17.5004%
12	-do-	-do-	C210	LHR-11-23000031	EG content: 14.4483%
13	-do-	-do-	A210	LHR-11-23000047	EG content: 12.7868%
14	-do-	-do-	B225	LHR-11-23000032	EG content: 10.9240%
15	-do-	-do-	A230	LHR-11-23000033	EG content: 12.0895%
16	Ulcofin syrup	-do-	B209	LHR-11-23000027	Complies with standard
17	-do-	-do-	L218	LHR-11-23000046	Complies with standard
18	Lorate suspension	-do-	J210	LHR-11-23000049	EG content: 1.9558%
19	Iropal syrup	-do-	H225	LHR-11-23000052	EG content: 12.8300%

7. Furthermore, Therapeutic Goods Administration (TGA) Australia has also declared the presence of said impurities in samples sent to them for the purpose of test/analysis by Maldives Food and Drug Authority, Maldives.
8. In the light of above-mentioned, the division of QA&LT, issued letter for suspension of production in the oral liquid section and show-cause notice to M/s. Pharmix Laboratories Lahore vide letter 03-41/2023-QC dated 08-12-2023.
9. M/s. Pharmix Laboratories Lahore vide letter dated 30-12-2023 has made following submissions:

- “(1) Before receiving Lab Test reports from anywhere, we recalled all Liquid syrup & suspension batches manufactured in the year 2022 which even were not mentioned in DRAP Alert No. No I/S/11-23-40 and complete recall data is attached herewith.*
- (2) On 08-11-2023, our Maldivian importer informed that MFDA is suspecting EG/DEG impurity in Alergo Syrup but still the batch number has not been declared and when MFDA will confirm the Batch number, they will inform us. On receiving this information, we immediately sent samples of our Alergo Syrup batch K222 to PCSIR for EG/DEG testing as we were not aware about the batch number reportedly suspected by MFDA, so we sent samples to PCSIR of the Last batch which we exported to Maldives. We received report from PCSIR Labs on 21-11-2023 that No DEG/EG impurity has been detected (PCSIR report of Alergo Batch K222 which was manufactured in 2022 is attached) whereas for the same Alergo Batch Number K 222 mentioned in MFDA Alert reports that EG is present (Copy is attached).*
 - (3) The CDL reports for batch numbers B220 & L210 of Alergo Syrup state that both DEG & EG impurities are present while WHO has mentioned that as per TGA Australia only EG impurity is present for the both above batches.*
 - (4) Your kind self know that in liquid manufacturing whole of the batch manufacturing process is completed in ONE CYCLE (“batch” means a quantity of any drug produced during a given cycle of manufacture;). At the Packing Stage companies pack in 60 ml & 120 ml as per their market need. DRAP officials took samples of Alergo Syrup Batch No L210 in both pack sizes i.e. 60ml & 120 ml to send to CDL. On receiving the reports, we found that in 60 ml pack sample CDL Lab result, DEG Was Not detected WHILE in 120ml pack size, both DEG & EG were detected WHEREAS in both reports of 60 & 120 ml, the value of EG were also different and can be checked in CDL Reports. (5) On 06-12-2023 we sent Alergo Syrup Batch number J242 to PCSIR for DEG & EG testing. PCSIR report declares that there is No DEG/EG impurity in Glycerin & Propylene glycol used (Report is attached) while for the same batch number J242 Sample, CDL declared that EG impurity is Present. Respected Sir, we respectfully want to express that quantification of DEG/EG impurity from the Finished pharmaceutical product is different because your kindness know that in finished products other than solvents (sorbitol, glycerin & propylene glycol) some other excipients and different API are also present and without analyzing /extracting on individual excipients, the lab results could be perplexing.*
 - (6) Sir, the reference limit (0.1%) mentioned on CDL reports are for individual solvents (Glycerin. Propylene glycol & Sorbitol) Not For The finished pharmaceutical products. Regarding Finished Pharmaceutical Products limits, we humbly request you to please check below mentioned Allowable Threshold of DEG & EG which is 0.5 mg/Kg Body weight per day. (Jakarta Indonesia BPOM reference - A PIC/S member country regulatory body (<https://picscheme.org/en/members>))*
 - (7) We are in syrup manufacturing since more than 12 years and by the grace of Allah SWT hundreds of thousand packs of our manufactured syrups have been safely consumed in Pakistan and in other countries. We are in practice to perform pharmacovigilance, Adverse reporting data forms of different products from doctors of different cities of Pakistan. Adverse drug reporting forms of Mucorid and Alergo syrup are attached here with (thanks to Allah SWT no Adverse reaction has been reported- ADR data is attached).*
 - (8) Sir, Pakistan Pharmacopoeia, European Pharmacopoeia 10th addition & BP 2023 clearly state that ONLY GLYCERIN should be tested. Whereas European Pharmacopoeia Commission (EPC) has just revised monograph on Propylene glycol in November 2023 (Pharmacopoeial Test References Are Attached) while we started*

tests for the impurities of solvents (Sorbitol, glycerin, Propylene glycol) by TTI Labs & PCSIR before any alert and in this regard want to bring in your kind knowledge that the current lots of Solvents (Sorbitol, Glycerin and Propylene glycol) present in our warehouse have also been sampled by respected Federal Inspector of drugs Lahore which has been declared Standard Quality by CDL (Reports are attached). ”

10. Keeping in view the above-mentioned facts, representatives of firm are called before the Board for personal hearing.

11. Proceedings and decision of 335th meeting of the Board:

In compliance to the show cause and personal hearing letter issued, Dr. Shahzad Ahmad, Director and Mr. Fayyaz Ahmad, Director of M/s. Pharmix Laboratories Lahore appeared before the Board. The representatives of the firm raised concerns regarding the testing method adopted by the Central Drugs Laboratory Karachi and assured the Board that they have revised their procedures so that such incidents could not occur in future. The Board after thorough deliberations, considering the facts of the case and keeping in view the submission made by representatives of M/s. Pharmix Laboratories Lahore decided as under:

- i. *The division of QA&LT to conduct a GMP inspection of firm by a panel nominated by the Director (QA&LT) at the earliest as the production has been resumed which was suspended by the QA Division on 08-12-2023*
- ii. *Destruction of stocks recalled by the firm. The process of destruction of stocks will be carried out in the presence of area FID Lahore or a person nominated by the Additional Director DRAP Lahore. The area FID Lahore or the nominated person will submit a detailed report of the process to the division of QA&LT.*
- iii. *In addition, the board directed the QA division to revise the advisory regarding the testing of EG & DEG and allow the testing from all WHO prequalified labs and CDL, Karachi.*

12. In compliance to decision of 335th meeting of registration Board Panel compromising of Mr. Faisal Shazad, Additional Director, DRAP, Lahore and Mr. Ishtaiq Shafiq Assistant Director, Lahore conducted inspection of M/s Pharmix Laboratories, Lahore dated 2-10-2024 & 19-11-2024. The Panel recommended that:

- i. The firm must review all the process and re-initiate or review in depth their quality risk management process taken for the EG/DEG contamination control. Accordingly develop a comprehensive CAPA plan and implement CAPA before applying for resumption of production in syrup section.
- ii. CAPA implementation must be verified by panel of experts from DRAP to ensure that necessary steps have been implemented to avoid reported contamination.
- iii. The firm must develop an overall contamination control strategy to cover all the products so to avoid any such incidence in future.
- iv. Training of technical persons and staff must be conducted on risks associated with contamination and contamination controls.
- v. And/or any other course of action as the Competent Authority or relevant Board under the DRAP, Act 2012 may deem fit.

13. Letter to M/s Pharmix Laboratories, Lahore was issued by Division of QA&LT vide letter of even No. F.No.03-41/2023-QC dated 28th January, 2025 for developing a comprehensive CAPA plan and implementation of CAPA before applying resumption of production in Syrup Section.
14. M/s Pharmix Laboratories (Private) Limited submitted CAPA dated 04th February, 2025 in response to this division letter as per the recommendations of the DRAP inspection panel. They also submitted CAPA report to the Lahore office.
15. Letter to panel comprising of Mr. Ishtaiq Shafiq, Deputy Director, DRAP, Lahore and Mr. Umar Latif, Deputy Director QA&LT, DRAP, Islamabad for CAPA verification of M/s Pharmix Laboratories Lahore was issued vide letter No. F.03-41/2023-QC dated 19th February, 2025.
16. The Panel conducted inspection regarding CAPA verification dated 13-06-2025. The recommendation of panel are as follow:

Conclusion & Recommendation:

The inspection of M/s. Pharmix Laboratories (Pvt.) Ltd., Lahore was conducted on 13-06-2025 with reference to DRAP Islamabad letter no. F.03-41/2023-QC, dated 19-02-2025 for to verify the rectification status of the observations regarding Oral liquid section from the inspection dated 02-10-2024 & 19-11-2024. There was no manufacturing activity going on at the time of inspection therefore active operations were not witnessed in Oral liquid section.

In the light of the inspection conducted by the panel and based on the findings given above, it was noted that the firm had rectified Majority of the shortcomings reported in the previous inspection. The firm was advised improvements as detailed above in the report.

In view of the above, the panel recommend the resumption of production in the Oral Liquid Section.

Proceeding and Decision of 351st meeting of Registration Board

The Board, after considering the facts of the case, recommendations of panel of experts in its report dated 13.06.2025 and thorough deliberations, decided to allow resumption of production activities in the Oral liquid section of M/s. Pharmix Laboratories (Pvt.) Ltd., 21-Km Ferozpur Road, Lahore.

**Case No. 8: MANUFACTURE AND SALE OF SUBSTANDARD MANADOL
SUSPENSION (PARACETAMOL) BATCH NO. 4MD-005
MANUFACTURED BY M/S MASFA INDUSTRIES (PVT.) LTD LAHORE**

FID-III, DRAP, Lahore dated 10-09-2014 took the sample from M/s Masfa Industries (Pvt.) Ltd Lahore. CDL vide report No. LHR230/214 dated 02-10-2014 declared the sample as substandard on the basis of assay test i.e. 70.15% (Limit 95% – 105%). Thereafter, the firm challenged the test/analysis report and requested for appellate testing. Appellate laboratory vide their test report No. 020MNHSR/2014 declared the sample as of substandard for assay (54.7%) and description, as the glass bottle was having undissolved masses which do not disperse even on shaking.

2. Accordingly, a show-cause notice was issued dated 24-11-2015. Registration Board in its 257th meeting dated 24-25/03/2016 decided to suspend the registration of Manadol suspension (Paracetamol) for 6 months and to conduct the PSI from the following panel;
 - i. Director DTL Punjab, Lahore.
 - ii. Area FID.
 - iii. ADC, Lahore.
3. The report from DRAP office Lahore dated 27-12-2016 was received and the case was presented before the Registration Board in its 266th meeting held on 07-02-2017 and board decided as under;
 - i. QA Division should consider the GMP issues of the firm M/s Masfa Industries (Pvt.) Ltd, Lahore, like use of old bottles in syrup manufacturing instead of new ones as it is violation of GMP.
 - ii. The firm M/s Masfa Industries (Pvt.) Ltd, Lahore, shall submit accelerated and real time stability studies of 03 batches for 06 months of the product Manadol suspension.
 - iii. The registration of the product Manadol Suspension, Reg. No. 071558 will remain suspended till the submission of stability studies by firm M/s Masfa Industries (Pvt.) Ltd, Lahore, for consideration of Registration Board.
4. The above decision of the Registration board was issued on 2-05-2017 and in response the firm submitted a reply which was presented before registration Board in its 274th meeting. The Registration Board after detailed discussion, deliberation and necessary evaluation of stability studies submitted by the firm decided that firm M/s Masfa Industries (Pvt.) Ltd., Lahore will resubmit the stability studies as per decision of the Registration Board in its 266th meeting dated 07th February, 2017. The registration of the product Manadol Suspension, Reg. No. 071558 will remain suspended till the submission of stability studies by firm M/s Masfa Industries (Pvt.) Ltd, Lahore, as per decision of the Registration Board
5. The firm on 06-09-2018 submitted their reply wherein they have enclosed the accelerated and real time stability studies of 03 batches for 06 months, Purchase invoice of raw material, HPLC chromatograms for assay determination, Stability chamber study data, Storage condition for long term and accelerated condition. Provided data was evaluated by QC section and was not accepted and accordingly, letter was issued to the firm dated 26-10-2018.
6. The case is now placed before Registration Board for guidance on the matter as the product is suspended since March 2016.
7. **Proceedings and decision of 339th meeting of the Board:**

Registration Board decided to conduct the product specific inspection for verification of manufacturing and testing facilities of the said product and submit report within 15 working days for consideration of the board.
8. Letter to panel comprising of Mr. Asadullah Deputy Director, DRAP, Islamabad and Mr. Hafiz Sanaullah Babar Deputy Director, DRAP, Islamabad was issued vide letter No. F.03-28/2024-DDLT (339-RB) dated 30th October, 2024.
9. After resignation from the post of Mr. Asadullah Deputy Director, DRAP, Islamabad, Mr. Ishtaiq Shafiq, Deputy Director, DRAP, Lahore was nominated.
10. Panel conducted product specific inspection dated 14-02-2025 and 08-08-2025.

Details of Product Specific Inspection (PSI) of Manadol suspension:

Minutes of 351st Meeting of Registration Board (23rd – 24th September, 2025)

To conduct the analytical method verification, product development and stability studies as directed by the Board, the Firm had developed six batches of product Manadol suspension (Paracetamol 120mg/5ml) i.e. three batches TBM-1A, TBM-2A and TBM-3A for accelerated stability studies (storage conditions: Temp: 40°C ± 2°C; RH: 75% ± 5%) and three batches TBM-1L, TBM-2L and TBM-3L for long term stability studies (storage conditions: Temp: 30°C ± 2°C; RH: 65% ± 5%). The duration of the stability study was of six months i.e. from 09-02-2018 onwards and the size of each batch was 2L.

Firm had tested the samples of each batch at 0, 3 and 6 months' interval. After the stated intervals, the firm had conducted following analysis as per provided COA: Physical description, odor & taste, average volume, pH, weight/mL and assay. Firm is utilizing BP testing protocol for chemical analysis details of chromatic conditions are as follows:

System	: HPLC (LC 110)
Column	: C-18 type SS
Dimensions	: 25cm*4.6mm
Temperature	: Ambient
Flow rate	: 1ml/min
Detector	: UV at 243nm
Injection volume	: 20 microliters

Copies of Paracetamol Oral suspension BP monograph, Stability protocol and stability data of mentioned batches provided by the firm. The results of the stability studies provided by the firm were reviewed and found to be satisfactory.

CONCLUSION & RECOMMENDATIONS

In conclusion, after reviewing the documentation submitted by the firm, inspecting the premises, noting the positive attitude and intent of the management, the panel is of the view that M/s. MASFA industries (Pvt.) Ltd., 17-Km Sheikhpura Road, Lahore may be granted resumption of production of their product namely "Manadol suspension (Paracetamol 120mg/5ml) subject to the standard test/analysis report of the product from CDL Karachi of first three full scale batches of product.

Proceeding and Decision of 351st meeting of Registration Board

The Board, after considering the facts of the case, recommendation of panel in its report dated 08.08.2025 and thorough deliberations, decided as follows:

- i. To resume production of Manadol Suspension, Registration Number 071558 of M/s. MASFA industries (Pvt.) Ltd., Lahore.**
- ii. Firm shall inform area FID to take sample from 1st commercial batch for the purpose of test/analysis by CDL Karachi and sale of the product is subject to declaration of samples as of standard quality by the Central Drugs Laboratory, Karachi and subsequent approval by Director (QA&LT).**

Item No. IV Additional / Supplementary Minutes.

Miscellaneous

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 Submitted Not

5.	030525	Globinan 1Ml Injection Hydroxy Progesterone	Global Pharmaceuticals Pvt Ltd	Renewal Submitted	Not
6.	013624	VIO-DEPOT INJ Each ml contains: Hydroxyprogesterone caproate.....250mg	Venus Pharma, 23 Km Multan Road Lahore. , Lahore	Renewal Submitted	Not
7.	003746	HYDROXYPROGESTERONE INJECTION Each ml contains: Hydroxyprogesterone caproate.....250mg	Haji Medicines, Rawalpindi	Renewal Submitted	Not
8.	003833	HYDROXYPROGESTERONE Each ml contains: Hydroxyprogesterone caproate.....250mg		Renewal Submitted	Not

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 Submitted Not
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) of the Drug Act, 1976 read with section 42 thereof 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.

9. (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., Hydroxyprogesterone 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, Iran, 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.
If 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 (Hydroxyprogesterone 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 (Hydroxyprogesterone 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 establishes 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. *Currently 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.

If 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.

16. **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 was called for personal hearing.

17. **Proceedings of 331st Meeting:**

Dr. Aftab Ahmed Khan, Head of Regulatory Affairs and Dr Masroor Ahmed, Sr. Medical 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 Proluton of M/s. Bayer. Proluton is also available in Austria which was also confirmed from website

<https://aspreghister.basg.gv.at/aspreghister/faces/aspreghister.jspx;jsessionid=MBTSW0JJJ6iHyhL8nRipVJit>

[Ty-3qEb7-xNnE54qIcZaCU5sSJMr!2098280154?_adf.ctrl-state=11ajcl0qd9_4.](https://aspreghister.basg.gv.at/aspreghister/faces/aspreghister.jspx;jsessionid=MBTSW0JJJ6iHyhL8nRipVJit)

Firm has also submitted Austria approved indication of Proluton 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.

If 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.

18. **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.

19. 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

19. Decision of 343rd meeting of Registration Board:

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.

20. Proceedings of 346th meeting of Registration Board:

In light of above decision of the Board, showcause letters have been issued to firms and firm have also been called for personal hearing. In response to show cause notice, following firms submitted their responses which is as under:

Sr. No.	Name of Firm	Brief Response
1.	M/s Bayer Pakistan (Pvt) Limited Karachi.	We, Bayer Pakistan (Pvt) Ltd, would like to highlight that based on the recommendations of EMS's Pharmacovigilance Risk Assessment Committee (PRAC), we have already informed DRAP via letter no. BPPL-DRAP-24-039 dated 01 st Aug 2024 stating that registration of Proluton Depot is no longer valid and has lapsed following the divestment of the licensed facility to OBS Pakistan.
2.	M/s. Global Pharmaceutical (Pvt) Ltd, Islamabad.	In accordance with the esteemed registration board's guidance, we have decided to withdraw the registration of our product.

21. Decision of 346th meeting of Registration Board:

Registration Board considered the below mentioned decision of Coordination Group for Mutual Recognition and Decentralized Procedures – Human (CMDh) of European Medicine Agency (EMA):

“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 light of above decision of European Medicine Agency for suspension of medicines containing 17-Hydroxyprogesterone caproate (17-OHPC), Registration Board under Section 7 (11)(b), (c) and (d) of the Drugs Act, 1976 read with rule 30(10) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 decided as under:

- i. To suspend the registration of following products containing 17-Hydroxyprogesterone caproate (17-OHPC):***

Sr. No.	Reg. No.	Product Name & Composition	Registration Holder / Manufacturer
1.	096479	Nandrosol 250mg Injection Each ml contains: Hydroxyprogesterone caproate....250mg	Pharmasol (Pvt) Ltd, Plot 549, Sunder Industrial estate, Lahore., Lahore
2.	094205	Hygest Injection Each ml contains: Hydroxyprogesterone caproate....250mg	Shaigan Pharmaceuticals (Pvt) Ltd
3.	003531	Hydroxyprogesterone Injection Each ml contains: Hydroxyprogesterone caproate....250mg	M/s. Zafa Pharmaceutical, Karachi.
4.	030526	Globinan 2Ml Injection Hydroxy Progesterone Caproate.... 250mg	Global Pharmaceuticals Pvt Ltd
5.	030525	Globinan 1Ml Injection Hydroxy Progesterone	Global Pharmaceuticals Pvt Ltd
6.	013624	VIO-DEPOT INJ Each ml contains: Hydroxyprogesterone caproate.....250mg	Venus Pharma, 23 Km Multan Road Lahore. , Lahore
7.	003746	HYDROXYPROGESTRONE INJECTION Each ml contains: Hydroxyprogesterone caproate.....250mg	Haji Medicines, Rawalpindi

- ii. Registration of Proluton Depot bearing Registration No. 000899 in name of M/s Bayer Pakistan (Pvt) Limited 108 Kot Lakpat Industrial Estate Lahore is no longer valid as it was not divested to any company in Pakistan after acquisition of of aforesaid facility by M/s OBS Pakistan.***
- iii. Decision of suspension of 17-Hydroxyprogesterone caproate (17-OHPC) shall be placed again before the Registration Board once matter is further proceeded by the Coordination Group for Mutual Recognition and Decentralized Procedures – Human (CMDh) of EU.***
- iv. To issue show cause and personal hearing notice to the companies having registration of 17-Hydroxyprogesterone caproate (17-OHPC) in combination with other drugs.***

In line with the point **iv** of above-mentioned decision, show cause notices were issued to following firms on 27.06.2025.

Sr. No.	Reg. No.	Product Name & Composition	Registration Holder / Manufacturer	Renewal Status
1.	103324	Kevi Injection Each ml contains: Hydroxyprogesterone Caproate.....250mg Estradiol valerate.....5mg	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.....250mg Estradiol Valerate.....5mg	Shaigan Pharmaceuticals (Pvt) Ltd	Renewal is valid
3.	077108	Z-Bron Injection Each ml contains: Hydroxyprogesterone Caproate.....250mg Estradiol Valerate.....5mg	Pharma Health Pakistan (Pvt) Ltd.	Renewal is valid
4.	011155	Vio-Depot Injection Hydroxyprogesterone Carpoate..... 250mg Estradiol 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

Subsequently, above-mentioned firms have also been called for personal hearing before the Board on 24.09.2025 at 10:00 AM (vide notices issued on 04.09.2025).

Proceeding of the 351st meeting of the Board

Mr. Humayoun Mughal on behalf of M/s. OBS Pharma (Pvt) Ltd., Lahore appeared before the Registration Board and requested to grant four months time for submission of safety and efficacy data of under question product. He informed that Agha Khan Hospital, Karachi has the data of the use of this product in local population since year 2001 and they have signed an agreement with Agha Khan Hospital, Karachi for sharing this data. Data sharing and its compilation will take time. The Registration Board may decide the case on the basis of actual data of safety and efficacy in local population.

Decision:-

The Registration Board acceded to the request of the firm for granting four months time for sharing data of local use of the Gravibinon Injection with the condition that agreement be shared immediately with PE&R Division after signing with Agha Khan Hospital.

Case No. 02: Applications for Registration of Capsules Containing Linaclotide, a Synthetic Tetradecapeptide.

The pharmaceutical Evaluation and Registration (PE&R) Division has received multiple applications for registration of Linaclotide capsules. Some of them are approved and some are under evaluation. The applications and their status is tabulated below;

Table 1				
S. No	Track ID	Company	Product	Status
1.	1BU-WE8-JVS1	PHARMEVO (PVT) LTD.	Lintide 145mcg Capsule Linaclotide.... 145 mcg	Approved
2.	3PN-M7L-NE24	Ferozsons Laboratories Limited	Linaxa Capsules 290mcg Linaclotide.... 290 mcg	under process
3.	3XU-AZV-1TZQ	AGP Limited	Linatide 145mcg Capsule Linaclotide pellets eq. to linaclotide.... 145 mcg	under screening
4.	7GP-JTL-RZ1E	AGP Limited	Linatide 72mcg Capsule Linaclotide pellets eq. to Linaclotide.... 72mcg mcg	under screening
5.	EJU-M2J-LQ2W	PHARMEVO (PVT) LTD.	Lintide 72mcg Capsule Linaclotide.... 72 mcg	Approved
6.	EYS-RB3-YPUE	Kaizen Pharmaceuticals (Pvt) Ltd	Linaclo 72mcg Capsule Linaclotide 72 mcg	under process
7.	H9E-GQ2-A7V1	Ferozsons Laboratories Limited	Linaxa Capsules 145mcg Linaclotide.... 145 mcg	under process
8.	JAE-A1N-EDAP	Nabiqasim Industries (Pvt) Ltd.,	Lizcap 72mcg Capsules Linaclotide.... 72 mcg	Approved
9.	LEW-7AV-JQDR	Kaizen Pharmaceuticals (Pvt) Ltd	Linaclo 290mcg Capsule Linaclotide 290 mcg	Under Process
10.	LSA-34E-AXRG	AGP Limited	Linatide 290mcg Capsule Linaclotide pellets eq. to linaclotide.... 290 mcg	Under Screening
11.	MJ8-159-48A1	Nabiqasim Industries (Pvt) Ltd.,	Lizcap 290mcg Capsules Linaclotide.... 290 mcg	Approved
12.	PHT-A3B-WLH8	Neutro Pharma (Pvt.) Ltd.,	Cloti Capsule Linaclotide.... 290 mcg	Under Process
13.	TSN-H1B-LPXM	PHARMEVO (PVT) LTD.	Lintide 290mcg Capsule Linaclotide.... 290 mcg	Under Process
14.	WXE-8PN-W37Y	Ferozsons Laboratories Limited	Linaxa Capsules 72mcg Linaclotide.... 72 mcg	Under Process
15.	X8Z-AJZ-BJUW	Nabiqasim Industries (Pvt) Ltd.,	Lizcap 145mcg Capsules Linaclotide.... 145 mcg	Approved
16.	YM4-D8Y-25PN	Kaizen Pharmaceuticals (Pvt) Ltd	Linaclo 145mcg Capsule Linaclotide 145 mcg	Under process

2. Linaclotide 0.25mg film coated tablet of M/s Kaizen Pharmaceuticals (Pvt.) ltd. Karachi was approved in 347th meeting of the Registration Board and its registration has been issued vide No. 127951.

3. Linaclotide is a 14 aminoacid synthetic peptide with sequence CCEYCCNPACTGCY. It is used for treatment of constipation. It acts as an agonist of cell surface receptor of guanylate cyclase 2C in small intestines and results in stimulation of secretion of chloride ions, bicarbonate

ions and water into the intestines, resulting in accelerated transit in intestines. The drug is not absorbed in the blood; it acts on surface of intestines.

4. Being a peptide, its qualitative and quantitative assessment requires determination of Amino acids (AAA) and their sequence, determination of Optical Purity of Amino Acid derivatives and Peptides, oligomers/aggregated states etc. Further small synthetic peptides like semaglutide and tirzepatide are being considered by Biological Evaluation and Research (BE&R) Division and require Bio-Tech Section as per decision of 349th meeting of the Registration Board which is reproduced below;

“Registration Board deliberated the matter and decided that till finalization of guidelines on registration of Peptide containing formulation, Export only registrations of peptide containing formulations shall only be granted to those firm’s having Section approval from Central Licensing Board for bio-tech, r DNA or non-rDNA of DRAP provided that the manufacturer proves contaminations controls including cleaning validation according to relevant guidelines.”

5. The matter of small peptide drugs like Tirzepatide (39 amino acids) and Semaglutide (31 aminoacids) was deliberated, in detail, in 350th meeting of the Registration Board wherein BE&R division presented a working paper for registration of peptide containing products and the Board decided as under;

“The Board acknowledged the efforts of the Biological Evaluation & Research Division and approved the above criteria for the evaluation and approval of Peptide Drug Products either biotechnologically or chemically derived, with the following additional requirements:

- i. *Registration holders of Semaglutide and Tirzepatide shall conduct pharmacokinetic/ pharmacodynamic (PK/PD) equivalence studies using the reference product within six months of obtaining registration.*
- ii. *Initially, the registration holder shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so:*
 - a. *Peptide mapping.*
 - b. *Impurity profiling specifically peptide-related impurities.*

Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA&LT.

- iii. *Registration holders shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP’s licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.*
- iv. *The above requirements shall be incorporated as condition of registration and any violation shall be dealt in accordance with law including the cancellation of registration.*
- v. *This criterion shall be applicable on cases where registrations had been granted or under processing of issuance or will be processed in future.”*

6. As per decisions of 349th and 350th meeting of the Registration Board, linacotide, being a peptide drug requires to be manufactured in Biotech facility and its applications shall be processed by BE&R division to ensure harmonized process of evaluation for all peptides.

7. Matter is placed before the Board to decide the fate of products mentioned in Table-1, as some are approved and some are still under process. Further fate of Lincalo 0.25mg Tablet of M/s Kaizen Pharma needs to be decided as its registration is granted vide No. 127951 in general manufacturing facility.

Decision: The Board deliberated on the matter and keeping in view above facts about linacotide's recommended use and mode of action, decided that it shall continue to be manufactured in general products manufacturing facility and cases shall continue to be processed by PE&R Division as per guidelines for registration of pharmaceutical drug products.

Case No. 03: M/s E. Pharm Laboratories Karachi; Appeal No. 80/2024 before the Drugs Appellate Board in its 172nd Sitting.

Decision of appeal of M/s E. Pharm Laboratories Karachi against the Decision of Registration Board regarding "Ekasin-250mg" Injection made in its 339th meeting was received wherein the matter is remanded back to the Registration Board.

2. The case of the firm was presented in 339th meeting and was disposed off for being incomplete. The firm had approached the Appellate Board and their manufacturing facility details were verified from the licensing division.

3. The licensing division had stated that as per their record DML of the firm is valid and they forwarded a renewal letter wherein Sterile Liquid Injection(Ampoule/vials) is mentioned. On the basis of this Appellate Board has decided as under;

"4. Consequent to the above, the matter is remanded back to the Registration Board for deciding the appellant's application for registration of Ekasin-250mg Injection (Amikacin) afresh in accordance with law."

4. The extract of case presented in 339th meeting of the Registration board is given below for consideration in light of decision of 172nd sitting of the Appellate Board;

1.	Name and address of manufacture / Applicant	M/s Epharm Laboratories, A-40, Road No. 1, S.I.T.E, Super Highway, Karachi.
	Brand Name + Dosage Form and Strength	Injection AMIKACIN 250mg
	Composition	Each 2ml vial contains:- Amikacin (as Sulphate).....250mg
	Dairy No. date of R &I fee	Fast Track 23/10/2013, Dy# 264 R&I dated 23/10/2013 (Rs. 60,000/-)
	Pharmacological Group	
	Type of form	Form- 5
	Finished product specifications	USP
	Pack size and Demand Price	Rs.150 per 1x1ml, 1's
	Approval status of product in Reference Regulatory Authorities	

Me-too-status	Grasil Sami
GMP Status	
Remark of the Evaluator.	
Decision of 257 th RB	Deferred for confirmation of approval status of dosage form (250mg per 2ml) in same strength in reference regulatory authorities.
Remark of the Evaluator.	The firm vide letter No. nil dated 27.1.2023 has stated that RRA reference of applied formulation is not available so they want to revise the label as under; Each 1ml Ampoule contains; Amikacin (as Sulphate) 250mg (USP Specifications) The firm has submitted fee of Rs. 30,000/- vide slip No. 36503086. The firm has not submitted section approval letter and GMP certificate from which manufacturing facility could be verified.
Decision of 339th meeting of the Registration Board.: Considering the fact that firm has not submitted the section confirmation letter, the application is disposed off.	
Decision: APPROVED with following label claim; Each 1ml Ampoule contains; Amikacin Sulphate eq. to Amikacin 250mg (USP Specifications)	

Case No: 04: Amendment in Common Technical Document (CTD) Guidelines

The Division of Pharmaceutical Evaluation and Registration (PE&R) proposes updates to the "GUIDANCE DOCUMENT FOR SUBMISSION OF APPLICATION ON FORM 5-F (CTD)" to reflect recent, binding decisions of the Registration Board. These decisions were made to strengthen the regulatory framework concerning quality, safety, and efficacy and to meet the recommendations of World Health Organization (WHO) for regulatory benchmarking of DRAP for maturity level 3. The amendments will revise the relevant sections of Document PE&R/GL/AF/004 to include the following requirements:

- To ensure therapeutic equivalence and patient safety, the guidance will be updated to mandate that **Bioequivalence Studies** form an integral part of the registration application, per the Board's decision and subsequent notification of PE&R dated 17th July 2025.
- To improve the efficiency and completeness of dossier reviews, the guidance will now require the **Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL)** to be submitted concurrently with the CTD Dossier (Form 5-F) as per PE&R notification dated 01st August, 2025.

Approval is requested to formally amend the guidance document as per following details, thereby ensuring its alignment with current regulatory standards and Board directives.

Existing	Proposed

1.5.14 Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP). The submission against this point is optional.	1.5.14 Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP). The submission against this point is mandatory. The applicant shall submit as part of a Form 5F as per Annex-A of the DRAP Guidance document on SUMMARY OF PRODUCT CHARACTERISTICS GUIDELINES, that includes: • Name of drug product. • Qualitative and quantitative composition: <i><Clarify API's strength including its salt form or equivalency with respect to quantity of the active moiety (if applicable). The declaration of strength should appear only in Section 2 of the SmPC (Qualitative and Quantitative Composition) in a standardized format (active substance per dosage unit or per volume). For reference see DRAP Guidance document on SUMMARY OF PRODUCT CHARACTERISTICS GUIDELINES .></i> • Pharmaceutical form. • Clinical particulars: <i><For products on which DRAP has implemented interchangeability requirements as part of registration application, the clinical particulars shall be same as approved for the reference product by Reference Regulatory Authorities (RRA).></i> • <i>< Any clinical manifestations and effects on plasma levels and AUC of parent compounds or active metabolites and/or on laboratory parameters shall be mentioned for the applied products in concurrence with the BE studies performed by the applicant. In case of those products which does not currently fall under DRAP's BE notification, the submission of this information is optional.></i> • Pharmacological properties. • Pharmaceutical properties: <i>< In addition to the requisite information as outlined in the DRAP Guidance document on SUMMARY OF PRODUCT CHARACTERISTICS GUIDELINES, the details of diluents and reconstitution procedures should be included in the SmPC of such products which require reconstitution.></i> • Marketing authorization/ Registration holder. • Marketing authorization/Registration number. • Date from which marketing is authorized. • Date of revision of the text.
3.2.R Regional Information Product Interchangeability (Bioequivalence study reports): The submission against this point is optional.	3.2.R Regional Information Product Interchangeability (Bioequivalence study reports): The applicant will submit Bio-equivalence studies for molecules mentioned in the notification No-F-348-DRB-Addl-Dir (PE&R-I)/2025 dated 17th July, 2025. < While summary BE data may be presented in Module 2 of the Form 5F, the detailed study reports must be submitted under Modules 3 and 5 of the CTD, which should be considered mandatory for all applicable cases.>

	All Studies including comparative pharmacokinetic studies & comparative clinical trials or any other studies involving human subjects shall only be conducted after approval from the Clinical Studies Committee (CSC) as per the Bio-Study Rules, 2017. <i><For imported products, the approval of BE protocols from the regulatory authority of the country of origin/ or where BE studies have been performed shall be submitted.></i> The studies must be performed as per DRAP's GUIDELINE ON REGISTRATION REQUIREMENTS TO ESTABLISH THE INTERCHANGEABILITY OF PHARMACEUTICAL DRUG PRODUCTS.

Decision: The Registration Board approved the above stated revisions in CTD modules exemptions for compliance of IDPs for WLA and notification shall be issued for information and compliance by the stakeholders.

Case No: 05: Format for Summary Evaluation Report for Registration of Drug

To enhance regulatory efficiency and align with global standards, a standardized format for the Summary Evaluation and Report for registration of drugs has been developed to streamline and harmonize the assessment and evaluation procedures of Form 5-F among various evaluators within PEC.

This initiative is based on best international practices, including guidelines from leading regulatory authorities such as the European Medicines Agency (EMA), the U.S. Food and Drug Administration (FDA), and the World Health Organization (WHO). Adopting a unified reporting format facilitates consistent documentation, improves transparency, and supports rigorous, evidence-based decision-making across various stakeholders.

Moreover, the adoption of this Summary Evaluation Report is also a critical part of DRAP's journey toward regulatory benchmarking and achieving Maturity Level 3 as outlined in the WHO Global Benchmarking Tool (GBT). At this maturity level, regulatory processes are expected to be well-structured, standardized, and integrated ensuring both regulatory predictability and international trust.

Formal adoption and approval of the following Summary Evaluation and Report format are recommended to reinforce DRAP's commitment to quality, efficiency, and harmonization in pharmaceutical product evaluation, enabling it to meet internationally recognized regulatory standards and enhance public health protection.



Summary Evaluation Report for Registration of Drug <Name of the Drug, dosage form, Strength>

Product Name	i. [Proprietary Name] ii. [Generic Name]
Dosage Form	[e.g., Tablets, Injection]
Strength	[e.g., 10 mg, 250 mg/5 mL]
Route of Administration	[e.g., Oral, Intravenous]
Applicant	[Name and Address]
Application Number	[e-App Tracking ID]
Date of Submission	[DD-MM-YYYY]
Evaluator	[Name and Title]

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1. Executive Summary

1. General introduction to the product
2. Pharmacological class and intended clinical use
3. Marketing authorization status in Reference Regulatory Authorities
4. Summary of API and FPP characteristics
5. Manufacturing process overview
6. Control strategy and specifications
7. Bioequivalence requirements

2. Chemistry, Manufacturing, and Controls

2.1 Drug Substance

- a. **Manufacturer:** [The active substance is manufactured at <name and address of the site>. Satisfactory evidence of GMP compliance has been presented]
- b. **Evaluation:** [In case of provision of CEP by EDQM or provision of ASMF, mention < The relevant information has been assessed by the EDQM before issuing the Certificate of Suitability.> or < Detailed information on the manufacturing of the active substance has been provided in the restricted part of the ASMF>]
 - i. **Synthesis and Manufacturing:** [Adequacy of the manufacturing process and process controls.]
 - ii. **Characterization:** [Evaluation of structure elucidation and impurity profile (ICH Q3A/B).]
 - iii. **Specifications:** [Justification of specifications and analytical methods (ICH Q6A).]
 - iv. **Stability:** [Adequacy of stability data and proposed re-test period.]

2.2 Drug Product

1. **Manufacturer:** [Name of manufacturer and site(s)]
2. **Evaluation:**
 - a. **Formulation:** [Evaluation of the formulation, excipients, and justification.]
 - b. **Manufacturing Process:** [Adequacy of the manufacturing process, validation, and in-process controls.]
 - c. **Control of the Drug Product:** [Evaluation of specifications, analytical procedures, and validation (ICH Q2).]
 - d. **Stability:** [Evaluation of stability data and proposed shelf life.]

3. Nonclinical Study Reports

1. **Summary of Nonclinical Findings:** [Review of study protocols, results, and conclusions.]
2. **Safety Margin Assessment:** [Is the proposed human dose supported by adequate safety margins in animal studies? What are the No-Observed-Adverse-Effect-Level (NOAEL) and Lowest-Observed-Adverse-Effect-Level (LOAEL) values? For example, a NOAEL of 100 mg/kg/day in rats.]

3. **Toxicity:** [Identification and characterization of any target organ toxicities or other significant adverse findings.]

4. Clinical Study Reports

1. **Summary of Clinical Findings:** [Review of pivotal clinical efficacy and safety studies.]
2. **Efficacy:** [Critique of the study designs, statistical analyses, and clinical relevance of the results. Did the product demonstrate a significant effect, e.g., p-value <0.05?]
3. **Safety:** [Analysis of the clinical safety profile, including frequency and severity of adverse events, and identification of any unexpected safety concerns. Evaluate the risk/benefit ratio.]
4. **Pharmacology:** [Assessment of clinical pharmacology studies, including dose-response, drug-drug interactions, and special populations.]

5. Conclusion and Final Recommendation

1. **Summary:** Reiterate the key findings and the final recommendation.
2. **Conditions/Commitments:** List any conditions for approval (e.g., post-marketing studies, risk management plan, changes to labeling).
3. **Final Decision:** [Approved / Denied / Approved with Conditions]

Decision: The Registration Board approved the format of summary evaluation report for submission of cases before the Board for compliance of IDPs for WLA.

Case No. 06: Priority Consideration of Anti Neo Plastic Drugs

The Board deliberated that anti cancer drugs, especially anti neo plastic drugs under WHO ATC L01 shall be considered on priority to ensure access of patients to requisite anti cancers.

RRR Section

Case No.01 M/s. Basel Pharmaceuticals, 227 Phase II, Multan Industrial Estate, Multan.

1.	Brand Name + Dosage Form and Strength	Aramfen-50mg Tablet
	Composition	Each enteric coated tablet contains: Diclofenac Sodium.....50mg
	Dairy No. date of R & I fee	Rs.38700/- (Tracking ID: T3U-5X6-NMUZ)
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	Not provided
	RRA Status	Voltaren 50mg tablet MHRA
	GMP Status	DML renewal inspection dated 16-03-2023 Tablet (General) and Capsule (General) sections are approved
	Remark of the Renewal section	Registration of Aramfen-50mg Tablet (077029) is applied afresh due to non- submission of

		renewal (in the light of 180 th Authority decision).
	Decision: Approved	
2.	Brand Name + Dosage Form and Strength	Basole 20mg Capsule
	Composition	Each Capsule contains: Omeprazole enteric coated pellets eq. to omeprazole.....20mg Source: EC pellets Omeprazole (8.5%) from M/s vision pharmaceutical(Pvt) Ltd
	Dairy No. date of R &I fee	Rs.38700/- (Tracking ID: JR3-XN1-PBGJ)
	Type of form	Fom-5
	Finished product specifications	USP specification
	Pack size and Demand Price	2x7's , As per SRO
	RRA Status	MHRA approved
	GMP Status	DML renewal inspection dated 16-03-2023 Tablet (General) and Capsule (General) sections are approved
	Remark of the Renewal section	Registration of Basole 20mg Capsule (077027) is applied afresh due to non- submission of renewal (in the light of 180 th Authority decision).
	Decision: Approved	
3.	Brand Name + Dosage Form and Strength	Bathycobal 0.5mcg tablet
	Composition	Each film coated tablet contains: Mecobalamin.....0.5mcg
	Dairy No. date of R &I fee	Rs.38700/- (Tracking ID: ANP-PR5-E8S3)
	Type of form	Fom-5
	Finished product specifications	USP specification
	Pack size and Demand Price	Not provided
	RRA Status	Methycobal 500mcg tablet (PMDA Japan)
	GMP Status	DML renewal inspection dated 16-03-2023 Tablet (General) and Capsule (General) sections are approved
	Remark of the Renewal section	Registration of Bathycobal 0.5mcg tablet (074121) is applied afresh due to non-submission of renewal (in the light of 180 th Authority decision). Finished product to be changed to JP As per decision of Registration Board (348th meeting)
	Decision: Approved. Finished product specification to be changed along with fee (as per SRO)	

4.	Brand Name + Dosage Form and Strength	Beflo 500mg tablet
	Composition	Each film coated Tablet contains: Ofloxacin.....200mg
	Dairy No. date of R &I fee	Rs.38700/- (Tracking ID: ZQ8-QT5-H839)
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	Not provided
	RRA Status	MHRA approved
	GMP Status	DML renewal inspection dated 16-03-2023 Tablet (General) and Capsule (General) sections are approved
	Remark of the Renewal section	Registration of Beflo 500mg tablet (071248) is applied afresh due to non- submission of renewal (in the light of 180 th Authority decision).
Decision: Approved		
5.	Brand Name + Dosage Form and Strength	Bravit 250mg tablet
	Composition	Each film coated Tablet contains: Levofloxacin as hemihydrate.....250mg
	Dairy No. date of R &I fee	Rs.38700/- (Tracking ID: BRH-HU1-S7LZ)
	Type of form	Fom-5
	Finished product specifications	Not provided
	Pack size and Demand Price	1x 10's, As per SRO
	RRA Status	USFDA approved
	GMP Status	DML renewal inspection dated 16-03-2023 Tablet (General) and Capsule (General) sections are approved
	Remark of the Renewal section	Registration of Bravit 250mg tablet (071246) is applied afresh due to non- submission of renewal (in the light of 180 th Authority decision).
Decision: Approved. Finished product specification to be provided along with fee (as per SRO)		
6.	Brand Name + Dosage Form and Strength	Bravit 500mg tablet
	Composition	Each film coated tablet contains: Levofloxacin as hemihydrate.....500mg
	Dairy No. date of R &I fee	Rs.38700/- (Tracking ID: NSP-G2B-VQQD)
	Type of form	Fom-5
	Finished product specifications	Not provided
	Pack size and Demand Price	1x10's , As per SRO
	RRA Status	USFDA approved
	GMP Status	DML renewal inspection dated 16-03-2023 Tablet (General) and Capsule (General) sections are approved

	Remark of the Renewal section	Registration of Bravit 500mg tablet (071247) is applied afresh due to non- submission of renewal (in the light of 180 th Authority decision).
	Decision: Approved. Finished product specification to be provided along with fee (as per SRO)	
7.	Brand Name + Dosage Form and Strength	Esole 20mg Capsule
	Composition	Each Capsule contains: Enteric coated pellets of Esomeprazole equivalent 20mg Source: EC pellets Esomeprazole Mg (22.5%) from M/s vision pharmaceutical(Pvt) Ltd
	Dairy No. date of R &I fee	Rs.38700/- (Tracking ID: L71-GGU-6PRS)
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	2x7's As per SRO
	RRA Status	USFDA APPROVED NEXUM
	GMP Status	DML renewal inspection dated 16-03-2023 Tablet (General) and Capsule (General) sections are approved.
	Remark of the Renewal section	Registration of Esole 20mg Capsule (071408) is applied afresh due to non- submission of renewal (in the light of 180 th Authority decision).
	Decision: Approved	
8.	Brand Name + Dosage Form and Strength	Esole 40mg Capsule
	Composition	Each Capsule contains: Enteric coated pellets of Esomeprazole equivalent 40mg Source: EC pellets Esomeprazole Mg (22.5%) from M/s vision pharmaceutical(Pvt) Ltd
	Dairy No. date of R &I fee	Rs.38700/- (Tracking ID: UEA-1R1-1PZ7)
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	2x7's As per SRO
	RRA Status	USFDA approved Nexum
	GMP Status	DML renewal inspection dated 16-03-2023

		Tablet (General) and Capsule (General) sections are approved.
	Remark of the Renewal section	Registration of Esole 40mg Capsule(071410) is applied afresh due to non- submission of renewal (in the light of 180 th Authority decision).
	Decision: Approved	
9.	Brand Name + Dosage Form and Strength	Goodcip 250mg tablet
	Composition	Each tablet contains: Ciprofloxacin (as HCl).....250mg
	Dairy No. date of R &I fee	Rs.38700/- (Tracking ID: R59-4UD-HL8H)
	Type of form	Fom-5
	Finished product specifications	USP
	Pack size and Demand Price	1x10's As per SRO
	RRA Status	USFDA approved Ciproxin
	GMP Status	DML renewal inspection dated 16-03-2023 Tablet (General) and Capsule (General) sections are approved.
	Remark of the Renewal section	Registration of Goodcip 250mg tablet (071245) is applied afresh due to non- submission of renewal (in the light of 180 th Authority decision). Label claim to be standardized as “each film coated tablet” in line with RRA along with fee.
	Decision: Approved. Label claim to be standardized in line with RRA along with fee (as per SRO).	
10.	Brand Name + Dosage Form and Strength	Goodcip 500mg tablet
	Composition	Each tablet contains: Ciprofloxacin (as HCl).....500mg
	Dairy No. date of R &I fee	Rs.38700/- (Tracking ID: 183-NSW-1ARX)
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	1x 10's As per SRO
	RRA Status	USFDA approved Ciproxin
	GMP Status	DML renewal inspection dated 16-03-2023 Tablet (General) and Capsule (General) sections are approved.
	Remark of the Renewal section	Registration of Goodcip 500mg tablet (071244) is applied afresh due to non- submission of renewal (in the light of 180 th Authority decision). Label claim to be standardized as “each film coated tablet” in line with RRA along with fee.

Decision: Approved. Label claim to be standardized in line with RRA along with fee (as per SRO).		
11.	Brand Name + Dosage Form and Strength	Baston 250mg tablet
	Composition	Each tablet contains: Mefenamic Acid.....250mg
	Dairy No. date of R &I fee	Rs.38700/- (Tracking ID: 7M2-PJ2-629D)
	Type of form	Fom-5
	Finished product specifications	BP Specifications
	Pack size and Demand Price	Not provided
	RRA Status	MHRA approved
	GMP Status	DML renewal inspection dated 16-03-2023 Tablet (General) and Capsule (General) sections are approved.
	Remark of the Renewal section	Registration of Baston 250mg tablet (074122) is applied afresh due to non- submission of renewal (in the light of 180 th Authority decision). Label claim to be standardized as “each film coated tablet” in line with RRA along with fee.
Decision: Approved. Label claim to be standardized in line with RRA along with fee (as per SRO).		

12.	Brand Name + Dosage Form and Strength	Aramfen 50mg Capsule
	Composition	Each capsule contains: Diclofenac sodium (Enteric coated pellets) 50mg Source: EC Diclofenac sodium pellets (24%) from M/s vision pharmaceutical(Pvt) Ltd
	Dairy No. date of R &I fee	Rs.37000/- (Tracking ID: PZR-43Z-GRQ2)
	Type of form	Fom-5
	Finished product specifications	Manufacturer's Specifications
	Pack size and Demand Price	Not provided
	Me-too status	Lifdik 50mg capsule by M/s Goodman
	RRA Status	HPRA (Ireland) approved Difene 50mg gastro resistant capsule
	GMP Status	DML renewal inspection dated 16-03-2023 Tablet (General) and Capsule (General) sections are approved
	Remark of the Renewal section	Registration of Aramfen 50mg Capsule (071411) is applied afresh due to non- submission of renewal (in the light of 180 th Authority decision).
Decision: Approved. Finished product specification to be provided along with fee (as per SRO).		

13.	Brand Name + Dosage Form and Strength	CPM 4mg tablet
	Composition	Each tablet contains: Chlorpheniramine maleate.....4mg
	Dairy No. date of R &I fee	Rs.38700/- (Tracking ID: DU2-MEE-B7YV)
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	Not provided
	RRA Status	MHRA approved
	GMP Status	DML renewal inspection dated 16-03-2023 Tablet (General) and Capsule (General) sections are approved
	Remark of the Renewal section	Registration of CPM 4mg tablet (074124) is applied afresh due to non- submission of renewal (in the light of 180 th Authority decision). Formulation approved in MHRA is uncoated tablet.
Decision: Approved. Label claim to be standardized in line with RRA along with fee (as per SRO).		



Drug Regulatory Authority of Pakistan
(Pharmaceutical Evaluation & Registration Division)



Pharmaceutical Evaluation Cell (PEC)

Sr. No	Title	Description
1	Case Category	Export Facilitation (Abdul Mughees)
	Name, address of Applicant.	Martin Dow Limited Plot no. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan (000267)
	Application Form Dy. No / Tracking ID & date of submission	(LSG-SEZ-6WG8, 2025-03-04)
	Detail of Fee Submitted	93000.0, 2025-01-29,
	The proposed proprietary name / brand name	Resmidow Tablet 60mg
	Label Claim	Each film coated tablet contains: Resmetirom.....60mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,20's-Free of Cost,30's-Free of Cost,40's-Free of Cost
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	A05BA11; lipotropic
	Name, address of Manufacturing site:	Martin Dow Marker Limited-07-Jail Road, Quetta, Pakistan.-
	Name & address of API manufacturer	Not Applicable
	Detail of stability batches of drug product	03 batches (PDS-311-24 , PDS-312-24 , PDS-313-24) of 8000 tablets each, 06 months real time and accelerated on Zone IV-a conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Rezdiffra Tablet 60mg by Medrigal Pharmaceuticals Inc batch 23H224A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
	The status in reference regulatory authorities	US-FDA Rezdiffra Tablet 60mg by Medrigal Pharmaceuticals Inc
	GMP status of the firm	GMP of Martin Dow Marked dated 18.03.2024.
	Evidence of approval of manufacturing facility	DML 000267 of Martin Dow Limited 000028 of Martin Dow Marker Limited
Evaluation Remarks		
Reference letter No. F.1-6/2019-PR-I(EFD) dated 10th June, 2025, the instant application is being replaced with Lastine Tablet (Bilastine) for consideration on priority on account of export facilitation. The firm was asked to submit 06 month stability data, which the firm has submitted.		
Decision		

Approved

2	Case Category	New Molecule/Formulation (Abdul Mughees)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(836-RE4-8STP, 2025-08-25)
	Detail of Fee Submitted	75000.0, 2025-05-21,
	The proposed proprietary name / brand name	Avala 50mg Tablets
	Label Claim	Avanafil 50mg/Tablets
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2, 4, 6, 8, 10, 14, 20, 28, 30, 40, 50, 60, 70, 80-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Avanafil belongs to the pharmacotherapeutic group of Urologicals; Drugs used in erectile dysfunction. Specifically, it is a phosphodiesterase type 5 (PDE5) inhibitor. Its mechanism of action involves inhibiting PDE5, which is an enzyme that plays a role in the development of erections.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CENTURY PHARMACEUTICALS LIMITED 103-106, GIDC, Halol Dist. Panchmahals- 389 350, India
	Detail of stability batches of drug product	Provided for 03 batches at Zone IVa conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed against Stendra
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
	The status in reference regulatory authorities	STENDRA™ (avanafil) tablets, for oral use Tablets: 50 mg, 100 mg, 200 mg Company: Manufactured for VIVUS, Inc., Mountain View, CA 94040, Manufactured in Osaka Japan.
	GMP status of the firm	Attached in Module 1 in section 1.3.5
	Evidence of approval of manufacturing facility	DML

Evaluation Remarks

Sr. No	Observation/ Shortcoming	Reply of the firm
1	Product Development: How you determined optimal ratio of fumaric acid to avanafil for targeted characteristics and dissolution?	Fumaric acid is used in the formulation as per innovator's formulation to enhance the dissolution. Commercial product (Spedra) innovator used fumaric Acid as inactive ingredient in the formulation to enhance the dissolution and there's no single "optimal" universal ratio defined of the same. As we used fumaric acid in very low quantity in the formulation i.e., 2.8% w/w.
2	CDP: It is recommended to take samples at 5, 10, 15, 20, 30, 45 and 60 minutes for an immediate-release	In the FDA literature of Avanafil, innovator used Q =__ at 15 minutes to achieve the required maximum results that is why we used 1 extra time point after 15

	dosage form. The provided CDP covers upto 20 minutes only. Please clarify.	minutes i.e., 5, 10, 15 & 20 minutes. As such no such reference is available for 30, 45 and 60 minutes. "As per regulatory guidelines (FDA, EMA, WHO), a minimum of three time points (excluding zero) are required for comparative dissolution profile evaluation".
3	CDP: At least 12 units should be used for determination of each profile. Mean dissolution values can be used to estimate the similarity factor, f_2 . Whereas you have calculated similarity factor by using data from 06 units in the provided CDP. Please provide complete dissolution data of 12 units for each reference and test products.	We revised Comparative Dissolution Profile on 12 units for each reference and test products to determine the similarity factor, f_2 .
4	Dissolution: Reasons for not performing HPLC analysis and using UV method.	As Avanafil is UV active material and shows stable spectrum in UV-Visible Spectrophotometer region and this is also In-House Validated Method which we had used. As avanafil testing Method is not available in any of the international pharmacopoeia.
5	Method validation: In the protocols, Batch number 13461001-AVN is mentioned for working standard whereas COA of working standard provided by you in analytical Method validation/verification bears batch number WS/AV001. Similarly, batch number on COA of raw material (avanafil) provided in the Batch analysis of DS part is 13461001-AVN whereas you have noted it to be CPL/WS/24/AVN/073. Please clarify.	In the Protocol for Method Validation of Avanafil, there is a clerical mistake by mentioning Working Standard batch number and Raw Material batch number (Both COA's are attached), Actual batch number of working standard is CPL/WS/24/AVN/073 and raw material batch number is 13461001-AVN.
6	Method validation: While performing method validation for DS, you reported under Repeatability that for Retention Time 3.194, your observed Peak Area was 5925008. Whereas, in validation of Analytical Procedures of DP, you reported that for retention time 3.113 your Peak Area is 6562205. Please justify robustness of your analytical method based on above observation.	In Method Validation of the Drug Substance & Drug Product, they have same retention time but due to change in sample injection volume both having different peak areas i.e. Drug Substance having 5µl injection volume while Drug Product having 10µl injection volume.
7	Stability: Submit 06-month stability data.	6th Month Stability Summary Sheets, Calculation Sheets & Chromatograms attached.

Decision

Approved

The Registration Board approved the product subject to the report of Product Specific Inspection (PSI) for verification of submitted data by a panel constituted by Chairman, Registration Board.

3	Case Category	New Molecule/Formulation (Abdul Mughees)

Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
Application Form Dy. No / Tracking ID & date of submission	(ZU1-HRR-6HTJ, 2025-08-25)
Detail of Fee Submitted	75000.0, 2025-05-21,
The proposed proprietary name / brand name	Avala 100mg Tablets
Label Claim	Avanafil 100mg/Tablets
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	2, 4, 6, 8, 10, 14, 20, 28, 30, 40, 50, 60, 70, 80-As per SRO
Shelf Life (Unit)	2 Year(s)Below 30°C
For generic drugs (me-too Status)	NA
Pharmacotherapeutic Group of (API)	Avanafil belongs to the pharmacotherapeutic group of Urologicals; Drugs used in erectile dysfunction. Specifically, it is a phosphodiesterase type 5 (PDE5) inhibitor. Its mechanism of action involves inhibiting PDE5, which is an enzyme that plays a role in the development of erections.
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	CENTURY PHARMACEUTICALS LIMITED 103-106, GIDC, Halol Dist. Panchmahals- 389 350, India
Detail of stability batches of drug product	Provided for 03 batches on Zone IVa conditions
Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed against Spedra
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
The status in reference regulatory authorities	STENDRA™ (avanafil) tablets, for oral use Tablets: 50 mg, 100 mg, 200 mg Company: Manufactured for VIVUS, Inc., Mountain View, CA 94040, Manufactured in Osaka Japan.
GMP status of the firm	Provided
Evidence of approval of manufacturing facility	DML

Evaluation Remarks

Sr. No	Observation/ Shortcoming	Reply of the firm
1	Product Development: How you determined optimal ratio of fumaric acid to avanafil for targeted characteristics and dissolution?	Fumaric acid is used in the formulation as per innovator's formulation to enhance the dissolution. Commercial product (Spedra) innovator used fumaric Acid as inactive ingredient in the formulation to enhance the dissolution and there's no single "optimal" universal ratio defined of the same. As we used fumaric acid in very low quantity in the formulation i.e., 2.8% w/w.
2	CDP: It is recommended to take samples at 5, 10, 15, 20, 30, 45 and 60 minutes for an immediate-release dosage form. The provided CDP covers upto 20 minutes only. Please clarify.	In the FDA literature of Avanafil, innovator used Q = ___ at 15 minutes to achieve the required maximum results that is why we used 1 extra time point after 15 minutes i.e., 5, 10, 15 & 20 minutes. As such no such reference is available for 30, 45 and 60 minutes. "As per regulatory guidelines (FDA, EMA, WHO), a

		minimum of three time points (excluding zero) are required for comparative dissolution profile evaluation”.
3	CDP: At least 12 units should be used for determination of each profile. Mean dissolution values can be used to estimate the similarity factor, f_2 . Whereas you have calculated similarity factor by using data from 06 units in the provided CDP. Please provide complete dissolution data of 12 units for each reference and test products.	We revised Comparative Dissolution Profile on 12 units for each reference and test products to determine the similarity factor, f_2 .
4	Dissolution: Reasons for not performing HPLC analysis and using UV method.	As Avanafil is UV active material and shows stable spectrum in UV-Visible Spectrophotometer region and this is also In-House Validated Method which we had used. As avanafil testing Method is not available in any of the international pharmacopoeia.
5	Stability: Submit 06-month stability data.	6th Month Stability Summary Sheets, Calculation Sheets & Chromatograms attached.

Decision

Approved

The Registration Board approved the product subject to the report of Product Specific Inspection (PSI) for verification of submitted data by a panel constituted by Chairman, Registration Board.

4	Case Category	New Molecule/Formulation (Abdul Mughees)
	Name, address of Applicant.	Welwrd Pharmaceuticals Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar (000574)
	Application Form Dy. No / Tracking ID & date of submission	(MHL-TVM-63P1, 2025-07-22)
	Detail of Fee Submitted	75000.0, 2025-03-17,
	The proposed proprietary name / brand name	Weldna 10mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Vardenafil as Hydrochloride Trihydrate 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Drugs used in erectile dysfunction ATC code: G04BE09.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited
	Detail of stability batches of drug product	03 batches having batch size of 1200 Tablets each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of loan letter from M/s WnsFeild pharma wherein they give 200gm of Vardenafil to M/s Welwerd pharma for the purpose of stability and dossier submission to DRAP dated 01-07-2024. They also submitted loan intimation to DRAP dated 15-07-2024 as per notification. They also submitted copy of GD and invoice. However, neither any license to import nor any clearance certificate is provided.

Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and PE studies are performed against innovator product i.e. Levitra 10mg Tablet, B. No. 639112-35, Exp. date 12-2026 manufactured by Rivopharm Pharma. Both innovator product and applied product have shown more than 85% release within 15 minutes in acidic medium & acetate buffer while in phosphate buffer the value of F2 is in acceptable range.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of 3 batches of drug substance as per Zone IV-B is submitted. Accelerated 06 months and real time for 60 months.
The status in reference regulatory authorities	LEVITRA® (Vardenafil HCl) tablets, USFDA approved. Vardenafil 5mg, 10 mg & 20mg tablets, MHRA approved.
GMP status of the firm	Firm has submitted copy of GMP certificate No. 11-76/2022-DRAP-69 dated 10-06-2022 issued on the basis of inspection conducted on 03-03-2022. Not valid.
Evidence of approval of manufacturing facility	Not submitted.

Evaluation Remarks

The reply of the firm for the first list of questions is as follows:

Sr. No	Observation/ Shortcoming	Reply of the firm
1	Valid copy of DML of the applicant shall be submitted • Valid Copy of GMP certificate of the applicant shall be submitted. • Evidence of approval of manufacturing facility/section from licensing division shall be submitted.	Attached in Annexure A
2	Section 1.5.6 has mentioned innovator specifications while official monograph is available in BP. Clarification shall be submitted.	Mistakenly written, as Vardenafil monograph is available in USP. The innovators (Levitra 10mg) and our product (Weldna 10mg) specifications are applied according to USP monograph.
3	Specifications and analytical procedures of the drug substance from drug product manufacturer shall be submitted.	Specifications and Complete analytical procedures of the drug substance is Attached in Annexure B.
4	Analytical method verification protocols along with complete results shall be submitted.	Complete analytical method verification protocols along with verification report is Attached in Annexure C
5	As per USP monograph, system suitability requires use of 7-methyl vardenafil, while the performed system suitability does not indicate any use of impurity. Clarification shall be submitted. Clarification shall be submitted.	As per the USP monograph, 7-methyl vardenafil is required for system suitability testing of impurities, but impurity test was not performed.
6	COA of the working standard submitted in section 3.2.S.5 has expiry of 05-04-2023. Clarification shall be submitted with respect to trial batch manufacturing i.e. 07-2024.	No reply
7	Different signs of Quality control manager are present at different parts of the application. Clarification shall be submitted.	Some parts are mistakenly signed by deputy manager instead of quality control manager.

8	Complete CDP studies for all the tablet at each time point shall be submitted rather than submitting only average percentage release.	CDP studies for all the tablet at each time point is given in Annexure D
9	Country of import (from where the innovator is imported) shall also be submitted.	Submitted in Annexure D

On evaluation, a second list of questions was sent for which the firm has replied as follows:

Sr. No	Observation/ Shortcoming	Reply of the firm
1	Annexure-A does not contain the attachments of DML and GMP.	Their absence earlier was by mistake. The missing DML and GMP are now attached in Annexure-A.
2	Rectify. In Analytical method verification, your provided specs and temperature is different from the ones mentioned in the USP monograph.	The method we wrote earlier was our validated internal method set for our lab conditions and it was mentioned by mistake. In fact we applied the specs and temperature as per USP monograph, the updated Analytical method verification report has now been updated and corrected in line with USP and is resubmitted in Annexure-B.
3	On page 5 of the Method verification report, the reported 0.42% is inconsistent with the provided mean and SD for peak area of Vardenafil HCl. Submit the correct %RSD.	The value of 0.42% RSD was a typing mistake. The correct %RSD, calculated from the mean and SD of Vardenafil HCl, is 0.62%. A corrected report is attached in Annexure-C.
4	While performing stability studies, which method for assay did you use? If it is not in line with USP monograph, then how will you justify change to current specifications?	For stability Study we used the assay method recommended by USP, the specification were also according to USP monograph. There was a typing mistake in the earlier submission. The corrected specifications and method use for assay are now resubmitted in Annexure-D.
5	The USP monograph specifies tailing factor in system suitability to be between 0.8 to 1.5, whereas the chromatograms you have submitted for verification studies as well as Zero month studies show TF exceeding 1.5. How will you justify suitability of method?	We noticed that the tailing factor was around 1.5 in some chromatograms. This happened because of column condition and system variation. We replaced the column and repeated the test using the improved method. The new chromatograms now show the tailing factor within the USP range are resubmitted in Annexure-E.

Decision

Approved

The Registration Board approved the product subject to the report of Product Specific Inspection (PSI) for verification of submitted data by a panel constituted by Chairman, Registration Board.

5	Case Category	New Molecule/Formulation (Abdul Mughees)
	Name, address of Applicant.	Welwrd Pharmaceuticals Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar (000574)
	Application Form Dy. No / Tracking ID & date of submission	(ML8-WGH-DG99, 2025-07-22)
	Detail of Fee Submitted	75000.0, 2025-03-17,
	The proposed proprietary name / brand name	Weldna 20mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Vardenafil as Hydrochloride Trihydrate 20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO

Shelf Life (Unit)	2 Year(s)Store below 25c
For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	Drugs used in erectile dysfunction ATC code: G04BE09.
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	
Detail of stability batches of drug product	03 batches having batch size of 1200 Tablets each.
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of loan letter from M/s WnsFeild pharma wherein they give 200gm of Vardenafil to M/s Welwerd pharma for the purpose of stability and dossier submission to DRAP dated 01-07-2024. They also submitted loan intimation to DRAP dated 15-07-2024 as per notification. They also submitted copy of GD and invoice. However, neither any license to import nor any clearance certificate is provided.
Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and PE studies are performed against innovator product i.e. Levitra 20mg Tablet, B. No. 640901-20, Exp. date 11-2026 manufactured by Rivopharm Pharma. Both innovator product and applied product have shown more than 85% release within 15 minutes in acidic medium & acetate buffer while in phosphate buffer the value of F2 is in acceptable range.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of 3 batches of drug substance as per Zone IV-B is submitted. Accelerated 06 months and real time for 60 months.
The status in reference regulatory authorities	LEVITRA® (Vardenafil HCl) tablets, USFDA approved. Vardenafil 5mg, 10 mg & 20mg tablets, MHRA approved.
GMP status of the firm	Firm has submitted copy of GMP certificate No. 11-76/2022-DRAP-69 dated 10-06-2022 issued on the basis of inspection conducted on 03-03-2022.
Evidence of approval of manufacturing facility	Not submitted.

Evaluation Remarks

The reply of the firm for the first list of questions is as follows:

Sr. No	Observation/ Shortcoming	Reply of the firm
1	Valid copy of DML of the applicant shall be submitted • Valid Copy of GMP certificate of the applicant shall be submitted. • Evidence of approval of manufacturing facility/section from licensing division shall be submitted.	Attached in Annexure A
2	Section 1.5.6 has mentioned innovator specifications while official monograph is available in BP. Clarification shall be submitted.	Mistakenly written, as Vardenafil monograph is available in USP. The innovators (Levitra 10mg) and our product (Weldna 10mg) specifications are applied according to USP monograph.
3	Specifications and analytical procedures of the drug substance from drug product manufacturer shall be submitted.	Specifications and Complete analytical procedures of the drug substance is Attached in Annexure B.
4	Analytical method verification protocols along with complete results shall be submitted.	Complete analytical method verification protocols along with verification report is Attached in Annexure C

5	As per USP monograph, system suitability requires use of 7-methyl vardenafil, while the performed system suitability does not indicate any use of impurity. Clarification shall be submitted. Clarification shall be submitted.	As per the USP monograph, 7-methyl vardenafil is required for system suitability testing of impurities, but impurity test was not performed.
6	COA of the working standard submitted in section 3.2.S.5 has expiry of 05-04-2023. Clarification shall be submitted with respect to trial batch manufacturing i.e. 07-2024.	No reply
7	Different signs of Quality control manager are present at different parts of the application. Clarification shall be submitted.	Some parts are mistakenly signed by deputy manager instead of quality control manager.
8	Complete CDP studies for all the tablet at each time point shall be submitted rather than submitting only average percentage release.	CDP studies for all the tablet at each time point is given in Annexure D
9	Country of import (from where the innovator is imported) shall also be submitted.	Submitted in Annexure D

On evaluation, a second list of questions was sent for which the firm has replied as follows:

Sr. No	Observation/ Shortcoming	Reply of the firm
1	Annexure-A does not contain the attachments of DML and GMP.	Their absence earlier was by mistake. The missing DML and GMP are now attached in Annexure-A.
2	Rectify. In Analytical method verification, your provided specs and temperature is different from the ones mentioned in the USP monograph.	The method we wrote earlier was our validated internal method set for our lab conditions and it was mentioned by mistake. In fact we applied the specs and temperature as per USP monograph, the updated Analytical method verification report has now been updated and corrected in line with USP and is resubmitted in Annexure-B.
3	On page 5 of the Method verification report, the reported 0.42% is inconsistent with the provided mean and SD for peak area of Vardenafil HCl. Submit the correct %RSD.	The value of 0.42% RSD was a typing mistake. The correct %RSD, calculated from the mean and SD of Vardenafil HCl, is 0.62%. A corrected report is attached in Annexure-C.
4	While performing stability studies, which method for assay did you use? If it is not in line with USP monograph, then how will you justify change to current specifications?	For stability Study we used the assay method recommended by USP, the specification were also according to USP monograph. There was a typing mistake in the earlier submission. The corrected specifications and method use for assay are now resubmitted in Annexure-D.
5	The USP monograph specifies tailing factor in system suitability to be between 0.8 to 1.5, whereas the chromatograms you have submitted for verification studies as well as Zero month studies show TF exceeding 1.5. How will you justify suitability of method?	We noticed that the tailing factor was around 1.5 in some chromatograms. This happened because of column condition and system variation. We replaced the column and repeated the test using the improved method. The new chromatograms now show the tailing factor within the USP range are resubmitted in Annexure-E.

Decision

Approved

The Registration Board approved the product subject to the report of Product Specific Inspection (PSI) for verification of submitted data by a panel constituted by Chairman, Registration Board.

6	Case Category	New Molecule/Formulation (Abdul Mughees)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(YQX-5RR-ZDV9, 2025-08-25)
	Detail of Fee Submitted	75000.0, 2025-07-11,
	The proposed proprietary name / brand name	Linza 100mg Tablets
	Label Claim	Linzagolix 100mg/Tablet
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2, 4, 6, 8, 10, 14, 20, 28, 30, 40, 50, 60, 70, 80-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	H01CC04; GnRH antagonist;
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	GANSU HAOTIAN PHARMACEUTICAL CO., LTD No.11, Chongqing Road, Baiyin District, Baiyin City, Gansu Province, China
	Detail of stability batches of drug product	Attached in Module 3 in section 3.2.P.8
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Perfomrmed against Yestly by Theramex Ireland Limited (PLGB 49876/0023-0024) Batch 4126255 B
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided tested 3 batches on Zone IV-a conditions (max. 24 months)
	The status in reference regulatory authorities	Yselty 100 mg film-coated tablets, for oral use Yselty 200 mg film-coated tablets, for oral use Linzagolix (as linzagolix choline) Approval: MHRA in January, 2025 Marketing Authorizations: Theramex Ireland Limited (PLGB 49876/0023-0024)
	GMP status of the firm	GMP certificate for Afghanistan issued 09th May, 2024
	Evidence of approval of manufacturing facility	DML 000572 wef 13.05.2015 and renewal request on eApp dated 09.05.2025

Evaluation Remarks

1. Provide Facility approval / GMP certification (translated) of the DS manufacturer from the regulatory authority of country of origin. Reply: Required from Manufacturer 2. DS: Please clarify from DS manufacturer documents which polymorphic form of the API has been used. Reply: Drug Manufactured provided documents of Crystalline salt form. 3. DS: Provide date of manufacturing of Stability batches for DS. Reply: Attached details of COA's 4. Assay: In your analytical method validation protocol & report for Assay (under 3.2.S.4) you have mentioned that gradient HPLC testing is performed. Please provide evidence of availability of gradient testing facility. Reply: We have Binary Gradient HPLC (QC-67) with Auto-sampler (Pictures attached) 5. WS: Please provide evidence for import of Working Standard of Linzagolix Choline. Reply: Working Standard is essential part of API Consignment, therefore not mentioned in invoice or other required documents. 6. CDP: Please provide Reference product's manufacturing date for b Batch 4126255 B. Reply: Manufacturing date is not mentioned on the reference pack of innovator, only expiry date is mentioned i.e., 08/2026 7. CDP: At least 12 units should be used

for determination of each profile. Mean dissolution values can be used to estimate the similarity factor, f_2 . Whereas you have calculated similarity factor by using data from 06 units in the provided CDP. Please provide complete dissolution data of 12 units for each reference and test products. Reply: Revised CDP is attached with 12 units of each test and reference product to calculate similarity factor F_2 . 8. 3.2.P.3 (Manufacturing): The innovator's manufacturing process steps include "milling". The submitted manufacturing method does not indicate that the process of milling has been performed by you. Keeping in view of the low solubility of drug substance in physiologically relevant media, the active substance is milled to increase its dissolution rate. This has not been discussed or performed by you as indicated by the submission data. A complete risk assessment shall be performed in this respect and submitted. Please justify. Reply: We are used Granulator instead of milling and pass the granules from the sieve #30 and the results of the dissolution found satisfactory. Even the hardness and friability also found satisfactory as the compressibility of the powder is satisfactory. 9. Stability of DP: Submit 06-month stability data with supporting documents and chromatograms. Reply: 6th Month Stability Data is attached.

Decision

Approved

The Registration Board approved the product subject to the report of Product Specific Inspection (PSI) for verification of submitted data by a panel constituted by Chairman, Registration Board.

7	Case Category	New Molecule/Formulation (Abdul Mughees)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(TYN-6ZV-DRV3, 2025-08-25)
	Detail of Fee Submitted	75000.0, 2025-07-11,
	The proposed proprietary name / brand name	Linza 200mg Tablets
	Label Claim	Linzagolix 200mg/Tablet
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2, 4, 6, 8, 10, 14, 20, 28, 30, 40, 50, 60, 70, 80-As per SRO
	Shelf Life (Unit)	2 Year Below 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Linzagolix: Belongs to hypothalamic hormones, specifically non peptide GnRH receptor antagonists used as anti gonadotropins.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	GANSU HAOTIAN PHARMACEUTICAL CO., LTD No.11, Chongqing Road, Baiyin District, Baiyin City, Gansu Province, China
	Detail of stability batches of drug product	Attached in Module 3 in section 3.2.P.8
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached in Module 3 in section 3.2.P.8
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in Module 3 in section 3.2. P.2.2
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached in Module 3 in section 3.2. S.7
	The status in reference regulatory authorities	Ysely 100 mg film-coated tablets, for oral use Ysely 200 mg film-coated tablets, for oral use Linzagolix (as linzagolix choline) Approval: MHRA in January, 2025 Marketing Authorizations: Theramex Ireland Limited (PLGB 49876/0023-0024)
	GMP status of the firm	Attached in Module 1 in section 1.3.5

Evidence of approval of manufacturing facility		Attached in Module 1 in section 1.3.5
Evaluation Remarks		
1. Provide Facility approval / GMP certification (translated) of the DS manufacturer from the regulatory authority of country of origin. Reply: Required from Manufacturer 2. DS: Please clarify from DS manufacturer documents which polymorphic form of the API has been used. Reply: Drug Manufactured provided documents of Crystalline salt form. 3. DS: Provide date of manufacturing of Stability batches for DS. Reply: Attached details of COA's 4. Assay: In your analytical method validation protocol & report for Assay (under 3.2.S.4) you have mentioned that gradient HPLC testing is performed. Please provide evidence of availability of gradient testing facility. Reply: We have Binary Gradient HPLC (QC-67) with Auto-sampler (Pictures attached) 5. WS: Please provide evidence for import of Working Standard of Linzagolix Choline. Reply: Working Standard is essential part of API Consignment, therefore not mentioned in invoice or other required documents. 6. CDP: Please provide Reference product's manufacturing date for b Batch 4126255 B. Reply: Manufacturing date is not mentioned on the reference pack of innovator, only expiry date is mentioned i.e., 08/2026 7. CDP: At least 12 units should be used for determination of each profile. Mean dissolution values can be used to estimate the similarity factor, f_2. Whereas you have calculated similarity factor by using data from 06 units in the provided CDP. Please provide complete dissolution data of 12 units for each reference and test products. Reply: Revised CDP is attached with 12 units of each test and reference product to calculate similarity factor F_2. 8. 3.2.P.3 (Manufacturing): The innovator's manufacturing process steps include "milling". The submitted manufacturing method does not indicate that the process of milling has been performed by you. Keeping in view of the low solubility of drug substance in physiologically relevant media, the active substance is milled to increase its dissolution rate. This has not been discussed or performed by you as indicated by the submission data. A complete risk assessment shall be performed in this respect and submitted. Please justify. Reply: We are used Granulator instead of milling and pass the granules from the sieve #30 and the results of the dissolution found satisfactory. Even the hardness and friability also found satisfactory as the compressibility of the powder is satisfactory. 9. Stability of DP: Submit 06-month stability data with supporting documents and chromatograms. Reply: 6th Month Stability Data is attached.		
Decision		
Approved		
The Registration Board approved the product subject to the report of Product Specific Inspection (PSI) for verification of submitted data by a panel constituted by Chairman, Registration Board.		
8	Case Category	Priority As Per 257-M of RB (Abdul Mughees)
	Name, address of Applicant.	Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan (01-374-0006)
	Application Form Dy. No / Tracking ID & date of submission	(66B-LRY-ENP6, 2025-02-17)
	Detail of Fee Submitted	300000.0, 2025-01-06,
	The proposed proprietary name / brand name	ZYDROX-500
	Label Claim	Each hard gelatin capsule contains: Hydroxyurea USP... 500mg Excipients..... q.s
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	24 MonthStore protected from moisture in dry, well ventilated place at a temperature not exceeding 30°C.
	For generic drugs (me-too Status)	Registration Number: 022625 Brand Name: Hydrine Capsule 500mg MAH: Al-Habib Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Zuvius Lifesciences Pvt. Ltd.-At.Kharuni-Lodhimajra Road, Vill. Nandpur, Baddi, Distt. Solan, (H.P.)-173205 India-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	

Name, address of Marketing Authorization Holder:	Zuvius Lifesciences Pvt. Ltd., At-Kharuni-Lodhimajra Road, Vill. Nandpur, Baddi, Distt. Solan (H.P.)173205 India, India
Details of Certificates (CoPP/FSC/cGMP):	
Details of Authorization Letter :	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
The status in reference regulatory authorities	HYDREA (Hydroxyurea) capsules, for oral use MAH: Bristol-Myers Squibb Company, Princeton, New jersey 08543 USA USFDA Approved

Evaluation Remarks

01	M/s Zuvius Lifesciences Pvt. Ltd. Holds loan license to manufacture drugs at premises of M/s Beta Drugs Ltd. Please clarify the scope of loan licenses as the license mentions two entities responsible for manufacture of the drug. Also what drugs are mentioned in Schedule C and C (1) of Drugs and Cosmetic Rules 1945, which are permitted to be manufactured by the local authorities?	Under the pr (Licensee) to the main ma facilities, and and overall vaccines, tox Hydroxyurea
02	Also provide valid GMP certificate of the manufacturer.	Please find competent St
03	Please clarify statement provided in Module 3 with API manufacturer as (Intended Manufacturer). What does it mean?	The terminol Ltd. for the st
04	The pictures of reference products provided in your module does not show batch number, manufacturing and expiry dates. Please clarify.	The initial im of reference required.
05	What is the composition and source of capsules? Include composition, manufacturer detail and CoA in appropriate section of module 3.	The capsule standards.Ma Chemicals A Analysis (Co
06	The claimed specification is USP, however, the dissolution method provided by the applicant differs from the USP monograph. Please provide justification for the following:a. The applicant has not used buffer solution along with menthol in solution 2;b. The applicant has not mentioned column temperature in their Assay procedure;	(a) Dissolutio menthol in b review.(b) C however, we

Decision

Deferred

The case is referred to the Legal Affairs Division for their comments on the loan-based license.

9	Case Category	New License (Abdul Mughees)
	Name, address of Applicant.	May and Baker (Pvt.) Ltd 23-Ghourri Block, Bahria Town, Lahore (000953)
	Application Form Dy. No / Tracking ID & date of submission	(L1P-EG4-MWJ9, 2025-03-04)
	Detail of Fee Submitted	37000.0, 2025-01-07,
	The proposed proprietary name / brand name	Baknal injection
	Label Claim	Each 5ml ampoule contains: NaCl.....0.9% w/v
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	as per DPC-As per SRO
	Shelf Life (Unit)	2 Year(s)below 24 degree
	For generic drugs (me-too Status)	Nisale injection
	Pharmacotherapeutic Group of (API)	Electrolyte
	Name, address of Manufacturing site:	Self Manufacturing

Name & address of API manufacturer	Rasino Herbs Pvt. Ltd, N-2, MIDC, Chemical Zone, Kupwad, Sangli-416436, Maharashtra, INDIA
Detail of stability batches of drug product	
Documents for the procurement of API with approval from DRAP (in case of Import)	
Pharmaceutical Equivalence and Comparative Dissolution Profile	Nasline Injection: PE studies performed
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Real time stability study is not provided
The status in reference regulatory authorities	FDA Approved
GMP status of the firm	28-04-2022: New DML
Evidence of approval of manufacturing facility	29-04-2022: New DML issuance letter specifies Injectable ampoule section (General)
Evaluation Remarks	
The firm was asked following questions for which they have submitted responses:1) Submit API stability study data as per zone IV-A submitted 2) Submit name of the manufacturer of the product against which pharmaceutical equivalence is conducted..... Pharmaceutical equivalence is conducted against medisoride 0.9% ampoule manufactured by mediate Pharmaceuticals Karachi3) Submit stability study data sheets.....Submitted4) Submit GMP certificate of API manufacturer.....Submitted 5) Submit loan letter, loan agreement, and clearance certificate of the manufacturer from which loan is taken (Global Pharma).....Loan letter is attached	
Decision	
Deferred	
The Registration Board deferred the case for verification of applicant's provided API loan issuance letter from M/s Global Pharmaceuticals (Pvt) Ltd.	
10	Case Category
	Export Facilitation (Abdul Mughees)
	Name, address of Applicant.
	Martin Dow Marker Limited 7, Jail Road Quetta. (000028)
	Application Form Dy. No / Tracking ID & date of submission
	(JY2-WA9-BNUQ, 2025-05-06)
	Detail of Fee Submitted
	30000.0, 93000.0 2024-06-24, 2025-01-24
	The proposed proprietary name / brand name
	Rosezet Tablet 5mg+10mg
	Label Claim
	Each Bilayer film coated tablet contains: Rosuvastatin calcium eq. to Rosuvastatin 20 mg Ezetimibe 10 mg
	Reference to Finished product specifications
	Any Other
	Proposed Pack Size
	As per DPC-As per SRO
	Shelf Life (Unit)
	2 Year(s)Below 30°C
	For generic drugs (me-too Status)
	Rovista EZ Tablet 5mg+10mg
	Pharmacotherapeutic Group of (API)
	A combination of rosuvastatin, an HMG CoA-reductase inhibitor (statin), and ezetimibe, a dietary cholesterol absorption inhibitor, indicated in adults
	Name, address of Manufacturing site:
	Martin Dow Limited-Plot No. 37, Sector 19, Korangi Industrial Area, Karachi-
	Name & address of API manufacturer
	CTX Life Sciences Pvt Ltd,Glenmark Life Sciences Limited
	Detail of stability batches of drug product
	Provided for 03 batches (NPD-T-2495-S, 1500 tabs; NPD-T-2505-S, 10000 tabs; NPD-T-2506-S, 10000 tabs) both accelerated and long term at Zone IV-a conditions

	Documents for the procurement of API with approval from DRAP (in case of Import)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Rolip EZ by Hilton Phrama
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided for both APIs at Zone IV-a conditions
	The status in reference regulatory authorities	ALZIL PLUS 5mg+10mg - Spanish Agency for Medicines and Health Products (SPAIN)
	GMP status of the firm	GMP certificate dated 18.03.2024
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The firm was asked to Provide/ clarify the following and the firm has submitted as below: With reference to the query regarding dissolution acceptance criteria, please note that we confirm adoption of the criterion NLT 85% (Q = 80%) in 30 minutes for both APIs. In alignment with the FDA-approved innovator product Roszet (NDA 213072), the following methods have been adopted and incorporated in our final product specifications for release and stability testing: Rosuvastatin: USP Apparatus II (Paddle), 50 rpm, 900 mL pH 6.6 citrate buffer, 37 ± 0.5 °C, 30 minutes. Ezetimibe: USP Apparatus I (Basket), 75 rpm, 900 mL pH 4.5 acetate buffer with 0.45% SLS, 37 ± 0.5 °C, 30 minutes. Supporting reference (FDA Product Quality Review of Roszet) is attached for justification. Please note that we have also enclosed 6th months stability studies.	
	Decision	
	Approved	
11	Case Category	Export Facilitation (Abdul Mughees)
	Name, address of Applicant.	Martin Dow Marker Limited 7, Jail Road Quetta. (000028)
	Application Form Dy. No / Tracking ID & date of submission	(LEM-3UJ-6W32, 2025-03-13)
	Detail of Fee Submitted	30000.0, 93000.0 2024-06-24, 2025-01-24
	The proposed proprietary name / brand name	Roszet Tablet 20mg+10mg
	Label Claim	Each Bilayer film coated tablet contains: Rosuvastatin calcium eq. to Rosuvastatin 20 mg Ezetimibe 10 mg
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	As per DPC-As per SRO
	Shelf Life (Unit)	2 Year Below 30°C
	For generic drugs (me-too Status)	Rovista EZ Tablet 20mg+10mg
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Martin Dow Limited-Plot No.37, Sector 19, Korangi Industrial Area-
	Name & address of API manufacturer	CTX Life Sciences Pvt Ltd, Glenmark Lifesciences Pvt Ltd
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	

The status in reference regulatory authorities	ALZIL PLUS 20mg+10mg - Spanish Agency for Medicines and Health Products (SPAIN)
GMP status of the firm	
Evidence of approval of manufacturing facility	
Evaluation Remarks	
The firm was asked to Provide/ clarify the following and the firm has submitted as below: With reference to the query regarding dissolution acceptance criteria, please note that we confirm adoption of the criterion NLT 85% (Q = 80%) in 30 minutes for both APIs. In alignment with the FDA-approved innovator product Roszet (NDA 213072), the following methods have been adopted and incorporated in our final product specifications for release and stability testing: Rosuvastatin: USP Apparatus II (Paddle), 50 rpm, 900 mL pH 6.6 citrate buffer, 37 ± 0.5 °C, 30 minutes. Ezetimibe: USP Apparatus I (Basket), 75 rpm, 900 mL pH 4.5 acetate buffer with 0.45% SLS, 37 ± 0.5 °C, 30 minutes. Supporting reference (FDA Product Quality Review of Roszet) is attached for justification. Please note that we have also enclosed 6th months stability studies.	
Decision	
Approved	

12	Case Category	Export Facilitation (Abdul Mughees)
	Name, address of Applicant.	Martin Dow Marker Limited 7, Jail Road Quetta. (000028)
	Application Form Dy. No / Tracking ID & date of submission	(YEW-Y5Q-EN43, 2025-05-07)
	Detail of Fee Submitted	30000.0, 93000.0 2024-06-24, 2025-01-24
	The proposed proprietary name / brand name	Roszet Tablet 10mg+10mg
	Label Claim	Each Bilayer film coated tablet contains: Rosuvastatin calcium eq. to Rosuvastatin 10 mg Ezetimibe 10 mg
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	As per DPC-As per SRO
	Shelf Life (Unit)	2 Year Below 30°C
	For generic drugs (me-too Status)	Rovista EZ Tablet 10mg+10mg
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Martin Dow Limited-Plot No.37, Sector 19, Korangi Industrial Area-
	Name & address of API manufacturer	CTX Life Sciences Pvt Ltd, Glenmark Lifesciences Ltd
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	ALZIL PLUS 10mg+10mg - Spanish Agency for Medicines and Health Products (SPAIN)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm was asked to Provide/ clarify the following and the firm has submitted as below: With reference to the query regarding dissolution acceptance criteria, please note that we confirm adoption of the criterion NLT 85% (Q = 80%) in 30 minutes for both APIs. In alignment with the FDA-approved innovator product Roszet (NDA 213072),	

the following methods have been adopted and incorporated in our final product specifications for release and stability testing: Rosuvastatin: USP Apparatus II (Paddle), 50 rpm, 900 mL pH 6.6 citrate buffer, 37 ± 0.5 °C, 30 minutes. Ezetimibe: USP Apparatus I (Basket), 75 rpm, 900 mL pH 4.5 acetate buffer with 0.45% SLS, 37 ± 0.5 °C, 30 minutes. Supporting reference (FDA Product Quality Review of Roszet) is attached for justification. Please note that we have also enclosed 6th months stability studies.

Decision

Approved

13	Case Category	New Molecule/Formulation (Abdul Mughees)
	Name, address of Applicant.	CRYSTOLITE PHARMACEUTICALS Plot # 1 & 2, street S-2, National Industrial Zone Rawat, Islamabad (000778)
	Application Form Dy. No / Tracking ID & date of submission	(DSE-J81-VYZT, 2025-09-22)
	Detail of Fee Submitted	75000.0, 2025-07-09,
	The proposed proprietary name / brand name	Avandra 200mg tablet
	Label Claim	each film coated tablet contains Avanafil 200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2's, 4's, 8's, 12's-As per SRO
	Shelf Life (Unit)	2 Year(s) store at room temperature
	For generic drugs (me-too Status)	no local reference
	Pharmacotherapeutic Group of (API)	phosphodiesterase-5 (PDE5) inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceutical limited
	Detail of stability batches of drug product	031T25, 032T25, 033T25
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached
	The status in reference regulatory authorities	MHRA approved
	GMP status of the firm	GMP certificate for Afghanistan dated 17th August 2022
	Evidence of approval of manufacturing facility	DML wef 30.08.2023
14	Evaluation Remarks	
	Decision	
	Approved	
14	The Registration Board approved the product subject to the report of Product Specific Inspection (PSI) for verification of submitted data by a panel constituted by Chairman, Registration Board.	
	Case Category	New Molecule/Formulation (Abdul Mughees)
	Name, address of Applicant.	CRYSTOLITE PHARMACEUTICALS Plot # 1 & 2, street S-2, National Industrial Zone Rawat, Islamabad (000778)
	Application Form Dy. No / Tracking ID & date of submission	(DZL-SMZ-R4MU, 2025-09-22)
	Detail of Fee Submitted	75000.0, 2025-07-09,

	The proposed proprietary name / brand name	Avandra 100mg tablet
	Label Claim	each film coated tablet contains avanafil 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2's,4's, 8's, 12's-As per SRO
	Shelf Life (Unit)	2 Yearstore at room temperature
	For generic drugs (me-too Status)	no local reference
	Pharmacotherapeutic Group of (API)	phosphodiesterase-5 (PDE5) inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceutical limited
	Detail of stability batches of drug product	028T25,029T25, 030T25
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached
	The status in reference regulatory authorities	MHRA approved
	GMP status of the firm	Attached
	Evidence of approval of manufacturing facility	Attached
	Evaluation Remarks	
	Decision	
	Approved	
	The Registration Board approved the product subject to the report of Product Specific Inspection (PSI) for verification of submitted data by a panel constituted by Chairman, Registration Board.	
15	Case Category	New Molecule/Formulation (Abdul Mughees)
	Name, address of Applicant.	CRYSTOLITE PHARMACEUTICALS Plot # 1 & 2, street S-2, National Industrial Zone Rawat, Islamabad (000778)
	Application Form Dy. No / Tracking ID & date of submission	(VR4-1PT-6H87, 2025-09-22)
	Detail of Fee Submitted	75000.0, 2025-07-09,
	The proposed proprietary name / brand name	Avandra 50mg Tablet
	Label Claim	Each film coated tablet contains; Avanafil.....50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2's,4's, 8's, 12's,30's,100's-As per SRO
	Shelf Life (Unit)	2 Yearstore at room temperature
	For generic drugs (me-too Status)	no local reference
	Pharmacotherapeutic Group of (API)	phosphodiesterase-5 (PDE5) inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceutical limited
	Detail of stability batches of drug product	025T25,026T25, 027T25
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached

Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached																																								
The status in reference regulatory authorities	MHRA approved																																								
GMP status of the firm	Attached																																								
Evidence of approval of manufacturing facility	Attached																																								
Evaluation Remarks																																									
Decision																																									
Approved																																									
The Registration Board approved the product subject to the report of Product Specific Inspection (PSI) for verification of submitted data by a panel constituted by Chairman, Registration Board.																																									
16	<table> <tr> <td>Case Category</td><td>Priority As Per 257-M of RB (Abdul Mughees)</td></tr> <tr> <td>Name, address of Applicant.</td><td>Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Lahore : Head office: SPL House No. 82, R-1 Johar Town, Lahore (000872)</td></tr> <tr> <td>Application Form Dy. No / Tracking ID & date of submission</td><td>(JN3-N22-H7RN, 2025-02-13)</td></tr> <tr> <td>Detail of Fee Submitted</td><td>37000.0, 2024-12-12,</td></tr> <tr> <td>The proposed proprietary name / brand name</td><td>Zolomid 20mg Capsule</td></tr> <tr> <td>Label Claim</td><td>Each Capsule Contains: Temozolomide.....20mg</td></tr> <tr> <td>Reference to Finished product specifications</td><td>United States Pharmacopeia</td></tr> <tr> <td>Proposed Pack Size</td><td>As Per SRO-As per SRO</td></tr> <tr> <td>Shelf Life (Unit)</td><td>2 Year(s)Do not store above 25°C.</td></tr> <tr> <td>For generic drugs (me-too Status)</td><td>Temomedac 20mg Hard Capsules (093923)-Amgomed Pharma</td></tr> <tr> <td>Pharmacotherapeutic Group of (API)</td><td>Anti neoplastic agent</td></tr> <tr> <td>Name, address of Manufacturing site:</td><td>Self Manufacturing</td></tr> <tr> <td>Name & address of API manufacturer</td><td>-</td></tr> <tr> <td>Detail of stability batches of drug product</td><td>E058, E059, E060 2500 cap, 2500 cap, 2500 cap. 30 ± 2o C/ 65% ± 5 % RH 40 ± 2o C/ 75% ± 5 % RH Interval: 1,2,3, 6</td></tr> <tr> <td>Documents for the procurement of API with approval from DRAP (in case of Import)</td><td>Temozolomide 0.16kg (Batch No: C22-20240101) imported from SUZHOU LIXIN PHARMACEUTICAL CO., LTD, No. 21, Tangxi Road, Suzhou New District, Suzhou P.R. of China. Clearance certificate was granted by I&E (DRAP, Lahore) dated 31.01.2024</td></tr> <tr> <td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Test product: Zolomid 20mg capsule Batch No: E058 Reference Product: Temomedac 20mg Batch No: K220496A Manufacturer: Haupat Pharma</td></tr> <tr> <td>Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)</td><td>M/s SUZHOU LIXIN PHARMACEUTICAL CO., LTD, CHINA C22-20181001 C22-20181002 C22-20181101 Long term stability data: 36 months Accelerated stability data: 6 months Conditions: Long term stability 25°C ± 2°C / 60 ± 5%RH Accelerated stability 2°C ± 8°C</td></tr> <tr> <td>The status in reference regulatory authorities</td><td>Temodal® 20 mg hard capsules (MHRA Approved)</td></tr> <tr> <td>GMP status of the firm</td><td>GMP certificate based on inspection dated 24-09-2024 and 25-09-2024 is provided</td></tr> <tr> <td>Evidence of approval of manufacturing facility</td><td>Tablet (Anti cancer) Human facility is approved by CLB dated 22.12.2017</td></tr> </table>	Case Category	Priority As Per 257-M of RB (Abdul Mughees)	Name, address of Applicant.	Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Lahore : Head office: SPL House No. 82, R-1 Johar Town, Lahore (000872)	Application Form Dy. No / Tracking ID & date of submission	(JN3-N22-H7RN, 2025-02-13)	Detail of Fee Submitted	37000.0, 2024-12-12,	The proposed proprietary name / brand name	Zolomid 20mg Capsule	Label Claim	Each Capsule Contains: Temozolomide.....20mg	Reference to Finished product specifications	United States Pharmacopeia	Proposed Pack Size	As Per SRO-As per SRO	Shelf Life (Unit)	2 Year(s)Do not store above 25°C.	For generic drugs (me-too Status)	Temomedac 20mg Hard Capsules (093923)-Amgomed Pharma	Pharmacotherapeutic Group of (API)	Anti neoplastic agent	Name, address of Manufacturing site:	Self Manufacturing	Name & address of API manufacturer	-	Detail of stability batches of drug product	E058, E059, E060 2500 cap, 2500 cap, 2500 cap. 30 ± 2o C/ 65% ± 5 % RH 40 ± 2o C/ 75% ± 5 % RH Interval: 1,2,3, 6	Documents for the procurement of API with approval from DRAP (in case of Import)	Temozolomide 0.16kg (Batch No: C22-20240101) imported from SUZHOU LIXIN PHARMACEUTICAL CO., LTD, No. 21, Tangxi Road, Suzhou New District, Suzhou P.R. of China. Clearance certificate was granted by I&E (DRAP, Lahore) dated 31.01.2024	Pharmaceutical Equivalence and Comparative Dissolution Profile	Test product: Zolomid 20mg capsule Batch No: E058 Reference Product: Temomedac 20mg Batch No: K220496A Manufacturer: Haupat Pharma	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	M/s SUZHOU LIXIN PHARMACEUTICAL CO., LTD, CHINA C22-20181001 C22-20181002 C22-20181101 Long term stability data: 36 months Accelerated stability data: 6 months Conditions: Long term stability 25°C ± 2°C / 60 ± 5%RH Accelerated stability 2°C ± 8°C	The status in reference regulatory authorities	Temodal® 20 mg hard capsules (MHRA Approved)	GMP status of the firm	GMP certificate based on inspection dated 24-09-2024 and 25-09-2024 is provided	Evidence of approval of manufacturing facility	Tablet (Anti cancer) Human facility is approved by CLB dated 22.12.2017
Case Category	Priority As Per 257-M of RB (Abdul Mughees)																																								
Name, address of Applicant.	Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Lahore : Head office: SPL House No. 82, R-1 Johar Town, Lahore (000872)																																								
Application Form Dy. No / Tracking ID & date of submission	(JN3-N22-H7RN, 2025-02-13)																																								
Detail of Fee Submitted	37000.0, 2024-12-12,																																								
The proposed proprietary name / brand name	Zolomid 20mg Capsule																																								
Label Claim	Each Capsule Contains: Temozolomide.....20mg																																								
Reference to Finished product specifications	United States Pharmacopeia																																								
Proposed Pack Size	As Per SRO-As per SRO																																								
Shelf Life (Unit)	2 Year(s)Do not store above 25°C.																																								
For generic drugs (me-too Status)	Temomedac 20mg Hard Capsules (093923)-Amgomed Pharma																																								
Pharmacotherapeutic Group of (API)	Anti neoplastic agent																																								
Name, address of Manufacturing site:	Self Manufacturing																																								
Name & address of API manufacturer	-																																								
Detail of stability batches of drug product	E058, E059, E060 2500 cap, 2500 cap, 2500 cap. 30 ± 2o C/ 65% ± 5 % RH 40 ± 2o C/ 75% ± 5 % RH Interval: 1,2,3, 6																																								
Documents for the procurement of API with approval from DRAP (in case of Import)	Temozolomide 0.16kg (Batch No: C22-20240101) imported from SUZHOU LIXIN PHARMACEUTICAL CO., LTD, No. 21, Tangxi Road, Suzhou New District, Suzhou P.R. of China. Clearance certificate was granted by I&E (DRAP, Lahore) dated 31.01.2024																																								
Pharmaceutical Equivalence and Comparative Dissolution Profile	Test product: Zolomid 20mg capsule Batch No: E058 Reference Product: Temomedac 20mg Batch No: K220496A Manufacturer: Haupat Pharma																																								
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	M/s SUZHOU LIXIN PHARMACEUTICAL CO., LTD, CHINA C22-20181001 C22-20181002 C22-20181101 Long term stability data: 36 months Accelerated stability data: 6 months Conditions: Long term stability 25°C ± 2°C / 60 ± 5%RH Accelerated stability 2°C ± 8°C																																								
The status in reference regulatory authorities	Temodal® 20 mg hard capsules (MHRA Approved)																																								
GMP status of the firm	GMP certificate based on inspection dated 24-09-2024 and 25-09-2024 is provided																																								
Evidence of approval of manufacturing facility	Tablet (Anti cancer) Human facility is approved by CLB dated 22.12.2017																																								

Evaluation Remarks

The firm was asked to submit clarification regarding: 1) Stability data on the Drug Substance has been performed at 40°C/75% RH (6 months) and 25°C/60%RH (24 months)<https://www.geneesmiddeleninformatiebank.nl/pars/h109658.pdf> while Drug Substance manufacturer performed stability studies at Long term stability: 25°C ± 2°C / 60 ± 5%RH, Accelerated stability: 2°C ± 8°C 2) Provide translated version of GMP certificate of Drug Substance manufacturer. In response, the firm has submitted: With reference to your queries, please find below justifications by our firm: 1. We hereby submit Temozolomide Sun Public Assessment report published in EMA (Temozolomide SUN, EMA/CHMP/197697/2011) in support to our submitted data. In the attached report under sub-section of Quality Aspects; Stability of Drug Substance have been submitted for long-term at 5°C ± 3°C and accelerated studies at 25°C/60%RH. The stability package for Temozolomide, as assessed and accepted by EMA/CHMP, supports the proposed retest period under refrigerated storage (2–8°C). This conclusion is in alignment with international regulatory standards and ensures the continued safety, efficacy, and quality of the product. EMA/CHMP Assessment Report (Temozolomide SUN) attached. 2. Please find attached valid DML of Drug substance manufacturer along with translated version. Notification for non-issuance of GMP certificate by Ministry of China is also attached for your kind reference.

Decision**Approved**

17

Case Category	New Section (Abdul Mughees)
Name, address of Applicant.	Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi (000333)
Application Form Dy. No / Tracking ID & date of submission	(SAJ-DPZ-ZJZ1, 2025-04-29)
Detail of Fee Submitted	37000.0, 2024-09-27,
The proposed proprietary name / brand name	CIOP 200mg/100ml Infusio
Label Claim	Each mL Contains 2mg ciprofloxacin as ciprofloxacin lactate 2.544mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	1's (100ml)-As per SRO
Shelf Life (Unit)	2 Yearstore in a cool and dry place below 30
For generic drugs (me-too Status)	Cipesta 200mg/100ml infusion Getz Pharma
Pharmaceutical Therapeutic Group of (API)	
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Zhejiang Guobang Pharmaceuticals
Detail of stability batches of drug product	
Documents for the procurement of API with approval from DRAP (in case of Import)	
Pharmaceutical Equivalence and Comparative Dissolution Profile	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
The status in reference regulatory authorities	Ciprofloxacin 2mg/ml Infusion
GMP status of the firm	
Evidence of approval of manufacturing facility	

Evaluation Remarks

First list of question was sent to firm and they replied: a) Clarify how your application falls under "New section" category b) Submit evidence of approval of the relevant section from Licensing Division, and clarify the section name where this product will be manufactured. Reply: Dear sir, New section approval is attached This product will be manufactured in Liquid injectables vial-SVP-II (General) (point iv second floor) The Second list of questions

was sent and the firm replied: Attach 06 month stability data alongwith chromatograms and data loggers. USP monograph contains lactic acid content testing using HPLC analysis. Provide evidence of testing, availability of USP sodium lactate RS and include the said test in specifications

Decision

Approved

The firm shall submit fee for revision of specifications.

18	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	Welwrd Pharmaceuticals Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar (000574)
	Application Form Dy. No / Tracking ID & date of submission	(7WJ-9Q9-QZE7, 2025-09-01)
	Detail of Fee Submitted	75000.0, 2025-06-12,
	The proposed proprietary name / brand name	Welfil 100mg Chewable Tablet
	Label Claim	Each Chewable Tablet Contains: Sildenafil Citrate eq. to Sildenafil 100mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	G04BE03 Phosphodiesterase-5 inhibitor (PDE5-I)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited 103-106, GIDC, Halol Dist. Panchmahals
	Detail of stability batches of drug product	WS13, WS14, WS15, 450 tablets each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan Letter along with Goods Declaration Attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Sildenafil Cinfa 100mg Masticables B. No. 0206GDA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IV-A Attached
	The status in reference regulatory authorities	CIMA Spain
	GMP status of the firm	GMP certificate issued 0on basis of inspection dated 30.03.2022 is submitted
	Evidence of approval of manufacturing facility	Tablet General Section Renewal letter dated 4.07.2022 is submitted
	Evaluation Remarks	
	Priority as per Decision of 214th meeting of RB	
	Firm has not performed system suitability as per BP monograph (use of impurity B i.e. made by degradation of Sildenafil in-situ). Firm was asked about it and they have confirmed that they have not performed it	
	Drug substance is taken loan from M/s Weatherfolds, and it was imported drug any approval from DRAP,	
	Decision	
	Deferred	
	Deferred for submission of revised method of test and analysis of drug product as per BP monograph along with its verification report.	
19	Case Category	Any Other (Adil Saeed)

Name, address of Applicant.	Welwrd Pharmaceuticals Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar (000574)
Application Form Dy. No / Tracking ID & date of submission	(H7D-X6Z-181J, 2025-09-01)
Detail of Fee Submitted	75000.0, 2025-06-12,
The proposed proprietary name / brand name	Welfil 50mg Chewable Tablet
Label Claim	Each Chewable Tablet Contains: Sildenafil as Citrate (BP).....50MG (Product complies BP Specs)
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 Year(s)Store below 25c
For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 inhibitor (PDE5-I)
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	
Detail of stability batches of drug product	WS 10, WS11, WS 12
Documents for the procurement of API with approval from DRAP (in case of Import)	Loan Letter along with Goods Declaration Attached
Pharmaceutical Equivalence and Comparative Dissolution Profile	Sildenafil cinfa 50mg Masticables M/s Cinfa B. No. 0102XRA
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IV-A Attached
The status in reference regulatory authorities	CIMA Spain
GMP status of the firm	Valid
Evidence of approval of manufacturing facility	Tablet General Section
Evaluation Remarks	
Priority as per Decision of 214th meeting of RB	
Firm has not performed system suitability as per BP monograph (use of impurity B i.e. made by degradation of Sildenafil in-situ). Firm was asked about it and they have confirmed that they have not performed it	
Drug substance is taken loan from M/s Weatherfolds, and it was imported drug any approval from DRAP,	
Decision	
Deferred	
Deferred for submission of revised method of test and analysis of drug product as per BP monograph along with its verification report.	
20	Case Category
	Any Other (Adil Saeed)
Name, address of Applicant.	Welwrd Pharmaceuticals Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar (000574)
Application Form Dy. No / Tracking ID & date of submission	(GM2-BSG-TT1U, 2025-06-25)
Detail of Fee Submitted	75000.0, 2025-03-17,
The proposed proprietary name / brand name	Welfil 100mg Tablet
Label Claim	Each Film Coated Tablet Contains: Sildenafil Citrate eq. to Sildenafil.....100mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	As per SRO-As per SRO

	Shelf Life (Unit)	2 Year(s)Store below 25c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	G04BE03 Drugs used in erectile dysfunction
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches, 600 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra 100mg Lot No. VS11426 Mfg Pfizer
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	UK MHRA approved
	GMP status of the firm	Renewal in 2024
	Evidence of approval of manufacturing facility	Renewal letter dated 11.06.2024 is submitted
	Evaluation Remarks	
	Priority as per decision of 214th RB	
	Drug substance is taken loan from M/s Weatherfolds, and it was imported drug any approval from DRAP, PSI of M/s Weatherfold for similar product has been conducted and product was approved.	
21	Decision	
	Approved	
	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	Welwrd Pharmaceuticals Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar (000574)
	Application Form Dy. No / Tracking ID & date of submission	(QH3-JNV-WWPM, 2025-07-22)
	Detail of Fee Submitted	75000.0, 2025-03-17,
	The proposed proprietary name / brand name	Silafold 50mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Sildenafil as Citrate (USP).....50mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	G04BE03 Drugs used in erectile dysfunction
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited 103-106, GIDC, Halol Dist. Panchmahals
	Detail of stability batches of drug product	3 batches, 600 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	-----
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra 50mg Tablets
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	EMA Europe

	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Renewal letter dated 4.07.2022 is submitted
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority	
	Drug substance is taken loan from M/s Weatherfolds, and it was imported without any approval from DRAP, PSI of M/s Weather fold for sildenafil tablet was conducted and product was approved.	
	Decision	
	Approved	
22	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	Martin Dow Marker Limited 7, Jail Road Quetta. (000028)
	Application Form Dy. No / Tracking ID & date of submission	(BP2-ZYW-Y1J2, 2025-09-19)
	Detail of Fee Submitted	97200, 2025-09-16,
	The proposed proprietary name / brand name	Vydra Tablets 100mg
	Label Claim	Each Film-coated Tablet contains: Sildenafil citrate equivalent to Sildenafil 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per DPC/SRO-As per SRO
	Shelf Life (Unit)	24 Year(s) Store below 30°C Protect from heat, Light and Moisture
	For generic drugs (me-too Status)	Hilagra Tablets 100mg
	Pharmacotherapeutic Group of (API)	Drugs used in erectile dysfunction
	Name, address of Manufacturing site:	Martin Dow Limited-Plot No. 37, Sector 19, Korangi Industrial Area, Karachi-
	Name & address of API manufacturer	Century Pharmaceuticals Limited, 103-106, GIDC, Halol Dist. Panchmahals- 389 350, India.
	Detail of stability batches of drug product	NPD-T-2703-S / 1500 Tablets, NPD-T-2724-S / 2500 Tablets, NPD-T-2725-S / 2500 Tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate mentioning 4.6kg drug substance is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra 100mg tablet Lot No. 3189217 Viatris Egypt SAE
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Viagra Tablets 100mg (USFDA)
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 15.08.2024 is submitted
	Evidence of approval of manufacturing facility	Renewal letter dated 15.09.2021 is submitted
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority	
	Decision	
	Approved	
23	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	Magns Pharmaceuticals Plot # 7B Value Addition City Sahianwala Road Khurrianwala (000849)

Application Form Dy. No / Tracking ID & date of submission	(2RM-X4R-N8BZ, 2025-05-22)
Detail of Fee Submitted	37000.0, 38000.0 2025-05-13, 2025-05-20
The proposed proprietary name / brand name	Magra 25mg Tablet
Label Claim	Each film coated Tablet Contains: Sildenafil citrate eq. to Sildenafil 25 mg
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	1 x4,s -De-Controlled
Shelf Life (Unit)	2 Year(s)store below 30 oC
For generic drugs (me-too Status)	Silden Tablet by Shaighan Pharma
Pharmacotherapeutic Group of (API)	Sildenafil as Citrate phosphodiesterase-5 (PDE-5) inhibitors
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Rakshit House, Plot No: 425/ 3RT, Sanjeeva Reddy Nagar, Hyderabad, Telangana 500038, India
Detail of stability batches of drug product	3 batches, 1200 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate mentioning 1.5kg drug substance is submitted
Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra 25mg B. No. B819305U Mfg Pfizer USA
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
The status in reference regulatory authorities	Viagra Tablet by Pfizer
GMP status of the firm	GMP certificate issued on basis of inspection conducted on 11.03.2022 is submitted
Evidence of approval of manufacturing facility	renewal letter dated 0706.2022 is submitted
Evaluation Remarks	
Priority as per decision of 214th meeting of Authority	
3.2.S.4 Analytical method verification protocol and report from drug product manufacturer is required.	A document titled Analytical testing method verification of sildenafil citrate of M/s Wimits pharmaceuticals is submitted.
3.2.P.2 In CDP only 6 units are used at every time point in different pH. ICH guidelines (Biopharmaceutical classification system based biowaivers) state that at least 12 units should be used	Instead of performing CDP with 12 units, firm has resubmitted same data that was submitted in Module 3.
3.2.P.5 Please submit chromatogram of system suitability run performed before the assay (it should be as per BP monograph)	System suitability is not performed as per BP monograph
3.2.P.8 3rd time point stability data is required.	Submitted
Decision	
Rejected	
Keeping in view the fact that firm has submitted documents of another manufacturer, the board rejected the case.	
24 Case Category	Any Other (Adil Saeed)
Name, address of Applicant.	Magns Pharmaceuticals Plot # 7B Value Addition City Sahianwala Road Khurrianwala (000849)
Application Form Dy. No / Tracking ID & date of submission	(SAM-SZL-D68P, 2025-05-23)

Detail of Fee Submitted	37000.0, 38000.0 2025-05-13, 2025-05-20
The proposed proprietary name / brand name	Magra
Label Claim	Each Film coated Tablet Contains: Sildenafil citrate eq. to Sildenafil. 100 mg
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	1 x4,s -De-Controlled
Shelf Life (Unit)	2 Year(s)store below 30 oC
For generic drugs (me-too Status)	Silden Tablet by Shaighan Pharma
Pharmacotherapeutic Group of (API)	Sildenafil as Citrate phosphodiesterase-5 (PDE-5) inhibitors
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Rakshit House, Plot No: 425/ 3RT, Sanjeeva Reddy Nagar, Hyderabad, Telangana 500038, India
Detail of stability batches of drug product	3 batches, 1100 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra 100mg Tablet B No. B808204U Pfizer USA
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
The status in reference regulatory authorities	Viagra Tablet by Pfizer
GMP status of the firm	GMP certificate issued on basis of inspection conducted on 11.03.2022 is submitted
Evidence of approval of manufacturing facility	renewal letter dated 0706.2022 is submitted
Evaluation Remarks	
Priority as per decision of 214th meeting of Authority	
3.2.S.4 Analytical method verification protocol and report from drug product manufacturer is required.	A document titled Analytical testing method verification of sildenafil citrate of M/s Wimits pharmaceuticals is submitted.
3.2.P.2 In CDP only 6 units are used at every time point in different pH. ICH guidelines (Biopharmaceutical classification system based biowaivers) state that at least 12 units should be used	Instead of performing CDP with 12 units, firm has resubmitted same data that was submitted in Module 3.
3.2.P.5 Please submit chromatogram of system suitability run performed before the assay (it should be as per BP monograph)	System suitability is not performed as per BP monograph
3.2.P.8 3rd time point stability data is required.	Submitted
Decision	
Rejected	
Keeping in view the fact that firm has submitted documents of another manufacturer, the board rejected the case.	
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Case Category	Any Other (Adil Saeed)
Name, address of Applicant.	Magns Pharmaceuticals Plot # 7B Value Addition City Sahianwala Road Khurrianwala (000849)
Application Form Dy. No / Tracking ID & date of submission	(T1Y-UVU-YWVS, 2025-05-23)
Detail of Fee Submitted	37000.0, 38000.0 2025-05-13, 2025-05-20

The proposed proprietary name / brand name	Magra 50mg Tablet
Label Claim	Each film coated Tablet Contains: Sildenafil citrate eq. to Sildenafil. 50 mg
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	1 x4,s -De-Controlled
Shelf Life (Unit)	2 Year(s)store below 30 oC
For generic drugs (me-too Status)	Silden Tablet by Shaighan Pharma
Pharmacotherapeutic Group of (API)	Sildenafil as Citrate phosphodiesterase-5 (PDE-5) inhibitors
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Rakshit House, Plot No: 425/ 3RT, Sanjeeva Reddy Nagar, Hyderabad, Telangana 500038, India
Detail of stability batches of drug product	3 batches, 1100 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted
Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra 50 mg tablet B. No. B799704U Pfizer USA
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
The status in reference regulatory authorities	Viagra Tablet by Pfizer
GMP status of the firm	cGMP certified (Certificate attached)
Evidence of approval of manufacturing facility	renewal letter dated 0706.2022 is submitted
Evaluation Remarks	
Priority as per decision of 214th meeting of Authority	
3.2.S.4 Analytical method verification protocol and report from drug product manufacturer is required.	A document titled Analytical testing method verification of sildenafil citrate of M/s Wimits pharmaceuticals is submitted.
3.2.P.2 In CDP only 6 units are used at every time point in different pH. ICH guidelines (Biopharmaceutical classification system based biowaivers) state that at least 12 units should be used	Instead of performing CDP with 12 units, firm has resubmitted same data that was submitted in Module 3.
3.2.P.5 Please submit chromatogram of system suitability run performed before the assay (it should be as per BP monograph)	System suitability is not performed as per BP monograph
3.2.P.8 3rd time point stability data is required.	Submitted
Decision	
Rejected	
Keeping in view the fact that firm has submitted documents of another manufacturer, the board rejected the case.	
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Case Category	Routine (Adil Saeed)
Name, address of Applicant.	AHSONS Drug Company T/1 S.I.T.E Tando Adam (000138)
Application Form Dy. No / Tracking ID & date of submission	(EMU-GVL-YZNH, 2025-01-14)
Detail of Fee Submitted	37000.0, 2024-11-12,
The proposed proprietary name / brand name	Cefra 500mg powder for solution for IM Injection
Label Claim	Each vial contains:Cephadrine (with L – Arginine) USP.....500mg

Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	1's-As per SRO
Shelf Life (Unit)	2 Year(s)Store bellows 30°C. Protect from light. Improper storage may deteriorate the medicine.
For generic drugs (me-too Status)	Brand Name: Velosef Injection Strength: 500mg Dosage Form: IV /IM Injection Pack Size: 1's Regn No.001866 Manufacturer: GlaxoSmithKline Pakistan Limited.
Pharmacotherapeutic Group of (API)	J01DD04 Third-generation cephalosporins
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Pharmagen Limited 5-A,Zafer Ali Road, Gulberg-V, Lahore, Pakistan.
Detail of stability batches of drug product	3 batches 500 vials each
Documents for the procurement of API with approval from DRAP (in case of Import)	Local purchased from Pharmagen
Pharmaceutical Equivalence and Comparative Dissolution Profile	Velosef 500mg BF3P
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
The status in reference regulatory authorities	Brand Name: Velosef Injection Strength: 500mg Market Authorization: M/s Apothecon Reference Regulatory Authority: USFDA Approved medicine.
GMP status of the firm	----
Evidence of approval of manufacturing facility	Renewal letter dated 11.05.2022 is submitted

Evaluation Remarks

3.2.P.5 In Assay the its mentioned that only peak of Cephadrine will be calculated, the monograph of older version of USP (which is followed as evident from your submission) states that quantity of Cephadrine and Cephalixin both needs to be considered. Further in chromatograms submitted, peak of cephalixin is not present. Please justify these deviations in analytical method and performance of assay.

Response: The firm has stated that; "No cephalixin peak is observed because cephalixin is notpresent in the tested samples. The assay for Cephadrine for injection is conducted strictly as perUSP Monograph with quantification based only on the Cephadrine peak. Cephalixin is not includedin assay calculations but is approximately controlled as a specified impurity under the relatedsubstances procedure. The absence of a cephalixin peak in assay chromatograms is consistent withvalidated method sensitivity, stability data and product quality."

The USP 2021 has monograph of Cephadrine for injection. The definition of product given inmonograph is;"Cephadrine for Injection contains not less than 90.0 percent and not more than 115.0percent of the labeled amount of cephradine, calculated as the sum of cephradine (C16H19N3O4S)and cephalixin (C16H17N3O4S)"Further the COA of drug substance lot No. 00401/22-02/002 (used in manufacturing of drug product) does indicate cephalixin content. Drug substance manufacturer (M/s Pharmagen) has quantified it as 2.48% whereas drug product manufacturer has quantified it as 2.59%. But in their response firm is claiming that "No Cephalixin peak is observed because cephalixin is not present in the tested samples."

Under heading of assay, procedure to calculate quantity is give as "Calculate the quantity, in mg, of cephradine (sum of cephradine and cephalixin) withdrawn from the container, or in the portion of constituted solution taken by the formula"

Firm was asked to justify that their application falls under category of new section as in renewal section Ceph dry powder inj section is not mentioned as new. The firm has replied as under;

"We M/s Ahsons Drug Company Plot No: T/1, S.I.T.E Tando Adam Sindh, wish to bring in your kind notice that, our newly established section of "Dry Powder Injection Section (Cephalosporin)"was inspected and recommended for grant on 22/02/2022 by the panel constituted by chairman Central Licensing Board. Subsequently renewal of DML was granted by the CLB with inclusion of new section of "Dry Powder Injection Section (Cephalosporin)" on 11/05/2022. Since the date of approval of our new section of "Dry Powder Injection Section (Cephalosporin)" by CLB we haven't applied for any product of the said section to the Registration Board"

Decision**Deferred**

for clarification from firm on queries of evaluator.

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Case Category	New Section (Adil Saeed)
Name, address of Applicant.	AHSONS Drug Company T/1 S.I.T.E Tando Adam (000138)
Application Form Dy. No / Tracking ID & date of submission	(44A-7G7-91M3, 2025-01-14)
Detail of Fee Submitted	37000.0, 2024-11-12,
The proposed proprietary name / brand name	Cefra 250mg Powder for solution for IM Injection
Label Claim	Each vial contains: Cephadrine (with L – Arginine) 250mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	1's-As per SRO
Shelf Life (Unit)	2 Year(s)Store bellow 30°C. Protect from heat, sunlight & moisture. Improper storage may deteriorate the medicine.
For generic drugs (me-too Status)	Brand Name: Velosef Injection Strength: 250mg Dosage Form: IV /IM Injection Pack Size: 1's Regn No.001870 Manufacturer: GlaxoSmithKline Pakistan Limited.
Pharmacotherapeutic Group of (API)	J01DB09 Third-generation cephalosporins
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	M/s Pharmagen Ltd. Kot Nabi Bukshwala, 34-Km Ferozepur Road, Lahore-Pakistan.
Detail of stability batches of drug product	3 batches 500 vials each
Documents for the procurement of API with approval from DRAP (in case of Import)	Local purchased from Pharmagen
Pharmaceutical Equivalence and Comparative Dissolution Profile	Velosef 250mg Injecion ML2J
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
The status in reference regulatory authorities	Brand Name: Velosef Injection Strength: 250mg Market Authorization: M/s Apothecon Reference Regulatory Authority: USFDA Approved medicine.
GMP status of the firm	----
Evidence of approval of manufacturing facility	Renewal letter dated 11.05.2022 is submitted

Evaluation Remarks

3.2.P.5 In Assay the its mentioned that only peak of Cephadrine will be calculated, the monograph of older version of USP (which is followed as evident from your submission) states that quantity of Cephadrine and Cephalixin both needs to be considered. Further in chromatograms submitted, peak of cephalixin is not present. Please justify these deviations in analytical method and performance of assay.

Response: The firm has stated that; "No cephalixin peak is observed because cephalixin is not present in the tested samples. The assay for Cephadrine for injection is conducted strictly as per USP Monograph with quantification based only on the Cephadrine peak. Cephalixin is not included in assay calculations but is approximately controlled as a specified impurity under the related substances procedure. The absence of a cephalixin peak in assay chromatograms is consistent with validated method sensitivity, stability data and product quality."

The USP 2021 has monograph of Cephadrine for injection. The definition of product given in monograph is;"Cephadrine for Injection contains not less than 90.0 percent and not more than 115.0percent of the labeled

amount of cephadrine, calculated as the sum of cephadrine (C₁₆H₁₉N₃O₄S) and cephalixin (C₁₆H₁₇N₃O₄S)"Further the COA of drug substance lot No. 00401/22-02/002 (used in manufacturing of drug product) does indicate cephalixin content. Drug substance manufacturer (M/s Pharmagen) has quantified it as 2.48% whereas drug product manufacturer has quantified it as 2.59%. But in their response firm is claiming that "No Cephalixin peak is observed because cephalixin is not present in the tested samples."

Under heading of assay, procedure to calculate quantity is give as "Calculate the quantity, in mg, of cephadrine (sum of cephadrine and cephalixin) withdrawn from the container, or in the portion of constituted solution taken by the formula"

Firm was asked to justify that their application falls under category of new section as in renewal section Ceph dry powder inj section is not mentioned as new. The firm has replied as under;

"We M/s Ahsons Drug Company Plot No: T/1, S.I.T.E Tando Adam Sindh, wish to bring in your kind notice that, our newly established section of "Dry Powder Injection Section (Cephalosporin)" was inspected and recommended for grant on 22/02/2022 by the panel constituted by chairman Central Licensing Board. Subsequently renewal of DML was granted by the CLB with inclusion of new section of "Dry Powder Injection Section (Cephalosporin)" on 11/05/2022. Since the date of approval of our new section of "Dry Powder Injection Section (Cephalosporin)" by CLB we haven't applied for any product of the said section to the Registration Board"

Decision

Deferred

for clarification from the firm for queries of evaluator.

28	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	Genome Pharmaceuticals (Pvt.) Ltd , Plot No. 16/1, Phase-IV, Industrial Estate Hattar Dist: Haripur (KPK)-PAKISTAN. (000454)
	Application Form Dy. No / Tracking ID & date of submission	(MHA-HQM-G6QN, 2025-05-22)
	Detail of Fee Submitted	37000.0, 38000.0 2025-05-09, 2025-05-21
	The proposed proprietary name / brand name	Genogra 50mg Tablets
	Label Claim	Each film coated tablet contains: Sildenafil citrate eq. to Sildenafil 50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 x 4's-As per SRO
	Shelf Life (Unit)	24 Month(s)Below 30°C
	For generic drugs (me-too Status)	Agelafil 50mg Tablet
	Pharmacotherapeutic Group of (API)	Phosphodiesterase 5 (PDE5) inhibitors, Urologicals
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rakshit Drugs Private Limited
	Detail of stability batches of drug product	3 batches, 2500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate mentioning 2kg drug substance is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra 50mg Tablet B No. 3204975
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	US FDA Approved
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 25.05.2023 is submitted
	Evidence of approval of manufacturing facility	Renewal letter dated 07.07.2021 is submitted

Evaluation Remarks

Priority as per decision of 214th meeting of Authority.

Decision

Approved

29	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	Genome Pharmaceuticals (Pvt.) Ltd , Plot No. 16/1, Phase-IV, Industrial Estate Hattar Dist: Haripur (KPK)-PAKISTAN. (000454)
	Application Form Dy. No / Tracking ID & date of submission	(VZX-6G3-PAEM, 2025-05-26)
	Detail of Fee Submitted	37000.0, 38000.0 2025-05-16, 2025-05-21
	The proposed proprietary name / brand name	Genogra 100mg Tablets
	Label Claim	Each film coated tablet contains: Sildenafil citrate eq. to Sildenafil 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 x 4's-As per SRO
	Shelf Life (Unit)	24 Month(s)Below 30°C
	For generic drugs (me-too Status)	Denasil 100mg Tablets
	Pharmacotherapeutic Group of (API)	Phosphodiesterase 5 (PDE5) inhibitors, Urologicals
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rakshit Drugs Private Limited. India
	Detail of stability batches of drug product	3 batches, 2500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate mentioning 2kg drug substance is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra 100mg Lot No. LN1075 M/s Viatris
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	US FDA Approved
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 25.05.2023 is submitted
	Evidence of approval of manufacturing facility	Renewal letter dated 07.07.2021 is submitted
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority.	
	Decision	
	Approved	
30	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	Dyson Research Laboratories (Pvt.) Ltd 28-Km Ferozpur Road Lahore (000559)
	Application Form Dy. No / Tracking ID & date of submission	(S11-DYN-3L95, 2025-09-23)
	Detail of Fee Submitted	38700.0, 2025-08-19,
	The proposed proprietary name / brand name	Pulmosil
	Label Claim	Each film coated tablet contains: Sildenafil citrate Equivalent to Sildenafil.....50mg
	Reference to Finished product specifications	United States Pharmacopeia

Proposed Pack Size	1 x 4's-As per SRO
Shelf Life (Unit)	2 Year(s)Store below 30C.
For generic drugs (me-too Status)	Ripple Tablet 50mg by Solaris Life Sciences Private Limited.
Pharmacotherapeutic Group of (API)	Selective Inhibitor of cyclic GMP-specific phosphodiesterase (Type V) with vasodilator action; Urological; Drugs used in erectile dysfunction.
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Rakshit Pharmaceuticals Limited., situated at Plot number 68/A, Jawaharlal Nehru Pharma City, Parawada Mandal, Anapalli district, Andhra Pradesh, India. 531021.
Detail of stability batches of drug product	3 batches 1000 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	ADC Computerized No: E-10722560409128, dated: 09 October, 2024.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra 50mg tablet B767805U
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
The status in reference regulatory authorities	Viagra Tablet 50mg, approved by USFDA.
GMP status of the firm	GMP certificate issued on basis of inspection dated 07.03.2024
Evidence of approval of manufacturing facility	Grant of letter by DRAP of section/facilities approval vide letter no: F. 1-7/2003-Lic (Vol-IV) dated: 08-06-2021.

Evaluation Remarks

Priority as per Decision of 214th meeting of the Authority

Decision

Approved

31	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	Platinum Pharmaceuticals A-20,North Western Industrial Zone Bin Qasim,Karachi (000415)
	Application Form Dy. No / Tracking ID & date of submission	(129-6PZ-6BVG, 2025-05-19)
	Detail of Fee Submitted	75000.0, 2025-05-02,
	The proposed proprietary name / brand name	Y-GRA 50MG TABLET
	Label Claim	Each film coated tablet contain: sildenafil citrate equivalent to 50mg of sildenafil
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO,14's-As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO,4's-As per SRO,7's-As per SRO,8's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	G04BE03 Phosphodiesterase-5 (PDE5) inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	RAKSHIT PHARMACEUTICALS LIMITED
	Detail of stability batches of drug product	3 batches, 1000 tablets each

	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate of 1.2kg drug substance is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra 50mg B No. B700010D MfgPharmazeutoscher Netherlands
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	GMP certificate issued on basis of inspection dated 13.11.2024
	Evidence of approval of manufacturing facility	Renewal letter dated 16.11.2022
	Evaluation Remarks	
	As per priority of 214th meeting of Authority	
	Decision	
	Approved	
32	Case Category	New Section (Dr. Farhad Ullah)
	Name, address of Applicant.	Hi-Med Pharmaceuticals 208C Sundar industrial estate Raiwind Road Lahore (000884)
	Application Form Dy. No / Tracking ID & date of submission	(1G1-6LZ-2SDL, 2025-07-22)
	Detail of Fee Submitted	37000.0, 2025-06-20,
	The proposed proprietary name / brand name	K-VIT INJECTION 10mg/ml
	Label Claim	Each ml ampoule contains: Phytomenadione (Vitamin K1) 10mg (Product Specs: BP Specs)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1 x 1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store Below 25 degree celcius
	For generic drugs (me-too Status)	K-LOT INJECTION 10MG/ML (GT PHARMACEUTICALS)
	Pharmacotherapeutic Group of (API)	Fat-soluble vitamin (Vitamin K1),Coagulation factor synthesis promoter
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Anhui Wanhe Pharmaceutical Co., Ltd
	Detail of stability batches of drug product	3 batches having batch size of 200 ampoules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of loan letter from M/s GT Pharma for procurement of API along with intimation of borrowing of API letter to PE&R division DRAP. Firm has also submitted copy of clearance certificate issued dated 15-08-2024 specifying 05kg Vitamin K1.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against K-LOT Injection 10mg/ml
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A
	The status in reference regulatory authorities	KONAKION MM AMPOULES 10 MG/ML SOLUTION FOR INJECTION (Neon Healthcare Limited 8 The Chase, John Tate Road, Hertford, SG13 7NN,United Kingdom) MHRA Approved
	GMP status of the firm	New section

Evidence of approval of manufacturing facility	Firm has submitted copy of letter for grant of additional section dated 02-12-2024 specifying Liquid Injectable (Small Volume Parenteral) (General)-New.

Evaluation Remarks

Shortcomings	Firm's Response
You have stated that we follow inhouse specifications for applied product in section 1.5.6 while monograph for applied product is available in BP. Clarification shall be submitted.	Product is available in pharmacopeia. We follow BP specifications for analytical testing of KVit Injection.
As per BP monograph assay content of API is calculated based on the content of sum of trans-phytomenadione and cis-phytomenadione isomers while you have reported the assay as of Phytomenadione in batch analysis of API, clarify	Firm has submitted revised COA of API in which the assay content has been reported as sum of trans-phytomenadione and cis-phytomenadione isomers
Stability study data of applied product at 6th month time point shall be submitted	Submitted.
As per the decision, applicant was supposed to intimate DRAP within 15 days of obtaining API loan. Please justify.	Firm have stated that, "the specific duration (for intimation of loan of API) was not in our knowledge. We will be careful next time."

Decision

Approved

Registration Board further decided that Registration letter will be issued after Verification of loan letter of API.

33	Case Category	New Section (Dr. Farhad Ullah)
	Name, address of Applicant.	Hi-Med Pharmaceuticals 208C Sundar industrial estate Raiwind Road Lahore (000884)
	Application Form Dy. No / Tracking ID & date of submission	(ZHY-5DB-2DTT, 2025-07-22)
	Detail of Fee Submitted	37000.0, 2025-06-20,
	The proposed proprietary name / brand name	K-VIT INJECTION 2mg/ml
	Label Claim	Each ml ampoule Contains: Phytomenadione (Vitamin K1)....2mg (Product Specs: BP Specs)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1 x 1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store Below 25 degree celcius
	For generic drugs (me-too Status)	K-LOT Injection 2mg/ml (GT PHARMACEUTICALS)
	Pharmacotherapeutic Group of (API)	Fat-soluble vitamin (Vitamin K1),Coagulation factor synthesis promoter
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Anhui Wanhe Pharmaceutical Co., Ltd
	Detail of stability batches of drug product	3 batches having batch size of 200 ampoules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of loan letter from M/s GT Pharma for procurement of API along with intimation of borrowing of API letter to PE&R division DRAP. Firm has also submitted copy of clearance certificate issued dated 15-08-2024 specifying 05kg Vitamin K1.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against K-LOT Injection 2mg/ml
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study of 03 batches of drug substance as per zone IV-A

The status in reference regulatory authorities	VITAMIN K1 INJECTION 2MG/ML (HOSPIRA PHARMACEUTICALS)
GMP status of the firm	New section
Evidence of approval of manufacturing facility	Firm has submitted copy of letter for grant of additional section dated 02-12-2024 specifying Liquid Injectable (Small Volume Parenteral) (General)-New.

Evaluation Remarks

Shortcomings	Firm's Response
You have stated that we follow inhouse specifications for applied product in section 1.5.6 while monograph for applied product is available in BP. Clarification shall be submitted.	Product is available in pharmacopeia. We follow BP specifications for analytical testing of K-Vit Injection.
Submit evidence of applied formulation in reference regulatory authorities in applied filled volume along with weblink	Firm has submitted the evidence of applied product in Health Canada. Details are; VITAMIN K1 1mg / 0.5ml by M/s Sandoz Canada Inc. Health Canada Approved Pediatric Formulation: 1mg / 0.5ml. However, the filled volume of applied product is different than RRA product.
As per BP monograph assay content of API is calculated based on the content of sum of trans-phytomenadione and cis-phytomenadione isomers while you have reported the assay as of Phytomenadione in batch analysis of API, clarify	Firm has submitted revised COA of API in which the assay content has been reported as sum of trans-phytomenadione and cis-phytomenadione isomers
Stability study data of applied product at 6th month time point shall be submitted	Submitted.
As per the decision, applicant was supposed to intimate DRAP within 15 days of obtaining API loan. Please justify.	Firm have stated that, "the specific duration (for intimation of loan of API) was not in our knowledge. We will be careful next time.

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.

34	Case Category	Export Facilitation (Dr. Farhad Ullah)
	Name, address of Applicant.	Swiss Pharmaceuticals Pvt. Ltd. A/159, S.I.T.E.-II, Super Highway (000438)
	Application Form Dy. No / Tracking ID & date of submission	(SJ9-SP9-3UH8, 2024-10-09)
	Detail of Fee Submitted	37000.0, 2024-09-27,
	The proposed proprietary name / brand name	CO-OLANZA 12mg/25mg CAPSULE
	Label Claim	Each Capsule contains: Olanzapine.....12mg Fluoxetine as Hydrochloride.....25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's, 14's, 20's, 28-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Olanzagat Capsule by M/s Getz Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Atypical Antipsychotic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Palam Pharma PVT. LTD,M/s. Vision Drugs Limited Hyderabad, India.
	Detail of stability batches of drug product	3 batches having batch size of 1000 capsule each

Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of loan letter from M/s Seraph Pharmaceutical for procurement of API along with intimation of borrowing of API letter to PE&R division DRAP. Firm has also submitted copy of clearance certificate for fluoxetine HCl issued dated 07-10-2022 specifying 25kg fluoxetine. Firm has also submitted copy of clearance certificate for Olanzapine issued dated 05-08-2020 specifying 05kg olanzapine.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Olanzagat 12mg/25mg Capsule by M/s Getz Pharma
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A
The status in reference regulatory authorities	Symbyax 12mg/25mg Capsule by Eli Lilly and Company Indianapolis, IN 46285, USA, USFDA Approved
GMP status of the firm	Firm has submitted copy of cGMP certificate issued based on inspection dated 26-10-2023.
Evidence of approval of manufacturing facility	Firm has submitted panel inspection report dated 31-07-2025 & 04-08-2025 for renewal of DML specifying Capsule (General) section
Evaluation Remarks	
Shortcomings	Firm's Response
Submit the registration number of applied product against which pharmaceutical equivalence and CDP studies has been performed as the same could not be verified from database	The firm submitted that due to a typographical error, the reference product was mistakenly mentioned as Olanzagat 12mg/25mg Capsule (Getz Pharma) in our submission. However, the actual studies for CoOlanza 12mg/25mg Capsule were conducted against Prozyn Plus 12mg/25mg Capsule (Platinum Pharmaceuticals). This error occurred as the format was adapted from the submissions of the other two applied strengths (Co-Olanza 3mg/25mg and 6mg/25mg Capsules). Please note that this discrepancy is limited to the reference product name for the 12mg/25mg strength only; the studies themselves were conducted accurately and remain valid. We sincerely regret this oversight. For reference, we have attached the reference pack picture of Prozyn Plus 12mg/25mg Capsule used in the study.
Submit pictorial evidence of reference pack clearly indicating batch number, manufacturing date and expiry date	Not submitted
Stability study data of applied product at 6th month time point shall be submitted	Submitted
The retest date of olanzapine API as per submitted COA is May-2023 while manufacturing date of trial batches is 06-2024. Clarification shall be submitted as manufacturing of trial batches is subsequent to retest date of API.	The firm submitted that the date "May-2023" mentioned on the certificate of analysis of olanzapine is the "Retest date" not the date of expiry of raw material. According to ICH Q7 guidelines "Good Manufacturing Practice for API" under sub section 11.61 defines that: "An API expiry or retest date should be based on an evaluation of data derived from stability studies. Common practice is to use a retest date, not an expiration date". Based on above guidelines the material was analyzed at the retest date and the results were found within the specifications and then used for trial batches. Moreover the API manufacturer has performed and provided the real time stability study up to 60 months (5years). The results are

	satisfactory and concordant to the specifications, which indicate that the material is stable for up to 5 years.
Since reference has been made to ICH Q7 ‘Good Manufacturing Practice for API’ under subsection 11.61 regarding retesting of APIs, it is noted that as per WHO guidelines (Annex 10: Stability testing of active pharmaceutical ingredients and finished pharmaceutical products, subsection 2.1.10), ‘after this retest period a batch of API destined for use in the manufacture of FPP could be retested and then, if in compliance with the specification, could be used immediately (e.g. within 30 days). Complete testing of API should be done.’ However, it is observed that the API was tested after more than one year and subsequently used. Please justify this practice.”	According to WHO TRS and ICH guidelines the API can be retested several times until the results are out of specifications. The retest periods is based on following conditions: Conditions for multiple retests 1. Scientific justification Stability data must support that the API remains stable over the cumulative storage period. * Each extension should not exceed the period supported by long-term stability studies 2. Packaging and storage · The container must remain intact and API stored under recommended conditions. · Any deviations (e.g., exposure to heat or humidity) disqualify the batch from further retest. 3. Analytical testing · At each retest, critical quality attributes (assay, impurities, appearance, water content, etc.) must meet specifications. · If a trend of degradation is observed (e.g., impurities rising toward limits), regulators may disallow further retests. For the API used in the trial batches the following justifications are considerable: · As for as stability studies are concerned the API manufacturer has performed the real time stability studies for a period of 60months (5 years). · At 60th month the all the results are within specifications meeting the WHO requirement. · The material was stored at controlled environmental conditions of humidity and temperature in raw material store. · At retesting, all the critical quality attributes were tested and found to be concordant with specifications. NOTE: The material after retesting is used only in the trial batches of Generic drug product. This retesting model is never practiced for the commercial batches.
Furthermore, evidence of purchase (procurement documents) of the impurities tested in the batch analysis of Olanzapine shall be submitted	The Olanzapine is a pharmacopoeal drug substance and its monograph is present in USP and BP. The material used in the trial batches are as per USP specifications. The impurities were tested as per USP method. In the impurities results calculation no impurity standard is used except suitability standard. The impurities results are calculated using standard solution of olanzapine and sample solution of Olanzapine raw material. Standard solution: 2 µg/mL of USP Olanzapine RS in Diluent Sample solution: 0.4 mg/mL of Olanzapine in Diluent Although we have not performed the suitability, however the impurities were calculated as per USP method, using the relative retention time given in table in the olanzapine monograph. Analysis Samples: Standard solution and Sample solution Calculate the percentage of each impurity in the portion of Olanzapine taken: $\text{Result} = (r_U / r_S) \times (C_S / C_U) \times (1/F) \times 100$ r_U = peak response of each impurity from the Sample solution r_S = peak response of olanzapine from the Standard solution C_S = concentration of USP Olanzapine RS in the Standard solution (mg/mL) C_U = concentration of Olanzapine in the Sample solution (mg/mL) F = relative response factor for each impurity from Table 2 Table 2 Given in USP monograph We have not imported the

impurities for the trial batches, as there is relaxation of impurity testing in the trial batches. However we commit to import and test the impurities in the commercial batches.

Decision

Rejected

The Board discussed that the shelf life / retest period of API can only be extended by API manufacturer supported by the stability data. In the instant case, May-2023 is the retest date for Olanzapine as per submitted COA of API manufacturer and the applicant i.e. finished product manufacturer has used the API after expiration of re-test period and manufactured the trial batches of finished product in June, 2024. Moreover, as per submitted COA of API from drug product manufacturer, the test results for quantification of impurities have been incorporated in the COA while the applicant has not imported the impurity standards. The applicant upon query, has stated that the impurities will be imported for testing of commercial batches.

The Board, in view of the above discussion, decided to Reject the application.

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Case Category	Export Facilitation (Dr. Farhad Ullah)
Name, address of Applicant.	Genome Pharmaceuticals (Pvt.) Ltd , Plot No. 16/1, Phase-IV, Industrial Estate Hattar Dist: Haripur (KPK)-PAKISTAN. (000454)
Application Form Dy. No / Tracking ID & date of submission	(PZM-S96-Y6JU, 2025-05-12)
Detail of Fee Submitted	37000.0, 2025-03-10,
The proposed proprietary name / brand name	DEUCRAVA 6mg TABLETS
Label Claim	Each film coated tablet contains: Deucravacitinib.....6mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1 x 10's-As per SRO
Shelf Life (Unit)	24 Year(s)Below 30°C
For generic drugs (me-too Status)	Dvanib 6mg Tablets
Pharmacotherapeutic Group of (API)	Immunosuppressants ATC Code; L04
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	GANSU HAOTIAN PHARMACEUTICAL CO., LTD
Detail of stability batches of drug product	3 batches having batch size of 5000 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate issued dated 09-07-2024 specifying 120gm Deucravacitinib.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against SOTYKTU 6mg Tablets by M/s Bristol-Myers Squibb Pharma Japan.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A
The status in reference regulatory authorities	SOTYKTU 6mg film-coated tablets USFDA Approved
GMP status of the firm	Firm has submitted copy of cGMP certificate issued based on inspection dated 24, 25-05-2023.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter for renewal of DML dated 07-07-2021 specifying Tablet (General) section.

Evaluation Remarks

Shortcomings	Firm's Response
Copy of BMR of only one batch is submitted. Copy of Executed BMR of all three batches shall be submitted	Copy of Executed BMR of all three batches is submitted

Clarification shall be submitted for using different chromatographic conditions for the assay test of the API by the drug product manufacturer compared to the drug substance manufacturer (e.g., wavelength, injection volume, mobile phase, and use of isocratic method instead of gradient).	The chromatographic method used by the drug product manufacturer differs from the drug substance manufacturer. The method has been scientifically developed and validated to ensure accurate and reliable assay results for Deucravacitinib in the drug and complies with all current regulatory guidelines. Method validation data is already attached in Module-III.
As per the TGA public assessment report: 'The drug product is a spray-dried dispersion of deucravacitinib in hypromellose acetate succinate. Dry granulation, tablet compression, and film coating result in the final drug product.' Clarification is required since spray drying of deucravacitinib with hypromellose acetate succinate has not been performed in your manufacturing method.	We would like to respectfully clarify that our manufacturing method, involves dry granulation, compression, and film coating with same excipients as used in innovator product. This manufacturing approach yields a product that is pharmaceutically equivalent to the reference product in terms of dosage form, strength, route of administration, and intended use. To address potential differences in formulation methodology, we have conducted comprehensive comparative studies, including · Pharmaceutical Equivalence details is mentioned in Module-III, 3.2 P 2.2.2 · Comparative Dissolution studies, details is mentioned in Module-III, 3.2 P 2.2.3 These data collectively demonstrate that omission of the spray-drying step does not impact the quality, safety, or efficacy of our product. The product remains consistent with the requirements of pharmaceutical equivalence and therapeutic equivalence relative to the innovator.

Decision

Approved

Registration Board further decided that registration letter will be issued after verification of the authenticity of the submitted stability data by the panel constituted by the Chairman, Registration Board.

36	Case Category	Export Facilitation (Dr. Farhad Ullah)
	Name, address of Applicant.	Maxitech Pharma (Pvt) Ltd. E-178, S.I.T.E., Super Highway Phase-II, Karachi (000851)
	Application Form Dy. No / Tracking ID & date of submission	(YU3-DUA-5X45, 2024-08-28)
	Detail of Fee Submitted	75000.0, 2024-08-07,
	The proposed proprietary name / brand name	Clascoderm Cream 1%
	Label Claim	Each gram of Clascoderm Cream 1% contains: Clascoterone..... 10mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	50gm-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a cool, dry place below 30 degrees Celsius.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Androgen Receptor Inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Xier Kangtai Pharmaceutical Co., Ltd
	Detail of stability batches of drug product	3 batches having batch size of 100 tubes each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Not submitted

Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against innovator's product.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV
The status in reference regulatory authorities	WINLEVI cream 1% by COSMO S.P.A USFDA Approved
GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 30-04-2024.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 25-11-2016 specifying Cream/Ointment/Lotion (General) section.
Evaluation Remarks	
Clascoterone cream is an androgen receptor inhibitor indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.	
Shortcomings	Firm's Response
Copy of executed Batch Manufacturing Record (BMR) for all the batches of drug product shall be submitted	Copy of executed Batch Manufacturing Record (BMR) for all the batches of drug product is submitted
Submit details of reference product including batch number, manufacturing and expiry dated and name of manufacturer against which Pharmaceutical Equivalence studies has been performed	The firm submitted brand name and manufacturer name of reference product; Brand Name: WINLEVI Cream by Cosmo S.p.A.
Commercial invoice or clearance certificate for procurement of API with approval from DRAP shall be submitted.	Firm has submitted copy of form 6 issued dated 18-09-2023 specifying 0.1kg Clascoterone. Firm has also submitted copy of commercial invoice, goods declaration and airway bill for procurement of API.
As per innovator's product literature the product should be stored at 2°C – 8°C. Justify the conduct of stability studies at 30 ± 2 °C / 65% ± 5% RH instead of 5 ± 3°C at real-time conditions, and at 40 ± 2°C / 75% ± 5% RH instead of 25 ± 2°C / 60% ± 5% RH at accelerated conditions.	The product has been tested under worst-case conditions to ensure its stability profile. Accelerated stability studies were conducted at 40 ± 2°C / 75% ± 5% RH, and real-time studies at 30 ± 2°C / 65% ± 5% RH, with results confirming that the product remains stable at these conditions. Since the product has demonstrated stability at room temperature (30 ± 2°C / 65% ± 5% RH) after opening, it can be reasonably concluded that it will also remain stable under the recommended refrigerated condition of 2°C – 8°C. Testing at these higher temperatures was therefore essential, as stability at room temperature post-opening is a critical requirement.
Decision	
Rejected	
The Board was apprised that the innovator has established the storage conditions of 5 ± 3°C for the finished product while the applicant has performed Real Time Stability studies at 30 ± 2 °C / 65% ± 5% RH and Accelerated stability at 40 ± 2°C / 75% ± 5% RH. The Board considering the above discussion and queries raised during the evaluation process, decided to Reject the application.	
37	Export Facilitation (Dr. Farhad Ullah)
Case Category	
Name, address of Applicant.	Searle Pakistan Limited C-14, Manghopir Road, SITE, Karachi (000012)
Application Form Dy. No / Tracking ID & date of submission	(8AT-Z6B-ZJUE, 2024-10-31)

Detail of Fee Submitted	30000.0, 7000.0 2024-08-16, 2024-10-11
The proposed proprietary name / brand name	Tiboron 2.5mg Tablet
Label Claim	Each tablet contains: Tibolone EP....2.5mg
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	As per DPC-As per SRO
Shelf Life (Unit)	2 Year(s)Store below 30 degree C.
For generic drugs (me-too Status)	Lobion-HRT 2.5mg Tablet by Platinum Pharmaceuticals (Pvt) Ltd
Pharmacotherapeutic Group of (API)	Other estrogens
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	NEWCHEM S.p.A.
Detail of stability batches of drug product	2 batches having batch size of 600000 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of invoice cleared by AD I&E DRAP dated 07-10-2021 specifying 01kg Tibolone.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Livial 2.5mg tablet, by N.V Organon Oss Holland.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV
The status in reference regulatory authorities	Livial 2.5mg Tablet by Organon Pharma (UK) Ltd (MHRA Approved)
GMP status of the firm	Firm has submitted copy of cGMP certificate issued based on inspection dated 06-03-2024.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter for renewal of DML dated 26-10-2020 specifying Tablet (General) section and Tablet Hormone section.

Evaluation Remarks

Tibolone is a synthetic steroid. Used in Hormone Replacement Therapy. Unlike most other HRTs that are actual hormones, tibolone is broken down in the body to produce hormones.

Shortcomings	Firm's Response
As the applied product is a synthetic steroid, evidence of the required manufacturing facility (steroidal tablet section) shall be submitted.	Firm has submitted copy of letter for renewal of DML dated 26-10-2020 specifying Tablet (General) section and Tablet Hormone section. We acknowledge DRAP's observation that Tibolone is classified as a synthetic steroidal. In fact, Tibolone is a synthetic steroid hormone. Its metabolites have oestrogenic, progestogenic, and androgenic properties. Therefore, it is to be manufactured in a dedicated hormonal tablet section, for which we already have approval.
Justification shall be submitted as the f_2 value in pH 4.5 medium is exactly 50 for the applied product, i.e., at the lower acceptance threshold for dissolution similarity.	According to the guideline" Guidance for Industry Dissolution Testing of Immediate Release Solid Oral Dosage Forms" For curves to be considered similar, f_1 values should be close to 0, and f_2 values should be close to 100. Generally, f_1 values upto 15 (0-15) and f_2 values greater than 50 (50-100) ensure sameness or equivalence of the two curves and, thus, of the performance of the test (postchange) and reference (prechange) products. Additionally, as per WHO TRS 1003 ANNEX 6 "Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability" The dissolution profile of the multisource product is similar to that of the comparator

		product in aqueous buffers at pH 1.2, pH 4.5 and pH 6.8 using the paddle method at 75 rpm or the basket method at 100 rpm and meets the criteria of dissolution profile similarity, $f_2 \geq 50$ (or equivalent statistical criterion). Also, as per guideline "ICH-M9 (BIOPHARMACEUTICS CLASSIFICATION SYSTEM-BASED BIOWAIVERS)" Two dissolution profiles are considered similar when the f_2 value is ≥ 50 . Since all guidelines acceptance criteria's allows f_2 value of 50 to be acceptable, therefore we request you to please accept the response.
	Clarification shall be submitted as two different API batches were used in the manufacturing of a single trial batch	The data submitted is of commercial batches of our registered product Tibol 2.5mg, Registration # 020050. As per usual practice, required quantity of API was not sufficient for one batch hence, two different lots of the same manufacturer were used in commercial batches.
	Clarification shall be submitted as two different API batches were used in the manufacturing of trial batches, while the imported API pertains to a single batch only.	In addition to already submitted API lot # NB2457 import documents, ADC clearance certificate of following two different API lots attached as Annex XIIA and Annex XIIB API Manufacturer Lot#: NB2544 API Manufacturer Lot#: ND0622 Firm has submitted copy of clearance certificate dated 02-06-2022 specifying 03 (piece/pack) Tibolone (NB2544) (3kg as per GD copy). Firm has submitted copy of clearance certificate dated 18-05-2023 specifying 3000grams Tibolone (ND0622).
	Clarification shall be submitted as one batch is manufactured in June 2022, while the second batch is manufactured in July 2023.	As these are commercial batches and per market demand it is a slow running product hence one batch was manufactured in June 2022 while the second one was manufactured in July 2023.
	Clarification shall be submitted as the registration number of product (020050) is mentioned in BMR of applied product	The firm has submitted that the same product was previously registered under the name Tibol (Registration No. 020050). Letter for Change of Registration Status from M/s OBS Pakistan (Pvt.) Ltd. to M/s Searle Pakistan Limited was provided. Subsequently, a 'Cancellation of Registration of Drug Product(s)' letter in the name of M/s Searle Pakistan Limited and a registration in the name of Aspin Pharma through contract manufacturing from M/s Searle Pharma were also submitted. As commercial batches data is submitted to DRAP, hence registration no. of registered product is present on the executed BMR.
	Justify the quantity of drug substance used in the manufacturing of trial batches with respect to the quantity of drug substance imported.	Quantity imported is mentioned in ADC clearance document, while quantity consumed in commercial batches is indicated in submitted Batch Documents.
	Decision	
	Approved	
38	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	Scotmann Pharmaceuticals Plot #5D , Industrial Area, I-10/3 Islamabad (000498)
	Application Form Dy. No / Tracking ID & date of submission	(EQ7-28N-VAJS, 2025-09-11)

Detail of Fee Submitted	37000.0, 2025-05-02,
The proposed proprietary name / brand name	Tadalafil Tablets 2.5mg
Label Claim	Each film coated tablet contains: Tadalafil 2.5mg (USP Specifications)
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	10's-De-Controlled,12's-De-Controlled,14's-De- Controlled,15's-De-Controlled,16's-De-Controlled,2's- De-Controlled,20's-De-Controlled,28's-De- Controlled,30's-De-Controlled,4's-De-Controlled,5's-De- Controlled,6's-De-Controlled,7's-De-Controlled,8's-De- Controlled
Shelf Life (Unit)	2 Year(s)Store below 30°C.
For generic drugs (me-too Status)	Fildil Tablets 2.5mg (Highnoon Laboratories Ltd.)
Pharmacotherapeutic Group of (API)	Phosphodiesterase (PDE) inhibitors
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Ami Lifesciences Private Limited.
Detail of stability batches of drug product	Accelerated & Real Time Stability Studies Performed on B. No. T-01, T-02 & T-03, B. Size: 1000 Tablets on Initial, 3, 6 Months testing intervals.
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance Certificate No. RO-5C4CA1 Dated 05/02/2025 for 0.5kg material is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence has been performed with Reference Product (Fildil Tablet 2.5mg) B. No. 252144 and Dissolution Profile of both products (Fildil Tablet 2.5mg and Tadalafil 2.5mg Tablet) was compared at 3 pH (1.2, 4.5 & 6.8) graphically and statistically.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months Accelerated & 24 months Real Time Stability Studies Performed on B. No. TDL/50040321, TDL/50050321, TDL/50060421 according to the conditions of zone IV-B.
The status in reference regulatory authorities	USFDA Approved
GMP status of the firm	last inspection report dated 22-02-2024.Renewal recommended.
Evidence of approval of manufacturing facility	General Tablet Section Approved and Renewed by CLB Dated: 26-02-2024
Evaluation Remarks	
The case has been entertained as per the decision of DRAP Authority.	
Decision	
Approved	
Case Category	Any Other (Farooq Aslam)
Name, address of Applicant.	Scotmann Pharmaceuticals Plot #5D , Industrial Area, I-10/3 Islamabad (000498)
Application Form Dy. No / Tracking ID & date of submission	(JNA-DYL-7S8X, 2025-09-18)
Detail of Fee Submitted	37000.0, 1700 2025-05-02, 2025-09-16
The proposed proprietary name / brand name	Tadalafil Tablets 10mg

Label Claim	Each film coated tablet contains: Tadalafil 10mg (USP Specifications)
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	10's-As per SRO,12's-As per SRO,14's-As per SRO,15's-As per SRO,16's-As per SRO,2's-As per SRO,20's-As per SRO,28's -As per SRO,30's-As per SRO,4's-As per SRO,5's-As per SRO,6's-As per SRO,7's -As per SRO,8's-As per SRO
Shelf Life (Unit)	2 Year(s)Store below 30°C.
For generic drugs (me-too Status)	Fildil Tablets 10mg (Highnoon Laboratories Ltd.)
Pharmacotherapeutic Group of (API)	Phosphodiesterase (PDE) inhibitors
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Ami Lifesciences Private Limited.
Detail of stability batches of drug product	Accelerated & Real Time Stability Studies Performed on B. No. T-01, T-02 & T-03, B. Size: 1000 Tablets on Initial, 3, 6 Months testing intervals.
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance Certificate No. RO-5C4CA1 Dated 05/02/2025 for 0.5kg material is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence has been performed with Reference Product (Fildil Tablet 10mg) B. No. 252146 and Dissolution Profile of both products (Fildil Tablet 10mg and Tadalafil 10mg Tablet) was compared at 3 pH (1.2, 4.5 & 6.8) graphically and statistically.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months Accelerated & 24 months Real Time Stability Studies Performed on B. No. TDL/50040321, TDL/50050321, TDL/50060421 according to the conditions of zone IV-B.
The status in reference regulatory authorities	USFDA Approved
GMP status of the firm	last inspection report dated 22-02-2024.Renewal recommended.
Evidence of approval of manufacturing facility	General Tablet Section Approved and Renewed by CLB Dated: 26-02-2024
Evaluation Remarks	
The application has been entertained out of queue in compliance to the decision of DRAP Authority.	
Decision	
Approved	
Case Category	Any Other (Farooq Aslam)
Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
Application Form Dy. No / Tracking ID & date of submission	(1JR-QUN-LUY4, 2025-08-25)
Detail of Fee Submitted	75000.0, 2025-06-05,
The proposed proprietary name / brand name	Talmac 10/40mg Tablets
Label Claim	Each film coated tablet contains: Macitentan.....10mg Tadalafil.....40mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	2, 4, 6, 8, 10, 14, 20, 28, 30, 40, 50, 60, 70, 80-As per SRO

Shelf Life (Unit)	2 Year(s)Below 30°C
For generic drugs (me-too Status)	NA
Pharmacotherapeutic Group of (API)	Macitentan: endothelin receptor antagonists (ERAs), Tadalafil: phosphodiesterase type 5 (PDE5) *the product is indicated for pulmonary arterial hypertension.
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	GANSU HAOTIAN PHARMACEUTICAL CO., LTD No.11, Chongqing Road, Baiyin District, Baiyin City, Gansu Province, China
Detail of stability batches of drug product	Batches: 2025-T-22, 2025-T-23, 2025-T-24 (Batch Size: 1000 tablets) 06 months real time and 06 months accelerated stability data is submitted.
Documents for the procurement of API with approval from DRAP (in case of Import)	Macitentan: Copy of form 6 (DIL-C-8AB371) for 0.1kg material, copy of unattested invoice and packing list Tadalafil: Clearance certificate dated 26-03-2025for 1kg material is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e Opsynvi 10/40mg by
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Mecitentan: 06 months accelerated and 24 months real time stability data of 03 batches according to the conditions of zone IV-A is submitted. Tadalafil: 06 months accelerated and 60 months real time stability data of 03 batches according to the conditions of zone IV-B is submitted.
The status in reference regulatory authorities	OPSYNVI® (Macitentan and Tadalafil) tablets, for oral use Initial U.S. Approval: 2024, Actelion Pharmaceuticals US, Inc. a Janssen Pharmaceutical Company Titusville, NJ 08560, USFDA Approved
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 11-01-2024.
Evidence of approval of manufacturing facility	Tablet General Section is approved.
Evaluation Remarks	
1. The case has been evaluated in compliance to the decision of DRAP Authority.2. The innovator's product approved by USFDA has established 30 minutes dissolution sampling time point, but the applicant had mentioned 60 minutes as sampling time point for dissolution. When the firm was asked about the reference of dissolution time point, the firm replied that they had followed (Guidance for Industry Dissolution Testing of Immediate Release Solid Oral Dosage Forms).The firm was communicated that the innovator has established 30 minutes dissolution time point and you have selected 60 minutes, the firm has replied that the dissolution time is 45 minutes.	
Decision	
Deferred	
for clarification of sampling time point for dissolution testing since the selected time i.e. 45 minutes is different from the sampling time as selected by the innovator i.e 30 minutes.The Board deferred the case for clarification of sampling time point for dissolution testing since the selected time i.e. 45 minutes is different from the sampling time as selected by the innovator i.e 30 minutes.	
41	Case Category
	Any Other (Farooq Aslam)
	Name, address of Applicant.
	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission
	(XE5-Q7B-YSJ5, 2025-08-25)
	Detail of Fee Submitted
	75000.0, 2025-08-13,

The proposed proprietary name / brand name	Talmac 10/20mg Tablets
Label Claim	Each film coated tablet contains: Macitentan.....10mg Tadalafil.....20mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	2, 4, 6, 8, 10, 14, 20, 28, 30, 40, 50, 60, 70, 80-As per SRO
Shelf Life (Unit)	2 Year(s)Below 30°C
For generic drugs (me-too Status)	NA
Pharmacotherapeutic Group of (API)	Macitentan: endothelin receptor antagonists (ERAs), Tadalafil: phosphodiesterase type 5 (PDE5) *the product is indicated for pulmonary arterial hypertension.
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	GANSU HAOTIAN PHARMACEUTICAL CO., LTD No.11, Chongqing Road, Baiyin District, Baiyin City, Gansu Province, China
Detail of stability batches of drug product	Batches: 2025-T-04, 2025-T-05, 2025-T-06 (Batch Size: 1000 tablets)
Documents for the procurement of API with approval from DRAP (in case of Import)	Macitentan: Copy of form 6 (DIL-C-8AB371) for 0.1kg material, copy of un attested invoice and packing list are submitted. Tadalafil: Clearance certificate dated 26-03-2025 for 1kg material is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e Opsynvi 10/20mg by M/s Janssen's UK.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Macitentan: 06 months accelerated and 24 months real time stability data of 03 batches according to the conditions of zone IV-A is submitted. Tadalafil: 06 months accelerated and 60 months real time stability data of 03 batches according to the conditions of zone IV-B is submitted.
The status in reference regulatory authorities	OPSYNVI® (Macitentan and Tadalafil) tablets, for oral use Initial U.S. Approval: 2024, Actelion Pharmaceuticals US, Inc. a Janssen Pharmaceutical Company Titusville, NJ 08560, USA
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 11-01-2024.
Evidence of approval of manufacturing facility	Tablet General Section is approved.

Evaluation Remarks

1. The case has been evaluated in compliance to the decision of DRAP Authority. 2. The innovator's product approved by USFDA has established 30 minutes dissolution sampling time point, but the applicant had mentioned 60 minutes as sampling time point for dissolution. When the firm was asked about the reference of dissolution time point, the firm replied that they had followed (Guidance for Industry Dissolution Testing of Immediate Release Solid Oral Dosage Forms). The firm was communicated that the innovator has established 30 minutes dissolution time point and you have selected 60 minutes, the firm has replied that the dissolution time is 45 minutes.

Decision

Deferred

The Board was apprised that the innovator has established 30 minutes dissolution sampling time point, but the applicant had mentioned 60 minutes as sampling time point for dissolution. When the applicant, upon query, had stated that the sampling time point for dissolution testing is 45 minutes.

The Board deferred the case for clarification of the above-mentioned query.

42	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	CRYSTOLITE PHARMACEUTICALS Plot # 1 & 2, street S-2, National Industrial Zone Rawat, Islamabad (000778)
	Application Form Dy. No / Tracking ID & date of submission	(L6J-WBM-UXL5, 2025-09-11)
	Detail of Fee Submitted	37000.0, 2025-07-09,
	The proposed proprietary name / brand name	Tiadil 10mg Tablet
	Label Claim	Each film coated tablet contains: Tadalafil 10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2's 4's 8's 28's 30's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 degree
	For generic drugs (me-too Status)	Zealus 10mg Tablet by Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572) approved in 347.
	Pharmacotherapeutic Group of (API)	phosphodiesterase 5 (PDE5) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CENNTURY PHARMACEUTICALS LIMITED
	Detail of stability batches of drug product	Batches: 013T25,014T25,015T25 (Batch size: 600 tablets) 06 months real time and 06 months accelerated stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 28-01-2025 is submitted for 0.1kg material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Cialis 10mg tablet.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 60 months real time stability data of 03 batches according to the conditions of zone IV-A is submitted.
	The status in reference regulatory authorities	usfda approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 16-12-2024.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
43	Evaluation Remarks	
	The case has been entertained in compliance to the decision of DRAP Authority.	
	Decision	
	Approved	
	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	CRYSTOLITE PHARMACEUTICALS Plot # 1 & 2, street S-2, National Industrial Zone Rawat, Islamabad (000778)
	Application Form Dy. No / Tracking ID & date of submission	(UD8-EL9-Q6YT, 2025-09-11)
	Detail of Fee Submitted	37000.0, 2025-06-12,
	The proposed proprietary name / brand name	Tiadil 20mg Tablet
	Label Claim	Each film coated tablet contains: Tadalafil 20mg

Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	2's 4's 8's 28's 30'-As per SRO
Shelf Life (Unit)	2 Year(s)Store below 30 degree
For generic drugs (me-too Status)	Fildil tablet by M/s Highnoon
Pharmacotherapeutic Group of (API)	phosphodiesterase 5 (PDE5) inhibitors
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	CENNTURY PHARMACEUTICALS LIMITED
Detail of stability batches of drug product	Batches: 010T25,011T25,012T25 (Batch size: 600 tablets) 06 months real time and 06 months accelerated stability data is submitted.
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 28-01-2025 is submitted for 0.1kg material.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Cialis 20mg tablet.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 60 months real time stability data of 03 batches according to the conditions of zone IV-A is submitted.
The status in reference regulatory authorities	usfda approved
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 16-12-2024.
Evidence of approval of manufacturing facility	Tablet General Section is approved.

Evaluation Remarks

The case has been entertained in compliance to the decision of DRAP Authority.

Decision

Approved

44	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	CRYSTOLITE PHARMACEUTICALS Plot # 1 & 2, street S-2, National Industrial Zone Rawat, Islamabad (000778)
	Application Form Dy. No / Tracking ID & date of submission	(XD1-4GW-NV43, 2025-09-11)
	Detail of Fee Submitted	37000.0, 2025-06-19,
	The proposed proprietary name / brand name	Tiadil 5mg Tablet
	Label Claim	Each film coated tablet contains: Tadalafil 5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2's 4's 8's 28's 30's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 degree
	For generic drugs (me-too Status)	Fildil tablet by M/s Highnoon
	Pharmacotherapeutic Group of (API)	phosphodiesterase 5 (PDE5) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CENNTURY PHARMACEUTICALS LIMITED
	Detail of stability batches of drug product	Batches: 016T25,017T25,018T25 (Batch size: 600 tablets) 06 months accelerated and 06 month real time stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 28-01-2025 is submitted for 0.1kg material.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Cialis 5mg tablet.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 60 months real time stability data of 03 batches according to the conditions of zone IV-A is submitted.
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 16-12-2024.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The case has been entertained in compliance to the decision of DRAP Authority.	
	Decision	
	Approved	
45	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	NAVEGAL LABORATORIES 41/1-A-2, PHASE-1, INDUSTRIAL ESTATE HATTAR, KPK, PAKISTAN (000591)
	Application Form Dy. No / Tracking ID & date of submission	(9Y1-JAB-MY3Q, 2025-09-22)
	Detail of Fee Submitted	93000.0, 2025-07-21,
	The proposed proprietary name / brand name	JANUS 5mg TABLETS
	Label Claim	Each Film Coated Tablet contains: Tofacitinib Citrate eq. to Tofacitinib.....5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Tofajak 5mg Tablets by Hirani's Pharma
	Pharmacotherapeutic Group of (API)	Janus kinase (JAK) inhibitors
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	UK Mhra Approved
	Detail of previous approval	Tofocib Tablet, DRB 343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
46	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	NAVEGAL LABORATORIES 41/1-A-2, PHASE-1, INDUSTRIAL ESTATE HATTAR, KPK, PAKISTAN (000591)
	Application Form Dy. No / Tracking ID & date of submission	(7N6-H4J-AM5J, 2025-09-22)

Detail of Fee Submitted	93000.0, 9400 2025-07-23, 2025-09-12
The proposed proprietary name / brand name	VONZIN 20mg Tablet
Label Claim	Each Film Coated Tablet contains: Vonoprazan Fumarate equivalent to Vonoprazan.....20mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 YearStore below 25c
For generic drugs (me-too Status)	Vonzin 20mg tablet by M/s Welmark Pharmaceuticals
Pharmacotherapeutic Group of (API)	A potassium-competitive acid blocker (P-CAB) used to treat gastric ulcer, duodenal ulcer and reflux esophagitis
Name, address of Manufacturing site:	M/s. Welmark Pharmaceuticals -Plot #122, Block B, Phase V, Industrial Estate, Hattar, Haripur, KPK-
The status in reference regulatory authorities	USFDA Approved
Detail of previous approval	Vonzin 20mg tablet, 324

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

47	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	NAVEGAL LABORATORIES 41/1-A-2, PHASE-1, INDUSTRIAL ESTATE HATTAR, KPK, PAKISTAN (000591)
	Application Form Dy. No / Tracking ID & date of submission	(V8U-EUL-9UN5, 2025-09-22)
	Detail of Fee Submitted	93000.0, 9400 2025-07-23, 2025-09-12
	The proposed proprietary name / brand name	Vonzin 10mg Tablet
	Label Claim	Each Film Coated Tablet contains: Vonoprazan fumarate equivalent to Vonoprazan.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25c
	For generic drugs (me-too Status)	Vonzin 10mg tablet by Welmark Pharmaceuticals
	Pharmacotherapeutic Group of (API)	A potassium-competitive acid blocker (P-CAB) used to treat gastric ulcer, duodenal ulcer and reflux esophagitis.
	Name, address of Manufacturing site:	M/s Welmark Pharmaceuticals, -Plot No. 122, Block - B, Phase - V, Industrial Estate hattar, KPK-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Vonzin 10mg tablet, 324

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other

conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

48	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	NAVEGAL LABORATORIES 41/1-A-2, PHASE-1, INDUSTRIAL ESTATE HATTAR, KPK, PAKISTAN (000591)
	Application Form Dy. No / Tracking ID & date of submission	(BRM-879-4N8U, 2025-09-22)
	Detail of Fee Submitted	93000.0, 2025-07-23,
	The proposed proprietary name / brand name	Vinas 10mg / 100mg Tablet
	Label Claim	Each Tablet Contains: Aspirin as Enteric Coated Tablet (USP).....100mg Vonoprazan as fumarate as Immediate Release Layer.....10mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25c
	For generic drugs (me-too Status)	Vinas 100/10 mg Tablet by Welmark Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Anti-ulcerative, Proton pump inhibitor
	Name, address of Manufacturing site:	M/s Welmark Pharmaceuticals, -Plot No. 122, Block - B, Phase - V, Industrial Estate hattar, KPK -
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Vinas 100/10 mg Tablet, 340
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
49	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	NAVEGAL LABORATORIES 41/1-A-2, PHASE-1, INDUSTRIAL ESTATE HATTAR, KPK, PAKISTAN (000591)
	Application Form Dy. No / Tracking ID & date of submission	(SD8-5N1-WQZU, 2025-09-22)
	Detail of Fee Submitted	93000.0, 2025-07-21,
	The proposed proprietary name / brand name	Levele
	Label Claim	Each Ampoule (5mL) Contains: Levocarnitine (USP) 1000mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25c

	For generic drugs (me-too Status)	L-Carda 1gm injection by M/s Wnsfeild Pharma
	Pharmacotherapeutic Group of (API)	Metabolic & Endocrine
	Name, address of Manufacturing site:	M/s Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK Pakistan -
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	L-Carda 1gm injection, 331
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
50	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	NAVEGAL LABORATORIES 41/1-A-2, PHASE-1, INDUSTRIAL ESTATE HATTAR, KPK, PAKISTAN (000591)
	Application Form Dy. No / Tracking ID & date of submission	(7D4-AEP-59AH, 2025-09-22)
	Detail of Fee Submitted	93000.0, 2025-07-21,
	The proposed proprietary name / brand name	65154595
	Label Claim	Each Ampoule (2mL) Contains: Citicoline as Sodium Salt (USP).....250Mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25c
	For generic drugs (me-too Status)	C-Kolin 250mg/2ml Injection by WnsFeild Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Anti-Parkinson
	Name, address of Manufacturing site:	M/s WNSFEILD PHARMACEUTICALS-PLOT NO. 122, PHASE-V, BLOCK-A, INDUSTRIAL ESTATE, HATTAR, KPK, PAKISTAN-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	C-Kolin 250mg/2ml Injection, 347
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
51	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

Name, address of Applicant.	Solaris Life Sciences Private Limited , Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992)
Application Form Dy. No / Tracking ID & date of submission	(77V-7R7-QVR2, 2024-05-16)
Detail of Fee Submitted	75000.0, 2024-05-03,
The proposed proprietary name / brand name	SOLDROP-D INJECTION Oral/ IM
Label Claim	Each ampoule contains: Cholecalciferol (200,000IU).....5mg
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	As Per SRO-As per SRO
Shelf Life (Unit)	2 Year30°C
For generic drugs (me-too Status)	Novel-D Injection Oral/ I.M By DANAS Pharmaceuticals Islamabad Reg. No. 073183
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Seraph Pharmaceuticals-Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad-PAKISTAN.-
The status in reference regulatory authorities	Cholecalciferol(5mg) injection (IM/ Oral) M/s Bouchara Recordate Laboratories, FRANCE (MHRA) Approved
Detail of previous approval	
Evaluation Remarks	
The firm initially selected no in data approval. Later they requested vide A2R-PL8-JLZR in general request that their products be considered under cross reference. Accordingly, In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. However, in 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer.	
Decision	
Approved	
52	Case Category
	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.
	Solaris Life Sciences Private Limited , Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992)
	Application Form Dy. No / Tracking ID & date of submission
	(WEB-WWU-DMAX, 2024-06-11)
	Detail of Fee Submitted
	75000.0, 2024-05-03,
	The proposed proprietary name / brand name
	SKORS INJECTION
	Label Claim
	Each 5ml ampoule contains: Iron (III) hydroxide sucrose equivalent to elemental iron..... 100mg
	Reference to Finished product specifications
	British Pharmacopeia
	Proposed Pack Size
	As Per SRO-As per SRO
	Shelf Life (Unit)
	2 Year30°C
	For generic drugs (me-too Status)
	G-FER Injection By Global Pharma
	Pharmacotherapeutic Group of (API)
	Name, address of Manufacturing site:
	Seraph Pharmaceuticals-Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad-PAKISTAN.-

The status in reference regulatory authorities	Venofer 20 mg iron /mL (Medicines and Healthcare products Regulatory Agency (MHRA) of UK)
Detail of previous approval	
Evaluation Remarks	
The firm initially selected no in data approval. Later they requested vide A2R-PL8-JLZR in general request that their products be considered under cross reference. Accordingly, In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. However, in 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer.	
Decision	
Approved	

53	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Solaris Life Sciences Private Limited , Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992)
	Application Form Dy. No / Tracking ID & date of submission	(PMW-B38-XADM, 2024-05-16)
	Detail of Fee Submitted	75000.0, 2024-05-03,
	The proposed proprietary name / brand name	ELBUFIN-10MG INJECTION
	Label Claim	Each Ampoule(1ml) contains: Nalbuphine hydrochloride 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year30°C
	For generic drugs (me-too Status)	Bunail-10mg/ml Injection By Bosch pharmaceuticals (Pvt.) ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Seraph Pharmaceuticals-Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad-PAKISTAN.-
	The status in reference regulatory authorities	NUBAIN Injection.....10mg/ml By Par Pharmaceutical USA, Approved in FDA.
	Detail of previous approval	
	Evaluation Remarks	
	The firm initially selected no in data approval. Later they requested vide A2R-PL8-JLZR in general request that their products be considered under cross reference. Accordingly, In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. However, in 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer.	
	Decision	
	Approved	

54	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Solaris Life Sciences Private Limited , Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992)
	Application Form Dy. No / Tracking ID & date of submission	(3HN-T4U-BVXA, 2024-07-05)
	Detail of Fee Submitted	75000.0, 2024-05-03,
	The proposed proprietary name / brand name	ELBUFIN-20MG INJECTION (IM/ IV)
	Label Claim	Each Ampoule (1ml) contains: Nalbuphine Hydrochloride.....20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year30°C
	For generic drugs (me-too Status)	Bunail-20mg/ml Injection By Bosch pharmaceuticals (Pvt.) ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Seraph Pharmaceuticals-Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad-PAKISTAN.-
	The status in reference regulatory authorities	NUBAIN Injection.....20mg/ml By Par Pharmaceutical USA, Approved in FDA.
	Detail of previous approval	
55	Evaluation Remarks	
	The firm initially selected no in data approval. Later they requested vide A2R-PL8-JLZR in general request that their products be considered under cross reference. Accordingly, In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. However, in 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer.	
	Decision	
55	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Solaris Life Sciences Private Limited , Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992)
	Application Form Dy. No / Tracking ID & date of submission	(YEP-73U-1YG1, 2024-05-14)
	Detail of Fee Submitted	75000.0, 2024-05-03,
	The proposed proprietary name / brand name	TORALAK-30MG INJECTION (IM/IV)
	Label Claim	Each ml contains: Ketorolac Tromethamine.....30mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year30°C
	For generic drugs (me-too Status)	Toralac 30mg/ml Injection By Global Pharmaceuticals Pakistan
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	Seraph Pharmaceuticals-Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad-PAKISTAN.-
	The status in reference regulatory authorities	Toradol 30mg/ml Injection By Roche Palo Alto LLC , California, US (FDA Approved)
	Detail of previous approval	
	Evaluation Remarks	
	The firm initially selected no in data approval. Later they requested vide A2R-PL8-JLZR in general request that their products be considered under cross reference. Accordingly, In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. However, in 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer.	
	Decision	
	Approved	
56	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Regal Pharmaceuticals Plot No. 2-A, Street No. S-5 National Industrial Zone RCCI Rawat (000839)
	Application Form Dy. No / Tracking ID & date of submission	(1MQ-MWM-LU4L, 2025-09-22)
	Detail of Fee Submitted	93000.0, 2025-07-10,
	The proposed proprietary name / brand name	Nebreg 5+25mg Tablet
	Label Claim	Each film coated tablet contains: Nebivolol as HCl.... 5mg Hydro chlorothiazide.... 25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per sro-As per SRO
	Shelf Life (Unit)	2 YearStore BELOW 27 c0
	For generic drugs (me-too Status)	Nebilet plus 5mg/25mg
	Pharmacotherapeutic Group of (API)	Antihypertensive
	Name, address of Manufacturing site:	Wimits Pharmaceuticals-Plot No 129, Sunder Industrial Estate, Lahore.-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Nebivol-HCT 5/25mg Tablet, 343rd
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
57	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	De-Mont Research Laboratories (Pvt.) Ltd. 20 Km, Lahore-Sheikhupura Road, Sheikhupura, Pakistan (000844)

Application Form Dy. No / Tracking ID & date of submission	(1NL-7A2-H2Y2, 2025-09-22)
Detail of Fee Submitted	93000.0, 2025-07-28,
The proposed proprietary name / brand name	BASTIN 10MG TABLET
Label Claim	Each Orodispersible Tablet Contains: Bilastine.....10mg (Innovators Specifications)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	AS PER SRO-As per SRO
Shelf Life (Unit)	2 Yearstore below 30 degree centigrade
For generic drugs (me-too Status)	Bilix 10 mg Orodispersible Tablet, AGP
Pharmacotherapeutic Group of (API)	Benzimidazoles
Name, address of Manufacturing site:	Wezen Pharmaceuticals-Plot No. 23 & 24, S-1, RCCI, Industrial Estate, Rawat-
The status in reference regulatory authorities	BILTEX TABLET, Menarini International Operations Luxembourg S.A. 1, Avenue de la Gare L-1611 Luxembourg, MHRA
Detail of previous approval	BILTEX 10mg Orodispersible Tablet, M# 335
Evaluation Remarks	
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
Decision	
Approved	
58	Case Category
	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.
	Nutraceuticals Pharmaceuticals PLOT NO 89- K/3 INDUSTRIAL ESTATE , HAYATABAD, PESHAWAR (001008)
	Application Form Dy. No / Tracking ID & date of submission
	(1TH-JPU-ABUW, 2025-09-22)
	Detail of Fee Submitted
	93000.0, 4200.0 2025-07-30, 2025-09-11
	The proposed proprietary name / brand name
	Trifol Dry Powder Injection 250mg
	Label Claim
	Trifol 250mg Injection Each Vial contains Ceftriaxone Sodium 250mg
	Reference to Finished product specifications
	United States Pharmacopeia
	Proposed Pack Size
	1's-As per SRO
	Shelf Life (Unit)
	2 Year(s)Below 30
	For generic drugs (me-too Status)
	Oxidil 250mg By Sami Pharmaceuticals Phar
	Pharmacotherapeutic Group of (API)
	Cephalosporins Antibiotics
	Name, address of Manufacturing site:
	Bio-Labs (Pvt) Ltd-Plot # 145 Industrial Triangle, Kahuta Road Islamabad-
	The status in reference regulatory authorities
	FDA approved
	Detail of previous approval
	Cefexo 250mg Injection ,316 meeting of Registration Board
Evaluation Remarks	

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

59	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Neutro Pharma (Pvt.) Ltd. , 9.5-Km, Sheikhpura Road, Lahore (000576)
	Application Form Dy. No / Tracking ID & date of submission	(2PD-G1Y-GGHN, 2025-09-22)
	Detail of Fee Submitted	93000.0, 4200.0 2025-07-15, 2025-08-12
	The proposed proprietary name / brand name	Amovact 1000mg Tablet
	Label Claim	Each film coated tablet contains: Amoxicillin trihydrate eq. to Amoxicillin.....875mg Potassium clavulanate eq. to Clavulanic acid....125mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	12's-As per SRO
	Shelf Life (Unit)	2 Yearstore at 25c
	For generic drugs (me-too Status)	Augmentin 1000mg Tablet
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	M/s Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhpura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	Approved
	Detail of previous approval	Amoxi 1000mg Tablet approved in 344th meeting
60	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Horizon HealthCare (Pvt) Ltd plot no 33 sunder industrial estate lahore (000782)
	Application Form Dy. No / Tracking ID & date of submission	(2R7-XYG-XLDV, 2025-09-22)
	Detail of Fee Submitted	93000.0, 2025-07-08,
	The proposed proprietary name / brand name	restiro
	Label Claim	Each Film-coated tablet contains: Resmetirom.....60mg (As per Innovator's specifications)

Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	AS PER SRO-As per SRO
Shelf Life (Unit)	2 Yearnormal
For generic drugs (me-too Status)	hamaz pharmaceuticals pvt.Ltd Multan (000427)
Pharmacotherapeutic Group of (API)	Shandong Chenghui Shuangda Pharmaceuticals Co., Ltd Address: Economic Development zone, Pingyuan country, Dezhou City, Shandong Province, China.
Name, address of Manufacturing site:	hamaz pharmaceuticals pvt ltd -13 km lutfabad bosan road multan -
The status in reference regulatory authorities	complies
Detail of previous approval	345 meeting... Restiro

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

61	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Carer Pharmaceuticals industries Plot no.27, Main Road Rawat Industrial Estate, Rawat (000925)
	Application Form Dy. No / Tracking ID & date of submission	(3XD-BS8-8YLM, 2025-09-22)
	Detail of Fee Submitted	93000.0, 2025-07-24,
	The proposed proprietary name / brand name	Absotela 250mg injection
	Label Claim	COMPOSITION: Each vial Contains: Ceftriaxone (as Sodium) ----- 250mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1,S-As per SRO
	Shelf Life (Unit)	2 YearStore between 15C-30C
	For generic drugs (me-too Status)	Oxidil 250mg IM injection By Sami Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Antibiotic ,Third-Generation Cephalosporin's
	Name, address of Manufacturing site:	Jupiter Pharma-PlotNo.25,Street No. S-6, National Industrial Zone (RCCI) Rawat, Rawalpindi -
	The status in reference regulatory authorities	FDA
	Detail of previous approval	DRAP ,M-320

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

62	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

Name, address of Applicant.	Regal Pharmaceuticals Plot No. 2-A, Street No. S-5 National Industrial Zone RCCI Rawat (000839)
Application Form Dy. No / Tracking ID & date of submission	(46B-T9D-LZMU, 2025-09-22)
Detail of Fee Submitted	93000.0, 2025-07-10,
The proposed proprietary name / brand name	Sold NS 20mg+375mg
Label Claim	Each Modified release tablet contains: Esomeprazole magnesium trihydrate eq to Esomeprazol....20mg (Immediate release coat) Naproxen....375mg (Enteric coated core)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per sro-As per SRO
Shelf Life (Unit)	2 YearStore BELOW 27 c0
For generic drugs (me-too Status)	Glomov 20/375mg Tablet
Pharmacotherapeutic Group of (API)	PPI+NSAID
Name, address of Manufacturing site:	Wimits Pharmaceuticals-Plot No 129, Sunder Industrial Estate, Lahore.-
The status in reference regulatory authorities	USFDA
Detail of previous approval	Napsom 20/375mg. 331st

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

63	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Scilife Pharma Private Limited FD-57/58-A2, Korangi Creek Industrial Park (KCIP) (000837)
	Application Form Dy. No / Tracking ID & date of submission	(511-M9S-7YXX, 2025-09-22)
	Detail of Fee Submitted	97200.0, 2025-08-12,
	The proposed proprietary name / brand name	Mibar 5mg Tablet
	Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to Mirogabalin.....5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's-As per SRO,2X10'S-As per SRO,2x7's-As per SRO,3X10'S-As per SRO,4X7'S-As per SRO
	Shelf Life (Unit)	2 YearStore at 25°C. Excursions permitted between 15°C and 30°C.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	N02BF Gabapentinoids indicated for Neuropathic pain
	Name, address of Manufacturing site:	M/s Wimits Pharmaceutical Pvt Ltd-Plot# 129, Sundar Industrial Estate, Lahore Pakistan.-
	The status in reference regulatory authorities	Tarlige Tablets 5mg of M/s Daiichi Sankyo Co., Ltd (PMDA Approved)

	Detail of previous approval	Mirogab 5mg Tablet, 344th RBM
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
64	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Kanel Pharma Plot No. 6, Street No. SS-3, National Industrial Zone, Rawat (000758)
	Application Form Dy. No / Tracking ID & date of submission	(56H-MYS-QYXR, 2025-09-22)
	Detail of Fee Submitted	93000.0, 2025-07-31,
	The proposed proprietary name / brand name	Gabanel 2.5mg Tablet
	Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to Mirogabalin...2.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearControlled Room Temperature
	For generic drugs (me-too Status)	Mgablin 2.5mg Tablet by Genix Pharma
	Pharmacotherapeutic Group of (API)	N02BF Gabapentinoids indicated for Neuropathic pain
	Name, address of Manufacturing site:	M/S WIMITS PHARMACEUTICALS PVT. LIMITED - Plot # 129, Sunder Industrial Estate Lahore-
	The status in reference regulatory authorities	PMDA Approved
	Detail of previous approval	Mirogab 2.5mg Tablet, 344th Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
65	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Allmed (Pvt.) Ltd Plot # 590 Sunder Industrial Estate Raiwind Road Lahore-Pakistan (000645)
	Application Form Dy. No / Tracking ID & date of submission	(5GW-DM9-PYLJ, 2025-09-22)
	Detail of Fee Submitted	93000.0, 2025-05-22,
	The proposed proprietary name / brand name	Ringet
	Label Claim	Each Vial contains: Pre-lyophilized Sterile Powder of Omperazole Sodium eq. to Omperazole 40 mg
	Reference to Finished product specifications	British Pharmacopeia

Proposed Pack Size	1's -As per SRO
Shelf Life (Unit)	2 Yearbelow 30C
For generic drugs (me-too Status)	Risek 40 mg Injection (IV) Getz Pharma
Pharmacotherapeutic Group of (API)	VISION Pharmaceuticals (Pvt.) Ltd. Plot # 22-23, Industrial Triangle, Kahutta road, Islamabad.Pakistan
Name, address of Manufacturing site:	Variant Pharmaceutical (Pvt.) Ltd.-Plot # 5 M2 Pharma Zone, 26-Km, Lahore Sharikhpur Road, Sheikhpura, Pakistan-
The status in reference regulatory authorities	Omeprazole 40 mg Powder for Solution for Infusion Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia
Detail of previous approval	VARIZOLE 40mg IV Injection 312 Registration Board Meeting (14 to 16th September, 2021).

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

66	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Regal Pharmaceuticals Plot No. 2-A, Street No. S-5 National Industrial Zone RCCI Rawat (000839)
	Application Form Dy. No / Tracking ID & date of submission	(5J4-Z1D-QYVH, 2025-09-22)
	Detail of Fee Submitted	93000.0, 2025-07-10,
	The proposed proprietary name / brand name	Nebreg 5+12.5mg Tablet
	Label Claim	Each film coated tablet contains: Nebivolol as HCl.....5mg Hydrochlorothiazide....12.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per sro-As per SRO
	Shelf Life (Unit)	2 YearStore BELOW 27 c0
	For generic drugs (me-too Status)	Nebilet 5mg/12.5mg
	Pharmacotherapeutic Group of (API)	Antihypertensive
	Name, address of Manufacturing site:	Wimits Pharmaceuticals-Plot No 129, Sunder Industrial Estate, Lahore.-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Nebivol-HCT 5/12.5mg Tablet, 343rd
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

Approved

67	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Regal Pharmaceuticals Plot No. 2-A, Street No. S-5 National Industrial Zone RCCI Rawat (000839)
	Application Form Dy. No / Tracking ID & date of submission	(5VH-795-LZUN, 2025-09-22)
	Detail of Fee Submitted	93000.0, 2025-07-10,
	The proposed proprietary name / brand name	Tepneg 100mg ER tablet
	Label Claim	Each film coated extended release tablet contains: Tapentadol HCL eq to Tapentadol.... 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per sro-As per SRO
	Shelf Life (Unit)	2 YearStore BELOW 27 c0
	For generic drugs (me-too Status)	Nucynta ER 100mg Tablet
	Pharmacotherapeutic Group of (API)	Opioid Analgesic
	Name, address of Manufacturing site:	Wimits Pharmaceuticals-Plot No 129, Sunder Industrial Estate, Lahore.-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Tofradol 100mg ER tablet, 347th
Evaluation Remarks		
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.		
Decision		
Approved		
The Registration Board approved the grant of registration of the applied product with the condition that manufacturer shall ensure the following directions for use on the labelling of the drug product in a clear manner: "To be used by patients 18 years of age or older for the management of moderate to severe chronic pain."		
68	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Kanel Pharma Plot No. 6, Street No. SS-3, National Industrial Zone, Rawat (000758)
	Application Form Dy. No / Tracking ID & date of submission	(68D-GTE-D5DD, 2025-09-22)
	Detail of Fee Submitted	97200.0, 2025-08-12,
	The proposed proprietary name / brand name	Norkan 2/0.5mg Tablet
	Label Claim	Each of the 11 white sugar coated tablets contains: Estradiol Valerate.....2mg Each of the 10 light brown sugar coated tablets contains: Estradiol Valerate.....2mg Norgestrel.....0.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 x 21's , 3x21's As-As per SRO-As per SRO

Shelf Life (Unit)	2 YearControlled Room Temperature
For generic drugs (me-too Status)	PROGYLUTON (Estradiol Valerate-Norgestral) Tablet by M/S Bayer Pakistan
Pharmacotherapeutic Group of (API)	Estrogen Hormones & Synthetic Prostaglandin
Name, address of Manufacturing site:	M/S SKYWIN PHARMACEUTICALS-Plot # 01, Al Badar Industrial Estate, Phase II Sheikhpura Road Lahore.-
The status in reference regulatory authorities	Progyluton Coated Tablet of M/s Bayer Weimar GmbH und Co. KG, Weimar, Germany
Detail of previous approval	Estragest 2/0.5mg Tablet, 347th Meeting
Evaluation Remarks	
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
Decision	
Approved	
69	Case Category
	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.
	BF Biosciences Limited 5-KM Sundar Raiwind Road, Raiwind, Lahore (000655)
	Application Form Dy. No / Tracking ID & date of submission
	(6BT-X4E-8VZ5, 2025-09-22)
	Detail of Fee Submitted
	97200.0, 2025-08-06,
	The proposed proprietary name / brand name
	Emaglin Trio 10mg/5mg/1000mg Tablets
	Label Claim
	Empagliflozin.....10mg Linagliptin.....5mg Metformin HCl.....1000mg (as extended release Core)
	Reference to Finished product specifications
	As per Innovators Specification
	Proposed Pack Size
	14's , 28's-As per SRO
	Shelf Life (Unit)
	24 MonthStore below 30°C, in a dry and dark place.
	For generic drugs (me-too Status)
	Tri-Xenglul of M/s Hilton Pharma (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)
	Combination of Oral Blood Glucose Lowering Drugs
	Name, address of Manufacturing site:
	Ferozsons Laboratories Limited-P.O Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa - Pakistan-
	The status in reference regulatory authorities
	TRIJARDY XR TABLAETS of Boehringer Ingelheim Pharmaceuticals, Inc approved by USFDA.
	Detail of previous approval
	Empagen-LM XR Tablets 10mg/5mg/1000mg" of M/s Ferozsons Laboratories Limited, approved in 336th Meet
Evaluation Remarks	
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
Decision	

Approved

70	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	jupiter Pharma Plot No 25 Street S-6 RCCI Rawat Rawalpindi (000838)
	Application Form Dy. No / Tracking ID & date of submission	(6UR-EEW-B1LG, 2025-09-22)
	Detail of Fee Submitted	93000.0, 2025-07-30,
	The proposed proprietary name / brand name	Jupe-D
	Label Claim	Each ml contains: Cholecalciferol 5mg (As per Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearStore between 15 to 25C
	For generic drugs (me-too Status)	Indrop D Injection M/s Neutro Pharmaceutical Pvt Ltd Pakistan., Reg. No. 023170
	Pharmacotherapeutic Group of (API)	Vitamin D analog
	Name, address of Manufacturing site:	Carer Pharmaceuticals-Plot No. 27, Main Road, Industrial Estate, Rawat -
	The status in reference regulatory authorities	Vitamin D3 Bon 200000 IU /1mL Solution for injection, ANSM France Approved.
	Detail of previous approval	Cara D Injection Meeting No.326
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
71	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Carer Pharmaceuticals industries Plot no.27, Main Road Rawat Industrial Estate, Rawat (000925)
	Application Form Dy. No / Tracking ID & date of submission	(7A3-V8M-JTGY, 2025-09-22)
	Detail of Fee Submitted	93000.0, 2025-07-24,
	The proposed proprietary name / brand name	Absotela 500mg IM Injection
	Label Claim	Each vial Contains: Ceftriaxone (as Sodium) ----- 500mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1,S-As per SRO
	Shelf Life (Unit)	2 YearStore between 15C-30C
	For generic drugs (me-too Status)	Oxidil 500mg IM injection
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	Jupiter Pharma-Plot No. 25,Street No. S-6, National Industrial Zone (RCCI) Rawat, Rawalpindi-
	The status in reference regulatory authorities	FDA

	Detail of previous approval	Ismaxone 500mg IM Injection
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
72	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Regal Pharmaceuticals Plot No. 2-A, Street No. S-5 National Industrial Zone RCCI Rawat (000839)
	Application Form Dy. No / Tracking ID & date of submission	(7D1-SA6-V31U, 2025-09-22)
	Detail of Fee Submitted	93000.0, 2025-07-10,
	The proposed proprietary name / brand name	Prezon 3mg Capsule
	Label Claim	Each Capsule contains: Cariprazine Hydrochloride equivalent to Cariprazine.....3mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per sro-As per SRO
	Shelf Life (Unit)	2 YearStore BELOW 27 c0
	For generic drugs (me-too Status)	Caripz 3mg Capsule
	Pharmacotherapeutic Group of (API)	antipsychotics.
	Name, address of Manufacturing site:	Skywin Pharmaceuticals Pvt. Ltd.-Plot No 1, Al-Badar industrial estate, Lahore, Sheihupura Faisalabad road, Lahore Pakistan-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Carip 3mg Capsule, 343rd
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
73	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	BF Biosciences Limited 5-KM Sundar Raiwind Road, Raiwind, Lahore (000655)
	Application Form Dy. No / Tracking ID & date of submission	(7YH-ZQP-8QP2, 2025-09-22)
	Detail of Fee Submitted	97200.0, 2025-08-06,
	The proposed proprietary name / brand name	Emaglin Trio 25mg/5mg/1000mg Tablets
	Label Claim	Each film coated tablet contains Empagliflozin.....25mg

	Linagliptin.....5mg Metformin HCl.....1000mg (as extended release Core)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	14's , 28's-As per SRO
Shelf Life (Unit)	24 MonthStore below 30°C, in a dry and dark place.
For generic drugs (me-too Status)	Tri-Xenglu of M/s Hilton Pharma (Pvt.) Ltd.
Pharmacotherapeutic Group of (API)	Combination of Oral Blood Glucose Lowering Drugs
Name, address of Manufacturing site:	Ferozsons Laboratories Limited-P.O Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa - Pakistan-
The status in reference regulatory authorities	TRIJARDY XR TABLAETS of Boehringer Ingelheim Pharmaceuticals, Inc approved by USFDA.
Detail of previous approval	Empagen-LM XR Tablets 25mg/5mg/1000mg” of M/s Ferozsons Laboratories Limited, approved in 336th Meet

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

74

Case Category	Contract Manufacturing (Incharge Evaluation Cell)
Name, address of Applicant.	Carer Pharmaceuticals industries Plot no.27, Main Road Rawat Industrial Estate, Rawat (000925)
Application Form Dy. No / Tracking ID & date of submission	(8WZ-7X4-6555, 2025-09-22)
Detail of Fee Submitted	97200.0, 2025-08-28,
The proposed proprietary name / brand name	Terbitar Cream
Label Claim	Each gram of cream contains: Terbinafine hydrochloride 10mg (JP Specifications)
Reference to Finished product specifications	Any Other
Proposed Pack Size	1,S-As per SRO
Shelf Life (Unit)	2 YearStore between 15C-30C
For generic drugs (me-too Status)	Terbiderm cream
Pharmacotherapeutic Group of (API)	Antifungal
Name, address of Manufacturing site:	Nagarsons Pharmaceuticals (Pvt) Ltd-Plot No. 34, and Street No. NS-2, National Industrial Zone, Rawat Islamabad.-
The status in reference regulatory authorities	MHRA
Detail of previous approval	Terbinag cream .DRAP 321

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

75	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Regal Pharmaceuticals Plot No. 2-A, Street No. S-5 National Industrial Zone RCCI Rawat (000839)
	Application Form Dy. No / Tracking ID & date of submission	(99B-M4Q-162D, 2025-09-22)
	Detail of Fee Submitted	93000.0, 2025-07-10,
	The proposed proprietary name / brand name	Actrox 100mg TABLET
	Label Claim	Each Film Coated Tablet contains Acotiamide HCl Hydrate.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per sro-As per SRO
	Shelf Life (Unit)	2 YearStore BELOW 27 c0
	For generic drugs (me-too Status)	Dyspenal Tablet 100mg
	Pharmacotherapeutic Group of (API)	gastroprokinetics
	Name, address of Manufacturing site:	Skywin Pharmaceuticals Pvt. Ltd.-Plot No 1, Al-Badar industrial estate, Lahore, Sheihupura Faisalabad road, Lahore Pakistan-
	The status in reference regulatory authorities	PMDA approved
	Detail of previous approval	Acotia 100mg Tablet., 344th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
76	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Regal Pharmaceuticals Plot No. 2-A, Street No. S-5 National Industrial Zone RCCI Rawat (000839)
	Application Form Dy. No / Tracking ID & date of submission	(9U8-YLW-XUTH, 2025-09-22)
	Detail of Fee Submitted	93000.0, 2025-07-10,
	The proposed proprietary name / brand name	Sold NS 20mg+500mg
	Label Claim	Each film coated modified release tablet contains: Esomeprazole magnesium trihydrate eq to Esomeprazole....20mg (immediate release coat) Naproxen 500mg (enteric coated core)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per sro-As per SRO
	Shelf Life (Unit)	2 YearStore BELOW 27 c0
	For generic drugs (me-too Status)	Glomov 20/500mg Tablet
	Pharmacotherapeutic Group of (API)	PPI+NSAID
	Name, address of Manufacturing site:	Wimits Pharmaceuticals-Plot No 129, Sunder Industrial Estate, Lahore.-

	The status in reference regulatory authorities	USFDA
	Detail of previous approval	
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
77	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	OBS Pharma (Pvt) Ltd 108 Kotlakhpat Industrial Estate, Lahore 54760 Pakistan (000243)
	Application Form Dy. No / Tracking ID & date of submission	(9UJ-YD4-3DPM, 2025-09-22)
	Detail of Fee Submitted	97200.0, 2025-08-20,
	The proposed proprietary name / brand name	Ciproxin Dry Suspension 250mg/5ml
	Label Claim	Each 5ml reconstituted Suspension contains: Ciprofloxacin ... 250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30 degree
	For generic drugs (me-too Status)	Novidat 250mg/5ml Dry Suspension
	Pharmacotherapeutic Group of (API)	Anti-infectives
	Name, address of Manufacturing site:	Solaris Life Sciences Private Limited-Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat-
	The status in reference regulatory authorities	CIPRO 250mg/5ml Dry Suspension, USFDA approved
	Detail of previous approval	Ciprocin 250mg/5ml Dry Suspension, Meeting Minutes 347
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
78	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Regal Pharmaceuticals Plot No. 2-A, Street No. S-5 National Industrial Zone RCCI Rawat (000839)
	Application Form Dy. No / Tracking ID & date of submission	(9YP-VQU-J6AQ, 2025-09-22)
	Detail of Fee Submitted	93000.0, 2025-07-10,
	The proposed proprietary name / brand name	Dustro 10MG TABLET

Label Claim	Each film coated tablet contains: Dydrogesterone.....10 mg
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	As per sro-As per SRO
Shelf Life (Unit)	2 YearStore BELOW 27 c0
For generic drugs (me-too Status)	Dydrogest 10mg Tablet.
Pharmacotherapeutic Group of (API)	Genito Urinary system and sex hormones.
Name, address of Manufacturing site:	Skywin Pharmaceuticals Pvt. Ltd.-Plot No 1, Al-Badar industrial estate, Lahore, Sheihupura Faisalabad road, Lahore Pakistan-
The status in reference regulatory authorities	Approved in HPRA of Ireland.
Detail of previous approval	D-gest 10mg tablet, 336th

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

79	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Carer Pharmaceuticals industries Plot no.27, Main Road Rawat Industrial Estate, Rawat (000925)
	Application Form Dy. No / Tracking ID & date of submission	(AGL-7JA-V2T3, 2025-09-22)
	Detail of Fee Submitted	97200.0, 2025-08-21,
	The proposed proprietary name / brand name	EBIVIZ 5MG/5ML SYRUP
	Label Claim	Each 5ml contains: Ebastine 5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1,S-As per SRO
	Shelf Life (Unit)	2 YearStore between 15C-30C
	For generic drugs (me-too Status)	Simstine 5mg/5ml Syrup Simz Pharmaceuticals (Pvt) Ltd. Plot No. 574-575 Punjab Industrial Estate Sundar Lahore, Lahore Reg.NO 074206
	Pharmacotherapeutic Group of (API)	Antihistamine
	Name, address of Manufacturing site:	Seraph Pharmaceuticals-SERAPH PHARMACEUTICAL Plot No 210, Industrial triangle, Kahuta road, Islamabad-Pakistan-
	The status in reference regulatory authorities	Spain Approved
	Detail of previous approval	DRAP ,M-336
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
80	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Regal Pharmaceuticals Plot No. 2-A, Street No. S-5 National Industrial Zone RCCI Rawat (000839)
	Application Form Dy. No / Tracking ID & date of submission	(AGP-YQV-2YNE, 2025-09-22)
	Detail of Fee Submitted	93000.0, 2025-07-10,
	The proposed proprietary name / brand name	Merox 10mg tablet
	Label Claim	Each film coated tablet contains: Mirogabalin besylate eq to Mirogabalin....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per sro-As per SRO
	Shelf Life (Unit)	2 YearStore BELOW 27 c0
	For generic drugs (me-too Status)	Tarlige 10mg tablet
	Pharmacotherapeutic Group of (API)	Gaa and its derivatives
	Name, address of Manufacturing site:	Wimits Pharmaceuticals-Plot No 129, Sunder Industrial Estate, Lahore.-
	The status in reference regulatory authorities	PMDA approved
	Detail of previous approval	Mirogap 10mg tablet/ 344th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
81	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	BF Biosciences Limited 5-KM Sundar Raiwind Road, Raiwind, Lahore (000655)
	Application Form Dy. No / Tracking ID & date of submission	(BT2-52D-W3GY, 2025-09-22)
	Detail of Fee Submitted	97200.0, 2025-08-06,
	The proposed proprietary name / brand name	Emaglin Trio 5mg/2.5mg/1000mg Tablets
	Label Claim	Each film coated tablet contains Empagliflozin.....5mg Linagliptin.....2.5mg Metformin HCl.....1000mg (as extended release Core)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's , 28's-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30°C, in a dry and dark place.
	For generic drugs (me-too Status)	Tri-Xengl of M/s Hilton Pharma (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Combination of Oral Blood Glucose Lowering Drugs
	Name, address of Manufacturing site:	Ferozsons Laboratories Limited-P.O Ferozsons, Amargarh, Nowshera, Khyber Pakhtunkhwa - Pakistan-

	The status in reference regulatory authorities	TRIJARDY XR TABLAETS of Boehringer Ingelheim Pharmaceuticals, Inc approved by USFDA.
	Detail of previous approval	Empagen-LM XR Tablets 5mg/2.5mg/1000mg” of M/s Ferozsons Laboratories Limited, approved in 336th Mee
	Evaluation Remarks	
	In light of Registration Board’s decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
82	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Kanel Pharma Plot No. 6, Street No. SS-3, National Industrial Zone, Rawat (000758)
	Application Form Dy. No / Tracking ID & date of submission	(BXV-9BU-GDEB, 2025-09-22)
	Detail of Fee Submitted	97200.0, 2025-08-12,
	The proposed proprietary name / brand name	Kelazole Lotion
	Label Claim	Each gm contains: Ketoconazole.....20mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	30 ml ,60ml, 100ml & 120ml-As per SRO
	Shelf Life (Unit)	2 YearControlled Room Temprature
	For generic drugs (me-too Status)	Ketowin Lotion by M/s Shaigan
	Pharmacotherapeutic Group of (API)	Antifungals For Topical Use
	Name, address of Manufacturing site:	M/S BIO-LABS PVT LTD-Plot No. 145, Industrial Triangle Kahuta Road Islamabad-
	The status in reference regulatory authorities	Nizoral Shampoo, MHRA Approved
	Detail of previous approval	KT-Zole Lotion, 336th Meeting
	Evaluation Remarks	
	In light of Registration Board’s decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
83	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	De-Mont Research Laboratories (Pvt.) Ltd. 20 Km, Lahore-Sheikhupura Road, Sheikhupura, Pakistan (000844)
	Application Form Dy. No / Tracking ID & date of submission	(DBY-8YE-3APQ, 2025-09-22)
	Detail of Fee Submitted	93000.0, 2025-07-28,
	The proposed proprietary name / brand name	BASTIN 20MG TABLET

Label Claim	Each Uncoated Tablet Contains: Bilastine.....20mg (Innovators Specifications)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	AS PER SRO-As per SRO
Shelf Life (Unit)	2 Yearstore below 30 degree centigrade
For generic drugs (me-too Status)	Bilaxten 20mg Tablet, Searle Pharma
Pharmacotherapeutic Group of (API)	Benzimidazoles
Name, address of Manufacturing site:	Wezen Pharmaceuticals-Plot No. 23 & 24, S-1, RCCI, Industrial Estate, Rawat-
The status in reference regulatory authorities	BILTEX TABLET, Menarini International Operations Luxembourg S.A. 1, Avenue de la Gare L-1611 Luxembourg, MHRA
Detail of previous approval	BILTEX 20mg Tablet, M# 335

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

84

Case Category	Contract Manufacturing (Incharge Evaluation Cell)
Name, address of Applicant.	Scilife Pharma Private Limited FD-57/58-A2, Korangi Creek Industrial Park (KCIP) (000837)
Application Form Dy. No / Tracking ID & date of submission	(EQN-AAM-34X4, 2025-09-22)
Detail of Fee Submitted	97200.0, 2025-08-12,
The proposed proprietary name / brand name	Mibar 10mg Tablet
Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to Mirogabalin.....10mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1x10's-As per SRO,2X10'S-As per SRO,2x7's-As per SRO,3X10'S-As per SRO,4X7'S-As per SRO
Shelf Life (Unit)	2 YearStore at 25°C. Excursions permitted between 15°C and 30°C.
For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	N02BF Gabapentinoids indicated for Neuropathic pain
Name, address of Manufacturing site:	M/s Wimits Pharmaceutical Pvt Ltd-Plot# 129, Sundar Industrial Estate, Lahore Pakistan.-
The status in reference regulatory authorities	Tarlige Tablets 5mg of M/s Daiichi Sankyo Co., Ltd (PMDA Approved)
Detail of previous approval	Mirogab 10mg Tablet, 344th RBM

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other

conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

85	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Kanel Pharma Plot No. 6, Street No. SS-3, National Industrial Zone, Rawat (000758)
	Application Form Dy. No / Tracking ID & date of submission	(EXU-9DG-V7XB, 2025-09-22)
	Detail of Fee Submitted	93000.0, 4200.0 2025-07-31, 2025-09-10
	The proposed proprietary name / brand name	Tagcil 50mg Injection
	Label Claim	Each Vial Contains: Tigecycline (Lyophilized powder)....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearControlled Room Temperature
	For generic drugs (me-too Status)	Tigewel Injection of M/s Welwrd Pharma (Reg.# 082530)
	Pharmacotherapeutic Group of (API)	Antibacterial agent
	Name, address of Manufacturing site:	M/S BIO-LABS PVT LTD-Plot No. 145, Industrial Triangle Kahuta Road Islamabad-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Bactcil 50mg Injection IV, 330th Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
86	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Carer Pharmaceuticals industries Plot no.27, Main Road Rawat Industrial Estate, Rawat (000925)
	Application Form Dy. No / Tracking ID & date of submission	(GMT-D2Q-N5JU, 2025-09-22)
	Detail of Fee Submitted	97200.0, 2025-08-28,
	The proposed proprietary name / brand name	Terbistar lotion
	Label Claim	Each gram of topical lotion contains: Terbinafine hydrochloride 10mg (JP Specifications)
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	1,S-As per SRO
	Shelf Life (Unit)	2 YearStore between 15C-30C
	For generic drugs (me-too Status)	Terbiderm Topical Lotion 1% M/s Atco (Pakistan) Limited
	Pharmacotherapeutic Group of (API)	Antifungal

	Name, address of Manufacturing site:	NAGARSONS Pharmaceuticals (Pvt) Ltd-M/s. Saptagir Laboratories Pvt. Ltd. Sy.No. Parts of 27, 46 & 50 to 56, Ananthasagar (Vill), Chegunta (Mandal), Medak (Dist.), Telangana, India.-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Terbinag 1% Lotion DRAP Meeting NO 347
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
87	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Regal Pharmaceuticals Plot No. 2-A, Street No. S-5 National Industrial Zone RCCI Rawat (000839)
	Application Form Dy. No / Tracking ID & date of submission	(GT9-RJH-1MMP, 2025-09-22)
	Detail of Fee Submitted	93000.0, 2025-07-10,
	The proposed proprietary name / brand name	Tenoreg 4.5g Inj
	Label Claim	Each Vial contains: Piperacillin (as Piperacillin Sodium) : 2.0 g Tazobactam (as Tazobactam Sodium) : 0.25 g (as lyophilized powder for IV injection)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per sro-As per SRO
	Shelf Life (Unit)	2 YearStore BELOW 27 c0
	For generic drugs (me-too Status)	Tanzo Injection
	Pharmacotherapeutic Group of (API)	β-Lactamase inhibitor.
	Name, address of Manufacturing site:	Skywin Pharmaceuticals Pvt. Ltd.-Plot No 1, Al-Badar industrial estate, Lahore, Sheihupura Faisalabad road, Lahore Pakistan-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Tazopip 2.25gm Inj, 336th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
88	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Scilife Pharma Private Limited FD-57/58-A2, Korangi Creek Industrial Park (KCIP) (000837)

Application Form Dy. No / Tracking ID & date of submission	(HTY-LRB-DD19, 2025-09-22)
Detail of Fee Submitted	97200.0, 2025-08-12,
The proposed proprietary name / brand name	Mibar 15mg Tablet
Label Claim	Each Film Coated Tablet contains:Mirogabalin Besylate equivalent to Mirogabalin.....15mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1x10's-As per SRO,2X10'S-As per SRO,2x7's-As per SRO,3X10'S-As per SRO,4X7'S-As per SRO
Shelf Life (Unit)	2 YearStore at 25°C. Excursions permitted between 15°C and 30°C.
For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	N02BF Gabapentinoids indicated for Neuropathic pain
Name, address of Manufacturing site:	M/s Wimits Pharmaceutical Pvt Ltd-Plot# 129, Sundar Industrial Estate, Lahore Pakistan.-
The status in reference regulatory authorities	Tarlige Tablets 15mg of M/s Daiichi Sankyo Co., Ltd (PMDA Approved)
Detail of previous approval	Mirogab 15mg Tablet, 344th RBM

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

89	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Regal Pharmaceuticals Plot No. 2-A, Street No. S-5 National Industrial Zone RCCI Rawat (000839)
	Application Form Dy. No / Tracking ID & date of submission	(JJB-WHE-VQ3U, 2025-09-22)
	Detail of Fee Submitted	93000.0, 2025-07-10,
	The proposed proprietary name / brand name	Tepneg IR 50mg
	Label Claim	Each Film Coated Tablet contains: Tapentadol HCl eq. To Tapentadol -----50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per sro-As per SRO
	Shelf Life (Unit)	2 YearStore BELOW 27 c0
	For generic drugs (me-too Status)	Palexia IR 50mg Tablet
	Pharmacotherapeutic Group of (API)	Opioid Analgesic
	Name, address of Manufacturing site:	Wimits Pharmaceuticals-Plot No 129, Sunder Industrial Estate, Lahore.-
	The status in reference regulatory authorities	MHRA approved.
	Detail of previous approval	Tydol 50mg IR Tablet, 343rd

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for

cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

The Registration Board approved the grant of registration of the applied product with the condition that manufacturer shall ensure the following directions for use on the labelling of the drug product in a clear manner:

"To be used by patients 18 years of age or older for the management of moderate to severe chronic pain."

90	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winthrox Laboratories Pvt. Ltd K-219-A, SITE, Super Highway Phase II, Karachi (000807)
	Application Form Dy. No / Tracking ID & date of submission	(LMZ-X37-M7AZ, 2025-09-22)
	Detail of Fee Submitted	93000.0, 2025-06-19,
	The proposed proprietary name / brand name	Gynoxa 75mcg/20mcg Tablet
	Label Claim	Each Tablet Contains: Gestodene.....0.075mg Ethinylestradiol 0.020mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Meliane(Gestodene-Ethinylestradiol) Tablet Marketed by: Medipharma (Pvt.) Ltd., 108- kotlakhpat Industrial Estate, Lahore
	Pharmacotherapeutic Group of (API)	progesterone / synthetic estrogen
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Address: Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhpura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	Brand Name: Millinett 20/75 microgram coated tablets Registration holder's name and address: Gedeon Richter Plc.Gyö mrő i ú t 19-211103 Budapest, Hungary Manufacturer's name and address: Gedeon Richter (UK) Ltd, 127 Shirland Road, London, W9 2EP, UK.
	Detail of previous approval	Gestodol Tablet in 347th Meeting of DRB
91	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
91	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Sarco Chemicals Industries 17-Km. Lahore Road Multan (000203)

Application Form Dy. No / Tracking ID & date of submission	(M48-RD8-6S5R, 2025-09-22)
Detail of Fee Submitted	93000.0, 2025-07-24,
The proposed proprietary name / brand name	Ogest 10mg Tablet
Label Claim	Each film coated tablet contains: Dydrogesterone 10mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	As per SRO / DPC-De-Controlled
Shelf Life (Unit)	2 YearStore at room temperature below 30
For generic drugs (me-too Status)	Dydrogest 10mg Tablet of M/s OBS Pakistan Pvt. Ltd.
Pharmacotherapeutic Group of (API)	Genito Urinary system and sex hormones.
Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhpura Road, Lahore-Pakistan-
The status in reference regulatory authorities	Duphaston 10 mg film-coated tablets is Approved in HPRA of Ireland.
Detail of previous approval	D-Gest 10mg Tablet (336th Meetingof DRB)

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

92	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Martin Dow Limited Plot no. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan (000267)
	Application Form Dy. No / Tracking ID & date of submission	(NVH-AJA-GMVL, 2025-09-22)
	Detail of Fee Submitted	93000.0, 2025-07-28,
	The proposed proprietary name / brand name	Binari IV Infusion 1000mg + 300mg
	Label Claim	Each 100ml contains: Paracetamol.....1000mg Ibuprofen (as sodium dihydrate) 300mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's vial-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30°C
	For generic drugs (me-too Status)	Acetamol-IP 1000mg/300mg IV Infusion by Vision Pharmaceuticals (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	Paracetamol: Analgesic & Antipyretic , Ibuprofen: NSAID
	Name, address of Manufacturing site:	M/s Vision Pharmaceuticals (Pvt) Ltd-Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad-
	The status in reference regulatory authorities	MAXIGESIC IV paracetamol 1000 mg and ibuprofen (as sodium dihydrate) 300 mg in 100 mL solution for infusion vial By TGA-Australia
	Detail of previous approval	Co-Acetamol 1000mg/300mg IV Infusion , 343rd DRB Meeting

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision**Approved**

93	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Kanel Pharma Plot No. 6, Street No. SS-3, National Industrial Zone, Rawat (000758)
	Application Form Dy. No / Tracking ID & date of submission	(PQ6-RS1-RQX8, 2025-09-22)
	Detail of Fee Submitted	97200.0, 2025-08-12,
	The proposed proprietary name / brand name	Elagix 200mg Tablet
	Label Claim	Each film coated tablet contains: Elagolix Sodium equivalent to Elagolix ... 200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearControlled Room Temperature
	For generic drugs (me-too Status)	Eladiol 150mg Tablet of M/s Nabiqasim Industries (Pvt) Ltd.
	Pharmacotherapeutic Group of (API)	H01CC03, Anti-gonadotropin-releasing hormone
	Name, address of Manufacturing site:	M/S WIMITS PHARMACEUTICALS PVT. LIMITED - Plot # 129, Sunder Industrial Estate Lahore-
	The status in reference regulatory authorities	ORLISSA 200mg Tablets of M/s AbbVie USFDA approved
	Detail of previous approval	ORLIX 200mg Tablets, 343rd Meeting
94	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Martin Dow Limited Plot no. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan (000267)
	Application Form Dy. No / Tracking ID & date of submission	(Q7L-XN4-Q59S, 2025-09-22)
	Detail of Fee Submitted	93000.0, 2025-07-16,
	The proposed proprietary name / brand name	Beclodow-S Suspension for Nebulization

Label Claim	Each 2ml of respule contains: Beclomethasone dipropionate..... 0.8mg Salbutamol sulphate 1.928mg equivalent to Salbutamol 1.6mg																																
Reference to Finished product specifications	As per Innovators Specification																																
Proposed Pack Size	2ml x 1's-As per SRO,2ml x 10's-As per SRO,2ml x 5's-As per SRO																																
Shelf Life (Unit)	24 MonthStore below 30°C																																
For generic drugs (me-too Status)	Beeko Plus from Hudson Pharma (Pvt) Ltd																																
Pharmacotherapeutic Group of (API)	Beclomethasone: Corticosteroid Salbutamol: Short acting beta 2 adrenergic agonist																																
Name, address of Manufacturing site:	M/s Hudson Pharma (Pvt) Ltd-D-93, North West Industrial Zone, Port Qasim Authority, Karachi-																																
The status in reference regulatory authorities	Clenil Compositum 0.8mg + 1.6mg / 2ml																																
Detail of previous approval	Beeko Plus 0.8mg + 1.6mg / 2ml Suspension for Nebulisation ; 322nd DRB Meeting minutes																																
Evaluation Remarks																																	
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.																																	
Decision																																	
Approved																																	
95	<table> <tr> <td>Case Category</td><td>Contract Manufacturing (Incharge Evaluation Cell)</td></tr> <tr> <td>Name, address of Applicant.</td><td>Regal Pharmaceuticals Plot No. 2-A, Street No. S-5 National Industrial Zone RCCI Rawat (000839)</td></tr> <tr> <td>Application Form Dy. No / Tracking ID & date of submission</td><td>(RAU-E73-T2V1, 2025-09-22)</td></tr> <tr> <td>Detail of Fee Submitted</td><td>93000.0, 2025-07-10,</td></tr> <tr> <td>The proposed proprietary name / brand name</td><td>Promeg 5mg Tablet</td></tr> <tr> <td>Label Claim</td><td>Each Tablet contains: Norethisterone.....5mg</td></tr> <tr> <td>Reference to Finished product specifications</td><td>British Pharmacopeia</td></tr> <tr> <td>Proposed Pack Size</td><td>As per sro-As per SRO</td></tr> <tr> <td>Shelf Life (Unit)</td><td>2 YearStore BELOW 27 c0</td></tr> <tr> <td>For generic drugs (me-too Status)</td><td>Primolut N (Norethisterone) 5mg Tablet</td></tr> <tr> <td>Pharmacotherapeutic Group of (API)</td><td>Synthetic progestational hormone</td></tr> <tr> <td>Name, address of Manufacturing site:</td><td>Skywin Pharmaceuticals Pvt. Ltd.-Plot No 1, Al-Badar industrial estate, Lahore, Sheihupura Faisalabad road, Lahore Pakistan-</td></tr> <tr> <td>The status in reference regulatory authorities</td><td>MHRA Approved</td></tr> <tr> <td>Detail of previous approval</td><td>Just-N 5mg, 347th</td></tr> <tr> <td colspan="2">Evaluation Remarks</td></tr> <tr> <td colspan="2">In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.</td></tr> </table>	Case Category	Contract Manufacturing (Incharge Evaluation Cell)	Name, address of Applicant.	Regal Pharmaceuticals Plot No. 2-A, Street No. S-5 National Industrial Zone RCCI Rawat (000839)	Application Form Dy. No / Tracking ID & date of submission	(RAU-E73-T2V1, 2025-09-22)	Detail of Fee Submitted	93000.0, 2025-07-10,	The proposed proprietary name / brand name	Promeg 5mg Tablet	Label Claim	Each Tablet contains: Norethisterone.....5mg	Reference to Finished product specifications	British Pharmacopeia	Proposed Pack Size	As per sro-As per SRO	Shelf Life (Unit)	2 YearStore BELOW 27 c0	For generic drugs (me-too Status)	Primolut N (Norethisterone) 5mg Tablet	Pharmacotherapeutic Group of (API)	Synthetic progestational hormone	Name, address of Manufacturing site:	Skywin Pharmaceuticals Pvt. Ltd.-Plot No 1, Al-Badar industrial estate, Lahore, Sheihupura Faisalabad road, Lahore Pakistan-	The status in reference regulatory authorities	MHRA Approved	Detail of previous approval	Just-N 5mg, 347th	Evaluation Remarks		In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
Case Category	Contract Manufacturing (Incharge Evaluation Cell)																																
Name, address of Applicant.	Regal Pharmaceuticals Plot No. 2-A, Street No. S-5 National Industrial Zone RCCI Rawat (000839)																																
Application Form Dy. No / Tracking ID & date of submission	(RAU-E73-T2V1, 2025-09-22)																																
Detail of Fee Submitted	93000.0, 2025-07-10,																																
The proposed proprietary name / brand name	Promeg 5mg Tablet																																
Label Claim	Each Tablet contains: Norethisterone.....5mg																																
Reference to Finished product specifications	British Pharmacopeia																																
Proposed Pack Size	As per sro-As per SRO																																
Shelf Life (Unit)	2 YearStore BELOW 27 c0																																
For generic drugs (me-too Status)	Primolut N (Norethisterone) 5mg Tablet																																
Pharmacotherapeutic Group of (API)	Synthetic progestational hormone																																
Name, address of Manufacturing site:	Skywin Pharmaceuticals Pvt. Ltd.-Plot No 1, Al-Badar industrial estate, Lahore, Sheihupura Faisalabad road, Lahore Pakistan-																																
The status in reference regulatory authorities	MHRA Approved																																
Detail of previous approval	Just-N 5mg, 347th																																
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In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.																																	

	Decision	
	Approved	
96	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Genetics Pharmaceuticals Pvt. Ltd 539-A Sundar Industrial Estate Raiwind Road Lahore (000845)
	Application Form Dy. No / Tracking ID & date of submission	(RJP-VBD-ZSJQ, 2025-09-22)
	Detail of Fee Submitted	93000.0, 2025-07-29,
	The proposed proprietary name / brand name	Mirgab 10mg Tablet
	Label Claim	Each Film coated Tablet Contains: Mirogabalin Besylate equivalent to Mirogabalin..... 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	2 YearBelow 25°C
	For generic drugs (me-too Status)	Mirogab 10mg Tablet (Wimits Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	M/s Shandong Kehui Pharmaceutical Co., Ltd.
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt.) Ltd.-129-Sundar Industrial Estate, Raiwind Road, Lahore, Pakistan.-
	The status in reference regulatory authorities	Tarlige Tablets 5mg (Daiichi Sankyo Co., Ltd)
	Detail of previous approval	Mirogab 10mg Tablet 344th (31-12-2024)
97	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	De-Mont Research Laboratories (Pvt.) Ltd. 20 Km, Lahore-Sheikhupura Road, Sheikhupura, Pakistan (000844)
	Application Form Dy. No / Tracking ID & date of submission	(RX7-PQV-64UR, 2025-09-22)
	Detail of Fee Submitted	97200.0, 2025-08-26,
	The proposed proprietary name / brand name	ENLITEN 600MG INJECTION
	Label Claim	Each vial contains; Glutathione as sodium 600mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,1's -As per SRO
	Shelf Life (Unit)	2 Yearstore below 30 degree centigrade
	For generic drugs (me-too Status)	Bio-Labs (Pvt) Ltd. Islamabad, Regn No. 127448
	Pharmacotherapeutic Group of (API)	Antidotes. ATC code V03AB32
	Name, address of Manufacturing site:	M/s Bio Labs Pvt Ltd.-Plot # 145, Industrial Triangle, Kahuta Road, Islamabad-
	The status in reference regulatory authorities	TAD-600, Biomedica Foscama Industria, Italy

	Detail of previous approval	Siti-Gluta 600mg Injection, M#347
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
98	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wallace Pharma Evolutions Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (000951)
	Application Form Dy. No / Tracking ID & date of submission	(SJ1-BSY-936T, 2025-09-22)
	Detail of Fee Submitted	93000.0, 2025-07-22,
	The proposed proprietary name / brand name	Biltex 10mg Tablet Disp
	Label Claim	Each Orodispersible Tablet contains: Bilastine 10MG (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Biltino Tablet by Wezen Pharma
	Pharmacotherapeutic Group of (API)	Benzimidazoles
	Name, address of Manufacturing site:	Wezen Pharmaceuticals-Plot No. 23 & 24, S-1, RCCI Industrial Estate, Rawat-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Biltex, DRB 335
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
99	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Horizon Healthcare (pvt.) ltd. 35-A Small Industrial Estate - Taxila (000856)
	Application Form Dy. No / Tracking ID & date of submission	(T78-YLD-ZJHN, 2025-09-22)
	Detail of Fee Submitted	97200.0, 2025-08-19,
	The proposed proprietary name / brand name	daprodustat
	Label Claim	Each Film-coated tablet contains Daprodustat....6mg
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	AS PER SRO-As per SRO
	Shelf Life (Unit)	2 Yearnormal
	For generic drugs (me-too Status)	hamaz pharmaceuticals pvt.Ltd Multan (000427)
	Pharmacotherapeutic Group of (API)	Neutan Pharma (Anhui) Co., Ltd, China. Address: No 1018 Jin an Road Economic & Technology Development District Suzhou Anhui Province 234001, China China
	Name, address of Manufacturing site:	hamaz pharmaceuticals pvt ltd -13KM LUTAFABAD BOSAN ROAD MULTAN-
	The status in reference regulatory authorities	complies
	Detail of previous approval	daptro....347 meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
100	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Fedro Pharmaceutical Labs Pvt Ltd 149 Industrial Estate Hayatabad Peshawar (000238)
	Application Form Dy. No / Tracking ID & date of submission	(U8H-Y23-P8WX, 2025-09-22)
	Detail of Fee Submitted	97200.0, 2025-08-19,
	The proposed proprietary name / brand name	Fedgesic Injection 75mg/3ml
	Label Claim	Each 3ml ampoule contains: Diclofenac Sodium.....75mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3mlx5's, 3ml x 50's, 3ml x 100's-As per SRO
	Shelf Life (Unit)	2 YearStore below 25C at cool and dry place
	For generic drugs (me-too Status)	Dicloran 75mg/3ml Injection by M/s Sami Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Non Steroidal Anti-inflammatory Drugs
	Name, address of Manufacturing site:	M/s Lawari International-Valley Road, Gulkada, Saidu Sharif, Swat, KPK, Pakistan-
	The status in reference regulatory authorities	Voltarol Ampoules 75mg/3ml, solution for injection. (EMA approved)
	Detail of previous approval	Diclo-Wari Injection 75mg/3ml, Meeting 344th of DRB (Tracking ID:275-WZB-N7LM)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

Approved

101	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	BF Biosciences Limited 5-KM Sundar Raiwind Road, Raiwind, Lahore (000655)
	Application Form Dy. No / Tracking ID & date of submission	(UUN-LVR-BERJ, 2025-09-22)
	Detail of Fee Submitted	97200.0, 2025-08-06,
	The proposed proprietary name / brand name	Emaglin Trio 12.5mg/2.5mg/1000mg Tablets
	Label Claim	Each film coated tablet contains Empagliflozin.....12.5mg Linagliptin.....2.5mg Metformin HCl.....1000mg (as extended release Core)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's , 28's-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30°C, in a dry and dark place.
	For generic drugs (me-too Status)	Tri-Xenglut of M/s Hilton Pharma (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Combination of Oral Blood Glucose Lowering Drugs
	Name, address of Manufacturing site:	Ferozsons Laboratories Limited-P.O Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa - Pakistan-
	The status in reference regulatory authorities	TRIJARDY XR TABLAETS of Boehringer Ingelheim Pharmaceuticals, Inc approved by USFDA.
	Detail of previous approval	Empagen-LM XR Tablets 12.5mg/2.5mg/1000mg” of M/s Ferozsons Laboratories Limited, approved in 336th
Evaluation Remarks		
In light of Registration Board’s decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.		
Decision		
Approved		
102	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Scilife Pharma Private Limited FD-57/58-A2, Korangi Creek Industrial Park (KCIP) (000837)
	Application Form Dy. No / Tracking ID & date of submission	(VN6-QY7-GAGZ, 2025-09-22)
	Detail of Fee Submitted	97200.0, 2025-08-12,
	The proposed proprietary name / brand name	Mibar 2.5mg Tablet
	Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to Mirogabalin.....2.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's-As per SRO,2X10'S-As per SRO,2x7's-As per SRO,3X10'S-As per SRO,4X7'S-As per SRO
	Shelf Life (Unit)	2 YearStore at 25°C. Excursions permitted between 15°C and 30°C.
	For generic drugs (me-too Status)	N/A

	Pharmacotherapeutic Group of (API)	N02BF Gabapentinoids indicated for Neuropathic pain
	Name, address of Manufacturing site:	M/s Wimits Pharmaceutical Pvt Ltd-Plot# 129, Sundar Industrial Estate, Lahore Pakistan.-
	The status in reference regulatory authorities	Tarlige Tablets 2.5mg of M/s Daiichi Sankyo Co., Ltd (PMDA Approved)
	Detail of previous approval	Mirogab 2.5mg Tablet, 344th RBM
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
103	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Genetics Pharmaceuticals Pvt. Ltd 539-A Sundar Industrial Estate Raiwind Road Lahore (000845)
	Application Form Dy. No / Tracking ID & date of submission	(WDX-G6Q-TRY2, 2025-09-22)
	Detail of Fee Submitted	93000.0, 2025-07-29,
	The proposed proprietary name / brand name	Mirgab 5mg Tablet
	Label Claim	Each Film coated tablet contains Mirogabalin besilate equivalent to Mirogabalin..... 5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	2 YearBelow 25°C
	For generic drugs (me-too Status)	Mirogab 5mg Tablet (Wimits Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	M/s Shandong Kehui Pharmaceutical Co., Ltd.
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt.) Ltd.-129-Sundar Industrial Estate, Raiwind Road, Lahore, Pakistan.-
	The status in reference regulatory authorities	Tarlige Tablets 5mg (Daiichi Sankyo Co., Ltd)
	Detail of previous approval	Mirogab 5mg Tablet 344th (31-12-2024)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
104	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Regal Pharmaceuticals Plot No. 2-A, Street No. S-5 National Industrial Zone RCCI Rawat (000839)
	Application Form Dy. No / Tracking ID & date of submission	(WZ5-J8D-DSWZ, 2025-09-22)

Detail of Fee Submitted	93000.0, 2025-07-10,
The proposed proprietary name / brand name	Tepneg 50mg ER Tablet
Label Claim	Each film coated extended release tablet contains: Tapentadol HCl eq to Tapentadol.....50mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per sro-As per SRO
Shelf Life (Unit)	2 YearStore BELOW 27 c0
For generic drugs (me-too Status)	Nucynta ER 50mg Tablet
Pharmacotherapeutic Group of (API)	Opioid Analgesic
Name, address of Manufacturing site:	Wimits Pharmaceuticals-Plot No 129, Sunder Industrial Estate, Lahore.-
The status in reference regulatory authorities	USFDA
Detail of previous approval	Tofradol 50mg ER tablet, 347th

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

The Registration Board approved the grant of registration of the applied product with the condition that manufacturer shall ensure the following directions for use on the labelling of the drug product in a clear manner:

"To be used by patients 18 years of age or older for the management of moderate to severe chronic pain."

105	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Martin Dow Limited Plot no. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan (000267)
	Application Form Dy. No / Tracking ID & date of submission	(YBP-A1D-W9HQ, 2025-09-22)
	Detail of Fee Submitted	93000.0, 2025-07-16,
	The proposed proprietary name / brand name	Beclodow Suspension for Nebulization
	Label Claim	Each 2ml of respule contains: Beclomethasone dipropionate....0.8mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2ml x 1's-As per SRO,2ml x 10's-As per SRO,2ml x 5's-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30°C
	For generic drugs (me-too Status)	Beeko from Hudson Pharma (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Beclomethasone: Corticosteroid , Salbutamol: Short acting beta 2 adrenergic agonist
	Name, address of Manufacturing site:	M/s Hudson Pharma (Pvt.) Ltd-D-93, North West Industrial Zone, Port Qasim Authority, Karachi-
	The status in reference regulatory authorities	Clenil 800mcg Suspension for Nebulizer by AIFA,Italy

Detail of previous approval	Beeko 0.8mg / 2ml Suspension for Nebulisation ; 320th DRB Meeting Minutes

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

106	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Regal Pharmaceuticals Plot No. 2-A, Street No. S-5 National Industrial Zone RCCI Rawat (000839)
	Application Form Dy. No / Tracking ID & date of submission	(YR5-PE8-17X8, 2025-09-22)
	Detail of Fee Submitted	93000.0, 2025-07-24,
	The proposed proprietary name / brand name	Tenoreg 4.5g Inj
	Label Claim	Each Vial contains: Piperacillin (as Piperacillin Sodium) : 4.0 g Tazobactam (as Tazobactam Sodium) : 0.5 g (as lyophilized powder for IV injection)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1,S-As per SRO
	Shelf Life (Unit)	2 YearStore BELOW 27 c0
	For generic drugs (me-too Status)	Tanzo Injection
	Pharmacotherapeutic Group of (API)	Beta lactamase inhibitor
	Name, address of Manufacturing site:	Skywin Pharmaceuticals Pvt. Ltd.-Plot No 1, Al-Badar industrial estate, Lahore, Sheihupura Faisalabad road, Lahore Pakistan-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Tazopip 4.5gm Inj, 336th
107	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Dyson Research Laboratories (Pvt.) Ltd 28-Km Ferozpur Road Lahore (000559)
	Application Form Dy. No / Tracking ID & date of submission	(YSZ-Q4D-AMTY, 2025-09-22)
	Detail of Fee Submitted	93000.0, 2025-07-16,
	The proposed proprietary name / brand name	Jaxira ER Tablet 15mg

Label Claim	Each film coated, extended-release tablet contains: Upadacitinib hemihydrate eq. to upadacitinib 15 mg.
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	30's-As per SRO
Shelf Life (Unit)	2 YearStore below 30C.
For generic drugs (me-too Status)	Upada ER Tablet 15 mg by Searle Company Limited, situated at Karachi.
Pharmacotherapeutic Group of (API)	Janus Kinase (JAK) inhibitor.
Name, address of Manufacturing site:	M/s McOlson Research Laboratories (Pvt.) Ltd.-26-Km, Lahore Sharikhpur Road, District Sheikhpura.-
The status in reference regulatory authorities	Rinvoq Tablet 15 mg, applied formulation is registered in Medicines and Healthcare products Regulatory Agency (MHRA) UK.
Detail of previous approval	Upadacitinib ER Tablet 15mg (Upadacitinib hemihydrate), approved in 343 meeting of registration board

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

108	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(9X1-5VE-PZ6X, 2025-08-22)
	Detail of Fee Submitted	93000.0, 2024-11-27,
	The proposed proprietary name / brand name	CINACET 60MG TABLETS
	Label Claim	Each Film Coated Tablet contains: Cinacalcet Hcl eq. to Cinacalcet.....60mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO -As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Censipar Tablet 60mg CCL Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	WNSFEILD Pharmaceuticals, -PLOT NO.122, PHASE-V, BLOCK-A, INDUSTRIAL ESTATE, HATTAR, KPK, PAKISTAN-
	The status in reference regulatory authorities	Product Name = CINACALCET HCL 60mg TABLET UK MHRA Reference: https://www.medicines.org.uk/emc/product/11483/smpc#g
	Detail of previous approval	343rd
	Evaluation Remarks	

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

109	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(D95-EUN-2SRZ, 2025-08-22)
	Detail of Fee Submitted	93000.0, 2024-11-27,
	The proposed proprietary name / brand name	CEFTIV 2.5gm Injection
	Label Claim	Each Vial Contains: Ceftazidime as Pentahydrate.....2000mg Avibactam as Sodium Salt.....500mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO -As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	ZAVICEFTA 2.5GM INJECTION (PFIZER)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-PLOT NO.122, PHASE-V, BLOCK-A, INDUSTRIAL ESTATE, HATTAR, KPK, PAKISTAN-
	The status in reference regulatory authorities	Approved by UK MHRA https://www.medicines.org.uk/emc/product/2465/smpc Product Name = CEFTAZIDIME + AVIBACTAM 2.5gm Injection
	Detail of previous approval	343rd
110	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
110	Case Category	Priority As Per 257-M of RB (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan (01-374-0006)
	Application Form Dy. No / Tracking ID & date of submission	(3SP-H2B-YSX8, 2025-08-12)
	Detail of Fee Submitted	300000.0, 2025-06-25,

The proposed proprietary name / brand name	BENDASOLE
Label Claim	Each Vial Contains: Bendamustine Hydrochloride.... 100mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	1's-As per SRO
Shelf Life (Unit)	24 MonthStore at 2-8°C. Protect from light.
For generic drugs (me-too Status)	BENDALAB 100mg/Vial Bendamustine 100mg/Vial MAH: Lab Diagnostic Systems (SMC) Pvt. Ltd
Pharmacotherapeutic Group of (API)	Anti-Cancer
Name, address of Manufacturing site:	Kindos Pharmaceuticals Co., Ltd-No.8-9 Kexin Road. Chengdu Hi-Tech Comprehensive Bonded Zone.Chengdu, Sichuan, 611731, P. R. China-China
Pharmaceutical Equivalence and Comparative Dissolution Profile	The proposed abbreviated new drug application (ANDA) for Bendamustine Hydrochloride for Injection, available in 25 mg/vial and 100 mg/vial, is developed based on the FDA-approved reference listed drug (RLD), TREANDA® (Bendamustine Hydrochloride) for Injection, manufactured by CEPHALON INC (Application No. 022249). TREANDA® was originally approved on March 20, 2008, and the proposed formulation is intended to match the reference product in terms of quality, safety, and efficacy.
Name, address of Marketing Authorization Holder:	Meitheal Pharmaceuticals Inc.,, 8700 West Bryn Mawr Avenue, Suite 600S, Chicago, IL 60631 United States of America, United States of America
Details of Certificates (CoPP/FSC/cGMP):	Valid
Details of Authorization Letter :	NA
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies of Bendamustine Hydrochloride Monohydrate are carried out by drug substance manufacturer, Chongqing Huapont Shengchem Pharmaceutical Co., Ltd., under long term conditions (25±2 °C/60±5%RH for 72 months) and accelerated conditions (40±2 °C/75±5%RH for 6 months) as per ICH Q1A
The status in reference regulatory authorities	TREANDA® (Bendamustine Hydrochloride) for Injection Originally developed and marketed by Cephalon Inc., which was later acquired by Teva Pharmaceuticals USA, Inc. USFDA Approved
Evaluation Remarks	
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Decision	
Approved	
As per current import policy, the firm shall submit the original legalized CoPP and a Letter of Authorization before issuance of the letter.	
111	
Case Category	Priority As Per 257-M of RB (Muhammad Sarfraz Nawaz)
Name, address of Applicant.	Merixil Pharma Office 28, 2nd Floor, Rose Plaza , I-8 Markaz (DHO-ISB-174)
Application Form Dy. No / Tracking ID & date of submission	(PMM-EQ7-B458, 2025-09-22)

Detail of Fee Submitted	75000.0, 238500.0 2025-05-08, 2025-08-26
The proposed proprietary name / brand name	PLERIXAFOR SEACROSS 24MG/1.2ML
Label Claim	Each ML contain PLERIXAFOR 20MG/ML- Each vial contain PLERIXAFOR 24MG/1.2ML
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's-De-Controlled
Shelf Life (Unit)	60 MonthBELOW 30 C
For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	ATC code : L03AX16, (ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS)
Name, address of Manufacturing site:	Sichuan Huiyu Pharmaceutical Co., Ltd-Building 3, No333 Hanyang Road, Shizhang District, Neijiang, Sichuan,-China
Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached
Name, address of Marketing Authorization Holder:	Seacross Pharmaceuticals Limited , BEAUMONT BUSINESS CENTRES, 6 SNOW HILL, LONDON, EC1A 2AY,, United Kingdom
Details of Certificates (CoPP/FSC/cGMP):	Complined
Details of Authorization Letter :	N/A
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached
The status in reference regulatory authorities	US FDA/MHRA/EMA-Mozobil Injection

Evaluation Remarks

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Decision

Approved

As per current import policy, the firm shall submit the original legalized CoPP and a Letter of Authorization before issuance of the letter.

112	Case Category	Export Facilitation (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Reign Pharmaceuticals PCSIR - KLC (Pvt.) Ltd. TBIC Building - I, PCSIR Laboratories Complex, Shahrah e Dr. Salim - uz - Zaman Siddiqui Off University Road. (000757)
	Application Form Dy. No / Tracking ID & date of submission	(66U-6WE-EBLA, 2025-05-12)
	Detail of Fee Submitted	37000.0, 2025-04-08,
	The proposed proprietary name / brand name	Nutrizin Dispersible 20mgTablet
	Label Claim	Each dispersible tablet contains: Zinc sulfate monohydrate equivalent to Elemental Zinc--- 20mg (USP Specs.)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	3 x 10s-As per SRO
	Shelf Life (Unit)	2 YearRoom temperature
	For generic drugs (me-too Status)	Zincor D Tabs (Genome Pharmaceutical)
	Pharmacotherapeutic Group of (API)	Mineral supplements
	Name, address of Manufacturing site:	Self Manufacturing

	Name & address of API manufacturer	Aries Laboratories
	Detail of stability batches of drug product	Stability Studies Attached in Module-III-P8 (Drug Product)
	Documents for the procurement of API with approval from DRAP (in case of Import)	API Documents Attached in Module-III (Annexure-C)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence study with reference Product Attached in Module -III-P2 (Drug Product)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Studies Attached in Module-III-S7 (Drug Substance)
	The status in reference regulatory authorities	WHO Approved
	GMP status of the firm	Attached in Module-I
	Evidence of approval of manufacturing facility	DML Attached in Module-I
	Evaluation Remarks	
	.	
	Decision	
	Approved	
113	Case Category	Import (Najia Saleem)
	Name, address of Applicant.	Brand Station 69 Wocland Villas, Near Raiwind Road (05-352-0065)
	Application Form Dy. No / Tracking ID & date of submission	(NZN-2ZN-PAJG, 2024-04-02)
	Detail of Fee Submitted	300000.0, 9000.0 2024-03-12, 2025-07-27
	The proposed proprietary name / brand name	Floro BS (Oral Solution)
	Label Claim	Each milliliter contains: Florfenicol 100mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	Bottles: 10; 20; 30;-De-Controlled
	Shelf Life (Unit)	36 Month(s)Store in dry, cool place. Stay away from direct sunlight. FOR VETERINARY USE ONLY.
	For generic drugs (me-too Status)	122898 FLORI SOVE 10 ORAL LIQUID of M/S. SUAVE PHARMACEUTICALS PVT. LTD., FAISALABAD
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	M/s THIENQUAN JOINT STOCK COMPANY-Lot 17F2-F8, road 5, Tra Noc 1 Industrial zone, Binh Thuy District, Can Tho city, Vietnam-Vietnam
	Name, address of Marketing Authorization Holder:	M/s BRAND STATION, 69 Wocland villas lahore, near Raiwind road, Lahore, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Scanned copy of legalized GMP certificate of the manufacturer dated 28-04-2022, valid for 5 years Scanned copy of FSC valid for two years.
	Details of Authorization Letter :	Sole agency agreement between the supplier and the applicant
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 36 months real time stability studies data as per zone IV-A conditions is submitted
	Evaluation Remarks	
	The firm has submitted fee Rs. 9000/- dated 27 July vide challan No. 3422097944 for revision of FPP specifications.	
	Decision	

Approved

with as per innovator's specification, subject to compliance with current import policy for finished drugs. Moreover, firm shall submit original legalized valid sole agency/ distribution agreement, FSC and GMP certificate, before issuance of registration letter, since the already submitted copies are scanned.

114	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(455-LBG-TRTQ, 2024-10-26)
	Detail of Fee Submitted	37000.0, 9400.0 2024-10-22, 2025-08-06
	The proposed proprietary name / brand name	CYNO-1000 INJECTION
	Label Claim	Each ml contain :- Cynacobalamin 1000 mcg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10ML-De-Controlled
	Shelf Life (Unit)	2 YearStore below 25 °C. Protect from light
	For generic drugs (me-too Status)	CYANOZON EXTRA INJECTION Reg. No. 119706 (AMAZON PHARMACEUTICALS (PCT.)LTD,BHIMBER.AJ & K,)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has revised FPP specifications from as per innovator to USP specifications along with fee Rs. 9400/- vide challan No. 81751537344	
115	Decision	
	Deferred	
	till resumption of production in liquid injectable (General) section in compliance with GMP.	
	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(5N1-X9W-E294, 2024-08-27)
	Detail of Fee Submitted	30000.0, 2024-08-21,
	The proposed proprietary name / brand name	ADEKA EXCEL ORAL SOLUTION
	Label Claim	Each Litre Contains:-Vitamin A 100MIUVitamin D3 20MIUVitamin E 20gmVitamin K3 8gmVitamin C 100gm(As per Innovator's Specs.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Liter-De-Controlled,100ml -De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light

	For generic drugs (me-too Status)	LIPOVIT ORAL SOLUTION. Reg.No.026479 M/S ALINA COMBINE PAKISTAN (PVT.) LTD.KARACHI
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
116	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(8TX-4PT-VDHT, 2024-11-27)
	Detail of Fee Submitted	37000.0, 2024-11-25,
	The proposed proprietary name / brand name	TRIBEN INJECTION (10ML)
	Label Claim	Each ml contains:Sulphadiazine 400mgTrimethoprim 80mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	ZINTRAN INJECTION. REG. NO. 063568 (ZAKFAS PHARMACEUTICALS (PVT.) LTD, MULTAN)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Deferred	
	till resumption of production in liquid injectable (General) section in compliance with GMP.	
117	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(5D5-MMP-4SEQ, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	TIA INJECTION
	Label Claim	Each ml contains Tylosin Tartrate eq. to Tylosin 180mg (BP Vet Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	50 ml-De-Controlled

Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat, light and moisture.
For generic drugs (me-too Status)	Tylocure 180 (Vetline pharmaceuticals)
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	Satisfactory
Evidence of approval of manufacturing facility	

Evaluation Remarks

TLA INJECTION /TYSIN 18% INJECTION already registered on REG#063841

Decision

Approved

118	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(8DM-LA3-UQ2B, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	Ivomex C3 injection
	Label Claim	Each ml contains Ivermectin 20mg Clorsulon 10mg (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	50 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	endex injection (ici pakistan)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Already registered with IVOMEX C3 INJECTION on Reg# 063825	
	Decision	
	Approved	
	Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.	

119	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(D2U-BJS-RNSH, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Florfenicol oral Liquid
	Label Claim	Each ml containsFlorfenicol 250mg(Manufacturer's Specification)

	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1 litre-De-Controlled,100 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Product Name:: Fagofol 250 Liquid Registration No: 092175 Farm Aid Group
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
120	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(DUU-H2G-QLV4, 2025-09-11)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Albabak 10 Oral Suspension
	Label Claim	Each 100ml contains Albendazole 10gm (B.P VET Specification)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1 litre-De-Controlled,100 ml-De-Controlled,150ml-De-Controlled,250 ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Alba 10 plus
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	ALBABAK-10 ORAL SUSPENSION already registered on Reg#034536	
	Decision	
	Approved	
121	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(E8J-PXX-Y7T5, 2025-09-12)

Detail of Fee Submitted	38700, 2025-09-11,
The proposed proprietary name / brand name	Tiamubak 45% Oral Powder
Label Claim	Each 100gm contains Tiamulin Hydrogen Fumarate eq. to Tiamulin Base 45gm
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1 kg-De-Controlled, 10 kg-De-Controlled, 100 gm-De-Controlled, 25 kg-De-Controlled, 250 gm-De-Controlled, 5 kg-De-Controlled, 500 gm-De-Controlled
Shelf Life (Unit)	2 Year(s) store at controlled room temperature. protect from heat, light and ,moisture
For generic drugs (me-too Status)	Product Name:: SB Tiamulin 45% Oral Powder Registration No: 048221 Company Name: SB PHARMA
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	Satisfactory
Evidence of approval of manufacturing facility	

Evaluation Remarks

Tiamubak 45% Oral Powder already registered on Reg# 048170

Decision

Approved

122	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(ELH-WTH-99J9, 2025-09-13)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	RESPI BRO ORAL LIQUID
	Label Claim	Each ml contains Doxycycline HCl 200mg Tylosin tartrate 100mg Colistin sulphate 500,000IU Bromhexine HCl 5mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1 litre-De-Controlled, 100 ml-De-Controlled, 150 ml-De-Controlled, 250 ml-De-Controlled, 500 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s) store at controlled room temperature. protect from heat, light and ,moisture
	For generic drugs (me-too Status)	Product Name:: Respidox-T Oral Liquid Registration No: 079120 Company Name: Hawk Bio Pharma (Pvt.) Ltd
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	

Evaluation Remarks

Decision

Approved

123	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(G18-4NX-3H5T, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Nilzamaar Super Ds Suspension
	Label Claim	Each 100ml contains Oxyclozanide 6% Levamisole 3% Cobalt chloride 0.05% (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1 litre-De-Controlled,100 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Product Name:: Cloza LC Liquid Registration No: 093242 Company Name: Inshal Pharmaceutical Industries
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Nilzamaar Super Ds Suspension already registered on Reg# 063834	
	Decision	
	Approved	
	Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.	
124	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(GY5-4HD-2MZL, 2025-09-13)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	IVO Z injection
	Label Claim	Each ml containsIvermectin 20mg(BP VET Specification)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Ivovectin Injection Registration No: 079289 Vetz Pharmaceutical
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory

	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
125	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(HRY-3A6-1ZS5, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Trigold water soluble powder
	Label Claim	Each 1000gm contains Trichlorophon (USP/BP) 980gm (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	10 gm-De-Controlled,100 gm-De-Controlled,1000 gm-De-Controlled,5 gm-De-Controlled,50 kg-De-Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Trichlovet 98% w/s powder (vetz pharma) Registration No: 080768
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Trigold water soluble powder already registered on Reg# 049700	
	Decision	
	Approved	
	Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.	
126	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(HXE-A6Z-9ZEJ, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Fosfatyl Powder
	Label Claim	Each gram contains:-Fosfomycin Calcium 200mgTylosin as Tartrate 100mgFructose 1,6 Diphosphate 180mgSodium phosphate 150mgMagnesium phosphate.....100mg(As per Innovator's Specifications)

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gm-De-Controlled,1000 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Product Name:: Fosfo-20 Oral Powder Registration No: 088861 Company Name: Evergreen Pharmaceutical
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The Fosfatyl Powder is already registered on Reg # 118587	
	Decision	
	Approved	
127	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(HDR-YE7-VN98, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	CRD SUPER injection
	Label Claim	Each ml containsTylosin 60mgColistin sulphate 10mgDihydrostreptomycin 100mg(Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	50 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Product Name:: T-Septo Injection Registration No: 078293
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	CRD SUPER injection already registered on Reg#062151	
	Decision	
	Approved	
	Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.	
128	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)

Application Form Dy. No / Tracking ID & date of submission		(JLA-DQA-LYNW, 2025-09-13)
Detail of Fee Submitted		38700, 2025-09-11,
The proposed proprietary name / brand name		Tycostrep injection
Label Claim		Each ml contains Tylosin 100mg Colistin sulphate 20mg Dihydrostreptomycin 200mg (Manufacturer's Specification)
Reference to Finished product specifications		Manufacturers Specification
Proposed Pack Size		50 ml-De-Controlled
Shelf Life (Unit)		2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
For generic drugs (me-too Status)		TCS Injection (Leads pharma)
Pharmacotherapeutic Group of (API)		
Name, address of Manufacturing site:		--
GMP status of the firm		Satisfactory
Evidence of approval of manufacturing facility		
Evaluation Remarks		
Tycostrep injection already registered on Reg# 062154		
Decision		
Approved		
Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.		
129	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(JPR-HYB-EU4M, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Triclobak S.C Oral Suspension
	Label Claim	Each ml containsTriclabendazole 50mgCobalt sulphate 1.67mgSodium selenite 0.35mg(Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1 litre-De-Controlled,100 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Product Name:: ENDOMALL SC ORAL DRENCH Registration No: 058921 Company Name: MALLARD PHARMACEUTICALS (PVT) LTD
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
Evaluation Remarks		
Triclobak S.C Oral Suspension already registered on Reg# 062166		
Decision		

Approved

Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.

130	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(JR2-AW9-2THJ, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Clozafen Suspension
	Label Claim	Each ml containsOxfendazole 22.65mgOxyclozanide 62.5mg Cobalt as sulphate 1.67mgSelenium as Sodium selenate 0.5mg(Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1 litre-De-Controlled,100 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Product Name:: Oxy Cob Registration No: 113671 Company Name: Medhouse Pharmaceuticals (PVT) Ltd
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Clozafen Suspension already registered on Reg# 062139	
131	Decision	
	Approved	
	Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.	
	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(JT9-E44-1X53, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	TG-65 INJECTION
	Label Claim	Each 100ml containsGentamycin sulphate 5gmColistin sulphate 50MIUTylosin tartrate 10gm(Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	100 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Product Name:: GENTAFATE INJECTION Registration No: 099348 Company Name: Inshal Pharmaceutical
	Minutes of 351st Meeting of Registration Board (23rd – 24th September, 2025)	
	930	

	Industries																																				
Pharmacotherapeutic Group of (API)																																					
Name, address of Manufacturing site:	--																																				
GMP status of the firm	Satisfactory																																				
Evidence of approval of manufacturing facility																																					
Evaluation Remarks																																					
TG-65 INJECTION already registered on Reg# 071065																																					
Decision																																					
Approved																																					
132	<table> <tr> <td>Case Category</td><td>New License (Sabahat Zehra)</td></tr> <tr> <td>Name, address of Applicant.</td><td>Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)</td></tr> <tr> <td>Application Form Dy. No / Tracking ID & date of submission</td><td>(L2M-QE8-JAZA, 2025-09-13)</td></tr> <tr> <td>Detail of Fee Submitted</td><td>38700, 2025-09-11,</td></tr> <tr> <td>The proposed proprietary name / brand name</td><td>Ivobak injection</td></tr> <tr> <td>Label Claim</td><td>Each ml contains Ivermectin (B.P) 10mg(B.P VET Specifications)</td></tr> <tr> <td>Reference to Finished product specifications</td><td>British Pharmacopeia</td></tr> <tr> <td>Proposed Pack Size</td><td>50 ml-De-Controlled</td></tr> <tr> <td>Shelf Life (Unit)</td><td>2 Year(s)store at controlled room temperature.protect from heat,light and ,moisture</td></tr> <tr> <td>For generic drugs (me-too Status)</td><td>Product Name:: Ivomec 1%Injectable Solution Registration No: 009597 Company Name: SAADAT INTERNATIONAL Product Name:: Ivomec 1%Injectable Solution Registration No: 009597 Company Name: SAADAT INTERNATI</td></tr> <tr> <td>Pharmacotherapeutic Group of (API)</td><td></td></tr> <tr> <td>Name, address of Manufacturing site:</td><td>--</td></tr> <tr> <td>GMP status of the firm</td><td>Satisfactory</td></tr> <tr> <td>Evidence of approval of manufacturing facility</td><td></td></tr> <tr> <td colspan="2">Evaluation Remarks</td></tr> <tr> <td colspan="2">already registered on Reg# 053908</td></tr> <tr> <td colspan="2">Decision</td></tr> <tr> <td colspan="2">Approved</td></tr> </table>	Case Category	New License (Sabahat Zehra)	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)	Application Form Dy. No / Tracking ID & date of submission	(L2M-QE8-JAZA, 2025-09-13)	Detail of Fee Submitted	38700, 2025-09-11,	The proposed proprietary name / brand name	Ivobak injection	Label Claim	Each ml contains Ivermectin (B.P) 10mg(B.P VET Specifications)	Reference to Finished product specifications	British Pharmacopeia	Proposed Pack Size	50 ml-De-Controlled	Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat,light and ,moisture	For generic drugs (me-too Status)	Product Name:: Ivomec 1%Injectable Solution Registration No: 009597 Company Name: SAADAT INTERNATIONAL Product Name:: Ivomec 1%Injectable Solution Registration No: 009597 Company Name: SAADAT INTERNATI	Pharmacotherapeutic Group of (API)		Name, address of Manufacturing site:	--	GMP status of the firm	Satisfactory	Evidence of approval of manufacturing facility		Evaluation Remarks		already registered on Reg# 053908		Decision		Approved	
Case Category	New License (Sabahat Zehra)																																				
Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)																																				
Application Form Dy. No / Tracking ID & date of submission	(L2M-QE8-JAZA, 2025-09-13)																																				
Detail of Fee Submitted	38700, 2025-09-11,																																				
The proposed proprietary name / brand name	Ivobak injection																																				
Label Claim	Each ml contains Ivermectin (B.P) 10mg(B.P VET Specifications)																																				
Reference to Finished product specifications	British Pharmacopeia																																				
Proposed Pack Size	50 ml-De-Controlled																																				
Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat,light and ,moisture																																				
For generic drugs (me-too Status)	Product Name:: Ivomec 1%Injectable Solution Registration No: 009597 Company Name: SAADAT INTERNATIONAL Product Name:: Ivomec 1%Injectable Solution Registration No: 009597 Company Name: SAADAT INTERNATI																																				
Pharmacotherapeutic Group of (API)																																					
Name, address of Manufacturing site:	--																																				
GMP status of the firm	Satisfactory																																				
Evidence of approval of manufacturing facility																																					
Evaluation Remarks																																					
already registered on Reg# 053908																																					
Decision																																					
Approved																																					
133	<table> <tr> <td>Case Category</td><td>New License (Sabahat Zehra)</td></tr> <tr> <td>Name, address of Applicant.</td><td>Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)</td></tr> <tr> <td>Application Form Dy. No / Tracking ID & date of submission</td><td>(L3Q-P1T-7XAM, 2025-09-12)</td></tr> <tr> <td>Detail of Fee Submitted</td><td>38700, 2025-09-11,</td></tr> <tr> <td>The proposed proprietary name / brand name</td><td>Doxybak powder</td></tr> </table>	Case Category	New License (Sabahat Zehra)	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)	Application Form Dy. No / Tracking ID & date of submission	(L3Q-P1T-7XAM, 2025-09-12)	Detail of Fee Submitted	38700, 2025-09-11,	The proposed proprietary name / brand name	Doxybak powder																										
Case Category	New License (Sabahat Zehra)																																				
Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)																																				
Application Form Dy. No / Tracking ID & date of submission	(L3Q-P1T-7XAM, 2025-09-12)																																				
Detail of Fee Submitted	38700, 2025-09-11,																																				
The proposed proprietary name / brand name	Doxybak powder																																				

	Label Claim	Each 100gm contains Doxycycline HCl (B.P) 50gm (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	10 kg -De-Controlled, 100 gm-De-Controlled, 1000 gm-De-Controlled, 25 kg-De-Controlled, 250 gm-De-Controlled, 5 kg-De-Controlled, 500 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s) store at controlled room temperature. protect from heat, light and ,moisture
	For generic drugs (me-too Status)	Product Name:: Fairo Dox 50 Powder Registration No: 063782 Company Name: MALLARD PHARMACEUTICALS (PVT) LTD.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Doxybak powder already registered on Reg# 053918	
	Decision	
	Approved	
	Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.	
134	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(LNL-1BD-RY56, 2025-09-13)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	Neo-Mix w/s powder
	Label Claim	Each 1000gm contains Oxytetracycline HCl 200gm Neomycin sulphate 100gm Erythromycin thiocyanate 100gm (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1 kg-De-Controlled, 10 kg-De-Controlled, 100 gm-De-Controlled, 25 kg-De-Controlled, 250 gm-De-Controlled, 5 kg-De-Controlled, 500 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s) store at controlled room temperature. protect from heat, light and ,moisture
	For generic drugs (me-too Status)	Product Name:: Eter Neo OX Oral Powder Registration No: 130211 Company Name: Eterna Pharma Pvt Ltd
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	

135	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(MLM-8T4-PEW5, 2025-09-13)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	Asperbak w/s powder
	Label Claim	Each 1000gm contains Aspirin (BP) 67gm Vitamin C (BP) 200gm Potassium chloride (BP) 3gm Sodium citrate (BP) 7gm (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1 kg-De-Controlled, 10 kg-De-Controlled, 100 gm-De-Controlled, 25 kg-De-Controlled, 250 gm-De-Controlled, 5 kg-De-Controlled, 500 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s) store at controlled room temperature. protect from heat, light and ,moisture
	For generic drugs (me-too Status)	Product Name:: Vita Shell Water Soluble Powder Registration No: 075772 Company Name: Inshal Pharmaceutical Industries
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
Evaluation Remarks		
ASPERBAK WS POWDER already registered on Reg# 048174		
Decision		
Approved		
Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.		
136	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(GYY-V66-GH51, 2025-09-13)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	Colifast powder
	Label Claim	Each 100gm contains Colistin sulphate 460,000,000 IU (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1 KG-De-Controlled, 10 KG-De-Controlled, 100 GM-De-Controlled, 25 KG-De-Controlled, 250 GM-De-Controlled, 50 KG-De-Controlled, 500 GM-De-Controlled
	Shelf Life (Unit)	2 Year(s) store at controlled room temperature. protect from heat, light and ,moisture
	For generic drugs (me-too Status)	Product Name:: Polymix Powder Registration No: 088035 Company Name: Farm Aid Group

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
137	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(R5N-M92-BVMD, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Coccis powder
	Label Claim	Each gm containsSulfadimerazine Na 200mgSulfaquinoxaline Na 25mgPyrimethamine 25mgFuraltadone 25mgVitamin A 15,000 I.U.Vitamin K3 05mg(Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1 kg-De-Controlled,10 kg-De-Controlled,100 gm-De-Controlled,25 kg-De-Controlled,250 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Product Name:: FAR-COX Oral Powder Registration No: 043239 Company Name: Farm Aid Group
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The formulation contains furaltadone as ingredient.	
	Decision	
	Deferred	
	The instant case for review of formulation to Sub-committee on veterinary drugs.	
138	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(N5L-4B8-DQWG, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Toltrabak Oral Solution
	Label Claim	Each ml containsToltrazuril 25mg(As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	1 litre-De-Controlled,100 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Product Name:: Mili Toltrazuril Oral Liquid Registration No: 112196 Company Name: Mili Vet Pharmaceuticals (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Toltrabak Oral Solution already registered on Reg# 048168	
	Decision	
	Approved	
139	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(NBX-4T7-Z9PE, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Enrobak 20 Oral solution
	Label Claim	Each 100ml contains Enrofloxacin 20gm (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1 litre-De-Controlled,100 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Product Name:: Bio-Enro 20% Liquid Registration No: 021290 Company Name: Bio-Labs(Pvt) Ltd
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	ENROBAK 20 ORAL SOLUTION already registered on 034540	
	Decision	
	Approved	
	Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.	
140	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)

	Application Form Dy. No / Tracking ID & date of submission	(NDS-ERX-MD7Q, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	Tylobak 20 injection
	Label Claim	Each ml contains Tylosin tartrate eq. to Tylosin 200 mg (BP Vet Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Tylomac Injection (star laboratories)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Tylobak 20 injection already registered on Reg# 049694	
	Decision	
	Approved	
141	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(QJR-R8L-XY12, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	FEN FOX ORAL LIQUID
	Label Claim	Each ml containsRafoxanide (BP vet) 50mgFenbendazole 50mg(Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1 litre-De-Controlled,100 ml-De-Controlled,150 ml-De- Controlled,250 ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Product Name:: FEN FOXAMIDE LIQUID Registration No: 058837 Company Name: Leads Pharma (Pvt) Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	FEN FOX ORAL LIQUID already registered on Reg# 062170	
	Decision	
	Approved	
	Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.	

142	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(XNT-BUU-U2P8, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	CRD SUPER injection
	Label Claim	Each ml contains Tylosin 60mg Colistin sulphate 10mg Dihydrostreptomycin 100mg (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	100 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s) store at controlled room temperature. protect from heat, light and ,moisture
	For generic drugs (me-too Status)	Product Name:: T-Septo Injection Registration No: 078293 Company Name: Nawal Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	CRD SUPER injection already registered on Reg#062151	
	Decision	
143	Approved	
	Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.	
	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(XL6-E3S-2ARN, 2025-09-13)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	Frusabak powder
	Label Claim	Each 1000gm contains: Furosemide 20gm Sodium chloride 35gm Magnesium sulphate 35gm Calcium carbonate 45gm (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1 kg-De-Controlled, 10 kg-De-Controlled, 100 gm-De-Controlled, 25 kg-De-Controlled, 250 gm-De-Controlled, 5 kg-De-Controlled, 500 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s) store at controlled room temperature. protect from heat, light and ,moisture
	For generic drugs (me-too Status)	Product Name:: Salix M Powder Registration No: 103855 Company Name: Inshal Pharmaceutical Industries)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--

	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Frusabak powder already registered on Reg# 053929	
	Decision	
	Approved	
	Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.	
144	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(UU7-35B-P97V, 2025-09-13)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	Deworm w/s powder
	Label Claim	Each 100gm contains Levamisole HCl 50gm(Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1 kg-De-Controlled, 10 kg-De-Controlled, 100 gm-De-Controlled, 250 gm-De-Controlled, 250 kg-De-Controlled, 5 kg-De-Controlled, 500 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s) store at controlled room temperature. protect from heat, light and moisture
	For generic drugs (me-too Status)	Product Name:: Levosin 50gm/100gm Powder Registration No: 058946 Company Name: A&K Pharmaceutical
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Deworm w/s powder already registered on Reg# 053927	
	Decision	
	Approved	
	Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.	
145	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(TLE-5PA-VPVD, 2025-09-17)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	EC Cool solution
	Label Claim	Each 1000ml contains Ascorbic acid 60gm Potassium chloride 1.5gm Sodium chloride 9.5gm Sodium citrate

		3.9gm (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1 litre-De-Controlled,100 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Electrovit-c solution (Leads pharma pvt ltd.)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	EC COOL SOLUTION already registered on Reg# 034544	
	Decision	
	Approved	
	Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.	
146	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(MVY-EB6-LUPD, 2025-09-13)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	Bella Flush w/s powder
	Label Claim	Each 100gm containsFurosemide 2gmBelladona Extract 0.2gm(Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1 kg-De-Controlled,10 kg-De-Controlled,100 gm-De-Controlled,25 kg-De-Controlled,250 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Product Name:: Flush B Powder Registration No: 075742 Company Name: DMAARSON PHARMACTUICALS
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
147	Case Category	New License (Sabahat Zehra)

Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
Application Form Dy. No / Tracking ID & date of submission	(NQQ-JRW-LB5N, 2025-09-12)
Detail of Fee Submitted	38700, 2025-09-11,
The proposed proprietary name / brand name	NEOMYCIN 70% POWDER
Label Claim	Each 100gm contains Neomycin sulphate 70gm(Manufacturer's Specifications)
Reference to Finished product specifications	Manufacturer Specification
Proposed Pack Size	1 KG-De-Controlled,10 KG-De-Controlled,100 GM-De-Controlled,25 GM-De-Controlled,250 GM-De-Controlled,5 KG-De-Controlled,500 GM-De-Controlled
Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat,light and ,moisture
For generic drugs (me-too Status)	Product Name:: Neocin Powder 70% Registration No: 063714 Company Name: Leads Pharma (Pvt) Ltd.
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	Satisfactory
Evidence of approval of manufacturing facility	

Evaluation Remarks

Decision

Approved

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Case Category	New License (Sabahat Zehra)
Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
Application Form Dy. No / Tracking ID & date of submission	(L66-4E3-69WY, 2025-09-12)
Detail of Fee Submitted	38700, 2025-09-11,
The proposed proprietary name / brand name	Amantabak 10% powder
Label Claim	Each 100gm contains Amantadine HCl 10gm (Manufacturer's Specification)
Reference to Finished product specifications	Manufacturers Specification
Proposed Pack Size	1 kg-De-Controlled,10 kg-De-Controlled,100 gm-De-Controlled,25 kg-De-Controlled,250 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled
Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
For generic drugs (me-too Status)	Fludin-10 powder (Hawk biopharma)
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	Satisfactory
Evidence of approval of manufacturing facility	

Evaluation Remarks

	Decision	
	Approved	
149	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(MVM-XE7-LWVZ, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Levofas oral suspension
	Label Claim	Each 100ml contains Oxyclozanide 3gm Levamisole HCl 1.5gm Cobalt chloride 0.382gm (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 litre-De-Controlled, 100 ml-De-Controlled, 150 ml-De-Controlled, 250 ml-De-Controlled, 500 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s) store at controlled room temperature. protect from heat, light and ,moisture
	For generic drugs (me-too Status)	Product Name:: Paramezole Plus Oral Liquid Registration No: 078278 Company Name: Elegance Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
150	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(YV7-9HM-NGXG, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	Fosfaplus injection
	Label Claim	Each ml contains Toldimfos sodium 100mg Vitamin B12 50µg (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	100 ml-De-Controlled
	Shelf Life (Unit)	2 Year store at controlled room temperature. protect from heat, light and ,moisture
	For generic drugs (me-too Status)	Phosfa Shell Injection (inshal Pharmaceutical Industries)
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Fosfaplus injection already registered on Reg# 062179	
	Decision	
	Approved	
	Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.	
151	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(YUN-9AW-TAJ5, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Clozanide Suspension
	Label Claim	Each ml contains Oxyclozanide B.P 46.875mg Oxfendazole BP 16.9875mg (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1 litre-De-Controlled,100 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Oxy-zol suspension (Inshal Pharmaceutical Industries)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Clozanide Suspension already registered on Reg# 049774	
	Decision	
	Approved	
	Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.	
152	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(YBM-Z34-WXY2, 2025-09-13)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	Pulmonil water soluble powder
	Label Claim	Each gm contains Neomycin sulphate 60mg Chlortetracycline HCl 200mg Streptomycin sulphate 20mg (Manufacturer's Specification)

	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1 kg-De-Controlled,10 kg-De-Controlled,100 gm-De-Controlled,25 kg-De-Controlled,250 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	NC-Strep w/s powder (Leads Pharma pvt ltd)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Pulmonil water soluble powder already registered on Reg# 058895	
	Decision	
	Approved	
	Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.	
153	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(Y6N-UHS-TYY4, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	Fosfaplus injection
	Label Claim	Each ml containsToldimfos sodium 100mgVitamin B12 50µg(Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	50 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Product Name:: VITA FOS DM INJECTION Registration No: 078338 Company Name: DMAARSON PHARMACTUICALS
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Fosfaplus injection already registered on Reg# 062179	
	Decision	
	Approved	
	Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.	
154	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)

Application Form Dy. No / Tracking ID & date of submission	(SSH-B1Z-G4JU, 2025-09-13)
Detail of Fee Submitted	38700, 2025-09-11,
The proposed proprietary name / brand name	Fenbak 10 oral Suspension
Label Claim	Each 100ml containsFenbendazole 10gm(B.P VET Specification)
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	1 litre-De-Controlled,100 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,500 ml-De-Controlled
Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat,light and ,moisture
For generic drugs (me-too Status)	Product Name:: Prifen 10% Oral Liquid Registration No: 080762 Company Name: PRIX PHARMACEUTICA (PRIVATE) LIMITED
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	Satisfactory
Evidence of approval of manufacturing facility	
Evaluation Remarks	
FENBAK 10 ORAL suspension already registered on Reg# 034554	
Decision	
Approved	

155	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(T9B-ZS3-DQYT, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	E COL 23 LIQUID
	Label Claim	Each 100ml containsEnrofloxacin 20%Colistin sulphate 3.0%(Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1 litre-De-Controlled,100 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Product Name:: Enro 23 Oral Liquid Registration No: 087965 Company Name: Farm Aid Group
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	E-Col 23 liquid already registered on Reg #071060	
	Decision	
	Approved	

Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.

156	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(VUG-8T6-N1WJ, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Nilzole Liquid
	Label Claim	Each 100ml contains Oxyclozanide 03gm Levamisole HCl 1.5gm Sodium selenide 0.035gm Cobalt Chloride 0.075gm (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	10 litre-De-Controlled, 100 ml-De-Controlled, 150 ml-De-Controlled, 250 ml-De-Controlled, 500 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s) store at controlled room temperature. protect from heat, light and ,moisture
	For generic drugs (me-too Status)	Product Name:: WAL-Nilzo SA Oral Suspension Registration No: 078358 Company Name: Nawal Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	

Evaluation Remarks

NILZOLE LIQUID already registered on Reg# 034545

Decision

Approved

Approved with as per innovator's specifications. Firm shall submit fee Rs. 9400/- for correction of FPP specifications as per S.R.O. 1399(I)12025 dated 01-08-2025, before issuance of registration letter.

157	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(XAD-H3S-V7P6, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	OXYNO PLUS W/S POWDER
	Label Claim	Each 1000gm contains Oxytetracycline HCl 200gm Neomycin sulphate 200gm Colistin sulphate 240MIU (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1 kg-De-Controlled, 10 kg-De-Controlled, 100 gm-De-Controlled, 250 gm-De-Controlled, 250 kg-De-Controlled, 5 kg-De-Controlled, 500 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s) store at controlled room temperature. protect from heat, light and ,moisture
	For generic drugs (me-too Status)	Product Name:: Clortin Water Soluble Powder Registration No: 074074 Company Name: DMAARSON

		PHARMACTUICALS
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
158	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(TV1-3XN-Y21A, 2025-09-13)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	TB Dox Powder
	Label Claim	Each 1000gm contains Doxycycline HCl 400gm Tylosin tartrate 200gm Bromhexine HCl 5gm (Manufacturer's Specification)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1 kg-De-Controlled, 10 kg-De-Controlled, 100 gm-De-Controlled, 25 kg-De-Controlled, 250 gm-De-Controlled, 5 kg -De-Controlled, 500 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s) store at controlled room temperature. protect from heat, light and ,moisture
	For generic drugs (me-too Status)	Product Name:: Morin Forte Powder Registration No: 069612 Company Name: NOBLE PHARMA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
159	Case Category	Export Facilitation (Saima Hussain)
	Name, address of Applicant.	Highnoon Laboratories Ltd 17.5 KM, Multan Road, (000155)
	Application Form Dy. No / Tracking ID & date of submission	(2EX-MS5-ZYBU, 2025-06-17)
	Detail of Fee Submitted	37000.0, 2025-01-29,
	The proposed proprietary name / brand name	Loprin 81mg Tablet
	Label Claim	Each enteric-coated tablet contains: Aspirin.....81mg

Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	100's-As per SRO,30's-As per SRO,50's-As per SRO,60's-As per SRO
Shelf Life (Unit)	2 Year(s)Do Not Store Above 30°C
For generic drugs (me-too Status)	Aslow-81 Tablet (076199)
Pharmacotherapeutic Group of (API)	Salicylates for local oral treatment (NSAID) ATC Code: A01AD05
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Not Applicable
Detail of stability batches of drug product	Stability data of batches RDP0041-02, RDP0041-03,RDP0041-04 (8000 tablets) batch size
Documents for the procurement of API with approval from DRAP (in case of Import)	clearance certificate is submitted
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP is performed against the innovator product Low Dose 81mg Aspirin Tablet of M/s. Bayer
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability as per zone-IV condition is submitted by the firm
The status in reference regulatory authorities	ASPIRIN® 81mg in Health Canada
GMP status of the firm	GMP certificate dated 25-06-2024 is submitted by the firm.
Evidence of approval of manufacturing facility	GMP certificate dated 25-06-2024 mentioned that firm has tablet (general) section.

Evaluation Remarks

Sr.no.	Observations	Response of the Firm
1.	Submit specification and detailed analytical procedure of drug substance by drug product manufacturer.	Firm submit the specification and detailed analytical procedure of drug substance by drug product manufacturer.
2.	Submit analytical method verification report of drug substance performed by drug product manufacturer.	Firm Submit analytical method verification report of drug substance performed by drug product manufacturer.
3.	Submit stability data of drug substance as per zone-IV condition till the claimed re-test date.	Firm submit stability data of drug substance as per zone-IV condition till the claimed re-test date.
4.	The claimed quantity of Aspirin in the proposed formulation is 81 mg per tablet, whereas the composition table provided in section 3.2.P.1 indicates 83.430 mg per tablet. Please clarify and justify the rationale for the excess quantity of active ingredient included in the formulation.	Firm replied that Overage in trial batches is used to compensate for the process loss while results show that without overage the product is stable. Further, we undertake that we will not use the overage in our commercial batches. Undertaking and Composition without overage is attached.
5.	Provide evidence of a reference product that includes simethicone as an antifoaming agent in the enteric coating solution of their formulation. Furthermore, furnish a scientific justification for the use of simethicone, including its functional role and compatibility when utilized in conjunction with an organic solvent.	Firm replied that, in the applied product, Simethicone has been utilized as an excipient in the coating. Its primary role as an excipient, as documented in the Handbook of Pharmaceutical Excipients, is to function as an anti-foaming agent during pharmaceutical manufacturing processes. Reference studies are attached
6.	Justify for not performing the identification test as per the BP	Firm revised the specification in accordance with BP.

	monograph for Aspirin Gastro-resistant Tablets, which recommends identification by infrared absorption spectroscopy. Instead, the identification was carried out based on the acceptance criterion that the retention time of the major peaks in the sample solution corresponds to that of the standard solution, as obtained in the assay. Provide a scientific rationale for adopting this approach in place of the monograph-specified method.	
7.	Submit the COA of reference/working standard aspirin impurity standard that has been used for system suitability during the assay of drug product.	Firm submit COA of primary reference standard complied of Eur. Ph.

Decision

Approved

160	Case Category	Export Facilitation (Saima Hussain)
	Name, address of Applicant.	SAMI Pharmaceuticals Pvt. Ltd. F-95 Hub River Road S.I.T.E Karachi (000072)
	Application Form Dy. No / Tracking ID & date of submission	(8X4-WPX-X13B, 2025-09-15)
	Detail of Fee Submitted	75000.0, 2025-02-21,
	The proposed proprietary name / brand name	REGOLIX (Relugolix) 120mg Tablet
	Label Claim	Each film coated tablet contains: Relugolix 120mg Innovator's Specs.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	De regulated-De-Controlled
	Shelf Life (Unit)	2 Year(s)Do not store over 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	gonadotropin-releasing hormone (GnRH) receptor antagonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Stability data (lab-1,lab-2,lab3) batch size 1500 tablet each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form-6 is submitted by the firm.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP is performed against the innovator product Orgovyx 120mg Tablet of M/s. Sumitomo Pharma (Batch no.W08878A)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone-IV is submitted by the firm.
	The status in reference regulatory authorities	ORGOVYX Tablet 120mg, FDA
	GMP status of the firm	GMP certificate dated 12th August,2024 IS SUBMITTED BY THE FIRM.

Evidence of approval of manufacturing facility	GMP certificate dated 12th August,2024 MENTIONED THAT FIRM HAS TABLET (GENERAL) section.

Evaluation Remarks	
ORGOVYX is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the treatment of adult patients with advanced prostate cancer.Recommended Dosage: A loading dose of 360 mg on the first day of treatment followed by 120 mg taken orally once daily, at approximately the same time each day (2.1). • ORGOVYX can be taken with or without food (2.1, 12.3). Instruct patients to swallow tablets whole and not to crush or chew tablets (2.1).Relugolix is a free base white to off-white to slightly yellow solid, without chiral centers. Based on the less than 120 mg amount of drug that can fully dissolve in 250 mL media at final pH above 5.5, relugolix is classified as a low solubility drug substance per BCS criteria. Rapid in Low pH Media; Slow in pH > 5.5 Media	

Decision	

Approved	

161	Case Category	New Section (Saima Hussain)
	Name, address of Applicant.	Hi-Med Pharmaceuticals 208C Sundar industrial estate Raiwind Road Lahore (000884)
	Application Form Dy. No / Tracking ID & date of submission	(4UH-22X-7NR7, 2025-07-17)
	Detail of Fee Submitted	37000.0, 2025-05-14,
	The proposed proprietary name / brand name	D3 Vibe Injection 5mg/ml
	Label Claim	Each 1ml Contains: Cholecalciferol (Vitamin D3) 5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 x 1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at below 25 degree celcius
	For generic drugs (me-too Status)	New-D injection (NP News Pharma)
	Pharmacotherapeutic Group of (API)	Vitamin D Analogs
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Sichuan Province Yuxin Pharmaceutical Co. Ltd.
	Detail of stability batches of drug product	T01 2000 Ampoules 28-12-2024 27-12-2026 T02 2000Ampoules 28-12-2024 27-12-2026 T03 2000Ampoules 28-12-2024 27-12-2026
	Documents for the procurement of API with approval from DRAP (in case of Import)	Borrowing of API intimation letter is submitted. Loan has been taken from M/s. trigon pharmaceuticals.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence has been performed against the comparator product New-D injection.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	stability data as per zone-iv is submitted by the firm
	The status in reference regulatory authorities	VITAMIN D3 CHOLECALCIFEROL (VITAMIN INJECTION AMPOULES(PROVIDENT HOUSE 44 HARPUR STREET BEDFORD MK40 2QT)
	GMP status of the firm	GMP Certificate attached (Valid till 22-09-2027)
	Evidence of approval of manufacturing facility	Grant of additional section: Liquid Injectable small volume Parental approved by CLB Attached dated 02nd december,2024

Evaluation Remarks	

Sr.no.	Observations	Response of the Firm

1.	Submit stability data of drug substance performed as per zone-IV conditions.	Firm submit the stability data of drug substance performed as per zone-IV conditions.
2.	Submit detailed about sterilization procedure that have adopted for the sterilization of drug product.	Firm replied that Injection is manufactured under aseptic conditions. Since the formulation contains heat-labile ingredients, terminal sterilization is not feasible. Therefore, the product is sterilized by filtration using a 0.22 µm & .45µm (cartridge filter) sterilizing-grade membrane filter, followed by aseptic filling under Grade A conditions in a Grade B background. All components, including primary packaging materials, are sterilized appropriately.

Decision

Approved

162	Case Category	New Section (Saima Hussain)
	Name, address of Applicant.	Hi-Med Pharmaceuticals 208C Sundar industrial estate Raiwind Road Lahore (000884)
	Application Form Dy. No / Tracking ID & date of submission	(683-7L8-9QAJ, 2025-07-17)
	Detail of Fee Submitted	37000.0, 2025-05-14,
	The proposed proprietary name / brand name	Thiomed Injection 4mg / 2ml
	Label Claim	Each 2ml Contains: Thiocolchicoside 4mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2ml x 5's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at below 25 degree celcius
	For generic drugs (me-too Status)	THIOLAX (SOLACE PHARMA)
	Pharmacotherapeutic Group of (API)	nervous system muscle relaxant, anti-inflammatory, and analgesic drug
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Sarv Biolabs
	Detail of stability batches of drug product	Attached
	Documents for the procurement of API with approval from DRAP (in case of Import)	Intimation letter to DRAP dated 16-12-2024 attached. 600gm of API is borrowing from Medpharm Research Lab. Dated on 15-12-2024 located at 28Km Ferozpur Road Lahore'
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies has been performed against the comparator product Thiolax injection 4mg/2ml
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached
	The status in reference regulatory authorities	RELIEF 4MG/2ML INJECTION (IASIS PHARMA HELLAS S.A (137 Filis Ave,134 51 Athens,Greece.)
	GMP status of the firm	GMP Certificate attached (Valid till 22-09-2027)

Evidence of approval of manufacturing facility		Section approval letter of Liquid Injectable (small volume parenteral) dated 02nd December,2024 is submitted
Evaluation Remarks		
Sr.no.	Observations/Shortcomings	Response of the firm
1.	Provide evidence of approval of the applied formulation by approved reference regulatory agencies.	Firm submit the evidence of availability of applied formulation in Italy, Muscoril Thiocolchicoside 4mg/2ml IM injection
2.	Justify the omission of sterility testing and bacterial endotoxin testing during batch analysis of the drug substance by the drug product manufacturer, when these tests are performed by the drug substance manufacturer.	Firm submit the revised COA of drug substance performed by drug product manufacturer including the sterility test and BET test.
3.	Submit the updated stability data of the drug product, as only three-month data has been submitted.	Firm submit the updated stability data of drug product till six month.
4.	Submit the raw data sheets for the performance of pH test, bacterial endotoxin test, and sterility test.	Firm submit the raw data sheet of pH test, bacterial endotoxin test, and sterility test.
Decision		
Approved		
163	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	Martin Dow Marker Limited 7, Jail Road Quetta. (000028)
	Application Form Dy. No / Tracking ID & date of submission	(3R1-SLX-HVRL, 2024-03-25)
	Detail of Fee Submitted	30000.0, 2024-03-07,
	The proposed proprietary name / brand name	Zinc Sulphate Syrup 20mg/5ml
	Label Claim	Zinc Sulphate Syrup 20mg/5ml Each 5ml contains: Zinc Sulphate monohydrate is equivalent to elemental Zinc.....20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per DPC-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Zincat OD Syrup 20mg/5ml
	Pharmacotherapeutic Group of (API)	Electrolyte Solution
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vasa Pharmachem Pvt. Ltd. Survey No.1354, Bhetawada, Bhetawada-Trasad Road, Dholka-382225, Dist.-Ahmedabad , Gujarat, Ind
	Detail of stability batches of drug product	PDS-72-23 06 Litres PDS-73-23 06 Litres PDS-74-23 06 Litres
	Documents for the procurement of API with approval from DRAP (in case of Import)	DRAP attested commercial invoice is attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE has been performed against the comparator product Zincat-OD Syrup 20mg/5ml Batch No: PR0061 Mfg. Date: 03/2023 Manufactured By: ATCO LABORATORIES LIMITED

Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone-IV condition is submitted.
The status in reference regulatory authorities	Zinc Sulfate - WHO Essential Medicines List
GMP status of the firm	Firm submit the copy of DML RENEWED 28-04-2020
Evidence of approval of manufacturing facility	Firm submit the regularization of section letter issued by Licensing Division dated 31st May,2021 in which mentioned that firm has Liquid(syrup) general section,

Evaluation Remarks

Sr.no.	Observations/Shortcomings	Response of the Firm
1.	Please provide evidence of the approval status of the applied strength, i.e., 20 mg/5 ml, in a recognized reference regulatory authority (RRA). The information provided in Section 1.5.9 only confirms the availability of zinc sulfate in oral dosage forms, but does not specifically support the approval of the proposed strength. Furthermore, the applied strength is not listed in the WHO prequalified list of finished pharmaceutical products.	The firm has submitted a WHO reference indicating that the concentration of zinc in oral solutions may be 10 mg/5 mL. However, the Pediatric Zinc Sulfate Oral Solution monograph in the International Pharmacopoeia specifies that the available strengths can be either 10 mg or 20 mg of zinc per 5 mL.
2.	In your submission under section 3.2.S.5 (Reference Standards or Materials), it is stated that no reference or working standard was used for analytical purposes as per IP, BP, Ph. Eur., or USP requirements. However, a secondary reference standard was reportedly prepared by calibration against a primary official standard for comparison purposes. Additionally, it is mentioned that an in-house material, selected from a commercial batch manufactured by Vasa Pharmachem Pvt. Ltd., was used for routine control of the product. In this context, please clarify the following: How were the assay and identification tests performed in the absence of a formally qualified reference or working standard standardized against a recognized primary standard? What scientific rationale supports the use of in-house material from a commercial batch for routine control purposes in lieu of a fully qualified reference standard? How was analytical accuracy, specificity, and validity ensured when using this in-house material for quality control testing of the drug substance?"	Firm in their reply submit the undertaking from the API manufacturer stated that "We, VASA PHARMACHEM PVT. LTD. hereby declare that we do not use any reference standard for the Product Zinc Sulphate Monohydrate, but instead use the working standard of our commercial batch for the routine comparison of assay and other parameters"
3.	Submit stability data of drug substance performed as per zone-IV- condition till the claimed re-test date since you have been submitted the long term data of only six months.	Firm Submit stability data of drug substance performed as per zone-IV- condition till the claimed re-test date.
4.	As per the submitted solubility data of API Zinc Sulfate Monohydrate, it is practically insoluble in ethanol. Despite this, ethanol (96%) is included in the formulation at a concentration of 8.100 mg/ml (~0.81% w/v) mentioning the role as a solvent. Please provide a clear scientific rationale for its inclusion, addressing that "what is the specific functional role of ethanol in the formulation, given it does not act as a solvent for the active ingredient."	In reference to Zinc Sulphate Syrup 20mg/5ml formulation specific functional role of ethanol 96% as solvent because we solubilize the ethyl hydroxy benzoate in ethanol 96%. However,

Decision

Approved

164	Case Category	Routine (Sana Kanwal)		
	Name, address of Applicant.	Kaizen Pharmaceuticals (Pvt) Ltd Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi (000755)		
	Application Form Dy. No / Tracking ID & date of submission	(WYD-UX3-YR15, 2024-02-13)		
	Detail of Fee Submitted	75000.0, 2024-01-03,		
	The proposed proprietary name / brand name	Hyalinfa Gel		
	Label Claim	Each gram contains: Hyaluronic acid sodium salt.....2mg		
	Reference to Finished product specifications	As per Innovators Specification		
	Proposed Pack Size	30g-As per SRO		
	Shelf Life (Unit)	2 Year(s)Store in a cool and dry place. Below 30 oC		
	For generic drugs (me-too Status)	None		
	Pharmacotherapeutic Group of (API)	Tissue Lubricant		
	Name, address of Manufacturing site:	Self Manufacturing		
	Name & address of API manufacturer	Shandong AWA Biopharm Co., Ltd. Address: No.488 Huanghe 12 Road Binzhou City, China.		
	Detail of stability batches of drug product	3 batches: 1000g each TF-2 TF-03 and TF-04		
	Documents for the procurement of API with approval from DRAP (in case of Import)	Commercial invoice no. NO.: 20221018 dated 18-10-2022 wherein 300g sodium hyaluronate was imported from AMHWA BIOPHARM CO., LTD,CHINA		
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CONNETTIVINA Gel of fidia Pharma (AIFA approved product)		
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches as per Zone IV-A		
	The status in reference regulatory authorities	AIFA Italy Approved		
	GMP status of the firm	03-01-2023: GMP certificate inspection date		
	Evidence of approval of manufacturing facility	Section approval letter dated 19-06-2025 specifies semi solid (Cream /ointment/ gel) general section		
Evaluation Remarks				
S.No		Observations	Reply	Remarks
1.		Please submit original/legalized copy of GMP certificate of Drug Substance manufacturer along with translated version (English)	copy of DML of Drug Substance manufacturer along with translated version (English) is provided	DML No. 20160315Valid till: May 30th 2026
2.		Please clarify specifications of different quality parameters (including assay)of Drug Substance and their acceptance criteria as adopted by Product manufacturer w.r.t Drug substance manufacturer.Since striking differences were observed in acceptance criteria of	The product manufacturer, has adopted the Japanese Pharmacopoeia (JP) specifications for the drug substance. However, the drug substance manufacturer has adopted the European Pharmacopoeia (EP) specifications. Due to this difference in pharmacopoeial standards,	DS manufacturer adopted chinese pharmacopoeia while Drug Product manufacturer tested Drug Substance as per JP.

	Drug substance in both CoA by DS manufacturer and Drug Product manufacturer.	certain test parameters and their acceptance criteria may not be fully aligned between the two specifications. We confirm that all critical quality attributes, including assay and impurity limits, meet the requirements of the adopted pharmacopoeial standard (JP) at the product manufacturer's end.
Decision		
Approved		
Approved.		
165	Case Category	Export Facilitation (Shahrukh Ali)
	Name, address of Applicant.	SAMI Pharmaceuticals Pvt. Ltd. F-95 Hub River Road S.I.T.E Karachi (000072)
	Application Form Dy. No / Tracking ID & date of submission	(NPV-QTS-SYJ1, 2025-02-07)
	Detail of Fee Submitted	37000.0, 2024-11-28,
	The proposed proprietary name / brand name	ONTIV 4mg/5ml Oral Solution
	Label Claim	Each 5ml of oral solution contains: Ondansetron Hydrochloride Dihydrate Equivalent to Ondansetron.....4mg USP Specs
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store over 30°C
	For generic drugs (me-too Status)	Onset
	Pharmacotherapeutic Group of (API)	Serotonin (5HT3) antagonists
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	60 bottles 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	CLEARANCE CERTIFICATE E-5611764236782Date of issue: 08-Jun-2023
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Onset Oral Solution B. No ONSO72417
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	ZOFRAN Oral Solution, USFDA approved
	GMP status of the firm	Certificate No. 116/2024, Karachi the, 12th August 2024
	Evidence of approval of manufacturing facility	No. F.2-9/2007-Lic (Vol-II)dated 13 oct, 2023 mentioning oral liq (General),
Evaluation Remarks		
	1.3.5 Valid copy of DML	Submitted
	Section approval letter submitted	Submitted
	1.6.5 valid copy of GMP certificate of drug substance manufacturer	Submitted

Decision		
Approved		
166	Case Category	Priority As Per 257-M of RB (Shahrukh Ali)
	Name, address of Applicant.	HIMMEL PHARMACEUTICALS (PVT.) LTD Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Zazaria e Pakistan Lahore (05-352-0065)
	Application Form Dy. No / Tracking ID & date of submission	(45T-AUB-7WB2, 2024-10-08)
	Detail of Fee Submitted	300000.0, 2024-09-09,
	The proposed proprietary name / brand name	Xevirol 5 Tablet
	Label Claim	Each Tablet contains.....Everolimus INN 5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 x 10's-As per SRO
	Shelf Life (Unit)	24 Month(s)Store below 30°C.
	For generic drugs (me-too Status)	Afinitor 5mg Tablet (Novartis)
	Pharmacotherapeutic Group of (API)	Antineoplastic agents, Pyrimidine analogues ATC code: L01EG02
	Name, address of Manufacturing site:	Beacon Pharmaceuticals Limited.-Kathali, Bhaluka, Mymensingh Bangladesh -Bangladesh
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies are conducted Afinitor ® Novartis Pharmaceuticals /
	Name, address of Marketing Authorization Holder:	Beacon Pharmaceuticals Limited., Kathali, Bhaluka, Mymensingh Bangladesh , Bangladesh
	Details of Certificates (CoPP/FSC/cGMP):	COPP expired 23.08.25
	Details of Authorization Letter :	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IV-A
	The status in reference regulatory authorities	Afinitor 5mg Tablet (Novartis, UK)
Evaluation Remarks		
	1.6.5: Valid copy of Legalized and notarized COPP required	Firm has stated that they have submitted valid COPP submission and now it requires time for legalization
	3.2.P.2.1 Components of the Finished Pharmaceutical Product. Excipients used are not as per innovator. Clarification required	Firm has submitted drug excipient compatibility studies stated that Excipients comply with B.P specs showing satisfactory results of assay dissolution and impurity so excipients are suitable.
	3.2.P.8.3 Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA. Firm has provided only summary data sheets etc.	Submitted
	Pl submit bioequivalence study as in compliance to notification No F-348-DRB-Addl-Dir(PER-I)/2025 dated 17-07-25	Firm has only submitted bioequivalence study for 10mg
Decision		
Approved		
Registration letter will be issued after submission of Valid copy of Legalized and notarized COPP required		
167	Case Category	Priority As Per 257-M of RB (Shahrukh Ali)
	Name, address of Applicant.	HIMMEL PHARMACEUTICALS (PVT.) LTD Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah
Minutes of 351st Meeting of Registration Board		(23rd – 24th September, 2025) 955

	Zazaria e Pakistan Lahore (05-352-0065)
Application Form Dy. No / Tracking ID & date of submission	(6DY-9EM-N83R, 2024-10-08)
Detail of Fee Submitted	300000.0, 2024-09-09,
The proposed proprietary name / brand name	Xevirol 10 Tablet
Label Claim	Each tablet contains.....10mg Everolimus INN
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	10's-As per SRO
Shelf Life (Unit)	36 Month(s)Store below 30°C.
For generic drugs (me-too Status)	Afinitor 10mg Tablet (Novartis)
Pharmacotherapeutic Group of (API)	Antineoplastic agents, Pyrimidine analogues ATC code: L01EG02
Name, address of Manufacturing site:	Beacon Pharmaceuticals Limited.-Kathali, Bhaluka, Mymensingh Bangladesh -Bangladesh
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies are conducted Afinitor 10mg ® Novartis Pharmaceuticals /
Name, address of Marketing Authorization Holder:	Beacon Pharmaceuticals Limited., Kathali, Bhaluka, Mymensingh Bangladesh , Bangladesh
Details of Certificates (CoPP/FSC/cGMP):	COPP expired 23.08.25
Details of Authorization Letter :	import
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
The status in reference regulatory authorities	Afinitor 10mg Tablet (Novartis, UK)

Evaluation Remarks

1.6.5: Valid copy of Legalized and notarized COPP required	Firm has stated that they have submitted valid COPP submission and now it requires time for legalization
3.2.P.2.1 Components of the Finished Pharmaceutical Product. Excipients used are not as per innovator. Clarification required	Firm has submitted drug excipient compatibility studies stated that Excipients comply with B.P specs showing satisfactory results of assay dissolution and impurity so excipients are suitable.
3.2.P.8.3 Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA. Firm has provided only summary data sheets etc.	Submitted
Pl submit bioequivalence study as in compliance to notification No F-348-DRB-Addl-Dir(PER-I)/2025 dated 17-07-25	Firm has submitted bioequivalence study for 10mg

Decision

Approved

Registration letter will be issued after submission of Valid copy of Legalized and notarized COPP required

168	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (000790)
	Application Form Dy. No / Tracking ID & date of submission	(AX3-ZS4-WUTN, 2024-04-18)
	Detail of Fee Submitted	75000.0, 2024-03-14,
	The proposed proprietary name / brand name	TERBIWIN 1% Cream

Label Claim	Each gm Contains: Terbinafine Hydrochloride.....10mg (Product complies JP Specs)
Reference to Finished product specifications	Any Other
Proposed Pack Size	As Per SRO-As per SRO
Shelf Life (Unit)	2 Year(s)20-25C
For generic drugs (me-too Status)	Bina 1% Cream by Linta Pharmaceuticals 080268
Pharmacotherapeutic Group of (API)	D01 ANTIFUNGALS FOR DERMATOLOGICAL USE
Name, address of Manufacturing site:	M/s Winbrains Research Laboratories-PLOT #69/1, BLOCK B, PHASE-I&II, INDUSTRIAL ESTATE, HATTAR.-
Name & address of API manufacturer	
Detail of stability batches of drug product	200 tubes 3 batches
Documents for the procurement of API with approval from DRAP (in case of Import)	00160/2022-DRAP 28.1.22
Pharmaceutical Equivalence and Comparative Dissolution Profile	Terbisil Cream 1 % w/w saffron Pharmaceuticals
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
The status in reference regulatory authorities	MHRA Approved
GMP status of the firm	Certificate no 163 dated 12-10-22 Winbrains contract acceptor
Evidence of approval of manufacturing facility	No F.3-7/2007-Lic dated 11-April-2017 mentioning cream/ointment/gel section

Evaluation Remarks

1.6.5: Valid copy of GMP certificate of the drug product & Substance manufacturer issued by concerned/relevant regulatory authority shall be submitted

Submitted

Decision

Approved

169	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	Neutro Pharma (Pvt.) Ltd., 9.5-Km, Sheikhpura Road, Lahore (000576)
	Application Form Dy. No / Tracking ID & date of submission	(WZE-2R1-XSLG, 2024-03-12)
	Detail of Fee Submitted	30000.0, 2024-02-13,
	The proposed proprietary name / brand name	Neuvoxine Tablet 50mg
	Label Claim	Each Film Coated Tablet contains: Fluvoxamine Maleate.....50mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's, 20's, 30's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F)
	For generic drugs (me-too Status)	Faverin Tablet 50mg by Abbot Laboratories
	Pharmacotherapeutic Group of (API)	Selective Serotonin Reuptake Inhibitors (SSRIs) N06AB08
	Name, address of Manufacturing site:	Self Manufacturing

Name & address of API manufacturer	ZCL Chemicals Ltd. 'C' Wing, 819-821, 215Atrium, Chakala, Andheri-Kurla Road, Andheri (East), Mumbai-400 093 Maharashtra, INDIA. +91 022 61539999 +91 022 61539997 enquiries@zclchemicals.com www.zclch
Detail of stability batches of drug product	Three batches having 1500 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	16023/2020 DRAP dated: 28-OCT-2020
Pharmaceutical Equivalence and Comparative Dissolution Profile	Voxamine Tablet 50mg Batch # 2C197 PharmEvo (Pvt.) Ltd
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-B
The status in reference regulatory authorities	Luvox Tablet 50mg by ANI Pharmaceuticals Inc.
GMP status of the firm	145/2025-DRAP(AD-5053118354) dated 02.09.25
Evidence of approval of manufacturing facility	No. F.1-3/2003-LIC dated 4 -07-2020 mentioning Tablet section

Evaluation Remarks

1.3.5 Valid copy of DML	Submitted
1.6.5: Valid copy of GMP certificate of the drug product & Substance manufacturer issued by concerned/relevant regulatory authority shall be submitted.	Submitted

Decision

Approved

170	Case Category	Export Facilitation (Shahrukh Ali)
	Name, address of Applicant.	Genome Pharmaceuticals (Pvt.) Ltd , Plot No. 16/1, Phase-IV, Industrial Estate Hattar Dist: Haripur (KPK)-PAKISTAN. (000454)
	Application Form Dy. No / Tracking ID & date of submission	(J4L-ZJ7-VXR1, 2025-07-03)
	Detail of Fee Submitted	75000.0, 2025-06-16,
	The proposed proprietary name / brand name	FIXGRAF 0.5mg XR CAPSULE
	Label Claim	Each prolonged release Capsule contains; Tacrolimus (as monohydrate).....0.5 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3x10-As per SRO
	Shelf Life (Unit)	24 Year(s)Real time: 30°C ± 2°C / 65% ± 5%RH, Accelerated: 40°C ± 2°C / 75% ± 5%RH
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Calcineurin inhibitors (Immunosuppresant)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	BILLS BIOTECH PVT. LTD, Plot No. P/01, Biotech Park Phase 1, GIDC, Manjusar Industrial Estate, Manjusar, Savli - Vadodara, Gujarat, 391775,India .
	Detail of stability batches of drug product	5000 capsule 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	ADC Clearance Certificate, Computerized No: E-9989102283179 (Attached in Module3)

Pharmaceutical Equivalence and Comparative Dissolution Profile	Brand Name: Advagraf 0.5mg Capsule Manufactured by: Astella Pharma US
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
The status in reference regulatory authorities	FDA Approved
GMP status of the firm	Certificate No. F.11-34 /2023-DRAP (P)477 the, 6-June 2023
Evidence of approval of manufacturing facility	No. F.3-7/95-Lic (Vol-II)dated 7 July, 2021 mentioning Capsule (General),

Evaluation Remarks

3.2.S.7: Drug substance stability study tests of optical rotation & residue on ignition not provided as per USP monograph, signed and stamped stability data sheets required.	Updated stability study sheets provided by drug substance manufacturer with sign and stamp
3.2.P.2.1 Please provide evidence of Reference / Innovator / Comparator Packs used for Pharmaceutical Equivalence and CDP.	Reference product picture are attached with Batch no and Exp visible
3.2.P.8 Stability: Submitted chromatograms have no wavelength. Blank sample chromatograms not submitted. Clarification shall be submitted	Due to auto report format setting Shimadzu Lab Solutions software, the detection wavelength was not displayed on the chromatograms. Blank Sample Chromatogram are attached for your kind consideration.
As firm is manufacturing in general Capsule area, manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs	Personal safety is addressed in Risk/Hazard Assessment and Actions Plan of Genome pharmaceutical in Capsule section and action plans are implemented. Risk/Hazard Assessment and Actions Plan sheet is attached.

Decision

Approved

Registration Board Approved the said case subject to verification of the authenticity of the submitted stability data by the panel constituted by the Chairman, Registration Board.

171	Case Category	Export Facilitation (Shahrukh Ali)
	Name, address of Applicant.	Genome Pharmaceuticals (Pvt.) Ltd , Plot No. 16/1, Phase-IV, Industrial Estate Hattar Dist: Haripur (KPK)-PAKISTAN. (000454)
	Application Form Dy. No / Tracking ID & date of submission	(VE7-SY3-Y43E, 2025-07-03)
	Detail of Fee Submitted	75000.0, 2025-06-17,
	The proposed proprietary name / brand name	FIXGRAF 1mg XR CAPSULE
	Label Claim	Each prolonged release capsule contains; Tacrolimus as monohydrate.....1mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3x10-As per SRO
	Shelf Life (Unit)	24 Year(s)AC time: 40°C ± 2°C / 75% ± 5% Real time: 30°C ± 2°C / 65% ± 5%RH
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Calcineurin inhibitors (Immunosuppresant)
	Name, address of Manufacturing site:	Self Manufacturing

Name & address of API manufacturer	BILLS BIOTECH PVT. LTD, Plot No. P/01, Biotech Park Phase 1, GIDC, Manjusar Industrial Estate, Manjusar, Savli - Vadodara, Gujarat, 391775, India .
Detail of stability batches of drug product	5000 capsules 3 batches
Documents for the procurement of API with approval from DRAP (in case of Import)	ADC Clearance Certificate, Computerized No: E-9989102283179 (Attached in Module3)
Pharmaceutical Equivalence and Comparative Dissolution Profile	Advagraf 1mg prolong release Capsules
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
The status in reference regulatory authorities	FDA Approved
GMP status of the firm	Certificate No. F.11-34 /2023-DRAP (P)477 the, 6-June 2023
Evidence of approval of manufacturing facility	No. F.3-7/95-Lic (Vol-II)dated 7 July, 2021 mentioning Capsule (General),

Evaluation Remarks

3.2.S.7: Drug substance stability study tests of optical rotation & residue on ignition not provided as per USP monograph, signed and stamped stability data sheets required.	Updated stability study sheets provided by drug substance manufacturer with sign and stamp
3.2.P.2.1 Please provide evidence of Reference / Innovator / Comparator Packs used for Pharmaceutical Equivalence and CDP.	Reference product picture are attached with Batch no and Exp visible
3.2.P.8 Stability: Submitted chromatograms have no wavelength. Blank sample chromatograms not submitted. Clarification shall be submitted	Due to auto report format setting Shimadzu Lab Solutions software, the detection wavelength was not displayed on the chromatograms. Blank Sample Chromatogram are attached for your kind consideration.
As firm is manufacturing in general Capsule area, manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs	Personal safety is addressed in Risk/Hazard Assessment and Actions Plan of Genome pharmaceutical in Capsule section and action plans are implemented. Risk/Hazard Assessment and Actions Plan sheet is attached.

Decision

Approved

Registration Board Approved the said case subject to verification of the authenticity of the submitted stability data by the panel constituted by the Chairman, Registration Board.

172	Case Category	Export Facilitation (Shahrukh Ali)
	Name, address of Applicant.	Genome Pharmaceuticals (Pvt.) Ltd , Plot No. 16/1, Phase-IV, Industrial Estate Hattar Dist: Haripur (KPK)-PAKISTAN. (000454)
	Application Form Dy. No / Tracking ID & date of submission	(VGH-BD8-U8MA, 2025-08-22)
	Detail of Fee Submitted	37000.0, 2025-04-25,
	The proposed proprietary name / brand name	Fixgraf 0.5mg Capsule
	Label Claim	Each Capsule contains; Tacrolimus (as monohydrate).....0.5 mg
	Reference to Finished product specifications	United States Pharmacopeia

Proposed Pack Size	3x10-As per SRO
Shelf Life (Unit)	24 Year(s)Room Temperature
For generic drugs (me-too Status)	INOGRAF 0.5mg Capsule
Pharmaceutical Group of (API)	Immunosuppressant
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	BILLS BIOTECH PVT. LTD
Detail of stability batches of drug product	5000 capsules 3 batches
Documents for the procurement of API with approval from DRAP (in case of Import)	ADC Clearance attached (Computerized No: E-9989102283179)
Pharmaceutical Equivalence and Comparative Dissolution Profile	Prograf 0.5mg Capsule
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
The status in reference regulatory authorities	US FDA Approved
GMP status of the firm	Certificate No. F.11-34 /2023-DRAP (P)477 the, 6-June 2023
Evidence of approval of manufacturing facility	No. F.3-7/95-Lic (Vol-II)dated 7 July, 2021 mentioning Capsule (General),

Evaluation Remarks

3.2.S.7: Drug substance stability study tests of optical rotation & residue on ignition not provided as per USP monograph, signed and stamped stability data sheets required.	Updated stability study sheets provided by drug substance manufacturer with sign and stamp
3.2.P.2.1 Please provide evidence of Reference / Innovator / Comparator Packs used for Pharmaceutical Equivalence and CDP.	Reference product picture are attached with Batch no and Exp visible
3.2.P.8 Stability: Submitted chromatograms have no wavelength. Blank sample chromatograms not submitted. Clarification shall be submitted	Due to auto report format setting Shimadzu Lab Solutions software, the detection wavelength was not displayed on the chromatograms. Blank Sample Chromatogram are attached for your kind consideration.
As firm is manufacturing in general Capsule area, manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs	Personal safety is addressed in Risk/Hazard Assessment and Actions Plan of Genome pharmaceutical in Capsule section and action plans are implemented. Risk/Hazard Assessment and Actions Plan sheet is attached.
Justification required for not performing system suitability as part of Assay in USP monograph as adopted by firm in 3.2.P.5.1. "System suitability:Sample: Standard solution [NOTE—The relative retention times for tacrolimus 19-epimer and tacrolimus are 0.67 and 1.0, respectively.]"	System suitability results and chromatograms are provided

Decision

Approved

Registration Board Approved the said case subject to verification of the authenticity of the submitted stability data by the panel constituted by the Chairman, Registration Board.

Item No. V Division of Biological Evaluation & Research

Case#01: Imported Human Biologicals applied by M/s Bio Link Karachi deferred in 326th meeting

M/s Bio Link (Pvt) Ltd., Karachi applied for the registration of following human biologicals:

Name of Manufacture	Name of Product	Dy. No., Date of Application & Fee Status/ Pack Size
M/s Sichuan Yuanda-Shuyang Pharmaceutical Co., Ltd., China	SUYA-HB 100 IU/mL	Dy. No.9721(R&I) Dated 11-02-2021 Rs.100,000/- 1's vial
	SUYA-HR 200 IU/mL	Dy.No.9722 (R&I) Dated 11-02-2021 Rs.100,000/- Dated 11-02-2021 1's vial

It is pertinent to mention that firm has submitted applications on Form-5A instead of Form-5F (CTD). Applicant was advised vide this division letter dated 10th February, 2022 to submit following documents for further processing of the case:

- Applications on Form-5F (CTD) for both products.
- Original valid legalized CoPP/ FSC & GMP.
- Original or Notarized copy of letter of sole agency authorization.

Now the firm M/s Bio Link (Pvt) Ltd., Karachi in their reply on 27th January 2023 submitted following:

- Module I of Form-5F (CTD) for both products which is also incomplete.
- Original valid legalized CoPP for SUYA-HB 100 IU/mL & SUYA-HR 200 IU/mL
- Copy of letter of sole agency authorization for product SUYA-HB 100 IU/mL only.

Evaluation by DBER:

It is submitted that both application of firm is still incomplete for following documents:

- Module I (In-complete)
- Module II
- Module III
- Module IV
- Module V
- Original or notarized copy of sole agency authorization for both products

Decision of 326th meeting: Registration Board deferred the case for the following:

- Submit Applications on Form-5F (CTD) including all its modules for both products.
- Original or notarized copy of sole agency authorization for both products.

Evaluation by BE&R:

The applicant has submitted some documents again on case management query Tracking ID:VV1-6M4-ZXHT and Tracking ID:X21-XTD-WJR7 but not on CTD format. Complete application on CTD format is still required.

Decision of 351st meeting:

Registration Board rejected the case due non submission of registration application on Form-5F (CTD) as per decision taken by the Board in its 326th meeting.

Case#02: Imported human biological applied by M/s OBS AGP Limited deferred in 344th meeting

Name, address of Applicant / Importer	M/s OBS AGP (Private) Limited. Plot no. B-23-C, 2nd Floor S.I.T.E., Karachi-75700, Pakistan.
Details of Drug Sale License of importer	License No: 024 Address: OBS AGP Private Limited Address of Godown: PLOT NO. B-23-C, 2nd FLOOR S.I.T.E KARACHI. Status: License to sell, stock & exhibit for sale, distribute and sell drugs by way of whole sale by of manufacturer, importer or indenter Valid Upto: 27-03-2028
Name and address of 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
Name, address of manufacturer(s)	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
Name of exporting country	INDIA
Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized copy of CoPP certificate (No. COPP/CERT/KD/120672/2022/11/42600/208255) dated 1810-2022 issued by Food & Drug Administration, MS. Bandra (E) Mumbai-400 051 The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection once a year. <u>The name of importing country on CoPP is mentioned as Islamic Republic of Pakistan. Furthermore, the CoPP is valid till 29 March, 2025</u> GMP: Firm has submitted original, legalized copy of GMP certificate (NEW-WHO GMP/CERT/KD/107921/2022/11/39826) dated 04-July-2022 issued by Food & Drug Administration, MS. Bandra (E) Mumbai-400 051 Maharashtra state. India.
Details of letter of authorization / sole agency agreement	Firm has submitted original and legalized copy of letter of Authorization certificate from M/s Bharat Serums and Vaccines Limited. The letter species that the manufacturer appoints M/s AGP Limited 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 ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
Dy. No. and date of submission	Dy. No. 15845, 22-06-2023
Details of fee submitted	PKR 150,000/-: 14-06-2023
The proposed proprietary name / brand name	Foligraph 75IU. [Recombinant-Human Follicle Stimulating Hormone for Injection (Freeze Dried)]
Strength / concentration of drug of Active Pharmaceutical ingredient	Each Vial Contains:

(API) per unit	Recombinant- Follitropin Concentrated Solution 75.IU. (Freeze Dried) <u>Diluent for Reconstitution</u> One ampoule of sterile water for injection 0.5ml
Pharmaceutical form of applied drug	Freeze Dried Powder for Injection.
Pharmacotherapeutic Group of (API)	Human Follicle Stimulating Hormone
Reference to Finished product specifications	Innovators specs
Proposed Pack size	Each pack of Foligraph 75I.U. contains:
	1 vial of Recombinant- Human Follicle Stimulating Hormone for Injection (Freeze Dried) 1 ampoule of Sterile Water for Injection 0.5ml
Proposed unit price	-
The status in reference regulatory authorities	Gonal-f (Follitropin alpha) developed by Serono International, SA
For generic drugs (me-too status)	Gonadopin 75 I.U. Injection by M/s Matrix Pharma (Pvt.) Ltd
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 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, 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 of API (BB1116002, BB1116006, BB1117001) conducted at accelerated conditions 5°C ± 3°C RH for 6 months as well as real time conditions. The real time stability data is conducted at -20°C ± 5°C 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 bioequivalence studies against reference product Gonal-f (Follitropin alpha) developed by Serono International, SA (formerly, Ares-Serono SA)
Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
Container closure system of the drug product	One tray contains one vial (2 ml USP Type I) with one ampoule of sterile water for injection 0.5ml. One carton contains one tray with one insert.

	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches (B08616004, B08616005, B08617001) The accelerated stability study data is conducted at 25°C ± 2°C / 60% ± 5%RH for 6 months. The real time stability data is conducted at 2-8°C for 24 months.	
Decision of 344 th meeting: Deferred for the submission of following along with comparative clinical data with reference product:			
i. Documented study reports and non-clinical data of pharmacological, pharmacokinetics, toxicology including single-dose and repeat dose toxicity studies, genotoxicity, carcinogeneicity, reproductive and developmental toxicity (including range-finding studies and supportive toxicokinetics evaluations), local tolerance and other toxicological studies: ii. Documented and published clinical studies, biosimilarity studies including In-vitro, In vivo Correlation Study Reports, Reports of Bioanalytical and Analytical Methods for Human Studies, Human Pharmacokinetic and Pharmacodynamics studies, Study Reports of Controlled Clinical Studies Pertinent to the claimed indication: iii. Documented and published study reports of pre-clinical, Clinical trial reports establishing the safety and efficacy of the product: iv. Post-marketing surveillance (Pharmacovigilance) study reports.			
Evaluation by BE&R:			
Sr.No.	Shortcomings	Response of the firm	Remarks
1	Documented study reports and non-clinical data of pharmacological, pharmacokinetics, toxicology including single-dose and repeat dose toxicity studies, genotoxicity, carcinogenicity, reproductive and developmental toxicity (including range-finding studies and supportive toxicokinetics evaluations), local tolerance and other toxicological studies:	The requested points are already provided in Module 4 Non-clinical data. Enclosing the data in USB again for your reference.	Firm has submitted following; i) “Single dose pharmacokinetic study of r-hFSH in comparison with Gonal-f in wistar rats by subcutaneous route.” The study was conducted to evaluate the pharmacokinetic profile of Recombinant Human Follicle Stimulating Hormone (r-hFSH) product developed by Bharat Serums and Vaccines Ltd in comparison with Gonal –f. Test product is r-hFSH 75 IU /150 IU Lyophilized Powder for Injection. ii) “Acute toxicity study of r-hFSH in comparison with Gonal-f in Swiss albino mice by subcutaneous route.” The study was conducted to evaluate the safety and toxicity profile of Recombinant Human Follicle Stimulating Hormone (r-hFSH) product developed by Bharat Serums and Vaccines Ltd in comparison with Gonal –f. Test product is r-FSH 75IU/150IU Lyophilized Powder for Injection. iii) “Repeat dose toxicity and local tolerance study of FOLIGRAF in comparison with reference product Minutes of 345th meeting of Registration Board (19th – 21st February, 2025) 618 (Gonal F) in Wistar rats by subcutaneous route”. The study was conducted to assess the toxicity profile of FOLIGRAF and reference product (Gonal F) in Wistar Rats at dose levels of 9 and 90 IU/kg body weight thrice in a week over a period of 90 days by subcutaneous route. Repeat dose administration did not show any clinical signs and mortality at any of the treated dose groups. Animals injected thrice
2	Documented and published clinical studies, biosimilarity studies including In-vitro, In vivo Correlation Study Reports, Reports of Bioanalytical and Analytical Methods for Human Studies, Human Pharmacokinetic and Pharmacodynamics studies, Study Reports of Controlled Clinical Studies Pertinent to the claimed indication:	All our clinical trial data provided are pertaining to claimed indication; Anovulation and Stimulation of multifollicular development in patients undergoing superovulation for assisted reproductive technologic (ART). The requested points are already provided in Module 5 Non-clinical data. Enclosing the data in USB again for your reference.	
3	Documented and published study reports of pre-clinical, Clinical trial reports establishing the safety and efficacy of the product:	Pre-clinical study report and Clinical trial data (Phase I, II and IV) is provided in module 4 and 5 respectively. Enclosing the data in USB for your reference.	

4	Post-marketing surveillance (Pharmacovigilance) study reports.	Safety study has been provided in Phase IV study in Module 05.	a week over a 90 days did not show any gross pathological abnormalities as well as histopathological change at injection site. The test product is Foligraf 75IU (Lyophilized powder for Injection). Firm has submitted Literature references in clinical part (Module 5).
Concluding remarks: i. The innovator product Gonal-f is available in pack size 75IU vial + 1ml solvent in pre-filled syringe. However, the applied product is 75IU vial + 0.5ml solvent ampoule. ii. Module 5 (Clinical data) is not provided. Only literature references attached.			
Decision of 351st meeting: Registration Board deferred the case for submission of following documents/ clarifications; i. Module 5 (Clinical/efficacy data) of applied product. ii. The innovator product Gonal-f is available in pack size of 75IU vial + 1ml solvent in pre-filled syringe while the applied product is 75IU vial + 0.5ml solvent ampoule.			

Case# 03: Imported human biological applied by M/s OBS AGP Limited deferred in 344th meeting

Name, address of Applicant / Importer	M/s OBS AGP (Private) Limited. Plot no. B-23-C, 2nd Floor S.I.T.E., Karachi-75700, Pakistan.
Details of Drug Sale License of importer	License No: 024 Address: OBS AGP PRIVATE LIMITED Address of Godown: PLOT NO. B-23-C, 2nd FLOOR S.I.T.E KARACHI. Status: License to sell, stock & exhibit for sale, distribute and sell drugs by way of whole sale by of manufacturer, importer or indenter Valid Upto: 27-03-2028
Name and address of 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
Name, address of manufacturer(s)	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
Name of exporting country	INDIA

Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized copy of CoPP certificate (No.COPP/CERT/KD/120672/2022/11/42600/208254) dated 18-10-2022 issued by Food & Drug Administration, MS. Bandra (E) Mumbai-400 051 The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection once a year. <u>The name of importing country on CoPP is mentioned as Islamic Republic of Pakistan. Furthermore, the CoPP is valid till 29-March,2025</u> GMP: Firm has submitted original, legalized copy of GMP certificate (NEW-WHO GMP/CERT/KD/107921/2022/11/39826) dated 04-July-2022 issued by Food & Drug Administration, MS. Bandra (E) Mumbai-400 051Maharashtra state.India.
Details of letter of authorization / sole agency agreement	Firm has submitted original and legalized copy of letter of Authorization certificate from M/s Bharat Serums and Vaccines Limited. The letter species that the manufacturer appoints M/s AGP Limited 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 ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
Dy. No. and date of submission	Dy. No. 15846, 22-06-2023
Details of fee submitted	PKR 150,000/-: 14-06-2023
The proposed proprietary name / brand name	Foligraph 150IU [Recombinant-Human Follicle Stimulating Hormone for Injection (Freeze Dried)]
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Recombinant- Follitropin Concentrated Solution 150.IU. (Freeze Dried) <u>Diluent for Reconstitution</u> One ampoule of sterile water for injection 0.5ml
Pharmaceutical form of applied drug	Freeze Dried Powder for Injection.
Pharmacotherapeutic Group of (API)	Human Follicle Stimulating Hormone

Reference to Finished product specifications	Innovators specs
Proposed Pack size	Each pack of Foligraph 150.IU. contains: 1 vial of Recombinant- Human Follicle Stimulating Hormone for Injection (Freeze Dried) 1 ampoule of Sterile Water for Injection 0.5ml
Proposed unit price	-
The status in reference regulatory authorities	Gonal-f (Follitropin alpha) developed by Serono International, SA
For generic drugs (me-too status)	Follitrope 150 I.U. Injection by M/s Galaxy Pharmaceuticals (Pvt.) Ltd.
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 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, 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 of API (BB1116002, BB1116006, BB1117001) conducted at accelerated conditions 5°C ± 3°C RH for 6 months as well as real time conditions. The real time stability data is conducted at -20°C ± 5°C 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 bioequivalence studies against reference product Gonal-f (Follitropin alpha) developed by Serono International, SA (formerly, Ares-Serono SA)
Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
Container closure system of the drug product	One tray contains one vial (2 ml USP Type I) with one ampoule of sterile water for injection 0.5ml. One carton contains one tray with one insert.

Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches (B08717002, B08717004, B08718002) The accelerated stability study data is conducted at 25°C ± 2°C / 60% ± 5%RH for 6 months. The real time stability data is conducted at 2-8°C for 24 months.
Decision of 344th meeting: Deferred for the submission of following along with comparative clinical data with reference product: - Documented study reports and non-clinical data of pharmacological, pharmacokinetics, toxicology including single-dose and repeat dose toxicity studies, genotoxicity, carcinogenicity, reproductive and developmental toxicity (including range-finding studies and supportive toxicokinetics evaluations), local tolerance and other toxicological studies: - Documented and published clinical studies, biosimilarity studies including In-vitro, In vivo Correlation Study Reports, Reports of Bioanalytical and Analytical Methods for Human Studies, Human Pharmacokinetic and Pharmacodynamics studies, Study Reports of Controlled Clinical Studies Pertinent to the claimed indication: - Documented and published study reports of pre-clinical, Clinical trial reports establishing the safety and efficacy of the product: - Post-marketing surveillance (Pharmacovigilance) study reports.	

Evaluation by BE&R:

Sr.No.	Shortcomings	Response of the firm	Remarks
1	Documented study reports and non-clinical data of pharmacological, pharmacokinetics, toxicology including single-dose and repeat dose toxicity studies, genotoxicity, carcinogenicity, reproductive and developmental toxicity (including range-finding studies and supportive toxicokinetics evaluations), local tolerance and other toxicological studies:	The requested points are already provided in Module 4 Non-clinical data. Enclosing the data in USB again for your reference.	Firm has submitted following; i) "Single dose pharmacokinetic study of r-hFSH in comparison with Gonal-f in wistar rats by subcutaneous route." The study was conducted to evaluate the pharmacokinetic profile of Recombinant Human Follicle Stimulating Hormone (r-hFSH) product developed by Bharat Serums and Vaccines Ltd in comparison with Gonal -f. Test product is r-hFSH 75 IU /150 IU Lyophilized Powder for Injection.
2	Documented and published clinical studies, biosimilarity studies including In-vitro, In vivo Correlation Study Reports, Reports of Bioanalytical and Analytical Methods for Human Studies, Human Pharmacokinetic and Pharmacodynamics studies, Study Reports of Controlled Clinical Studies Pertinent to the claimed indication:	All our clinical trial data provided are pertaining to claimed indication; Anovulation and Stimulation of multifollicular development in patients undergoing superovulation for assisted reproductive technologies (ART). The requested points are already provided in Module 5 Non-clinical data. Enclosing the data in USB again for your reference.	ii) "Acute toxicity study of r-hFSH in comparison with Gonal-f in Swiss albino mice by subcutaneous route." The study was conducted to evaluate the safety and toxicity profile of Recombinant Human Follicle Stimulating Hormone (r-hFSH) product developed by Bharat Serums and Vaccines Ltd in comparison with Gonal -f. Test product is r-FSH 75IU/150IU Lyophilized Powder for Injection.
3	Documented and published study reports of pre-clinical, Clinical trial reports establishing the safety and efficacy of the product:	Pre-clinical study report and Clinical trial data (Phase I, II and IV) is provided in module 4 and 5 respectively. Enclosing the data in USB for your reference.	iii) "Repeat dose toxicity and local tolerance study of FOLIGRAF in comparison with reference product Minutes of
4	Post-marketing surveillance (Pharmacovigilance) study reports.	Safety study has been provided in Phase IV study in Module 05.	

			345th meeting of Registration Board (19th – 21st February, 2025) 618 (Gonal F) in Wistar rats by subcutaneous route”. The study was conducted to assess the toxicity profile of FOLIGRAF and reference product (Gonal F) in Wistar Rats at dose levels of 9 and 90 IU/kg body weight thrice in a week over a period of 90 day by subcutaneous route. Repeat dose administration did not show any clinical signs and mortality at any of the treated dose groups. Animals injected thrice a week over a 90 days did not show any gross pathological abnormalities as well as histopathological change at injection site. The test product is Foligraf 75IU (Lyophilized powder for Injection). Firm has submitted Literature references in clinical part (Module 5).

Concluding Remarks:

- i. Evidence of approval of applied product (150IU) in vial container closure system in any reference country as approved by Registration Board.
- ii. Repeat dose toxicity studies and Module 5 (clinical data) of applied product is not provided. Only literature references attached.

Decision of 351st meeting:

Registration Board deferred the case for submission of following documents/ clarifications;

- i. **Evidence of approval of applied product (150IU) in vial container closure system in any reference country as approved by Registration Board.**
- ii. **Repeat dose toxicity studies and Module 5 (clinical data) of applied product.**

Case#04: Imported human biological applied by M/s OBS AGP Limited deferred in 340th meeting:	
Name, address of Applicant / Importer	M/s OBS AGP (Private) Limited, B-23-C, 2nd Floor S.I.T.E., Karachi
Details of Drug Sale License of importer	License No:024 Plot No. B-23-C, 2 nd Floor, S.I.T.E, Karachi
	Godown: Muller and Phipps Pakistan Pvt., Ltd., Plot No 32-12 Sector 19, K.I.A, Karachi Validity : 27-03-2028
Name and address of marketing authorization holder (abroad)	M/s Bharat Serums and Vaccines Limited K-27, K-27 Part and K-27/1, Anand Nagar, Jambivili Village, Additional MIDC, Ambernath (East) Thane- 421506, Maharashtra, India.
Name, address of manufacturer(s)	M/s Bharat Serums and Vaccines Limited K-27, K-27 Part and K-27/1, Anand Nagar, Jambivili Village, Additional MIDC, Ambernath (East) Thane- 421506, Maharashtra, India.
Name of exporting country	India
Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	<u>Original, Legalized and valid CoPP</u> Certificate Number: COPP/CERT/KD/120551/2022/11/42570/208009 Certifying Authority: Joint Commissioner (HQ) and Controlling Authority Food and Drug Administration, M.S. Bandra (E), Mumbai, Maharashtra State, India Validity: 29, March 2025
Details of letter of authorization / sole agency agreement	<u>Original, Legalized and Valid Letter of Authorization</u> M/s BSV hereby appoint M/s OBS AGP Pvt. Ltd., will be responsible for the registration /marketing/sales/tender business of BSV Humog 150 HP Validity: 23-08-2028
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. 1743 Dated 18, December 2023.
Details of fee submitted	Deposit Slip no.2918568857 , PKR 150,000/- Dated: 20-07-2023
The proposed proprietary name / brand name	BSV Humog 150 HP

Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Menotropin equivalent to activity of Follicle stimulating hormone 150 IU Luteinizing hormone 150 IU Diluent for reconstitution: Each ampoule contains: Sodium Chloride...0.9%
Dosage form of applied drug	Freeze Dried Powder
	Route of Adm SC/IM
Pharmacotherapeutic Group of (API) and Indication	Human Menopausal Gonadotropin ATC Code: G03GA02
Reference to Finished product specifications	BP Specifications
Proposed pack size	1's vial, 1's ampoule.
Proposed unit price	As per SRO
Shelf life	36 months Diluent 60months
Storage conditions	2°C - 8°C
The status in reference regulatory authorities	Approved in Germany.
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	Manufacturing, Testing, Labeling, Packaging, Storage BSV Bioscience GmbH Max Planck-Strasse 12, 52499 Baesweiler, 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)	The submitted stability data is of 24 months.
Menotropin	

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	Bharat Serums and Vaccines Limited has developed In-house analytical procedures for BSVHUMOG- 150 HP [Menotrophin for Injection BP (Highly Purified) (Freeze Dried)] and these methods have been suitably validated as per the ICH requirements.
Container closure system of the drug product	2 ml Clear, Colourless glass, USP-Type 1 Vial ,13 mm slotted rubber bung, Aluminium Flip off Seal,13 mm Transparent Pink
Stability study data of drug product, shelf life and storage conditions	Based on available stability data of 6 Months at accelerated condition ($25 \pm 2^{\circ}\text{C}$ / $60 \pm 5\%\text{RH}$) and 36 Months at long term condition ($2^{\circ}\text{C} - 8^{\circ}\text{C}$), Bharat Serums proposes shelf life of 36 Months when stored at $2^{\circ}\text{C} - 8^{\circ}\text{C}$. Diluent Shelf life of 60 Months when stored at $2^{\circ}\text{C} - 8^{\circ}\text{C}$.
Diluent (0.9%w/v NaCl)	
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	Pharmacopeial analytical procedures method has been verified.
Container closure system of the drug product	2 ml amber coloured neutral borosilicate glass U.S.P. Type I ampoule with concave bottom, snap off ampoule with score on the constriction.
Stability study data of drug product, shelf life and storage conditions	Shelf life of 60 Months when stored at $2^{\circ}\text{C} - 8^{\circ}\text{C}$.
Module IV Non-Clinical	No Pharmacology and Pharmacokinetics studies have been conducted. Only Toxicology have been performed. Bharat Serums & Vaccines Limited (BSV) has performed preclinical toxicology evaluation of Human menopausal gonadotrophins (Humog®). The repeat toxicity dose toxicology in rats and rabbits was thoroughly investigated. Studies a) Repeat dose toxicity and local tolerance study of Humog® in New Zealand White rabbits by subcutaneous route (Study No: BSV/PC/11/11) b) Repeat dose toxicity and local tolerance study of Humog® in Wister rats by subcutaneous route (Study No: BSV/PC/11/10)

Module V Clinical Studies	5.2.1 Tabular listing of all clinical studies																	
	<table><tr><th>Type of Study</th><th>Study Identifier</th><th>Location of Study Report</th><th>Objectives of the study</th><th>Study design and Type of control</th><th>Test products; dosage Regimen; Route of Administration</th><th>Number of Subjects</th><th>Healthy Subjects or Diagnosis of Patients</th><th>Duration Treatment</th></tr><tr><td>BE</td><td>Project No. 613-14</td><td>Part IV-E</td><td>To compare the rate and extent of absorption of sponsor's test product (UpHMG-BSV) versus reference product (Menopur) in pituitary down-regulated healthy adult human female subjects</td><td>open label, balanced, randomized, two-treatment, two-sequence, two-period, single subcutaneous dose, crossover, bioequivalence study in pituitary down-regulated healthy adult human female subjects.</td><td>UpHMG-BSV (Humog) 75 IU Manufactured by BSVL Mumbai. Menopur 75 IU Manufactured by: Ferring GmbH</td><td>24 subject</td><td>non-smokers, premenopausal female subjects</td><td>Single dose One each in Part I and Part</td></tr></table>	Type of Study	Study Identifier	Location of Study Report	Objectives of the study	Study design and Type of control	Test products; dosage Regimen; Route of Administration	Number of Subjects	Healthy Subjects or Diagnosis of Patients	Duration Treatment	BE	Project No. 613-14	Part IV-E	To compare the rate and extent of absorption of sponsor's test product (UpHMG-BSV) versus reference product (Menopur) in pituitary down-regulated healthy adult human female subjects	open label, balanced, randomized, two-treatment, two-sequence, two-period, single subcutaneous dose, crossover, bioequivalence study in pituitary down-regulated healthy adult human female subjects.	UpHMG-BSV (Humog) 75 IU Manufactured by BSVL Mumbai. Menopur 75 IU Manufactured by: Ferring GmbH	24 subject	non-smokers, premenopausal female subjects
Type of Study	Study Identifier	Location of Study Report	Objectives of the study	Study design and Type of control	Test products; dosage Regimen; Route of Administration	Number of Subjects	Healthy Subjects or Diagnosis of Patients	Duration Treatment										
BE	Project No. 613-14	Part IV-E	To compare the rate and extent of absorption of sponsor's test product (UpHMG-BSV) versus reference product (Menopur) in pituitary down-regulated healthy adult human female subjects	open label, balanced, randomized, two-treatment, two-sequence, two-period, single subcutaneous dose, crossover, bioequivalence study in pituitary down-regulated healthy adult human female subjects.	UpHMG-BSV (Humog) 75 IU Manufactured by BSVL Mumbai. Menopur 75 IU Manufactured by: Ferring GmbH	24 subject	non-smokers, premenopausal female subjects	Single dose One each in Part I and Part										
	Reports of Biopharmaceutic Studies. BA And BE Comparability Report The two preparations were bioequivalent with respect to FSH and HCG immunoreactivity. Bioequivalence could not be proven for LH activity because of the small number of subjects. No invitro and invivo studies performed. Reports of Studies Pertinent to Pharmacokinetics Using Human Biomaterials																	
Remarks of the Evaluator	Observations ☐☐ Section 1.4.2 mentions both Domestic and Export sales. Clarification is required. ☐☐ Submit bio similarity studies with innovator product as per WHO template. ☐☐ Submit GMP of drug substance manufacturing site. ☐☐ In section 3.2.S.3.1 characterization drug substance has been compared with innovator product Menopur. Clarification/justification is required. ☐☐ The stability data of API is of 24 months, whereas, claimed shelf life is of 36 months. ☐☐ There is a significant difference in results of potency and specific activity for FSH and LH in section 3.2.S.7.3 when compared with section 3.2.S.4.4. The potency of FSH and LH is greater than 700IU/mg whereas, in stability summary sheets is greater than 300IU/mg. Same is the case with specific activity. Justification is required. ☐☐ Justification is required for not performing forced degradation studies for drug substance. ☐☐ Submit section 3.2.R, providing comparability exercise. ☐☐ The available monograph is menotrophin in water whereas, the applied formulation is menotrophin in sodium chloride. Clarification is required. ☐☐ The section 3.2.5.1 of menotrophin drug product mentions reference of specs BP whereas, section 3.2.P.5.3 mentions inhouse analytical procedures. ☐☐ The section 3.2.R.3 includes the data of Menotrophin 75 IU whereas, the applied strength is 150IU. ☐☐ The non-clinical studies in white rabbits states that dose level till 100IU is safe whereas, applied strength is 150 IU. Clarification is required. ☐☐ The toxicology studies have been done only for SC route whereas, safety studies for IM route not established. ☐☐ Justification is required for not performing all the non-clinical studies. ☐☐ Evidence of availability of strength in Germany.																	
Decision of M-340 <i>The Registration Board deferred the case for the submission of above cited documents.</i>																		
Evaluation by BE&R:																		

Sr.No	Remarks of the Evaluator	Firms Response	Remarks
1.	Section 1.4.2 mentions both Domestic and Export sales. Clarification is required.	There is a typographic error in Form 5F. Whereas in Section 1.4.2 of Module 01, Correct option of Domestic sale was selected in a dossier.	-
2.	Submit bio similarity studies with innovator product as per WHO template	The study has been conducted according to EMA guidelines for biosimilars and guidelines for rFSH containing products. The WHO guidelines for BE has similar requirements enclosed as Annexure 1 . Hence the submitted study covers the requirements of WHO.	The product is not manufactured by rDNA technology rather prepared by Extraction of Active Substance from Natural Sources.
3.	Submit GMP of drug substance manufacturing site.	Please find valid GMP certificate of API manufacturer BSV BioScience enclosed as Annexure 2 .	Submitted
4.	In section 3.2.S.3.1 characterization drug substance has been compared with innovator product Menopur. Clarification/justification is required.	3.2.S.3.1 characterization drug substance is attached as Annexure 3 .	Firm has given statement that “In order to determine the structure and characteristics of the constituents, three lab scale batches (1HMG230502, 1HMG230717, 1HMG221114) were manufactured and sent to an external lab for characterization.” Detail about the lab where characterization was performed is not mentioned.
5.	The stability data of API is of 24 months, whereas, claimed shelf life is of 36 months.	Please find complete 36 Months stability data of API from API manufacturer BSV BioScience enclosed as Annexure 4 .	Submitted
6.	There is a significant difference in results of potency and specific activity for FSH and LH in section 3.2.S.7.3 when compared with section 3.2.S.4.4. The potency of FSH and LH is greater than 700IU/mg whereas, in stability summary sheets is greater than 300IU/mg. Same is the case with specific activity. Justification is required.	Response from API manufacturer: The minimum required potency is > 40 IU/mg for both FSH and LH according to EP. BSV's internal specification is >100IU/mg and the results are within the compliance limits. The stability data is from batches of 2020; currently our batches are in the range of 500 to 700IU/mg. This does not lead to an impact on the quality of the product, in fact a higher potency is better. For the DP, the drug substance is later dissolved and diluted to the required activity of the finished formulation. Similarly, the specific activity is adjusted later on as well.	-
7.	Justification is required for not performing forced degradation studies for drug substance.	A stress study at +40 °C was performed for one HMG batch. Please find attached data as Annexure 5 .	Submitted
8.	Submit section 3.2.R, providing comparability exercise.	BSV has conducted BE study (Phase I - Project No. 613-14) to compare the rate and extent of absorption of sponsor's test product (BSV Humog versus reference product (Menopur). Attaching the report as Annexure 6 .	Firm has submitted single study of “hpHMG-BSV 75 IU vial” which is not the applied product.

9.	The available monograph is menotrophin in water whereas, the applied formulation is menotrophin in sodium chloride. Clarification is required	In BSV Humog 150 IU, Water for injection is used as a solvent in the formulation (Please refer section 3.2.P.3.2 Batch formula) which is not present in finished product as the product is Lyophilized powder for injection. However, diluent 0.9% Sodium chloride' is used for reconstitution before administration.	-
10.	The section 3.2.5.1 of menotrophin drug product mentions reference of specs BP whereas, section 3.2.P.5.3 mentions in-house analytical procedures.	The section 3.2.P.5.3 claiming IH standard was erroneously mentioned, and the validation of analytical procedures is done as per BP monograph. Please find revised section 3.2.P.5.3 mentioning AMV done as per BP monograph as Annexure 7 .	Finished product specifications is BP.
11.	The section 3.2.R.3 includes the data of Menotrophin 75 IU whereas, the applied strength is 150IU	The dose of Menotrophin: The starting dose is normally 75-150 IU daily. This dose may be increased according to your response to the treatment up to a maximum of 225 IU per day. The dose should be increased by 37.5 IU per adjustment (and not more than 75 IU). Menotrophin administered depends on the dose required for patient as per the Investigator's assessment. Hence the different strength 75 IU or 150 IU or other strength would not affect the dose administration.	The data of 150IU strength is not provided.
12.	The non-clinical studies in white rabbits' states that dose level till 100IU is safe whereas, applied strength is 150 IU. Clarification is required.	Strength BSV HUMOG 150 IU i.e., per 60 kg of human, which is 40 folds higher when compared to 100 IU/kg of rabbit. The dose used for the toxicity study is 100 IU/kg in rabbits, equivalent to 2.5 IU/kg/day of human dose	-
13.	The toxicology studies have been done only for SC route whereas, safety studies for IM route not established	Both the Subcutaneous and Intramuscular routes are clinically intended uses for HUMOG 150 IU due to dose volume restriction in animals' the subcutaneous route is used in toxicology studies. The only difference is the delayed absorption in subcutaneous route, when compared to the intramuscular route, and both are clinically compared in terms of efficacy.	-
14.	Justification is required for not performing all the non-clinical studies	HUMOG 150 IU is a Generic Product. Hence, for Generic drugs it is not recommended to perform all non-clinical studies. Please refer to the EMA guideline for generic filing (Page no 13) enclosed as Annexure 8..	Not performed.
15.	Evidence of availability of strength in Germany.	Menopur 150 IU Powder and Solvent for Solution for Injection <u>Marketing Authorisation Holder:</u> Ferring Pharmaceuticals Ltd. Drayton Hall, Church Road, West Drayton, UB7 7PS, UK PL 03194/0109 <u>Manufacturer:</u> Ferring GmbH Wittland 11, D-24109 Kiel, Germany Reference attached as Annexure 9 .	Submitted

Concluding remarks:

- Complete clinical and non-clinical data is required as the applied product is a biological and prepared by Extraction of Active Substance from Natural Source.
- In-use stability data is required.
- Detail of the laboratory where characterization was performed and results of characterization is required.

Decision:

Registration Board deferred the case for submission of following documents/ clarifications;

- Complete clinical and non-clinical data is required as the applied product is a biological and prepared by Extraction of Active Substance from Natural Source.
- In-use stability data.
- Detail of the laboratory where characterization was performed and results of characterization.

Case#05: Imported human biological applied by M/s AJ Mirza Karachi deferred in 293rd meeting:

5	Name of Importer	M/s AJ Mirza (Pvt) Ltd, Karachi 2 nd floor Shafi- Court Civil Lines, Meriwether Road Karachi
	Details of DSL	Copy of DSL valid up to 22-05-2020.
	Name of Manufacturer	M/s Shenyang Sunshine Pharmaceutical Co., Ltd., China Address No 3 A1, Road 10, Shenyang Econ& Tech Development Zone, Shenyang 110027, China.
	Brand Name +Dosage Form + Strength	EPIAO 36000IU/mL Vial Recombinant Human Erythropoietin 36000IU/mL/Vial
	Composition	Each 1mL vial contains: Recombinant Human Erythropoietin (CHO Cell)....36000IU
	Finished product specifications	European Pharmacopeia
	Pharmacological Group	Hemopoietic recombinant protein
	Shelf life	24 Months
	International Availability of this product	Not available
	Similar Product already registered in Pakistan	Not Available
	Type of Form Dy No & Date of application, Fee submitted	Form-5A dated 3-12-2018. R&I Dy.No.26098 dated 30-07-2018. Rs.50,000/- dated 19-07-2018.
	Demanded Price/ Pack size	20,000 MRP/ 1's Vial
	General documentation	1. Legalized CoPP dated 26-12-2017
	Remarks of Evaluator	1. The product is not available in RRA. 2. Batches provided in stability data are not commercial batches. 3. The product is available in European Pharmacopeia while the firm has provided Chinese Pharmacopeia. 4. The firm in its latest document dated 29-10-2019 requested to consider the application in Registration Board meeting and are ready to accept the decision of Registration Board.
	Decision of 293 rd meeting: <i>Registration Board deferred the case for submission of evidence of availability of formulation in reference regulatory authorities and other countries.</i>	
	Evaluation by BE&R: The firm has given statement as below; "The justification of RRA evidence is MHRA is below	

EPREX 40,000 IU/mL solution for injection in pre-filled syringe
EPREX 30,000 IU/mL solution for injection in pre-filled syringe
A pre-filled syringe of 1.0 mL contains 40,000 IU (336.0 micrograms) of epoetin alfa
Our product contains 36000 IU/ml the Active are same and the Route of Administration is same as per the reference product.”

The reference given by the applicant is not relevant to the instant case. The applicant has applied for registration of 36000IU/ml vial while the reference given is of 40,000 and 30,000 IU/ml PFS.

Decision of 351st meeting:

Registration Board rejected the application as formulation in applied strength is not approved by any of the reference regulatory authorities as designated by the Registration Board.

Case#06: Imported human biological applied by M/s OBS AGP Limited deferred in 340th meeting:

Name, address of Applicant / Importer	M/s OBS AGP (Private) Limited. Plot no. B-23-C, 2nd Floor S.I.T.E., Karachi-75700, Pakistan.
Details of Drug Sale License of importer	License No: 024 Address: OBS AGP PRIVATE LIMITED Address of Godown: PLOT NO. B-23-C, 2nd FLOOR S.I.T.E KARACHI. Status: License to sell, stock & exhibit for sale, distribute and sell drugs by way of whole sale by of manufacturer, importer or indenter Valid Upto: 27-03-2028
Name and address of 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, Ambarnath (East), Thane 421506, Maharashtra State, India
Name, address of manufacturer(s)	M/s Bharat Serums and Vaccines Limited Plot No. K-27, K-27 Part and K-27/1, Anand Nagar, Jambivili Village, Additional MIDC, Ambarnath (East), Thane 421506, Maharashtra State, India
Name of exporting country	INDIA
Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized copy of CoPP certificate (No.COPP/CERT/KD/120672/2022/11/42600/208257) dated 18-10-2022 issued by Food & Drug Administration, MS. Bandra (E) Mumbai-400 051 The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection once a year. <u>The name of importing country on CoPP is mentioned as Islamic Republic of Pakistan. Furthermore, the CoPP is valid till 29march,2025</u> GMP: Firm has submitted original, legalized copy of GMP certificate (NEW-WHO GMP/CERT/KD/107921/2022/11/39826) dated 04-July-2022 issued by Food & Drug Administration, MS. Bandra (E) Mumbai-400 051 Maharashtra stat, India, valid till 29March,2025
Details of letter of authorization / sole agency agreement	Firm has submitted original and legalized copy of letter of Authorization certificate from M/s Bharat Serums and Vaccines Limited. The letter species that the manufacturer appoints M/s AGP Limited 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 ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
Dy. No. and date of submission	Dy. No. 17734: 14-07-2023 (Slip # 181426809656)
Details of fee submitted	PKR 150,000/-: 21-06-2023
The proposed proprietary name / brand name	U-Tryp 100,000 IU (Ulinastatin for injection)

Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ulinastatin 100,000.IU. (Liquid Injection)
Pharmaceutical form of applied drug	Liquid Injection.
Pharmacotherapeutic Group of (API)	Urinary Trypsin Inhibitor
Reference to Finished product specifications	BSV specs
Proposed Pack size	1's x 5ml Vial (4ml deliverable volume)
Proposed unit price	-
The status in reference regulatory authorities	MIRACLID by Mochida, Japan
For generic drugs (me-too status)	Roan 100,000 IU by M/s Techpool Bio Pharma Co, Ltd.
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 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, 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 of API (UTIV110314, UTIV110518, UTI120109) conducted at accelerated conditions 5°C ± 3°C RH for 6 months as well as real time conditions. The real time stability data is conducted at -20°C ± 5°C 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 bioequivalence studies against reference product MIRACLID developed by Mochida, Japan.
Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.

Container closure system of the drug product	U-TRYP 100,000 IU [Ulinastatin for Injection 100,000 IU (Liquid)] is packaged in Clear, Colourless, USP, Type I tubular flint glass vial of 5 ml capacity
Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches (A13317002, A13317003, A13317004) The accelerated stability study data is conducted at 25°C ± 2°C / 60% ± 5%RH for 6 months. The real time stability data is conducted at 2-8°C for 36 months.

Module IV	Following is submitted by firm: - Single dose toxicity studies - Repeat dose toxicity studies
Module V	A Prospective, Multicenter, Double-Blind, Randomized, Phase III Clinical Study to Compare the Efficacy and Safety of Intravenous Ulinastatin Versus Placebo Along with Standard Supportive Care in Subjects with Mild or Severe Acute Pancreatitis. 2. A Prospective, Multicentric, Double-Blind, Randomised, Phase III Clinical Study To Compare The Efficacy and Safety of Intravenous Ulinastatin Versus Placebo Along with Standard Supportive Care in Subjects of Severe Sepsis. 3. Prospective, single center, open label, balanced, randomized, multiple dose strengths, parallel group safety study to evaluate safety of Ulinastatin in healthy, adult, human subjects 4. A phase IV, prospective, multi-centric, double-blind, comparative, clinical study to compare the efficacy and safety of intravenous ulinastatin versus placebo along with standard supportive care in subjects with severe sepsis. At the time of this PSUR, the sponsor has recruited 7 subjects in this study. No major safety concern has been encountered till date.

Decision of 340th meeting:

Registration Board deferred the case for submission of comparative clinical trial data.

Evaluation by BE&R:

Firm has submitted following:

“Prospective, single center, Open Label, Balanced, Randomized, Multiple Dose strengths, Parallel group Safety Study to evaluate Safety of Ulinastatin in Healthy, Adult Human Subjects.”

- The reference product Miraclid Injection 100,000Units is available as 2ml ampoule in Japan while the applied product is 5ml vial. The reference product is verified from the following link:

<https://www.pmda.go.jp/PmdaSearch/iyakuSearch>

- Comparative clinical trial data is not provided by the manufacturer.

Decision of 351st meeting:

Registration Board decided to defer the case and grant final opportunity to the applicant for submission of following documents/ clarifications;

- The reference product Miraclid Injection 100,000Units is available as 2ml ampoule in Japan while the applied product is 5ml vial.
- Comparative clinical trial data of applied product with innovator.

Case#07: Registration application of Cecolin (WHO PQ Product) applied by M/s Lab Diagnostic Systems (SMS) Pvt. Ltd, Taxila Rawalpindi.

M/s Lab Diagnostic Systems (SMS) has applied for registration of following WHO PQ Product “Cecolin”. The product is under screening phase on e-app.

Name of product	Composition	Pack size	Manufacturer/ MA Holder	Tracking ID, Application No. and date of submission

Cecolin	Each dose of 0.5ml, vial contains; Recombinant human papillomavirus type16 L1 protein..... 40 µg Recombinant human papillomavirus type18 L1 protein..... 20 µg (Chinese Pharmacopoeia)	10's vial	M/s Xiamen Innovax Biotech Co., Ltd. Address: No.52 and No.60, Shanbianhong East Road, Haicang District, Xiamen, Fujian, China.	GRB-AJ9-LJ8Q 126324 September 10th, 2025

Evaluation by BE&R:

The product is already Registered in the name of M/s Hospital Services & Sales, Karachi as per following detail:

Reg. No.	Product Name, composition & Specifications	Date of Reg, Packing & Shelf life	Manufacturer
126128	Cecolin Recombinant Human Papillomavirus Bivalent (Types 16, 18) Vaccine (Escherichia. coli), Injection Each dose of 0.5mL contains: Recombinant human papillomavirus type 16 L 1 protein...40mcg Recombinant human papillomavirus type 18 L 1 protein...20mcg (Ph. Eur. Specifications)	31.08.2025 1's Vial (0.5ml) 24 Months (2-8°C)	M/s Xiamen Innovax Biotech Co., Ltd. No. 52, Shanbianhong East Road, Haicang District, Xiamen City, Fujian Province, China.

The applicant has also provided a Statement Letter from manufacturer of Cecolin which states that the manufacturer has terminated the collaboration with Hospital Services & sales.

"The case is hereby place before the Board for decision in accordance with the Rules, as the product is currently included in a government immunization campaign."

Decision of 351st meeting:

Registration Board directed BE&R division to issue show cause notice to M/s Hospital Services & Sales, Karachi for cancellation of registration of Cecolin Recombinant Human Papillomavirus Bivalent (Types 16, 18) Vaccine under Section 7 (11) (b) and 42 of the Drug Act, 1976 & Rule 24 (17) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 as the drug product manufacturer has terminated the agreement with M/s Hospital Services & Sales, Karachi.

Case#08: Imported human biological applied by M/s Bristol Mayer Biotech Lahore approved in 339th meeting:

Name, address of Applicant/Importer	M/s Bristol Mayer Biotech Pakistan 73-B, Guldast Town, Zarrar Shaheed Road, Lahore Cantt.
Details of Drug Sale License of importer	License No: 05-352-0068-029407D Address: 73-B, Guldast Town, Zarrar Shaheed Road, Lahore Cantt Address of Godown: NA Validity: 07.04.2027 Status: License to sell drugs as a distributor
Name and address of marketing authorization holder (abroad)	M/s. VINS Bioproducts Limited, India Office Address: 806, Essjay house, Road No.03, Banjara hills, Hyderabad-500034, Telangana, India. Site Address: Sy. No. 117, Thimmapur, Thimmapur Village,

	Kothur Mandal, Ranga Reddy District, Pin code 509325, Telangana State, India
Name, address of manufacturer (s)	M/s. VINS Bioproducts Limited, India Office Address: 806, Essjay house, Road No.03, Banjara hills, Hyderabad-500034, Telangana, India. Site Address: Sy. No. 117, Thimmapur, Thimmapur Village, Kothur Mandal, Ranga
Name of exporting country	India
Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	Free Sale Certificate: Firm has submitted original, legalized copy of Free Sale Certificate (No. 110372/TS/2023) dated 10/02/2023 issued by Drugs Control Administration Government of Telangana for Tetanus Antitoxin 1500 IU BP (1.0 ml liquid ampoule) . The Free Sale Certificate states that the product is on free sale in exporting country . GMP Certificate: Firm has submitted original, legalized copy of GMP certificate (No. 104134/TS/2023) dated 04/01/2023 issued by Drugs Control Administration Government of Telangana valid until 03/01/2024.
Details of letter of authorization/sole agency agreement	Firm has submitted copy of letter of authorization from VINS Bioproducts Limited, India . The letter specifies that the manufacturer appoints M/s Bristol Mayer Biotech Pakistan to register their products in Pakistan. The authorization letter is valid till 30th May, 2024.
Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
For imported products, specify one of these	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: 67341 Date of submission: 11-07-2023
Details of fee submitted	Rs: 150,000 Slip number: 1581129621 Dated :19/06/2023
The proposed proprietary name/brand name	Tetanus Antitoxin 1500 IU BP (1 ml liquid ampoule)
Strength / concentration of drug of Active	Tetanus Antitoxin 1500 IU (1ml liquid ampoule)
Pharmaceutical ingredient (API) per unit	Each ml contains Enzyme Refined, Equine Tetanus Antitoxin Immunoglobulin fragments NLT 1500 IU
Pharmaceutical form of applied drug	Liquid for Injection
Pharmacotherapeutic Group of (API)	Immune sera and immunoglobulin- Equine Tetanus antitoxic immunoglobulin ATC Code: J06AA02-Tetanus antitoxin
Reference to Finished product specifications	B.P.
Proposed Pack size	Tetanus antitoxin is supplied as 1ml liquid in a glass ampoule.
Proposed unit price	Rs. 600/Ampoule
Shelf Life	24 months (2 years)
Storage Conditions	The liquid Tetanus antitoxin should be stored at 2°C to 8°C. It should not be allowed to freeze.
The status in reference regulatory authorities	ANSM (France) Approved TETANEA 1500 IU/ml by SANOFI PASTEUR
For generic drugs (me-too status)	Reg. No: 059003

	Company Name: Hospital Services & Sales Brand Name: Tetanus Antitoxin 1500 IU Formulation: Each ml contains: - Tetanus Antitoxin....1500IU Pack Size: 1 Dose Amp /1ml
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.
Name, address of drug substance manufacturer	VINS Bioproducts Limited Survey No.117, Thimmapur (V) Kothur (M), Rangareddy Dist., Telangana, 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	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions.
(Conditions & duration of Stability studies)	The accelerated stability data is conducted at 25°C ± 2°C, RH 60 ± 5% for 6 months. The real time stability data is conducted at 5± 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	Not Required
Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product
Container closure system of the drug product	2 ml USP Type – 1 Flint ampoule
Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. The accelerated stability study data is conducted at 25°C ± 2°C, RH 60 ± 5% for 6 months. The real time stability study data is conducted at 5± 3°C the real time stability study data as per ICH guidelines.
Module-IV Non-Clinical	Study Report for Toxicology (4.2.3) is presented with title “Determination of potency of the test item Tetanus Antitoxin-1500 IU after administration subcutaneously in Mice.”
Module-V Clinical	Under 5.3 Clinical Study Report section, Report of Post-Marketing Experience (5.3.6) is presented with title “Safety of Equine Tetanus Antitoxin For Prophylactic Use In Ethiopia: A Multicenter Retrospective Study (TAT-Safe)”. Conclusion: VINS Bioproducts Limited’s equine tetanus antitoxin (TAT) is safe and well tolerated in adult patients with tetanus-prone wounds for prophylactic use in Ethiopia.
Remarks of Evaluator	☐ Evidence of ICH/WHO/EMA guideline that single dose and repeat dose toxicity is not required for this product. ☐ Finished product specifications in the light of decision of 267th Registration Board meeting.
Decision of 339th 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 and the clarification as per the remarks of evaluator.	
Evaluation by BE&R:	

The Product was approved in 339th meeting with some conditions. The applicant has submitted repeat dose toxicity study and submitted waiver request for single dose toxicity as under; WAIVER REQUEST FOR SINGLE-DOSE TOXICITY STUDY Based on the results of the repeat dose toxicity studies, which demonstrated no significant adverse effects, we request a waiver for single-dose toxicity studies for Rabies Antiserum. (VINRAB) and Tetanus Antitoxin. The Rationale for Waiver: 1. Established safety profile: Repeat dose toxicity studies showed no adverse effects. 2. Low risk: Single-dose administration is expected to have an even lower risk. Conclusion: Given the absence of adverse effects in repeat-dose toxicity studies and the established safety profile, we believe that conducting single-dose toxicity studies would not provide significant new information. We request a waiver for single-dose toxicity studies for Equine Rabies and Tetanus Antitoxin.
Decision of 351st meeting: Keeping in view the data submitted by the applicant, Registration Board advised BE&R division to process registration of Tetanus Antitoxin 1500IU Ampoule in the light of 339th meeting of Registration Board.

Case#09: Imported human biological applied by M/s Immunowell (Pvt.) Ltd., Lahore discussed in 347th Meeting.

Following product of M/s Immunowell (Pvt.) Ltd., Lahore was discussed in 347th meeting of Registration Board, however, no decision was recorded in minutes of meeting:

Name, address of Applicant / Importer	M/s. Immunowell (Pvt) Ltd, No. 473, Street No. 7, Block J-2, Johar Town, Lahore, Pakistan
Details of Drug Sale License of importer	License No.05-352-0066-100098D Address: 473, Street No. 7, Block J-2, Johar Town, Lahore, Pakistan Validity:17-Nov-2027 Status: License to sell, stock & exhibit for sale, distributor registered products on behalf of licensed pharmaceuticals manufacturer as his authorized agent on the premises
Name and address of marketing authorization holder (abroad)	M/s. Immunowell (Pvt) Ltd, No. 473, Street No. 7, Block J- 2, Johar Town, Lahore, Pakistan
Name, address of manufacturer(s)	M/s. Harbin Pacific Biopharmaceutical Co., Ltd No.77, Siping Road, Limin Economic and Technological Development Zone, Heilongjiang Province, China.
Name of exporting country	China
Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	The Firm has submitted original, Legalized CoPP (No. Heilongjiang 20220023) issued on 21-06-2022, valid upto 20-06-2024, issued by Heilongjiang Medical Products Administration, China. Legalized GMP Inspection Report issued by Heilongjiang Medical Products Administration, China.
Details of letter of authorization / sole agency agreement	Firm has submitted product specific with brand name Globin Well I.V. inj letter of Authorization, from Harbin Pacific Biopharmaceutical Co., Ltd according to the letter, M/s. HarbinPacific Biopharmaceutical Co., Ltd appoints Immunowell (Pvt) Ltd with address 473, Street No. 7, Block J-2, Johar Town, Lahore, Pakistan. It's representative for sole purpose of registration of the said product.
Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)

Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
Dy. No. and date of submission	Dy. No. Dated: 02-Jan-2022
Details of fee submitted	Rs.150, 000/- slip No.029922813 dated: 29-12-2022
The proposed proprietary name / brand name	Globin Well I.V. inj.
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Human Immunoglobulin(pH4) for intravenous Injection(IVIG) IgG 2.5gm.
Dosage form of applied drug	Injection
Pharmacotherapeutic Group of (API)	Intravenous Immunoglobulin
Reference to Finished product specifications	USP Specifications
Proposed Pack size	2.5gm/50mL Vial
Proposed unit price	Rs. 38,398/Vial
Shelf Life	36 months
Storage Conditions	2°C - 8°C
The status in reference regulatory authorities	Gamimune 5% (Immune Globulin Intravenous) Approved by USFDA.
For generic drugs (me-too status)	I.V. Globulin SN Injection registered in Pakistan.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to introduction, nomenclature, structure, general properties, solubility, physical form, Manufacture: manufacturers, description of manufacturing process and controls, controls of materials, control of critical steps and intermediates, process validation and /or evaluation, manufacturing process development, Elucidation of structure and other characteristics, impurities, specifications, Analytical procedures and its validation, batch analysis, justification of specification , reference standard or materials,

		container closure system and stability studies of drug substance. The firm has summarized information of drug product including its Description and composition of the drug product, pharmaceutical development, manufacture, batch formula, description of manufacturing process and process control, control of critical steps and intermediates, process evaluation and/or evaluation, control of excipients, control of drug product, specifications, analytical procedures and its validation, batch analysis, characterization of impurities and justification of specification, reference standard, container closure system and stability studies of drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	M/s. Harbin Pacific Biopharmaceutical Co., Ltd No.77, Siping Road, Limin Economic and Technological Development Zone, Heilongjiang Province, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and process controls. control of materials, control of critical steps and intermediates, Process Validation and/or evaluation, manufacturing process development, characterization, impurities and Elucidation of structure and other characteristics, control of Drug Substance: 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)	Bulk solution of human immunoglobulin for intravenous injection is a transitional phase, so the stability studies are inapplicable.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, & composition of the drug product, pharmaceutical development, manufacturer, batch formula, description of manufacturing process and process control, control of critical steps and intermediates, process validation and/or evaluation, control of excipients, control of drug product: specifications, analytical procedures, validation of analytical procedures, batch analysis, characterization of impurities, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted analytical methods as per in House Specs. Validation of analytical procedures, process validation, batch analysis and stability studies have been performed.
	Container closure system of the drug product	Injection vial made of molecule middle borosilicate glass, halogenated butyl rubber stopper for injection (brominated) and aluminum-plastic combination cap.
	Stability study data of drug product, shelf life and storage conditions	The studies are performed according to the current ICH stability guidelines. The studies cover long term storage conditions (2°C - 8°C) for 36 months and accelerated storage conditions (25°C±2°C) 60%±5% RH for 6 months.

		Based on the results from the long term and accelerated stability studies, the proposed shelf life of 36 months at 2°C ± 8°C
	Module-IV	Not submitted
	Module-V	Not submitted
	Remarks	Firm has not provided stability studies of drug substance with this justification that drug substance stability data is not required in china. Firm has not provided safety and efficacy data with this justification that brands like Gamarrass, HL Globin and our product are being used in china from decades and their safety and efficacy is established for many decades. So Module IV and V are exempted.

Decision in 334th RB meeting:

Registration Board deferred the product for the following:

For submission of Stability studies data of drug substance/evidence of ICH guideline indicating no requirement of stability data for this substance.

For submission of safety and efficacy studies of applied formulation/ evidence of ICH guideline indicating no requirement of safety and efficacy data for applied formulation.

Response of firm:

1. Module IV and Module V have not been submitted.

Answer: As per “Form 5-F” and “Guidance document for submission of application on Form 5F(CTD) for registration of Pharmaceutical Drug for Human Use” Module IV and Module V are optional., please find attached the Page No.39 of same Guidance. As per these guidance:

Module 4: (Non-clinical/ Safety)

For all drug products which are approved in the same combination, strength and dosage form by reference regulatory authorities adapted by Registration Board, the submission of documents in module 4 is optional.

Module 5: (Clinical/ efficacy)

For all drug products which are approved in the same combination, strength and dosage form by reference regulatory authorities adapted by Registration Board, the submission of documents in module 5 is optional”.

Competitors of our product with same combination, strength and dosage form are already registered in all reference countries and with DRAP in many brands.

Therefore, on the basis of above explanations you are requested to include our Product Globin Well I.V. Inj. In upcoming Registration Board Meeting for the approval.

Decision in 336th RB meeting:

Registration Board after detailed deliberations deferred the product for submission of required data as per evaluator remarks.

Response of firm:

Firm has submitted following:

- 1) Globin well is registered and available in country of origin.
-) Registered in India from 01-07-2011 to 30-06-2014 as per copy of Registration certificate submitted by the firm.

Previous Decision of M-339: The Registration Board deliberated that the matter in detail and decided to ask the firm to submit the following:

- Safety and Efficacy data of the product. OR
- The guidelines from country of origin on the basis of which the product was approved.
- Periodic Safety Update Report (PSUR) of last 5 years from countries where product has valid market authorization

Remarks of the Evaluator

Board Decision	Applicant Response
Safety and Efficacy data of the product.	-
The guidelines from country of origin on the basis of which the product was approved	SFDA regulations “ Regulations for the Implementation of the Drug Administration Law in China”
Periodic Safety Update Report (PSUR) of last 5 years from countries where product has valid market authorization	Periodic Safety Update Report (PSUR) of year 2015-2019.

Comments of BE&R Division in 347th Meeting:

Not recommended, as the PSUR covers the period from 2015 to 2019 and does not reflect the most recent five-year data. Furthermore, there is no supporting reference to regulatory guidelines from the NMPA (formerly SFDA) that exempt immunoglobulins from the requirement for non-clinical and clinical data/Biosimilarity Studies.

Remarks:

The firm has now vide tracking ID: W7E-MBX-UW23 submitted copy of registration certificate of a product issued by Hong Kong claiming that this product is also registered in Hong Kong. While in letter manufacturer is not mentioned.

Decision:

Registration Board provided one last chance to the firm to submit following documents:

- Safety and Efficacy data of the product.

OR

- The guidelines from country of origin on the basis of which the product was approved without Safety & Efficacy data along with Periodic Safety Update Report (PSUR) of last 5 years from countries where product has valid market authorization.

Case#10: Imported human biological applied by M/s Ghazi Brothers, Karachi deferred in 343rd Meeting.

Following product of M/s Ghazi Brother, Karachi was deferred in 343rd meeting as per following details:

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 ($\leq -70^{\circ}\text{C}$). The accelerated stability study of drug substance (3 lots) is completed up to 6 months under the influence of temperature ($5 \pm 3^{\circ}\text{C}$). 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 $5^{\circ}\text{C} \pm 3^{\circ}\text{C}$ (24 months submitted), • Accelerated Stability study for 6 months at $25 \pm 2^{\circ}\text{C}/\text{RH } 60 \pm 5\%$ • After Reconstitution for 24 hours at $5 \pm 3^{\circ}\text{C}$.

	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. <table><tr><th>Clinical Study</th><th>Study #No.</th><th>Reference</th><th>Purpose</th><th>Study design and control</th><th>Study drug, Dosage, Administration route</th><th>Number of Subject (Safety set)</th><th>Subject</th><th>Tr du</th></tr><tr><td rowspan="2">Safety and Efficacy</td><td rowspan="2">HU-014_P1/2</td><td rowspan="2">Section 5.3.5.1 5.3.5.2</td><td rowspan="2">Evaluation of Safety and Efficacy</td><td>A Single center, single arm</td><td rowspan="2">4 U/0.1 mL was injected intramuscularly (IM) into each of 5 sites for a total dose of 20 U/0.5 mL</td><td>Phase I: 12 subjects (Test group)</td><td rowspan="2">Subject with moderate to severe glabellar lines</td><td>P s admi and fol</td></tr><tr><td>A Single center, randomized, double-blind, active control</td><td>Phase II 54 subjects (Test group; 27, Control group; 27)</td><td>Pl s admi and fol</td></tr><tr><td>Safety and Efficacy</td><td>HU-014_P3</td><td>Section 5.3.5.1</td><td>Evaluation of Efficacy and Safety</td><td>Multi-center, randomized, double-blind, active control</td><td>4 U/0.1 mL was injected intramuscularly (IM) into each of 5 sites for a total dose of 20 U/0.5 mL</td><td>267 Subjects (Test group; 135, Control group; 132)</td><td>Subject with moderate to severe glabellar lines</td><td>s admi and fol</td></tr></table>	Clinical Study	Study #No.	Reference	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
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		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: <table border="1"> <thead> <tr> <th>Sr. No.</th><th>Shortcoming</th><th>Reply</th></tr> </thead> <tbody> <tr> <td>1</td><td>DSL is expired. Provide copy of valid DSL.</td><td>The DSL was valid at the time of dossier submission; however, we are now providing the updated valid DSL (Copy enclosed herewith)</td></tr> <tr> <td>2</td><td>Long term stability data of API is till 24 months while the product shelf life is 36 months.</td><td>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.</td></tr> <tr> <td>3</td><td>Compatibility studies with container closure systems is not provided.</td><td>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.</td></tr> <tr> <td>4</td><td>Detail of Reference standard or material under Module 2.3.P.6 is not provided.</td><td>Detail of reference standard for finished good is provided in 2.3. P.6.</td></tr> <tr> <td>5</td><td>Certificate of Reference standard under module 3 2.S.5.2 is not attached in the dossier.</td><td>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.</td></tr> </tbody> </table>	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.
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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 “ <i>manufacturer reference preparation: [please take four lines from monograph]</i> ”	
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: " <i>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</i> " 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” “ <i>TSE Control of raw materials used by Huons BioPharma complies with European Directorate for the Quality of Medicines (EDQM) regulations.</i>	
11	TSE, BSE free certificates for yeast extract, dextrose and casein used in API 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 6 th 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 ($\leq -70^{\circ}\text{C}$). 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 ($5 \pm 3^{\circ}\text{C}$). 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 ($2 - 8^{\circ}\text{C}$)

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 ($25 \pm 2^{\circ}\text{C}$, RH (60 $\pm$ 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 ($2 - 8^{\circ}\text{C}$) 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(I)12024 for extension of shelf life from 24 months to 36 months.

Response:

The firm submitted that their product is Clostridium Botulinum Toxin A (Onabotulinum Toxin A)

The said formulation is registered in USFDA with following two names having same formulation but different indications:

1. Botox
2. Botox Cosmetic

Indications of Botox as per USFDA:

BOTOX is a prescription medicine that is injected into muscles and used:

- to treat overactive bladder symptoms such as a strong need to urinate with leaking or wetting accidents (urge urinary incontinence), a strong need to urinate right away (urgency) and urinating often (frequency) in adults when another type of medicine (anticholinergic) does not work well enough or cannot be taken.
- to treat leakage of urine (incontinence) in adults with overactive bladder due to neurologic disease when another type of medicine (anticholinergic) does not work well enough or cannot be taken.
- to treat overactive bladder due to a neurologic disease in children 5 years of age and older when another type of medicine (anticholinergic) does not work well enough or cannot be taken.
- to prevent headaches in adults with chronic migraine who have 15 or more days each month with headache lasting 4 or more hours each day.
- to treat increased muscle stiffness in people 2 years of age and older with spasticity.
- to treat the abnormal head position and neck pain that happens with cervical dystonia (CD) in adults.
- to treat certain types of eye muscle problems (strabismus) or abnormal spasm of the eyelids (blepharospasm) in people 12 years of age and older.

BOTOX is also injected into the skin to treat the symptoms of severe underarm sweating (severe primary axillary hyperhidrosis) when medicines used on the skin (topical) do not work well enough.

Indications of Botox Cosmetic as per USFDA:

BOTOX Cosmetic is a prescription medicine for adults that is injected into muscles and used for a short period of time (temporary) to improve the look of:

- moderate to severe frown lines between the eyebrows (glabellar lines)
- moderate to severe crow's feet lines
- moderate to severe forehead lines
- moderate to severe vertical bands connecting the jaw and neck (platysma bands)

You may receive treatment for frown lines, crow's feet lines, forehead lines, and vertical bands connecting the jaw and neck at the same time.

The firm is requesting Botox Cosmetics indications for its product.

Decision:

Registration Board referred the case to DRAP Authority for guidance on processing of registration of products like Botox like having Clostridium Botulinum Toxin A as active ingredient.

Case#11: Imported Veterinary Biological Products Applied By M/S Ghazi Brother Karachi which are not Available in Exporting Country.

The following products of M/s Ghazi Brother Karachi were deferred in different meetings of Registration Board as per following details:

S r. #	Product License Holder/ Manufacturer	Brand Name & Composition	Documents details	Decision of RB
1.	M/s IZO S.P.A Via A. Binachi Italy	IZOVAC ND-FLU (Emulsified Inactivated Vaccine against Newcastle Disease and Avian influenza A) Each dose of 0.5 ml of vaccine contains: Inactivated Newcastle Disease Virus.....50 PD50 Inactivated whole avian influenza virus antigen f H5-N9 subtype strain A/ck/It/22A/98: HI.=6 Log2 in oil Emulsion	Form-5A Dy. No. 248 (R&I) 18-08-2009 Rs. 15000/- 15-07-2008 + Rs. 35000/- 19-03-2015 Legalized CoPP dated 08-1-2007 50 dose bottle (250ml)/	<i>Registration Board deferred the case till the finalization of Policy by DRAP Authority.</i> (M-293)
2.	License Holder: M/s. IZO S.r.l a socio unico, Via San Zeno 99/A-25124, Brescia, Italy. Manufacturer: M/s. IZO S.r.l a socio unico, Via S.S.234 Km 28,2-27013 Chignolo Po (PV), Italy.	Izovac Aviflu 9 Emulsified inactivated vaccine Each dose of 0.5ml of vaccine contains: - Inactivated Avian Influenza A, strain H9N2.....320U. HA Multi-dose Freeze-Dried Bottle	CoPP No.50/2017/ NC dated 24/04/2017 GMP No. NBF/54/2011/V dated 20/12/2011	

3.	M/s Ghazi Brothers Karachi. M/s IZO S.P.A Via A. Binachi Italy	Izovac CHB Freeze-dried live vaccine Each dose of vaccine contains:- Live attenuated Newcastle Disease Virus Strain Clone.....10⁶ EID₅₀ Live Attenuated Infectious Bronchitis Strain Massachusetts H120.....10³EID₅₀ Live Attenuated Infectious Bronchitis Strain 28/86.....10³EID₅₀ (Immunological) Shelf Life 24 months	Form-5A Dy. No.937 19/07/2012 Deposited fee 15000 dated 10/07/2012 Balance Fee 35000 Pack size: 1000 & 2500 doses Price: Decontrolled	Registration Board deferred the case and advised the firm to provide the evidence of registration, if above product manufactured in the applied facility is approved by any of the regulatory authorities from USFDA, EMA, PMDA Japan, Australia TGA, Health Canada, Switzerland or any of regulatory authority of former erstwhile Western Europe (United Kingdom, Germany, France, Switzerland, Netherlands, Austria, Belgium, Denmark, Finland, Sweden, Italy, Ireland, Luxemburg, Norway, Scotland and Spain) or three stringent regulatory bodies of former erstwhile Eastern Europe. (M-270)

The firm now vide tracking ID: 7JJ-ZSR-P453 submitted different references of registered products having same combinations and also submitted different research papers for need of such combinations. Firm has also submitted reference of one product **Gallimune H9+ND Injectable approved in 334th meeting which was approved without Free Sale Certificate.**

The firm requested to grant them approval of above product in light of above please.

Decision:

Registration Board decided as follows:

- For product at sr. no. 1, Registration Board deferred the product for submission of following by the firm:
 - i. Valid legalized CoPP/ FSC indicating valid justification of non-availability of product in country of origin.
 - ii. Immunological relevance & need of H5N9 vaccine for Pakistan and recommendation of Sub-Committee on Veterinary Drugs on provided data.
- For product at sr. no. 2, Registration Board deferred the product for submission of following by the firm:
 - i. Valid legalized CoPP/ FSC indicating valid justification of non-availability of product in country of origin.
 - ii. Evidence of registration & availability of any other Avian Influenza vaccine in Italy manufactured by this manufacturer.
- For product at sr. no. 3, Registration Board deferred the product for submission of following by the firm:
 - i. Valid legalized CoPP/ FSC indicating valid justification of non-availability of product in country of origin.
 - ii. Elaboration & Immunological relevance of strain of Newcastle Disease virus used in vaccine.

Case#12: Imported human Biologicals applied by M/s Inouku Animal Health (Pvt.) Ltd., Lahore approved in 344th meeting.

Following product of M/s Inouko Animal Health Pvt. Limited, Lahore was approved in 330th meeting of Registration Board as per following details:

Sr. No.	Name of MAH & Manufacturer	Brand Name & Composition	Decision of RB
1.	M/s Ceva Animal Health Inc. 131 Malcolm Road, Guelph, Ontario, Canada N1K1A8	Immucox ® 5 Eimeria Acervulina-Brunetti-Maxima-Necatrix –Tenella Vaccine, Live oocysts Each dose of vaccine contains: Eimeria acervulina.....at least 151 oocysts Eimeria brunetti.....at least 40 oocysts Eimeria maxima.....at least 50 oocysts Eimeria necatrix.....at least 51 oocysts Eimeria tenella.....at least 25 oocysts Innovator's Specifications	<i>Keeping in view legalized FSC indicating product availability in the country of origin, Registration Board approved the product subject to compliance to current import policy for finished drugs. The firm shall submit fee of 7500/- for correction/pre-approval change in Form-5A as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.</i> (Pages-117-118/corr.)

Later on, M/s Vigilant Pharma filed a complaint that the instant product is already registered in their name. The case was discussed in different meetings of Registration Board and in 344th meeting, following was decided:

"Keeping in view the email received from Lucas Figueiredo, Campus Director & Kelly Groskopf, Regulatory Affairs Specialist, Ceva Animal Health – Canada, the Board decided to regret the complaint lodged by M/s. Vigilant Veterinary Services (Pvt) Limited, Lahore, with the following directions;

- i. *The Board directed the Division of Biological Evaluation & Research to issue registration letter of Immucox-5 Vaccine already approved in 331st meeting of the Board in the name of M/s Inouko Animal Health (Private) Limited, Lahore.*
- ii. *The Board further directed the Division of Biological Evaluation & Research to issue show-cause notice and letter of personal hearing to M/s. Vigilant Veterinary Services (Pvt) Limited, Lahore as to why the registration of their product Immucox Vaccine (Reg. No. 015484) may not be cancelled?"*

Accordingly, registration letter was processed for issuance and it was advised by Chairman Registration Board to get updated LOA from M/s Inouko Animal Health and firm was advised to submit the same vide E-App External Communication tracking ID: MS8-8RL-LJ5W. The firm has not yet submitted any response.

Moreover, a show cause letter was issued to M/s Vigilant Veterinary Services (Pvt.) Limited, Lahore in response of which the firm submitted that the emails referred in notice were never shared to them by DRAP or Ceva Animal Health.

They asserted that it is their legal right to be furnished with aforesaid email, in order to effectively defend their rights and interests.

The firm further submitted that in absence of provision of the complete evidence upon which show cause notice is founded, the issuance of such notice is in contravention of principles of natural justice, due process, and the protection guaranteed under Articles 4 and 10A of Constitution.

The firm requested to withdraw show cause notice and prayed to provide them complete and original contents of the emails.

In light of above, a personal hearing letter was issued to the firm on 29th August to attend the meeting on 10th September. Later on, as the meeting was rescheduled, hence, another letter was issued on 17th September, 2025 to attend the meeting on 24th September. The copy of letter was also communicated to the firm through official E-App External Communication vide tracking ID: LM4-VJV-VU2M.

M/s Vigilant Services vide its letter dated 18-09-2025 authorized their counsel, Ms. Iram Iqbal Khan, Advocate High Court to represent them in proceeding before the Board. Ms. Iram Iqbal vide her letter dated 18-09-2025 requested to adjourn the hearing due to her professional engagement before the Honourable Lahore High Court. She further submitted that despite two prior letters for disclosure of the relevant e-mail correspondence, the same has not been furnished to date.

Decision:

Registration Board decided as follows:

- i. **M/s Inouku Animal Health shall be directed to provide the original valid Letter of Authorization from Product License Holder in its favor.**
- ii. **The request of M/s Vigilant Services for adjournment is acceded to till next meeting of Registration Board.**

The request of M/s Vigilant Services for provision of original contents of emails discussed in 344th meeting, is not acceded to as the complete contents of the emails are already included in 344th meeting of Registration Board and minutes of the said meeting are publically available at official website of DRAP @ <https://www.dra.gov.pk>.



Drug Regulatory Authority of Pakistan

(Biological Evaluation & Research Division)



Sr. No	Title	Description
1	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Hilton Pharma (Pvt.) Limited Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area Karachi, Pakistan (0647.)
	Application Form Dy. No / Tracking ID & date of submission	(TLS-MSX-P6ZJ, 2025-07-11)
	Detail of Fee Submitted	300000.0, 2025-07-09,
	The proposed proprietary name / brand name	Medivac IB Variant Freeze Dried vaccine for poultry
	Label Claim	Each dose contains: Infectious Bronchitis virus, M02 strain (M02 strain identical to Genotype GI-13 or 793B group).....at least $10^{3.5}$ EID ₅₀
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	2000 doses-De-Controlled
	Shelf Life (Unit)	24 Month(s) Vaccine is stored on temperature of 2 – 8°C, include temperature on its distribution. Vaccine is protected from heat and direct sunlight.
	For generic drugs (me-too Status)	Medivac IB Variant Vaccine (1000 doses) Reg No. 126158 by Hilton Pharma (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	PT MEDION FARMA JAYA-Jl. Raya Batujajar No 29, Cimareme, Ngamprah, Bandung Barat-Indonesia
	Name, address of Marketing Authorization Holder:	PT Medion Farma Jaya, Jl. Babakan Ciparay No. 282, Babakan Ciparay, Bandung,, Indonesia
	Details of Certificates (CoPP/FSC/cGMP):	Copy of Apostille CoPP No. 02D34/PI. 500/F/05/2025
	Details of Authorization Letter :	Copy of Apostille Agreement dated 01-02-2005 having updated list of products of 2024.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: 28A007, 28A008, 28A009 Storage Conditions: 2-8 Degree Celcius Frequency: 0, 3, 6, 9, 12, 18, 24, 27
Evaluation Remarks		
Decision		
Deferred		
Registration Board deferred the case for submission of following by the firm:		
Immunological relevance & need for Pakistan. Minutes of 351st Meeting of Registration Board (23rd – 24th September, 2025)		

- Recommendations of Sub-Committee on Veterinary Drugs on Immunological relevance & need submitted by the firm.

2

Case Category	Routine (M. Zubair Masood)
Name, address of Applicant.	Hilton Pharma (Pvt.) Limited Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area Karachi, Pakistan (0647.)
Application Form Dy. No / Tracking ID & date of submission	(NLN-DA8-XHP2, 2025-07-16)
Detail of Fee Submitted	300000.0, 2025-07-11,
The proposed proprietary name / brand name	Medivac ND La Sota Freeze dried live vaccine for Poultry
Label Claim	Each dose contains: Newcastle Disease (ND) Virus of La Sota strain.....at least 10^7 EID50
Reference to Finished product specifications	Manufacturer Specification
Proposed Pack Size	5000 doses-De-Controlled
Shelf Life (Unit)	24 Month(s)Vaccine is stored on temperature of 2 – 8°C and do not freeze, include temperature on its distribution. Vaccine is protected from heat and direct sunlight.
For generic drugs (me-too Status)	Medivac ND La Sota Vaccine Reg No. 033210 Manufactured by Hilton Pharma (Pvt) Ltd
Pharmacotherapeutic Group of (API)	Veterinary Vaccine
Name, address of Manufacturing site:	PT MEDION FARMA JAYA-Office Address: Jl. Babakan Ciparay No. 282, Babakan Ciparay, Bandung – Indonesia Plant Address: Jl. Raya Batujajar No 29, Cimareme, Ngamprah, Bandung Barat – Indonesia.- Indonesia
Name, address of Marketing Authorization Holder:	Hilton Pharma (Pvt.) Ltd, Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area, Karachi, Pakistan., Pakistan
Details of Certificates (CoPP/FSC/cGMP):	Copy of Apostille CoPP No. 2000g/PI. 500/F/02/2025 dated 20-02-2025.
Details of Authorization Letter :	Copy of Apostille Agreement dated 01-02-2005 having updated list of products of 2024.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: 18H072, 18H073, 18H074, Size: 6187, 6220, 6192 Storage Conditions: 2-8 Degree Celsius Frequency: 0, 3, 6, 9, 12, 18, 24, 27
Evaluation Remarks	
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Decision	
Approved	
Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
Case Category	Routine (M. Zubair Masood)
Name, address of Applicant.	Immuno Well (Pvt) Ltd House No. 473, Street No.7, Block J-2, Johar Town, Lahore (05-352-0066)
Application Form Dy. No / Tracking ID & date of submission	(LRS-TBA-A741, 2024-09-20)
Detail of Fee Submitted	300000.0, 7500.0 2024-07-24, 2025-06-20

The proposed proprietary name / brand name	FluLing Quad Influenza Vaccine (Split Virion), Inactivated, Quadrivalent; Injection
Label Claim	Each dose (0.5ml) contains: Hemagglutinin of each type of virus strains as recommended by WHO.....15mcg
Reference to Finished product specifications	Manufacturer Specification
Proposed Pack Size	1's-As per SRO
Shelf Life (Unit)	12 Month(s)2-8C
For generic drugs (me-too Status)	Influvac Tetra of M/s Abbott Laboratories
Pharmacotherapeutic Group of (API)	Inactivated Human Influenza Vaccine
Name, address of Manufacturing site:	Shanghai Institute of Biological Products Co., Ltd- 758,Guangfeng Road, Fengxian, District Shanghai-China
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
Name, address of Marketing Authorization Holder:	Shanghai Institute of Biological Products Co., Ltd, 758,Guangfeng Road, Fengxian, District Shanghai, China
Details of Certificates (CoPP/FSC/cGMP):	Copy of Apostille Copp No. Shanghai20250094 dated 12-03-2025.
Details of Authorization Letter :	Copy of Apostille Letter of Authorization dated 29-06- 2020.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: SFB202101, SFB202102, SFB202103, SFC202103, SFC202104, SFC202104, SFV202109, SFV202110, SFV202111, SFL202102, SFL202103, SFL202104 Conditions: Accelerated 25°C ± 2°C/relative humidity 60 ± 5%, Real time: 2-8 °C Frequency: Accelerated 0, 1, 2, 3, 6. Real Time: 0, 1, 2, 3, 6, 9, 12, 15 months
The status in reference regulatory authorities	Influvac Tetra
Evaluation Remarks	
Registration Board in its 348th meeting decided as follows:The Registration Board deferred the case to update the strains as per WHO recommendation for 2025-2026 northern hemisphere influenza vaccines and submit updated Module 3 with submission of requisite fee.Response:The firm submit an undertaking that they will inform well in time to DRAP about the change in strains of Influenza vaccines under the WHO guidelines every year before the start of production and flu season.	
Decision	
Not Applicable	
Keeping in view COPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. The Reg. Letter shall be issued with condition that strains shall be updated every year as per WHO recommendations for Northern Hemisphere.	
Case Category	Routine (M. Zubair Masood)
Name, address of Applicant.	Hilton Pharma (Pvt.) Limited Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area Karachi, Pakistan (0647.)
Application Form Dy. No / Tracking ID & date of submission	(84S-SY5-VSXJ, 2025-07-08)
Detail of Fee Submitted	300000.0, 9400 2025-06-03, 2025-09-12

The proposed proprietary name / brand name	Medivac Gumboro A (2000 doses) (Freeze dried live vaccine for Poultry)
Label Claim	Each dose contains: Infectious Bursal Disease (IBD) Virus, Winterfield 2512 strain.....at least 10 ^{2.0} EID50
Reference to Finished product specifications	European Pharmacopeia
Proposed Pack Size	2000 doses-De-Controlled
Shelf Life (Unit)	24 Month(s)Vaccine is stored on temperature of 2 – 8°C, include temperature on its distribution. Vaccine is protected from heat and direct sunlight.
For generic drugs (me-too Status)	Hilton Pharma Reg No. 126134 by Hilton Pharma (Pvt) Ltd
Pharmacotherapeutic Group of (API)	Live Veterinary Vaccine
Name, address of Manufacturing site:	PT Medion Farma Jaya-Jl. Raya Batujajar No 29, Cimareme, Ngamprah, Bandung Barat-Indonesia
Name, address of Marketing Authorization Holder:	PT Medion Farma Jaya, Jl. Babakan Ciparay No. 282, Babakan Ciparay, Bandung, Indonesia
Details of Certificates (CoPP/FSC/cGMP):	Apostille CoPP No. 10032/PI.500/F/01/2024 dated 10-01-2024.
Details of Authorization Letter :	Copy of Apostille Agreement dated 01-02-2005 with updated product list of 2024.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: 18F073, 18F074, 18F075 Storage Conditions: 2-8 Degree Celsius Batch Size:8373 Vials, 8538 Vials,8465 Vials.
Evaluation Remarks	
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Decision	
Approved	
Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
5 Case Category	Routine (M. Zubair Masood)
Name, address of Applicant.	PACIFICA RESEARCH LABORATORIES (PVT.) LTD., Sumya Garden, Plot No.28, Flat No. G-2, Ground Floor, Memon Co-Operative Housing Society, Ltd. Karachi. (0466)
Application Form Dy. No / Tracking ID & date of submission	(BNU-PU2-M44R, 2025-05-27)
Detail of Fee Submitted	300000.0, 2024-12-10,
The proposed proprietary name / brand name	VICENTIS 2.3mg/0.23ml Sterile Solution for Injection
Label Claim	Each vial (0.23ml) contains: Ranibizumab.....23mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's Vial-As per SRO
Shelf Life (Unit)	36 Month(s)2-8 degree centigrade
For generic drugs (me-too Status)	PATIZRA by Novartis - Pakistan
Pharmacotherapeutic Group of (API)	Monoclonal Antibody
Name, address of Manufacturing site:	Pooyesh Darou Co. (Pooyesh Darou Biopharmaceutical-Fanavari 18 St., Pardis Technology Park, Abali Highway 15 km Road, Tehran-Iran

Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
Name, address of Marketing Authorization Holder:	ARAcell Zist Darou, No. 34, West Saeb Tabrizi Street, Sheikh Bahaei Street, Mollasadra Street, Tehran, Iran
Details of Certificates (CoPP/FSC/cGMP):	Copy of CoPP No. 665/50754 dated 14-08-2024.
Details of Authorization Letter :	Copy of commercial agreement dated 12-11-2024.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	B-96-Fab-01, B-96-Fab-01, B-96-Fab-01 900 Vials, 1000 Vials, 1000 Vials Real time at -20C, Accelerated not provided
The status in reference regulatory authorities	LUCENTIS by Genentech Inc. - USA
Evaluation Remarks	
Summary of Biosimilarity data provided by firm is as under:	
Quality Comparison	Primary Structure: · Amino acid sequence by LC-MS peptide mapping · C-terminal sequencing by LC-MS/MS · Molecular mass (Da) by LC-MS Intact-protein · Molecular mass (Da) by LC-MS subunits Higher order structure · Secondary structure by Far UV-CD · Tertiary structure by Near UV-CD · Tertiary structure by DSC · Tertiary structure by FTIR · Di-sulfide bond formation by Fluorometric Thiol Purity/impurity · Isoforms by cIEF · HMWs and fragments by SE-HPLC · HMWs by Analytical Ultra Centrifugation · HMWs and fragments by CGE · Oxidation by RP-HPLC · Deamidation by IEX-HPLC · Modification by LC-MS Intact-protein & LC-MS subunits · Sub vis particles by NTA, MFI, RMM, Light Obscuration
Potency & Binding	· Association, binding and active concentration by Surface plasmon resonance (Biacore) · Potency by Gene Reporter Assay
Non-Clinical	A Pharmacokinetics Study of Two Formulations of Ranibizumab following a Single Bilateral Intravitreal Injection in the New Zealand White Rabbit to check · Compound related clinical signs · Changes in the body weights, Appetite or electroretinograms. · Systemic exposure (Cmax and AUC(0-t)) in serum and local exposure in ocular tissues · Microscopic changes of the right eye of animals
Clinical	A Phase 3, randomized, double-arm, double-blind (for both patients and assessors), active-controlled, non-inferiority clinical trial evaluating the efficacy and safety of Ranibizumab (Vicentis® AraCell Biopharma) compared to Ranibizumab (Lucentis®) in the treatment of patients with diabetic macular edema
The firm has not submitted Repeat Dose toxicity studies as required by WHO Guidelines as part of Non-clinical comparative studies.	
Decision	
Approved	
Keeping in view COPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs subject to submission of Repeat dose toxicity as per WHO Guidelines for similar Biotherapeutic products.	
6	Case Category
	Routine (M. Zubair Masood)
	Name, address of Applicant.
	BF Biosciences Limited 5-KM Sundar Raiwind Road, Raiwind, Lahore (000655)
	Application Form Dy. No / Tracking ID & date of submission
	(Z8S-DDL-YPGM, 2025-07-25)
	Detail of Fee Submitted
	75000.0, 2025-07-03,
	The proposed proprietary name / brand name
	Zeptide 10mg/0.5ml Solution for Injection in PFS

Label Claim	Each PFS (0.5ml) Contains: Tirzepatide.....10mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's & 4's -As per SRO
Shelf Life (Unit)	24 Month(s)Store between 2°C to 8°C
For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	GLP-I and GIP dual receptor agonist
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Sinopep-Allsino Biopharmaceutical Co., Ltd. (No. 28, Linpu Road, Economic & Technological Development Zone, Lianyungang, Jiangsu, 222000, China)
Detail of stability batches of drug product	Batches: 073D02, 073D03, 073D04 Size: 300 PFS Each Condition: Real Time 2-8C, Accelerated 25C
Documents for the procurement of API with approval from DRAP (in case of Import)	License No. DIL-C-81A64D dated 01-08-2024.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Batches: AT002230601, AT002230600, AT002230703 Size: 1000g each Conditions: -20C Realtime & 2-8 Accelerated
The status in reference regulatory authorities	MOUNJARO Injection of Eli Lilly and Company, Australia Approved By TGA Australia
GMP status of the firm	GMP Certificate dated 01-03-2024.
Evidence of approval of manufacturing facility	Copy of Section Approval letter dated 07-05-2024 issued by CLB

Evaluation Remarks

The product was deferred in 350th meeting. The queries as response is as under:

Sr. No.	Query	Response
1.	GMP certificate/DML mentioning Tirzepatide in its scope of inspection by authorized licensing authority	Copy of written confirmation for active substances exported to EU inspection dated 18th to 20th Feb, 2025.
2.	Section 3.2.S.2 (manufacturing process) is required.	Submitted.
3.	Determination of Enantiomeric purity on drug substance by GC-MS	Studies performed by a third party M/s Shanghai Milestone Pharma Co. Ltd., China.
4.	Inclusion and performance of following tests in drug substance specifications: a. Identity by peptide mapping, b. bio identity (Cell based bioassay GIP, GLP-1) c. residual solvents.	1. Identity by peptide mapping is done by a third party i.e. Ahanghai Applied Protein Technology Co., Ltd., China. 2. Bio identity (Cell based bioassay GIP, GLP-1) performed by DS manufacturer. 3. Residual Sovents are included in Specifications. However, data of performance is not submitted.
5.	Provide assay limit on as is basis which should be between 79.5% to 100% and peptide content should not be less than 94%. and oligomers 0.8%.	The firm has set Peptide content limit on as –is basis as NLT 80% and on anhydrous basis as 95%-105%. The oligomer limit is set as NMT 1.0%.
6.	Provide justifications of specification 6. Stress studies not performed on drug substance.	The firm submitted justification that specifications are based on general

		chapters of pharmacopoeia, ICH guidelines & development studies.
7.	Stability data of drug substance of 12 month is submitted, stability data till claimed shelf is required along with justification for not performing all tests as mentioned in section 3.2.S.4.1. Provide justification where NA	The firm has submitted 03 batches real time stability data at -20C for 24 months and accelerated stability data at 5±3C for 06 months including all tests mentioned section 3.2.S.4.1.
8.	Stress studies not performed on drug substance.	The firm has submitted stress study data of one batch of DS on 25C for 30 days, 40C for 30 days, 1.2*106Lux.hr for 10 days, 75RH/25C for 30 days.
9.	Identification tests like peptide mapping, osmolality, HMWP, dose accuracy are not performed on drug product at release. Inclusion and performance of HMWP, Purity, clarity and container closure integrity at next stability time point is required.	1. Test for peptide mapping has been included in Release specifications and will be performed at each stability time point 2- Osmolality is not a stability indicating parameter as the finished product contains same excipients (quantitatively) as that of innovator; so it is not required at every testing interval. 3- High Molecular Weight Species (HMWS) i.e “Oligomer” has not been performed as release parameter however we will include it at next stability time point. 4- Dose accuracy (i.e. extractable volume) is a part of our release parameter and container closure system is impermeable, therefore, extractable volume test is not required as a stability parameter. 5- Container closure integrity is part of release parameter and is performed at the end of stability studies i-e (6 month accelerated) and (24 months Real time stability studies) 6- Purity i.e. related substances has already been performed at each stability testing point. 7- Clarity i.e. (appearance of solution) has already been performed at each stability testing point.
10.	In comparibility report peptide mapping has performed by RP-HPLC and not MS. Clarification is required how analysis has been performed without MS with complete validation report.	Peptide Mapping by LC-MS has being performed on Finished product in comparison with RLD from Harvard Medical School, Taplin Mass Spectrometry Facility, 240 Longwood Ave. Boston, MA 02115
11.	Identification and quantification of product related impurities as per section 3.2.S.3 is required in COA/batch analysis and stability analysis.	Already are part of COA and stability data.
12.	Syringe Functionality Test to be performed by Finished product manufacturer. 12. Container closure integrity, break loose and glide force, and autoinjector testing during stability studies to be included in stability studies.	Provided. However, dose accuracy test is not performed.
13.	Audit trail of all batches from initial to 6 months' analysis is required.	Audit trail of all three batches along with audit trail of impurities is submitted.
14.	Identify the impurities with respect to RT and specify their names in specification of drug product 3.2.P.5.1 as per impurities characterization.	Firm has submitted impurities as part of specifications including names and relative retention time.

15.	Provide justification of finished product specifications.	The firm submitted justification that specifications are developed in-house based on general chapters of pharmacopoeia, ICH guidelines & development studies.
16.	Raw data sheets and chromatograms for impurities with impurity profiling from initial to 6 month analysis is required.	Submitted, but the submitted data is not of stability study batches provided with initial dossier as testing dates are different.
17.	Complete data logger data of 6 months.	Data Submitted is of Dec 2024, March & June, 2025.
18.	Clarification is required for walk in stability room for real time condition along with thermal mapping data	Submitted.

The enantiomeric Impurities are performed on UHPLC-HRMS instead of GCMS. The firm submitted the following justification: Both UHPLC-HRMS and GC-MS are used for measuring peptide enantiomers. UHPLC-HRMS (Ultra High Performance Liquid Chromatography coupled with High-Resolution Mass Spectrometry) provides high sensitivity, resolution, and accuracy for determination of enantiomers as compared to GC-MS. Due to nonvolatile and thermally labile nature, analysis by UHPLCHRMS (Ultra High-Performance Liquid Chromatography coupled with High-Resolution Mass Spectrometry) is more suitable as compared with GC-MS.

Decision

Approved

Approved as per innovator's specifications with following conditions:

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.
2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA&LT.
3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.
4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.
5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022. 6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

7	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	2 World Traders Pakistan Office 55/2, Main Khayaban-e-Hafiz DHA Karachi. (634)
	Application Form Dy. No / Tracking ID & date of submission	(JYX-P9P-3NR3, 2025-06-17)
	Detail of Fee Submitted	300000.0, 2025-06-04,
	The proposed proprietary name / brand name	TeTOX

Label Claim	Each dose of 0.5 mL contains: Tetanus Toxoid Adsorbed ≥ 40 IU Active ingredient: Tetanus toxoid. Excipients: Aluminum hydroxide adjuvant. Known residue: formaldehyde.
Reference to Finished product specifications	Any Other
Proposed Pack Size	10x0.5mL-As per SRO
Shelf Life (Unit)	42 Months
For generic drugs (me-too Status)	Yes
Pharmaceutical Group of (API)	
Name, address of Manufacturing site:	Wuhan Institute of Biological Products Co LTD-No.1 Huangjin Industrial Park Road, Zhengdian, Jiangxia District, Wuhan, Hubei, China Postal Code 430207 Tel 027-88913353 Website: www.wibp.com.cn-China
Pharmaceutical Equivalence and Comparative Dissolution Profile	
Name, address of Marketing Authorization Holder:	2 World Traders Pakistan, 55/2 Main Khayaban E Hafiz Phase-V, DHA Karachi Pakistan., Pakistan
Details of Certificates (CoPP/FSC/cGMP):	
Details of Authorization Letter :	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
The status in reference regulatory authorities	None

Evaluation Remarks

The firm has not provided data of Phase-I, II & III clinical studies and submitted the following justification: "Due to the extended timeline from development to initial market launch of the tetanus vaccine (which first became commercially available in China around the 1950s to 1960s), early clinical data is missing, and Phase IV clinical trials were subsequently conducted." Moreover, the firm has requested for 42 months shelf life while in RRAs, the shelf life of applied formulation is 36 months.

Decision

Deferred

Registration Board deferred the case for submission of following by the firm:

Safety and Efficacy data of applied product

OR

Reference of guidelines from country of origin indicating that safety and efficacy data is not required for registration of Tetanus Toxoid vaccine.

8

Case Category	Routine (M. Zubair Masood)
Name, address of Applicant.	Amson Vaccines & Pharma (Pvt.) Ltd 115, Industrial Triangle Kahuta Road (DHO-ISB-135)
Application Form Dy. No / Tracking ID & date of submission	(G44-QU4-1B4T, 2024-05-13)
Detail of Fee Submitted	300000.0, 9400.0 2024-02-20, 2025-09-05
The proposed proprietary name / brand name	GC FLU Quadrivalent Injection in Pre-filled Syringe (Influenza Vaccine, Split Virion, Inactivated, Solution for Injection)
Label Claim	1 Pre-filled Syringe (0.5ml) contains: Purified, inactivated influenza virus antigen....60ug A Victoria/4897/2022-IVR -238(H1N1).....15 ug

	Purified, inactivated influenza virus antigen type A (H3N2).....15 ug Purified, inactivated influenza virus antigen type B (Yamagata lineage) 15 ug Purified, inactivated influenza virus antigen type B (Victoria lineage) 15 ug Sodium chloride..... 4 mg Potassium chloride..... 0.1 mg Disodium hydrogen phosphate dehydrate..... 0. 6 mg Potassium dihydrogen phosphate.....0.1 mg Water for injection.....Q.S
Reference to Finished product specifications	European Pharmacopeia
Proposed Pack Size	1's-As per SRO
Shelf Life (Unit)	12 Month(s)Store at 2 – 8 °C
For generic drugs (me-too Status)	Brand name: Influvac Tetra Manufacturer: Abbott Bio Netherland (Registration No: 107910)
Pharmacotherapeutic Group of (API)	Human Influenza Vaccine, Quadrivalent
Name, address of Manufacturing site:	GC Biopharma Corp, (Hwasun Plant)-40 Sadan-gil, Hwasun-eup, Hwasun-gun, Jeollanam-do, 519-955, Republic of Korea Phone Number: +82-61-379-2100 Fax Number: +82 -61-379-2166-South
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
Name, address of Marketing Authorization Holder:	Amson Vaccines & Pharma (Pvt) Ltd, Distributor, Plot # 115,Industrial Triangle Kahuta Road Islamabad, Pakistan
Details of Certificates (CoPP/FSC/cGMP):	Copy of Apostille CoPP No. 2025-A1-1822 dated 06-08-2025.
Details of Authorization Letter :	Copy of sole agency certificate dated 23-10-2023.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Long-term stability testing (2 – 8 °C) was conducted for 3 batches of GC3110A (A/H1N1, A/H3N2, B/Yamagata, B/Victoria) manufactured at Hwasun Plant. Acceptable test results were obtained when stored for up to 24 months (for B/Brisbane/60/2008, up to 27 months).
The status in reference regulatory authorities	Brand name: GC FLU Quadrivalent inj.Name of NRA: Ministry of Food and Drug SafetyCountry: Republic of KoreaURL: http://www.mfds.go.kr/eng/index.do Reference authorities: WHO PQ

Evaluation Remarks

Decision of 348th Meeting: The Registration Board deferred the case for the submission of following documents:

Sr. No.	Query	Response
1.	Update the strains through a pre-registration variation, along with the corresponding updates to the relevant CTD module 1, Module 2 and Module 3 with requisite fee.	The firm has submitted updated Module-I, II & III with recommended strains along with fee of Rs. 9400/-.
2.	Hard copy of Original, legalized and valid COPP mentioning the composition of vaccine as per WHO recommended strain 2025- 2026.	The firm has submitted copy of Apostille CoPP with updated strains.
3.	Clinical studies of PFS.	The firm has already submitted clinical studies and container closure specific clinical studies are not required.
4.	Reactogenicity Profile after strain update.	The firm submitted that this data is not yet available for updated strains as post-marketing data is still being collected during the ongoing season.

5.	Risk Management Plan (RMP) for the WHO recommended strains for the year 2024-2025.	Provided.
6.	Periodic Safety Update Report (PSUR)/Periodic Benefit-Risk Evaluation Report (PBRER) for the WHO recommended strains for the year 2024-2025.	The firm has submitted PBRER of period Nov-2023 to Nov-2024 wherein 519 SAEs were reported along with 8 deaths.
7.	Adverse event following immunization report (summary of annual reports) in the country of origin or any other NRA.	There is no separate AEFI report; however, all relevant safety concerns have been addressed and included within the submitted RMP and PBRER.

Remarks: WHO in its recommendations for composition of influenza virus vaccines for use in the 2025-2026 northern hemisphere states the following: "The continued absence of confirmed detection of naturally occurring B/Yamagata lineage viruses after March 2020 is indicative of a very low risk of infection by B/Yamagata lineage viruses. Consistent with previous recommendations, it remains the opinion of the WHO influenza vaccine composition advisory committee that inclusion of a B/Yamagata lineage antigen in quadrivalent influenza vaccines is no longer warranted, and every effort should be made to exclude this component as soon as possible." The firm has submitted PBRER of period Nov-2023 to Nov-2024 wherein 519 SAEs were reported along with 8 deaths. For reactogenicity profile, the firm submitted that this data is not yet available for updated strains as post-marketing data is still being collected during the ongoing season.

Decision

Deferred

Registration Board deferred the case for Pharmacovigilance data of applied product available on Uppsala Monitoring Centre from Pharmacy Services Division of DRAP.

9	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Getz Pharma (Pvt) Limited 29-30/27, Korangi Industrial Area karachi (000284)
	Application Form Dy. No / Tracking ID & date of submission	(PPD-D2D-QXEL, 2025-03-26)
	Detail of Fee Submitted	300000.0, 2025-03-06,
	The proposed proprietary name / brand name	Denomab 60mg Injection
	Label Claim	Each vial (1ml) contains: Denosumab.....60mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1ml x 1vial-As per SRO
	Shelf Life (Unit)	2 Year(s) 2°C - 8°C
	For generic drugs (me-too Status)	Prolia Injection 60mg/mL (Reg. No.: Reg.No. 077527) by M/s GSK Pakistan
	Pharmacotherapeutic Group of (API)	Monoclonal Antibody
	Name, address of Manufacturing site:	Self Manufacturing
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Physicochemical and biological characterization study. Comparative in vitro and in vivo non-clinical studies (PK/PD study) Comparative clinical studies (PK, efficacy, safety and immunogenicity).
	Name, address of Marketing Authorization Holder:	, ,
	Details of Certificates (CoPP/FSC/cGMP):	Scanned Apostille CoPP No. Shandong20241260 valid till 08-12-2026.
	Details of Authorization Letter :	Manufacturing & Supply Agreement valid till 30-09-2029.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	According to ICH Q5C Stability Testing of Biotechnological/Biological Products, stability studies were conducted on Phase I/III clinical batch Drug

	Substance (201902001JNN) and 3 batches of Process Performance Qualification (PPQ) batches Drug Substance (202211002JNN, 202211003JNN, 202211004JNN) during clinical studies, of which long-term and accelerated stability studies were conducted on Phase I/III clinical batch Drug Substance, and comprehensive stability studies were conducted on 3 batches of PPQ batch Drug Substance. Conditions: Realtime at -20C & Accelerated at 2-8C. long-term tests of Drug Substance
The status in reference regulatory authorities	Prolia (Denosumab) Injection 60mg/mL by M/s Amgen Inc., USA
Evaluation Remarks	
Decision of Registration Board in its 348th meeting: The Registration Board deferred the case for the clarity in the comparison of clinical and non-clinical studies of applied strength with Prolia and Xgeva as both are different reference products intended for distinct clinical indications. Response: The firm has submitted evidence that they have performed PK, PD & Safety Efficacy Study of 60ml Injection with Prolia 60mg Innovator. However, toxicity study is performed without any specific strength of Innovator as in Toxicity study, dose is administered as mg/kg and same is done by Innovator product as evident from review available on official website of USFDA.	
Decision	
Approved	
Keeping in view COPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. M/s Getz Pharma (Pvt.) Ltd., 29-30/27, Korangi Industrial Area, Karachi shall be responsible for batch release of product.	
10	Case Category
	Routine (M. Zubair Masood)
	Name, address of Applicant.
	Getz Pharma (Pvt) Limited 29-30/27, Korangi Industrial Area karachi (000284)
	Application Form Dy. No / Tracking ID & date of submission
	(3EY-X3X-5495, 2025-04-07)
	Detail of Fee Submitted
	300000.0, 2025-03-06,
	The proposed proprietary name / brand name
	Denomab 120mg Injection
	Label Claim
	Each vial (1.7ml) contains: Denosumab.....60mg
	Reference to Finished product specifications
	As per Innovators Specification
	Proposed Pack Size
	1ml x 1vial-As per SRO
	Shelf Life (Unit)
	2 Year(s) 2°C - 8°C
	For generic drugs (me-too Status)
	Xgeva Injection 120mg/1.7mL (Reg. No.: Reg.No. 077528) by M/s GSK Pakistan
	Pharmacotherapeutic Group of (API)
	Monoclonal Antibody
	Name, address of Manufacturing site:
	Self Manufacturing
	Pharmaceutical Equivalence and Comparative Dissolution Profile
	Physicochemical and biological characterization study. Comparative in vitro and in vivo non-clinical studies (PK/PD study) Comparative clinical studies (PK, efficacy, safety and immunogenicity).
	Name, address of Marketing Authorization Holder:
	, ,
	Details of Certificates (CoPP/FSC/cGMP):
	Scanned Apostille CoPP No. Shandong20241260 valid till 08-12-2026.
	Details of Authorization Letter :
	Manufacturing & Supply Agreement valid till 30-09-2029.

Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	According to ICH Q5C Stability Testing of Biotechnological/Biological Products, stability studies were conducted on Phase I/III clinical batch Drug Substance (201902001JNN) and 3 batches of Process Performance Qualification (PPQ) batches Drug Substance (202211002JNN, 202211003JNN, 202211004JNN) during clinical studies, of which long-term and accelerated stability studies were conducted on Phase I/III clinical batch Drug Substance, and comprehensive stability studies were conducted on 3 batches of PPQ batch Drug Substance. Conditions: Realtime at -20C & Accelerated at 2-8C. long-term tests of Drug Substance
The status in reference regulatory authorities	Xgeva (Denosumab) Injection 120mg/1.7mL by M/s Amgen Limited., United Kingdom

Evaluation Remarks

Decision of Registration Board in its 348th meeting: The Registration Board deferred the case for the clarity in the comparison of clinical and non-clinical studies of applied strength with Prolia and Xgeva as both are different reference products intended for distinct clinical indications. Response: The firm has submitted evidence that they have performed PK, PD & Safety Efficacy Study of 120ml Injection with Xgeva 120mg Innovator. However, toxicity study is performed without any specific strength of Innovator as in Toxicity study, dose is administered as mg/kg and same is done by Innovator product as evident from review available on official website of USFDA.

Decision

Approved

Keeping in view COPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. M/s Getz Pharma (Pvt.) Ltd., 29-30/27, Korangi Industrial Area, Karachi shall be responsible for batch release of product.

11	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Amson Vaccines & Pharma (Pvt.) Ltd 115, Industrial Triangle Kahuta Road (DHO-ISB-135)
	Application Form Dy. No / Tracking ID & date of submission	(581-7SQ-WAVU, 2025-06-20)
	Detail of Fee Submitted	300000.0, 2025-03-05,
	The proposed proprietary name / brand name	Hepatitis A (Live) Vaccine, Freeze-dried
	Label Claim	Each human dose is 1.0ml, Containing not less than 6.50lg CCID50 of live hepatitis A virus.
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	24 Months2 – 8°C
	For generic drugs (me-too Status)	HAVRIX Vaccine
	Pharmaceutical Group of (API)	
	Name, address of Manufacturing site:	Institute of Medical Biology Chinese Academy of Me- No.935, Jiaoling Road, Kunming City, Yunnan Province, the People's Republic of China.-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	Amson Vaccines & Pharma Pvt Ltd , Plot No 115Industrial Triangle Kahuta Road Islamabad , Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter ;	

Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
The status in reference regulatory authorities	US-FDA

Evaluation Remarks

The Registration Board deferred the case for the submission of the following documents: ☐ Module 1 as per final guidance document for biological products. Minutes of 348th Meeting of Registration Board (01st – 02nd July, 2025) 936 ☐ Clarification is required whether the applied product is combo pack or otherwise. In case of combo pack separate P part is required. ☐ Legalized/apostille, valid and signed COPP is required. ☐ The Trade name is mentioned on COPP but not provided by applicant. ☐ The manufacturing site mentioned on DML is different than COPP. ☐ The provided evidence of approval in RRA is of Inactivated vaccine whereas, applied vaccine is Live. Provide RRA reference for Live attenuated vaccine in same in same dose, strength, route of administration and container closure system. ☐ Presence, prevalence, and public health relevance strain H2 in Pakistan. ☐ The recommended dose and route of administration is not as per WHO position paper. ☐ Provide vaccine is manufactured under which WHO TRS or is a new vaccine for which WHO TRS is not yet developed. ☐ The vaccine is indicated for 1.5 year and above with a dose of 1ml whereas WHO position paper states 0.5ml for children and 1 ml for adults. Moreover, WHO position paper October 2022 states that live attenuated vaccines are licensed for children above 18 months and administered via SC dose. ☐ Provide justification where NA has been mentioned for non-clinical study reports. ☐ The route of administrative in clinical study report is SC. ☐ The target population in phase III studies is 6-16 years whereas; it is indicated for 1.5 year. ☐ Justification is required for not performing phase II. ☐ Documents for shipping validation of finished product. ☐ List of countries whether the vaccine is imported. ☐ Peer-reviewed scientific publications or technical reports substantiating claims related to the strain's performance and relevance. ☐ Adverse Events Following Immunization (AEFI) reports and Periodic Safety Update Reports (PSUR)Remarks:The firm has submitted the response. but as per their response, the live attenuated vaccine is not available in any RRAs. Moreover, WHO PQ vaccines are also Inactivated vaccine.

Decision

Rejected

Keeping in view the fact that Live Hepatitis A Vaccine is not available in any of Reference Regulatory Authorities as approved in 275th meeting; Registration Board rejected the application for grant of registration.

12	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Martin Dow Marker Limited Nice Trade Orbit Building, 44-A, Block-6, P.E.C.H.S, Razi Road, Shahrah-e-Faisal, Karachi (0188)
	Application Form Dy. No / Tracking ID & date of submission	(HX4-2QB-92RR, 2024-09-13)
	Detail of Fee Submitted	300000.0, 2024-04-25,
	The proposed proprietary name / brand name	Rheumab 40mg Solution for Injection
	Label Claim	Each PFS (0.4ml) contains: Adalimumab.....40mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1ml-As per SRO
	Shelf Life (Unit)	2 Year(s)2 to 8°C
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	Monoclonal Antibody
	Name, address of Manufacturing site:	Shilpa Biologicals Private Limited -Plot 532-A, Belur Industrial Area, Dharwad, Karnataka, India.-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Biosimilarity data as per WHO Guidelines is submitted.
	Name, address of Marketing Authorization Holder:	Shilpa Biologicals Private Limited , Plot 532-A, Belur Industrial Area, Dharwad, Karnataka, India., India

Details of Certificates (CoPP/FSC/cGMP):	Copy of legalized CoPP No. DCD/SPL.CELL-I/CR-362/2023-24 dated 22-11-2023.
Details of Authorization Letter :	Copy of LOA dated 03-02-2024.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	For the process validation batches, accelerated and long-term stability data (6 months accelerated and 18 months long term) of adalimumab drug substance are evaluated and found that adalimumab drug substance is stable up to 18 months at long-term. Long term stability studies till 36 months program are on-going and updated stability data shall be provided upon completion.
The status in reference regulatory authorities	Adalimumab PFS (Health Canada))

Evaluation Remarks

Registration Board in its 345th meeting decided as follows:

Sr. No.	Query	Response
1.	Hard copy of original, legalized, signed and valid COPP.	Evidence submitted.
2.	Clarification is required for certifying authority "Office of Drugs Controller for the State of Karnata, Bangalore" for COPP.	Please be informed that since the manufacturing site of drug product Rheumab 40mg/0.4mL PFS is located at Plot no. 532-A, Belur Industrial Area, Dharwad, Karnataka-580011, India, therefore, the provided COPP is certified from the state regulatory authority of Karnataka i.e., Office of the Drugs Controller for the State of Bangalore.
3.	Hard copy of original or notarized Letter of Authorization.	Evidence submitted.
4.	Stability data of drug product of commercial batches till claimed shelf life i.e. 24 months.	Submitted.
5.	Comparability report of "Rheumab 40mg/0.4ml PFS" with reference product "Humira 40mg/0.4ml 3PFS" in section 3.2.R.1.1.	Submitted as follows:

Quality Comparison	Identity: · Reducing SDS PAGE · Non-Reducing SDS PAGE · Western Hybridization with anti-Human Fab antibody · Western Hybridization with anti-Human Fc antibody Peptide Fingerprinting · Tryptic peptides separated on RP-HPLC Intact Mass · LC-MS Deglycosylated Mass · LC-MS Reduced Tryptic digestion and mass analysis of fragments · LC - N Terminal sequence · LC - C Terminal sequence · HC - N Terminal sequence · HC - C Terminal sequence · Modifications · Site of Glycosylation Full Length sequencing · Reducing Tryptic fragments sequencing · Non 100% sequence coverage -reducing Tryptic/Chymotryptic Fragments sequencing · Non-Reducing Tryptic/Chymotryptic Digestion and mass analysis of fragments Disulphide Bridge Mapping · Non-Reducing Tryptic/Chymotryptic Digestion and mass analysis of fragments Far-UV CD: Spectral similarity Near-UV CD: Spectral similarity Intrinsic fluorescence: Spectral similarity Thermal stability: Tm1 and Tm2 Charge Variants cIEF: Profile rCE-SDS: Profile nrCE-SDS: Profile
Potency & Binding	· TNFα binding assay · FcRn binding assays · Binding to Fcγ receptors · FcγIIIa binding assay · Binding kinetics to FcγRIIa · FcγIa binding assay · TNF neutralization · Complement dependent cytotoxicity (CDC) · Antibody Dependent Cell Mediated Cytotoxicity (ADCC)
Non-Clinical	The repeated toxicology study (Comparative 4-Week Repeat Dose Subcutaneous Toxicity Study in Sprague Dawley Rats
Clinical	A Prospective, Randomized, Double Blind, Multidose, Multicenter, Parallel Group, Active Controlled Phase III Study to Compare Clinical Efficacy and Safety of Shilpa

Decision

Approved

Keeping in view COPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.

13	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	BF Biosciences Limited 5-KM Sundar Raiwind Road, Raiwind, Lahore (000655)
	Application Form Dy. No / Tracking ID & date of submission	(HM7-6AG-XZLN, 2025-07-25)
	Detail of Fee Submitted	75000.0, 2025-07-03,
	The proposed proprietary name / brand name	Zeptide 15mg/0.5ml Solution for Injection in PFS
	Label Claim	Each PFS (0.5ml) Contains: Tirzepatide.....15mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's & 4's -As per SRO
	Shelf Life (Unit)	24 Year(s)Store between 2°C to 8°C
	For generic drugs (me-too Status)	N/A
	Pharmaceutical Group of (API)	GLP-I and GIP dual receptor agonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Sinopep-Allsino Biopharmaceutical Co., Ltd. (No. 28, Linpu Road, Economic & Technological Development Zone, Lianyungang, Jiangsu, 222000, China)
	Detail of stability batches of drug product	Firm has submitted stability study data of following 03 batches. The accelerated stability study data is conducted at 25±2°C, 60%±5% RH for 6 months. The real time ongoing stability study data is conducted at 5°C±3°C for 6 months. Batch No. Batch Size Manufacturing date 075D02 300 PFS Oct 2024 075D03 300 PFS Oct 2024 075D04 300 PFS Oct 2024
	Documents for the procurement of API with approval from DRAP (in case of Import)	License No. DIL-C-81A64D dated 01-08-2024.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Batches: AT002230601, AT002230600, AT002230703 Size: 1000g each Conditions: -20C Realtime & 2-8 Accelerated
	The status in reference regulatory authorities	MOUNJARO Injection of Eli Lilly and Company, Australia Approved By TGA Australia
	GMP status of the firm	GMP Certificate dated 01-03-2024.
	Evidence of approval of manufacturing facility	Copy of Section Approval letter dated 07-05-2024 issued by CLB

Evaluation Remarks

Registration Board in its 350th meeting decided as follows:

Sr. No.	Query	Response
1.	GMP certificate/DML mentioning Tirzepatide in its scope of inspection by authorized licensing authority	Copy of written confirmation for active substances exported to EU inspection dated 18th to 20th Feb, 2025.
2.	Section 3.2.S.2 (manufacturing process) is required.	Submitted.
3.	Determination of Enantiomeric purity on drug substance by GC-MS	Studies performed by a third party M/s Shanghai Milestone Pharma Co. Ltd., China.
4.	Inclusion and performance of following tests in drug substance specifications: a. Identity by peptide mapping, b. bio identity (Cell based bioassay GIP, GLP-1) c. residual solvents.	1. Identity by peptide mapping is done by a third party i.e. Ahanghai Applied Protein Technology Co., Ltd., China.2. Bio identity (Cell based bioassay GIP, GLP-1) performed by DS manufacturer.3. Residual Solvents are included in Specifications. However, data of performance is not submitted.
5.	Provide assay limit on as is basis which should be between 79.5% to 100% and peptide content should not be less than 94%. and oligomers 0.8%.	The firm has set Peptide content limit on as –is basis as NLT 80% and on anhydrous basis as 95%-105%. The oligomer limit is set as NMT 1.0%.
6.	Provide justifications of specification 6. Stress studies not performed on drug substance.	The firm submitted justification that specifications are based on general chapters of pharmacopoeia, ICH guidelines & development studies.
7.	Stability data of drug substance of 12 month is submitted, stability data till claimed shelf is required along with justification for not performing all tests as mentioned in section 3.2.S.4.1.Provide justification where NA	The firm has submitted 03 batches real time stability data at -20C for 24 months and accelerated stability data at 5±3C for 06 months including all tests mentioned section 3.2.S.4.1.
8.	Stress studies not performed on drug substance.	The firm has submitted stress study data of one batch of DS on 25C for 30 days, 40C for 30 days, 1.2*106Lux.hr for 10 days, 75RH/25C for 30 days.
9.	Identification tests like peptide mapping, osmolality, HMWP, dose accuracy are not performed on drug product at release. Inclusion and performance of HMWP, Purity, clarity and container closure integrity at next stability time point is required.	1. Test for peptide mapping has been included in Release specifications and will be performed at each stability time point2- Osmolality is not a stability indicating parameter as the finished product contains same excipients (quantitatively) as that of innovator; so it is not required at every testing interval.3- High Molecular Weight Species (HMWS) i.e “Oligomer” has not been performed as release parameter however we will include it at next stability time point.4- Dose accuracy (i.e. extractable volume) is a part of our release parameter and container closure system is impermeable, therefore, extractable volume test is not required as a stability parameter.5- Container closure integrity is part of release parameter and is performed at the end of stability studies i-e (6 month accelerated) and (24 months Real time stability studies)6- Purity i.e. related substances has already been performed at each stability testing point.7- Clarity i.e. (appearance of solution) has already been performed at each stability testing point.

10.	In comparability report peptide mapping has performed by RP-HPLC and not MS. Clarification is required how analysis has been performed without MS with complete validation report.	Peptide Mapping by LC-MS has being performed on Finished product in comparison with RLD from Harvard Medical School, Taplin Mass Spectrometry Facility, 240 Longwood Ave. Boston, MA 02115
11.	Identification and quantification of product related impurities as per section 3.2.S.3 is required in COA/batch analysis and stability analysis.	Already are part of COA and stability data.
12.	Syringe Functionality Test to be performed by Finished product manufacturer. 12. Container closure integrity, break loose and glide force, and autoinjector testing during stability studies to be included in stability studies.	Provided.
13.	Audit trail of all batches from initial to 6 months' analysis is required.	Audit trail of all three batches along with audit trail of impurities is submitted.
14.	Identify the impurities with respect to RT and specify their names in specification of drug product 3.2.P.5.1 as per impurities characterization.	Firm has submitted impurities as part of specifications including names and relative retention time.
15.	Provide justification of finished product specifications.	The firm submitted justification that specifications are developed in-house based on general chapters of pharmacopoeia, ICH guidelines & development studies.
16.	Raw data sheets and chromatograms for impurities with impurity profiling from initial to 6 month analysis is required.	Submitted.
17.	Complete data logger data of 6 months.	Data Submitted
18.	Clarification is required for walk in stability room for real time condition along with thermal mapping data.	Submitted.

The enantiomeric Impurities are performed on UHPLC-HRMS instead of GCMS. The firm submitted the following justification: Both UHPLC-HRMS and GC-MS are used for measuring peptide enantiomers. UHPLC-HRMS (Ultra High Performance Liquid Chromatography coupled with High-Resolution Mass Spectrometry) provides high sensitivity, resolution, and accuracy for determination of enantiomers as compared to GC-MS. Due to nonvolatile and thermally labile nature, analysis by UHPLC-HRMS (Ultra High-Performance Liquid Chromatography coupled with High-Resolution Mass Spectrometry) is more suitable as compared with GC-MS.

Decision

Approved

Approved as per innovator's specifications with following conditions:

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.
2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA&LT.
3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.
4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022. 6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

14	Case Category		Routine (M. Zubair Masood)	
	Name, address of Applicant.		BF Biosciences Limited 5-KM Sundar Raiwind Road, Raiwind, Lahore (000655)	
	Application Form Dy. No / Tracking ID & date of submission		(ZMG-155-Q5SL, 2025-07-25)	
	Detail of Fee Submitted		75000.0, 2025-07-03,	
	The proposed proprietary name / brand name		Zeptide 5mg/0.5ml Solution for Injection in PFS	
	Label Claim		Each PFS (0.5ml) Contains: Tirzepatide.....5mg	
	Reference to Finished product specifications		As per Innovators Specification	
	Proposed Pack Size		1's & 4's -As per SRO	
	Shelf Life (Unit)		24 Month(s)Store between 2°C to 8°C	
	For generic drugs (me-too Status)		N/A	
	Pharmacotherapeutic Group of (API)		GLP-I and GIP dual receptor agonist	
	Name, address of Manufacturing site:		Self Manufacturing	
	Name & address of API manufacturer		Sinocep-Allsino Biopharmaceutical Co., Ltd. (No. 28, Linpu Road, Economic & Technological Development Zone, Lianyungang, Jiangsu, 222000, China)	
	Detail of stability batches of drug product		Firm has submitted stability study data of following 03 batches. The accelerated stability study data is conducted at 25±2°C, 60%±5% RH for 6 months. The real time ongoing stability study data is conducted at 5°C±3°C for 6months. Batch No. Batch Size Manufacturing date 071D02 380 PFS November 2024 071D03 380 PFS November 2024 071D04 380 PFS November 2024	
	Documents for the procurement of API with approval from DRAP (in case of Import)		License No. DIL-C-81A64D dated 01-08-2024.	
	Pharmaceutical Equivalence and Comparative Dissolution Profile		Provided	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		Batches: AT002230601, AT002230600, AT002230703 Size: 1000g each Conditions: -20C Realtime & 2-8 Accelerated	
	The status in reference regulatory authorities		MOUNJARO Injection of Eli Lilly and Company, Australia Approved By TGA Australia	
	GMP status of the firm		GMP Certificate dated 01-03-2024.	
	Evidence of approval of manufacturing facility		Copy of Section Approval letter dated 07-05-2024 issued by CLB	
Evaluation Remarks				
Registration Board in its 350th meeting decided as follows:				
Sr. No.	Query		Response	
1.	GMP certificate/DML mentioning Tirzepatide in its scope of inspection by authorized licensing authority		Copy of written confirmation for active substances exported to EU inspection dated 18th to 20th Feb, 2025.	
2.	Section 3.2.S.2 (manufacturing process) is required.		Submitted.	

3.	Determination of Enantiomeric purity on drug substance by GC-MS	Studies performed by a third party M/s Shanghai Milestone Pharma Co. Ltd., China.
4.	Inclusion and performance of following tests in drug substance specifications: a. Identity by peptide mapping, b. bio identity (Cell based bioassay GIP, GLP-1) c. residual solvents.	1. Identity by peptide mapping is done by a third party i.e. Ahanghai Applied Protein Technology Co., Ltd., China.2. Bio identity (Cell based bioassay GIP, GLP-1) performed by DS manufacturer.3. Residual Sovents are included in Specifications. However, data of performance is not submitted.
5.	Provide assay limit on as is basis which should be between 79.5% to 100% and peptide content should not be less than 94%. and oligomers 0.8%.	The firm has set Peptide content limit on as –is basis as NLT 80% and on anhydrous basis as 95%-105%. The oligomer limit is set as NMT 1.0%.
6.	Provide justifications of specification 6. Stress studies not performed on drug substance.	The firm submitted justification that specifications are based on general chapters of pharmacopoeia, ICH guidelines & development studies.
7.	Stability data of drug substance of 12 month is submitted, stability data till claimed shelf is required along with justification for not performing all tests as mentioned in section 3.2.S.4.1.Provide justification where NA	The firm has submitted 03 batches real time stability data at -20C for 24 months and accelerated stability data at 5±3C for 06 months including all tests mentioned section 3.2.S.4.1.
8.	Stress studies not performed on drug substance.	The firm has submitted stress study data of one batch of DS on 25C for 30 days, 40C for 30 days, 1.2*106Lux.hr for 10 days, 75RH/25C for 30 days.
9.	Identification tests like peptide mapping, osmolality, HMWP, dose accuracy are not performed on drug product at release. Inclusion and performance of HMWP, Purity, clarity and container closure integrity at next stability time point is required.	1. Test for peptide mapping has been included in Release specifications and will be performed at each stability time point2- Osmolality is not a stability indicating parameter as the finished product contains same excipients (quantitatively) as that of innovator; so it is not required at every testing interval.3- High Molecular Weight Species (HMWS) i.e “Oligomer” has not been performed as release parameter however we will include it at next stability time point.4- Dose accuracy (i.e. extractable volume) is a part of our release parameter and container closure system is impermeable, therefore, extractable volume test is not required as a stability parameter.5- Container closure integrity is part of release parameter and is performed at the end of stability studies i-e (6 month accelerated) and (24 months Real time stability studies)6- Purity i.e. related substances has already been performed at each stability testing point.7- Clarity i.e. (appearance of solution) has already been performed at each stability testing point.
10.	In comparibility report peptide mapping has performed by RP-HPLC and not MS. Clarification is required how analysis has been performed without MS with complete validation report.	Peptide Mapping by LC-MS has being performed on Finished product in comparison with RLD from Harvard Medical School, Taplin Mass Spectrometry Facility, 240 Longwood Ave. Boston, MA 02115
11.	Identification and quantification of product related impurities as per section 3.2.S.3.is required in COA/batch analysis and	Already are part of COA and stability data.

	stability analysis.	
12.	Syringe Functionality Test to be performed by Finished product manufacturer. 12. Container closure integrity, break loose and glide force, and autoinjector testing during stability studies to be included in stability studies.	Provided.
13.	Audit trail of all batches from initial to 6 months' analysis is required.	Audit trail of all three batches along with audit trail of impurities is submitted.
14.	Identify the impurities with respect to RT and specify their names in specification of drug product 3.2.P.5.1 as per impurities characterization.	Firm has submitted impurities as part of specifications including names and relative retention time.
15.	Provide justification of finished product specifications.	The firm submitted justification that specifications are developed in-house based on general chapters of pharmacopoeia, ICH guidelines & development studies.
16.	Raw data sheets and chromatograms for impurities with impurity profiling from initial to 6 month analysis is required.	Submitted.
17.	Complete data logger data of 6 months.	Data Submitted
18.	Clarification is required for walk in stability room for real time condition along with thermal mapping data.	Submitted.

The enantiomeric Impurities are performed on UHPLC-HRMS instead of GCMS. The firm submitted the following justification: Both UHPLC-HRMS and GC-MS are used for measuring peptide enantiomers. UHPLC-HRMS (Ultra High Performance Liquid Chromatography coupled with High-Resolution Mass Spectrometry) provides high sensitivity, resolution, and accuracy for determination of enantiomers as compared to GC-MS. Due to nonvolatile and thermally labile nature, analysis by UHPLCHRMS (Ultra High-Performance Liquid Chromatography coupled with High-Resolution Mass Spectrometry) is more suitable as compared with GC-MS.

Decision

Approved

Approved as per innovator's specifications with following conditions:

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.
2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA&LT.
3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.
4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.
5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022. 6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

15	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	BF Biosciences Limited 5-KM Sundar Raiwind Road, Raiwind, Lahore (000655)
	Application Form Dy. No / Tracking ID & date of submission	(1QJ-E3D-35RY, 2025-07-25)

Detail of Fee Submitted	75000.0, 2025-07-03,
The proposed proprietary name / brand name	Zeptide 12.5mg/0.5ml Solution for Injection in PFS
Label Claim	Each PFS (0.5ml) Contains: Tirzepatide.....12.5mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's , 4's-As per SRO
Shelf Life (Unit)	24 Month(s)Store at 2°C to 8°C.
For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	GLP-I and GIP dual receptor agonist
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Sinopep-Allsino Biopharmaceutical Co., Ltd. (No. 28, Linpu Road, Economic & Technological Development Zone, Lianyungang, Jiangsu, 222000, China)
Detail of stability batches of drug product	Firm has submitted stability study data of following 03 batches. The accelerated stability study data is conducted at 25±2°C, 60%±5% RH for 3 months. The real time ongoing stability study data is conducted at 5°C±3°C for 3months. Batch No. Batch Size Manufacturing date 074D02 300 PFS November 2024 074D03 300 PFS November 2024 074D04 300 PFS November 2024
Documents for the procurement of API with approval from DRAP (in case of Import)	License No. DIL-C-81A64D dated 01-08-2024.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Batches: AT002230601, AT002230600, AT002230703 Size: 1000g each Conditions: -20C Realtime & 2-8 Accelerated
The status in reference regulatory authorities	MOUNJARO Injection of Eli Lilly and Company, Australia Approved By TGA Australia
GMP status of the firm	GMP Certificate dated 01-03-2024.
Evidence of approval of manufacturing facility	Copy of Section Approval letter dated 07-05-2024 issued by CLB

Evaluation Remarks

Registration Board in its 350th meeting decided as follows:

Sr. No.	Query	Response
1.	GMP certificate/DML mentioning Tirzepatide in its scope of inspection by authorized licensing authority	Copy of written confirmation for active substances exported to EU inspection dated 18th to 20th Feb, 2025.
2.	Section 3.2.S.2 (manufacturing process) is required.	Submitted.
3.	Determination of Enantiomeric purity on drug substance by GC-MS	Studies performed by a third party M/s Shanghai Milestone Pharma Co. Ltd., China.
4.	Inclusion and performance of following tests in drug substance specifications: a. Identity by peptide mapping, b. bio identity (Cell based bioassay GIP, GLP-1) c. residual solvents.	1. Identity by peptide mapping is done by a third party i.e. Ahanghai Applied Protein Technology Co., Ltd., China.2. Bio identity (Cell based bioassay GIP, GLP-1) performed by DS manufacturer.3. Residual Sovents are included in Specifications. However, data of performance is not submitted.

5.	Provide assay limit on as is basis which should be between 79.5% to 100% and peptide content should not be less than 94%. and oligomers 0.8%.	The firm has set Peptide content limit on as –is basis as NLT 80% and on anhydrous basis as 95%-105%. The oligomer limit is set as NMT 1.0%.
6.	Provide justifications of specification 6. Stress studies not performed on drug substance.	The firm submitted justification that specifications are based on general chapters of pharmacopoeia, ICH guidelines & development studies.
7.	Stability data of drug substance of 12 month is submitted, stability data till claimed shelf is required along with justification for not performing all tests as mentioned in section 3.2.S.4.1. Provide justification where NA	The firm has submitted 03 batches real time stability data at -20C for 24 months and accelerated stability data at 5±3C for 06 months including all tests mentioned section 3.2.S.4.1.
8.	Stress studies not performed on drug substance.	The firm has submitted stress study data of one batch of DS on 25C for 30 days, 40C for 30 days, 1.2*106Lux.hr for 10 days, 75RH/25C for 30 days.
9.	Identification tests like peptide mapping, osmolality, HMWP, dose accuracy are not performed on drug product at release. Inclusion and performance of HMWP, Purity, clarity and container closure integrity at next stability time point is required.	1. Test for peptide mapping has been included in Release specifications and will be performed at each stability time point 2- Osmolality is not a stability indicating parameter as the finished product contains same excipients (quantitatively) as that of innovator; so it is not required at every testing interval. 3- High Molecular Weight Species (HMWS) i.e “Oligomer” has not been performed as release parameter however we will include it at next stability time point. 4- Dose accuracy (i.e. extractable volume) is a part of our release parameter and container closure system is impermeable, therefore, extractable volume test is not required as a stability parameter. 5- Container closure integrity is part of release parameter and is performed at the end of stability studies i-e (6 month accelerated) and (24 months Real time stability studies) 6- Purity i.e. related substances has already been performed at each stability testing point. 7- Clarity i.e. (appearance of solution) has already been performed at each stability testing point.
10.	In comparability report peptide mapping has performed by RP-HPLC and not MS. Clarification is required how analysis has been performed without MS with complete validation report.	Peptide Mapping by LC-MS has being performed on Finished product in comparison with RLD from Harvard Medical School, Taplin Mass Spectrometry Facility, 240 Longwood Ave. Boston, MA 02115
11.	Identification and quantification of product related impurities as per section 3.2.S.3 is required in COA/batch analysis and stability analysis.	Already are part of COA and stability data.
12.	Syringe Functionality Test to be performed by Finished product manufacturer. 12. Container closure integrity, break loose and glide force, and autoinjector testing during stability studies to be included in stability studies.	Provided.
13.	Audit trail of all batches from initial to 6 months' analysis is required.	Audit trail of all three batches along with audit trail of impurities is submitted.
14.	Identify the impurities with respect to RT and specify their names in specification of drug product 3.2.P.5.1 as per impurities characterization.	Firm has submitted impurities as part of specifications including names and relative retention time.

15.	Provide justification of finished product specifications.	The firm submitted justification that specifications are developed in-house based on general chapters of pharmacopoeia, ICH guidelines & development studies.
16.	Raw data sheets and chromatograms for impurities with impurity profiling from initial to 6 month analysis is required.	Submitted.
17.	Complete data logger data of 6 months.	Data Submitted
18.	Clarification is required for walk in stability room for real time condition along with thermal mapping data.	Submitted.

The enantiomeric Impurities are performed on UHPLC-HRMS instead of GCMS. The firm submitted the following justification: Both UHPLC-HRMS and GC-MS are used for measuring peptide enantiomers. UHPLC-HRMS (Ultra High Performance Liquid Chromatography coupled with High-Resolution Mass Spectrometry) provides high sensitivity, resolution, and accuracy for determination of enantiomers as compared to GC-MS. Due to nonvolatile and thermally labile nature, analysis by UHPLC-HRMS (Ultra High-Performance Liquid Chromatography coupled with High-Resolution Mass Spectrometry) is more suitable as compared with GC-MS.

Decision

Approved

Approved as per innovator's specifications with following conditions:

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.
2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA&LT.
3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.
4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.
5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022. 6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

16	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	BF Biosciences Limited 5-KM Sundar Raiwind Road, Raiwind, Lahore (000655)
	Application Form Dy. No / Tracking ID & date of submission	(896-U3Q-J1TH, 2025-07-25)
	Detail of Fee Submitted	75000.0, 2025-07-03,
	The proposed proprietary name / brand name	Zeptide 2.5mg/0.5ml Solution for Injection in PFS
	Label Claim	Each PFS (0.5ml) Contains: Tirzepatide.....2.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's , 4's-As per SRO

Shelf Life (Unit)	24 Month(s)Store at 2°C to 8°C.
For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	GLP-I and GIP dual receptor agonist
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Sinopep-Allsino Biopharmaceutical Co., Ltd. (No. 28, Linpu Road, Economic & Technological Development Zone, Lianyungang, Jiangsu, 222000, China)
Detail of stability batches of drug product	Firm has submitted stability study data of following 03 batches. The accelerated stability study data is conducted at 25±2°C, 60%±5% RH for 6 months. The real time ongoing stability study data is conducted at 5°C±3°C for 6months. Batch No. Batch Size Manufacturing date 070D02 550 PFS November 2024 070D03 550 PFS November 2024 070D04 550 PFS November 2024
Documents for the procurement of API with approval from DRAP (in case of Import)	License No. DIL-C-81A64D dated 01-08-2024.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Batches: AT002230601, AT002230600, AT002230703 Size: 1000g each Conditions: -20C Realtime & 2-8 Accelerated
The status in reference regulatory authorities	MOUNJARO Injection of Eli Lilly and Company, Australia Approved By TGA Australia
GMP status of the firm	GMP Certificate dated 01-03-2024.
Evidence of approval of manufacturing facility	Copy of Section Approval letter dated 07-05-2024 issued by CLB

Evaluation Remarks

Registration Board in its 350th meeting decided as follows:

Sr. No.	Query	Response
1.	GMP certificate/DML mentioning Tirzepatide in its scope of inspection by authorized licensing authority	Copy of written confirmation for active substances exported to EU inspection dated 18th to 20th Feb, 2025.
2.	Section 3.2.S.2 (manufacturing process) is required.	Submitted.
3.	Determination of Enantiomeric purity on drug substance by GC-MS	Studies performed by a third party M/s Shanghai Milestone Pharma Co. Ltd., China.
4.	Inclusion and performance of following tests in drug substance specifications: a. Identity by peptide mapping, b. bio identity (Cell based bioassay GIP, GLP-1) c. residual solvents.	1. Identity by peptide mapping is done by a third party i.e. Ahanghai Applied Protein Technology Co., Ltd., China.2. Bio identity (Cell based bioassay GIP, GLP-1) performed by DS manufacturer.3. Residual Sovents are included in Specifications. However, data of performance is not submitted.
5.	Provide assay limit on as is basis which should be between 79.5% to 100% and peptide content should not be less than 94%. and oligomers 0.8%.	The firm has set Peptide content limit on as –is basis as NLT 80% and on anhydrous basis as 95%-105%. The oligomer limit is set as NMT 1.0%.
6.	Provide justifications of specification 6. Stress studies not performed on drug substance.	The firm submitted justification that specifications are based on general chapters of pharmacopoeia, ICH guidelines & development studies.
7.	Stability data of drug substance of 12 month is submitted, stability data till claimed shelf is required along with	The firm has submitted 03 batches real time stability data at -20C for 24 months

	justification for not performing all tests as mentioned in section 3.2.S.4.1. Provide justification where NA	and accelerated stability data at 5±3C for 06 months including all tests mentioned section 3.2.S.4.1.
8.	Stress studies not performed on drug substance.	The firm has submitted stress study data of one batch of DS on 25C for 30 days, 40C for 30 days, 1.2*106Lux.hr for 10 days, 75RH/25C for 30 days.
9.	Identification tests like peptide mapping, osmolality, HMWP, dose accuracy are not performed on drug product at release. Inclusion and performance of HMWP, Purity, clarity and container closure integrity at next stability time point is required.	1. Test for peptide mapping has been included in Release specifications and will be performed at each stability time point. 2- Osmolality is not a stability indicating parameter as the finished product contains same excipients (quantitatively) as that of innovator; so it is not required at every testing interval. 3- High Molecular Weight Species (HMWS) i.e "Oligomer" has not been performed as release parameter however we will include it at next stability time point. 4- Dose accuracy (i.e. extractable volume) is a part of our release parameter and container closure system is impermeable, therefore, extractable volume test is not required as a stability parameter. 5- Container closure integrity is part of release parameter and is performed at the end of stability studies i.e (6 month accelerated) and (24 months Real time stability studies). 6- Purity i.e. related substances has already been performed at each stability testing point. 7- Clarity i.e. (appearance of solution) has already been performed at each stability testing point.
10.	In comparability report peptide mapping has performed by RP-HPLC and not MS. Clarification is required how analysis has been performed without MS with complete validation report.	Peptide Mapping by LC-MS has being performed on Finished product in comparison with RLD from Harvard Medical School, Taplin Mass Spectrometry Facility, 240 Longwood Ave. Boston, MA 02115
11.	Identification and quantification of product related impurities as per section 3.2.S.3 is required in COA/batch analysis and stability analysis.	Already are part of COA and stability data.
12.	Syringe Functionality Test to be performed by Finished product manufacturer. 12. Container closure integrity, break loose and glide force, and autoinjector testing during stability studies to be included in stability studies.	Provided.
13.	Audit trail of all batches from initial to 6 months' analysis is required.	Audit trail of all three batches along with audit trail of impurities is submitted.
14.	Identify the impurities with respect to RT and specify their names in specification of drug product 3.2.P.5.1 as per impurities characterization.	Firm has submitted impurities as part of specifications including names and relative retention time.
15.	Provide justification of finished product specifications.	The firm submitted justification that specifications are developed in-house based on general chapters of pharmacopoeia, ICH guidelines & development studies.
16.	Raw data sheets and chromatograms for impurities with impurity profiling from initial to 6 month analysis is required.	Submitted.
17.	Complete data logger data of 6 months.	Data Submitted
18.	Clarification is required for walk in stability room for real time condition along with thermal mapping data.	Submitted.

The enantiomeric Impurities are performed on UHPLC-HRMS instead of GCMS. The firm submitted the following justification: Both UHPLC-HRMS and GC-MS are used for measuring peptide enantiomers. UHPLC-HRMS (Ultra High Performance Liquid Chromatography coupled with High-Resolution Mass Spectrometry) provides high sensitivity, resolution, and accuracy for determination of enantiomers as compared to GC-MS. Due to nonvolatile and thermally labile nature, analysis by UHPLC-HRMS (Ultra High-Performance Liquid Chromatography coupled with High-Resolution Mass Spectrometry) is more suitable as compared with GC-MS.

Decision

Approved

Approved as per innovator's specifications with following conditions:

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.
2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA&LT.
3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.
4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.
5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022. 6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

17	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	BF Biosciences Limited 5-KM Sundar Raiwind Road, Raiwind, Lahore (000655)
	Application Form Dy. No / Tracking ID & date of submission	(XQ2-MDH-HRSM, 2025-07-25)
	Detail of Fee Submitted	75000.0, 2025-07-03,
	The proposed proprietary name / brand name	Zeptide 7.5mg/0.5ml Solution for Injection in PFS
	Label Claim	Each PFS (0.5ml) Contains: Tirzepatide.....7.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's , 4's-As per SRO
	Shelf Life (Unit)	24 Month(s)Store at 2°C to 8°C.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	GLP-I and GIP dual receptor agonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Sinopep-Allsino Biopharmaceutical Co., Ltd. (No. 28, Linpu Road, Economic & Technological Development

	Zone, Lianyungang, Jiangsu, 222000, China)
Detail of stability batches of drug product	Firm has submitted stability study data of following 03 batches. The accelerated stability study data is conducted at 25±2°C, 60%±5% RH for 6 months. The real time ongoing stability study data is conducted at 5°C±3°C for 6months. Batch No. Batch Size Manufacturing date 072D02 350 PFS November 2024 072D03 350 PFS November 2024 072D04 350 PFS November 2024
Documents for the procurement of API with approval from DRAP (in case of Import)	License No. DIL-C-81A64D dated 01-08-2024.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Batches: AT002230601, AT002230600, AT002230703 Size: 1000g each Conditions: -20C Realtime & 2-8 Accelerated
The status in reference regulatory authorities	MOUNJARO Injection of Eli Lilly and Company, Australia Approved By TGA Australia
GMP status of the firm	GMP Certificate dated 01-03-2024.
Evidence of approval of manufacturing facility	Copy of Section Approval letter dated 07-05-2024 issued by CLB

Evaluation Remarks

Registration Board in its 350th meeting decided as follows:

Sr. No.	Query	Response
1.	GMP certificate/DML mentioning Tirzepatide in its scope of inspection by authorized licensing authority	Copy of written confirmation for active substances exported to EU inspection dated 18th to 20th Feb, 2025.
2.	Section 3.2.S.2 (manufacturing process) is required.	Submitted.
3.	Determination of Enantiomeric purity on drug substance by GC-MS	Studies performed by a third party M/s Shanghai Milestone Pharma Co. Ltd., China.
4.	Inclusion and performance of following tests in drug substance specifications: a. Identity by peptide mapping, b. bio identity (Cell based bioassay GIP, GLP-1) c. residual solvents.	1. Identity by peptide mapping is done by a third party i.e. Ahanghai Applied Protein Technology Co., Ltd., China.2. Bio identity (Cell based bioassay GIP, GLP-1) performed by DS manufacturer.3. Residual Sovents are included in Specifications. However, data of performance is not submitted.
5.	Provide assay limit on as is basis which should be between 79.5% to 100% and peptide content should not be less than 94%. and oligomers 0.8%.	The firm has set Peptide content limit on as –is basis as NLT 80% and on anhydrous basis as 95%-105%. The oligomer limit is set as NMT 1.0%.
6.	Provide justifications of specification 6. Stress studies not performed on drug substance.	The firm submitted justification that specifications are based on general chapters of pharmacopoeia, ICH guidelines & development studies.
7.	Stability data of drug substance of 12 month is submitted, stability data till claimed shelf is required along with justification for not performing all tests as mentioned in section 3.2.S.4.1.Provide justification where NA	The firm has submitted 03 batches real time stability data at -20C for 24 months and accelerated stability data at 5±3C for 06 months including all tests mentioned section 3.2.S.4.1.
8.	Stress studies not performed on drug substance.	The firm has submitted stress study data of one batch of DS on 25C for 30 days, 40C for 30 days, 1.2*10 ⁶ Lux.hr for 10 days, 75RH/25C for 30 days.

9.	Identification tests like peptide mapping, osmolality, HMWP, dose accuracy are not performed on drug product at release. Inclusion and performance of HMWP, Purity, clarity and container closure integrity at next stability time point is required.	1. Test for peptide mapping has been included in Release specifications and will be performed at each stability time point. 2- Osmolality is not a stability indicating parameter as the finished product contains same excipients (quantitatively) as that of innovator; so it is not required at every testing interval. 3- High Molecular Weight Species (HMWS) i.e "Oligomer" has not been performed as release parameter however we will include it at next stability time point. 4- Dose accuracy (i.e. extractable volume) is a part of our release parameter and container closure system is impermeable, therefore, extractable volume test is not required as a stability parameter. 5- Container closure integrity is part of release parameter and is performed at the end of stability studies i.e (6 month accelerated) and (24 months Real time stability studies). 6- Purity i.e. related substances has already been performed at each stability testing point. 7- Clarity i.e. (appearance of solution) has already been performed at each stability testing point.
10.	In comparability report peptide mapping has performed by RP-HPLC and not MS. Clarification is required how analysis has been performed without MS with complete validation report.	Peptide Mapping by LC-MS has being performed on Finished product in comparison with RLD from Harvard Medical School, Taplin Mass Spectrometry Facility, 240 Longwood Ave. Boston, MA 02115
11.	Identification and quantification of product related impurities as per section 3.2.S.3 is required in COA/batch analysis and stability analysis.	Already are part of COA and stability data.
12.	Syringe Functionality Test to be performed by Finished product manufacturer. 12. Container closure integrity, break loose and glide force, and autoinjector testing during stability studies to be included in stability studies.	Provided.
13.	Audit trail of all batches from initial to 6 months' analysis is required.	Audit trail of all three batches along with audit trail of impurities is submitted.
14.	Identify the impurities with respect to RT and specify their names in specification of drug product 3.2.P.5.1 as per impurities characterization.	Firm has submitted impurities as part of specifications including names and relative retention time.
15.	Provide justification of finished product specifications.	The firm submitted justification that specifications are developed in-house based on general chapters of pharmacopoeia, ICH guidelines & development studies.
16.	Raw data sheets and chromatograms for impurities with impurity profiling from initial to 6 month analysis is required.	Submitted.
17.	Complete data logger data of 6 months.	Data Submitted
18.	Clarification is required for walk in stability room for real time condition along with thermal mapping data.	Submitted.

The enantiomeric Impurities are performed on UHPLC-HRMS instead of GCMS. The firm submitted the following justification: Both UHPLC-HRMS and GC-MS are used for measuring peptide enantiomers. UHPLC-HRMS (Ultra High Performance Liquid Chromatography coupled with High-Resolution Mass Spectrometry) provides high sensitivity, resolution, and accuracy for determination of enantiomers as compared to GC-MS. Due to nonvolatile and thermally labile nature, analysis by UHPLC-HRMS (Ultra High-Performance Liquid Chromatography coupled with High-Resolution Mass Spectrometry) is more suitable as compared with GC-MS.

Decision**Approved**

Approved as per innovator's specifications with following conditions:

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.
2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA&LT.
3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.
4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.
5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022. 6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

18

Case Category	Routine (M. Zubair Masood)
Name, address of Applicant.	HIMMEL PHARMACEUTICALS (PVT.) LTD Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Zazaria e Pakistan Lahore (05-352-0065)
Application Form Dy. No / Tracking ID & date of submission	(7X4-DQD-UMJ4, 2024-10-18)
Detail of Fee Submitted	300000.0, 2024-10-17,
The proposed proprietary name / brand name	Tirzix 2.5mg Injection
Label Claim	Each 0.5 mL solution contains: Tirzepatide.....2.5 mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's-As per SRO
Shelf Life (Unit)	24 Month(s)Store between 2-8°C.
For generic drugs (me-too Status)	Not available
Pharmacotherapeutic Group of (API)	GLP-1 & GIP Receptor Agonist
Name, address of Manufacturing site:	Beacon Pharmaceuticals PLC.-Kathali, Bhaluka , Mymensingh, -Bangladesh
Pharmaceutical Equivalence and Comparative Dissolution Profile	Not Provided.
Name, address of Marketing Authorization Holder:	Beacon Pharmaceuticals PLC., Kathali, Bhaluka , Mymensingh, , Bangladesh
Details of Certificates (CoPP/FSC/cGMP):	Copy of legalized CoPP No. DA/6-110/2016/16020 dated 08-09-2024.
Details of Authorization Letter :	Copy of letter of authorization dated 02-10-2024.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Real Time: -20C for 03 batches till 24 months. Accelerated: 2-8C for 03 batches till 06 months. Batch

	numbers: D20210915, D20210608 and D20210706
The status in reference regulatory authorities	Mounjaro 2.5 mg solution for injection in Pre-filled pen

Evaluation Remarks

	Query	Response	Remarks
	Peptide content studies are still not provided?	The firm submitted that The result of Peptide Content between 97-103%.	No studies are submitted, only limits provided.
	Purity Testing of API is performed by by RP-HPLC-UV instead of RP-LC-MS?	The RP-LC-UV testing, a single peak of a non-specific impurity exceeds 0.5%. This is done to determine whether the peak represents a single impurity or multiple co-eluting impurities. If it is a single impurity exceeding the limit, the product is considered non-compliant. If it consists of multiple impurities, each impurity is reported individually, and if all are below 0.5%, the product is compliant. Harbin Jixianglong's related substances testing method sets a limit of 0.5% for any single impurity.	In no later stages, firm has performed this testing.
	The provided COA is of finished product while the COA Verification and risk assessment performed by DP manufacturer was required to support omission of repeat testing of Sodium ions & Microbial limit of API at DP manufacturer site?	A formal risk assessment was conducted by the DP Quality Assurance team (Report No. RA-TIR-API2025-01) to evaluate whether repeat testing for sodium ions and microbial limits was necessary at the DP site.	Risk Assessment Report and API COA verification by Finished Product Manufacturer are still not submitted?
	Submit fee of Rs. 9400/- for update in API Bacterial Endotoxin specifications?	Challan No. 7542955762	
	Please explain that Purity & HMWS testing of API were not included in initially submitted stability data of API, now you have submitted the stability data of same batches manufactured in 2021 and included these tests at each time point?	in alignment with the expectations of the importing country and to support the ongoing registration process, we have now submitted updated stability data for the same API batches manufactured in 2021. This updated data includes both Purity and HMWS testing conducted at each designated time point. As these tests had already been performed as part of their internal quality protocols, they were able to furnish the necessary results upon our request.	
	Complete drug-excipient compatibility studies are still not submitted. Moreover, submitted document against this point states the following: "This document is prepared by Quality Control department of Beacon Pharmaceuticals PLC, Punjab Pakistan".	Firm has again submitted report by omitting Punjab Pakistan.	There is no detailed report and results in a table showing no compatibility of excipient and API.
	Peptide mapping of finished product by LC-	Peptide mapping is a crucial analytical technique used for the structural characterization and	Peptide mapping of finished product by

MS is still not performed instead RP-HPLC is used?	identity confirmation of peptides and proteins. This process typically involves enzymatic digestion followed by separation of the resulting peptides. According to the European Pharmacopoeia, Peptide Mapping, various techniques—such as ion-exchange HPLC, hydrophobic interaction HPLC, and capillary electrophoresis—can be employed for peptide separation. However, reversed-phase HPLC (RP-HPLC) is identified as the most commonly used method for peptide map analysis. While the innovator may have utilized LC-MS during drug development for detailed structural elucidation, it is important to recognize that, for identification of already established products, HPLC alone is adequate for comparing peptide maps with reference standards. Furthermore, the use of RP-HPLC for peptide mapping is well-supported by multiple monographs in recognized Pharmacopoeias.	LC-MS is required.
High Molecular Weight Species Testing of Finished product by SEC is not submitted, only general chapter is provided?	The firm has submitted a raw calculation sheet without any batch details along with chromatograms.	The areas in chromatogram of sample (5.9743 + 21923.1018) are slightly different from calculation sheet (5.9644+21824.1017).
Osmolality testing as part of finished product testing is still not submitted, instead general chapter on Osmolality & Osmolarity is submitted?	The firm has submitted SOP of Osmolality along with COA of one batch showing results of osmolality.	
Syringe Functionality Test of Finished product is still not submitted, instead general chapter is provided.	The firm has submitted a report	The submitted report is the copy of report submitted in another dossier of firm Tyzepa wherein this report was attached for pen injector test report of M/s Jiangsu Wanhai Medical Instruments Co., Ltd. The firm has removed the name of that company and manufacturer's name is written on it.
Dose accuracy (volume by weight), visual/functional inspection (inspection), and injection time (timing) tests for its device are still not submitted instead general chapter is provided.	The firm has submitted the SOPs.	Only SOPs are submitted. The firm has neither submitted revised specs with these test nor submitted any evidence of performance.

.	Please explain that Purity, HMWS, container closure integrity, break loose and glide force Testing of Finished product were not included in initially submitted stability data of finished product, now you have submitted the stability data of same batches manufactured in 2021 and included these tests at each time point?	Initially, there is no requirement for the Importer to perform tests such as purity, HMWS, container closure integrity, break-loose, and glide force. However, upon Importer request, we have provided updated stability data, including these tests, as part of the Accelerated and Long-term Stability Studies.	Purity, HMWS, container closure integrity, break loose and glide force Testing of Finished product were not included in initially submitted stability data of finished product, now you have submitted the stability data of same batches manufactured in 2021 and included these tests at each time point
.	The limit of HMWS in API is mentioned as not more than 0.8% while in stability data Finished product it is mentioned as not more than 3.0%? Please justify the increase in HMWS in light of RRA guidelines?	No response submitted.	Not Submitted.
.	Evidence of availability of prefilled syringe in RRAs as provided reference Mounjaro is a pre-filled pen?	In DRB Meeting No. 350, the Tirzi Injection 2.5 mg/0.5 mL Solution for Injection in a Pre-filled Syringe, manufactured by GETZ Pharma, was approved. GETZ Pharma provided a reference to Mounjaro, a product by Novartis, to support their submission.	The provided reference is of pre-filled syringe with autoinjector while no such device is mentioned for instant application.
.	Valid GMP Certificate of Drug Substance Manufacturer is issued by Pharmaceutical Profession Association instead of regulatory authority of country of origin?	The firm submitted justification that GMP is not issued by NMPA now.	
.	Ammonium counter ions are not tested by API manufacturer?	No International pharmaceutical quality guidelines do not specifically require ammonium counter-ions for the testing of Tirzepatide API. However, if the API is a salt form, its counter-ion identity and content must be characterized and controlled, regardless of whether it's ammonium or another ion. As per the guidelines name: FDA-1997-D-0005-0001_content.	At API level, the DS manufacturer has set impurity limits of individual impurity as not more than 0.5% while Draft Guidelines on synthetic peptides by EMA states that peptide-related impurities should be reported above 0.1%, identified above 0.5% and qualified above 1.0%.
.	Details of reports of comparative tests of Finished product with Innovator product?	Not Submitted	Not Submitted
.	Details of manufacturing section, in which FPP is	Firm has submitted GMP Certificate and Certificate of Renewal of Licence to	Peptide manufacturing is not indicated in any

	manufactured? Provide report of regulatory authority instead of a layout plan?	Manufacture Drugs.	of these documents.
.	Please provide the details of Tirzepatide reference standard used in Cell based Bio-assay study?		Not Submitted
.	In revised Specifications, there is still difference in limits of impurities in Drug Substance and FPP. Moreover, the impurity limits in API are more relaxed as compared to Finished product. Please justify in light of RRA guidelines?	The observed differences in impurity limits between the API and FPP are justified based on regulatory risk assessment principles. The more relaxed limits in the API are acceptable because the downstream manufacturing process either controls, removes, or does not allow the concentration of these impurities to exceed the tighter limits set in the FPP. All impurity limits are established based on safety data, process capability, and product stability, in alignment with ICH and RRA guidelines.	
.	You were asked about the justification/ scientific rational of identifying critical steps and intermediates of manufacturing process, instead of submitting critical steps and intermediates of manufacturing process?	The critical steps and intermediates of finished product (FP) manufacturing are well described in the process validation. These critical steps and intermediates are defined by our Subject Matter Experts (SMEs) and Quality Assurance (QA) team, who have extensive experience in the relevant field.	
.	Raw data sheets & chromatograms of stability study data?	The chromatograms submitted are of March, May & June 2025 while stability time points are of 2021 & 2022.	
.	Raw data sheets of Drug Excipient compatibility study?	Chromatograms provided are of Tirzepatide + Sodium Chloride only.	The Drug Excipient compatibility study submitted against point 6 is of year 2021 while the chromatograms submitted are of year 2023.

Decision

Deferred

Registration Board decided to provide one last opportunity to applicant to furnish following documents/ clarifications. In case the applicant fails to complete the application this time, the application shall be disposed of by the Board in its next meeting.

i. Clarification of 280.0% peptide content in Peptide content studies.

ii. Clarification of submitting same document for Peptide content studies as submitted in other application Tirzep manufactured by M/s Advance Chemical.

iii. List of product specific impurities in Drug Substance, their inclusion in API specifications & evidence of performance by API manufacturer.

iv. Risk Assessment Report and API COA verification by Finished Product Manufacturer are still not submitted.

- v. Raw data sheets & chromatograms of Purity & HMWS testing performed during stability studies of API of batches manufactured in 2021 for which stability data is submitted.
- vi. The limit of HMWS in API is mentioned as not more than 0.8% while in stability data Finished product it is mentioned as not more than 3.0%? Please justify the increase in HMWS in light of RRA guidelines?
- vii. Please clarify that applied product being synthetic peptide is manufactured by manufacturer in which section either Biological or non-biological section.
- viii. The provided evidence of Tirzi Injection of 350th meeting has an autoinjector with PFS, what is the status of your applied product.
- ix. In Drug Excipient compatibility performed by DSC, the curve should be a sum of individual components. However, DSC curves of single components are not performed to verify the compatibility.
- x. Peptide mapping of finished product by LC-MS is still not performed instead RP-HPLC is used. Please justify.
- xi. High Molecular Weight Species Testing of Finished product by SEC is not submitted, only general chapter is provided? The provided document is same as submitted in application of Tirzep manufactured by M/s Advance Chemical at pages-79-80 of response tracking ID: S56-LDG-R1DU dated 23-09-2025.
- xii. Please explain that the report submitted for syringe functionality is the copy of report submitted in another dossier of your firm Tyzepa wherein this report was attached for pen injector test report of M/s Jiangsu Wanhai Medical Instruments Co., Ltd. The name of that company has been removed and manufacturer's name is written on it.
- xiii. Please submit revised specs including Dose accuracy (volume by weight), visual/functional inspection (inspection), and injection time (timing) tests for your PFS. Also submit evidence of performance of these tests on finished product.
- xiv. Raw data sheets & chromatograms of Purity, HMWS, container closure integrity, break loose and glide force Testing of Finished product testing performed during stability studies of batches manufactured in 2021 for which stability data is submitted.
- xv. Ammonium counter ions are not tested by API manufacturer.
- xvi. Details of reports of comparative tests of Finished product with Innovator product.
- xvii. Please provide any official document from USA confirming that M/s Quality Control Chemicals Inc., USA is authorized to manufacture and sale Reference standards.
- xviii. Raw data sheets & chromatograms of stability study data as the chromatograms submitted are of March, May & June 2025 while stability time points are of 2021 & 2022.
- xix. Please explain that Drug Excipient Compatibility study is performed by DSC while you have submitted Chromatograms of Tirzepatide + Sodium Chloride.

19	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	HIMMEL PHARMACEUTICALS (PVT.) LTD Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Zazaria e Pakistan Lahore (05-352-0065)
	Application Form Dy. No / Tracking ID & date of submission	(B1X-J9G-GEBZ, 2024-10-18)
	Detail of Fee Submitted	300000.0, 2024-10-17,
	The proposed proprietary name / brand name	Tirzix 5mg Injection

Label Claim	Each 0.5 mL solution contains: Tirzepatide.....5 mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's-As per SRO
Shelf Life (Unit)	2 Year(s)Store between 2-8°C.
For generic drugs (me-too Status)	Not available
Pharmacotherapeutic Group of (API)	GLP-1 & GIP Receptor Agonist
Name, address of Manufacturing site:	Beacon Pharmaceuticals PLC.-Kathali, Bhaluka , Mymensingh, -Bangladesh
Pharmaceutical Equivalence and Comparative Dissolution Profile	Not Provided.
Name, address of Marketing Authorization Holder:	Beacon Pharmaceuticals PLC., Kathali, Bhaluka , Mymensingh, , Bangladesh
Details of Certificates (CoPP/FSC/cGMP):	Copy of legalized CoPP No. DA/ 6-110/2016/ 16019 dated 08-09-2024.
Details of Authorization Letter :	Copy of letter of authorization dated 02-10-2024.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Real Time: -20C for 03 batches till 24 months. Accelerated: 2-8C for 03 batches till 06 months. Batch numbers: D20210915, D20210608 and D20210706
The status in reference regulatory authorities	Mounjaro 5mg solution for injection in Pre-filled pen

Evaluation Remarks

The case was deferred in 350th meeting, the firm submitted the response which was again evaluated and shortcomings were communicated and the firm again submitted the response which is evaluated as follows. The firm has already been granted three opportunities to complete the application.

Q.	Query	Response	Remarks
	Peptide content studies are still not provided?	The firm submitted that The result of Peptide Content between 97-103%.	No studies are submitted, only limits provided.
	Purity Testing of API is performed by by RP-HPLC-UV instead of RP-LC-MS?	The RP-LC-UV testing, a single peak of a non-specific impurity exceeds 0.5%. This is done to determine whether the peak represents a single impurity or multiple co-eluting impurities. If it is a single impurity exceeding the limit, the product is considered non-compliant. If it consists of multiple impurities, each impurity is reported individually, and if all are below 0.5%, the product is compliant. Harbin Jixianglong's related substances testing method sets a limit of 0.5% for any single impurity.	In no later stages, firm has performed this testing.
	The provided COA is of finished product while the COA Verification and risk assessment performed by DP manufacturer was required to support omission of repeat testing of Sodium ions & Microbial limit of API at DP manufacturer site?	A formal risk assessment was conducted by the DP Quality Assurance team (Report No. RA-TIR-API2025-01) to evaluate whether repeat testing for sodium ions and microbial limits was necessary at the DP site.	Risk Assessment Report and API COA verification by Finished Product Manufacturer are still not submitted?
	Submit fee of Rs. 9400/- for update in API Bacterial Endotoxin specifications?	Challan No. 7542955762	

	Please explain that Purity & HMWS testing of API were not included in initially submitted stability data of API, now you have submitted the stability data of same batches manufactured in 2021 and included these tests at each time point?	in alignment with the expectations of the importing country and to support the ongoing registration process, we have now submitted updated stability data for the same API batches manufactured in 2021. This updated data includes both Purity and HMWS testing conducted at each designated time point. As these tests had already been performed as part of their internal quality protocols, they were able to furnish the necessary results upon our request.	
	Complete drug-excipient compatibility studies are still not submitted. Moreover, submitted document against this point states the following: "This document is prepared by Quality Control department of Beacon Pharmaceuticals PLC, Punjab Pakistan".	Firm has again submitted report by omitting Punjab Pakistan.	There is no detailed report and results in a table showing no compatibility of excipient and API.
	Peptide mapping of finished product by LC-MS is still not performed instead RP-HPLC is used?	Peptide mapping is a crucial analytical technique used for the structural characterization and identity confirmation of peptides and proteins. This process typically involves enzymatic digestion followed by separation of the resulting peptides. According to the European Pharmacopoeia, Peptide Mapping, various techniques—such as ion-exchange HPLC, hydrophobic interaction HPLC, and capillary electrophoresis—can be employed for peptide separation. However, reversed-phase HPLC (RP-HPLC) is identified as the most commonly used method for peptide map analysis. While the innovator may have utilized LC-MS during drug development for detailed structural elucidation, it is important to recognize that, for identification of already established products, HPLC alone is adequate for comparing peptide maps with reference standards. Furthermore, the use of RP-HPLC for peptide mapping is well-supported by multiple monographs in recognized Pharmacopeias.	Peptide mapping of finished product by LC-MS is required.
	High Molecular Weight Species Testing of Finished product by SEC is not submitted, only general chapter is provided?	The firm has submitted a raw calculation sheet without any batch details along with chromatograms.	The areas in chromatogram of sample (5.9743 + 21923.1018) are slightly different from calculation sheet (5.9644+21824.1017).
	Osmolality testing as part of finished product testing is still not submitted, instead general chapter on Osmolality & Osmolarity is submitted?	The firm has submitted SOP of Osmolality along with COA of one batch showing results of osmolality.	

.	Syringe Functionality Test of Finished product is still not submitted, instead general chapter is provided.	The firm has submitted a report	The submitted report is the copy of report submitted in another dossier of firm Tyzepa wherein this report was attached for pen injector test report of M/s Jiangsu Wanhai Medical Instruments Co., Ltd. The firm has removed the name of that company and manufacturer's name is written on it.
.	Dose accuracy (volume by weight), visual/functional inspection (inspection), and injection time (timing) tests for its device are still not submitted instead general chapter is provided.	The firm has submitted the SOPs.	Only SOPs are submitted. The firm has neither submitted revised specs with these test nor submitted any evidence of performance.
.	Please explain that Purity, HMWS, container closure integrity, break loose and glide force Testing of Finished product were not included in initially submitted stability data of finished product, now you have submitted the stability data of same batches manufactured in 2021 and included these tests at each time point?	Initially, there is no requirement for the Importer to perform tests such as purity, HMWS, container closure integrity, break-loose, and glide force. However, upon Importer request, we have provided updated stability data, including these tests, as part of the Accelerated and Long-term Stability Studies.	Purity, HMWS, container closure integrity, break loose and glide force Testing of Finished product were not included in initially submitted stability data of finished product, now you have submitted the stability data of same batches manufactured in 2021 and included these tests at each time point
.	The limit of HMWS in API is mentioned as not more than 0.8% while in stability data Finished product it is mentioned as not more than 3.0%? Please justify the increase in HMWS in light of RRA guidelines?	No response submitted.	Not Submitted.
.	Evidence of availability of prefilled syringe in RRAs as provided reference Mounjaro is a pre-filled pen?	In DRB Meeting No. 350, the Tirzi Injection 2.5 mg/0.5 mL Solution for Injection in a Pre-filled Syringe, manufactured by GETZ Pharma, was approved. GETZ Pharma provided a reference to Mounjaro, a product by Novartis, to support their submission.	The provided reference is of pre-filled syringe with autoinjector while no such device is mentioned for instant application.
.	Valid GMP Certificate of Drug Substance Manufacturer is issued by Pharmaceutical Profession	The firm submitted justification that GMP is not issued by NMPA now.	

	Association instead of regulatory authority of country of origin?		
.	Ammonium counter ions are not tested by API manufacturer?	No International pharmaceutical quality guidelines do not specifically require ammonium counter-ions for the testing of Tirzepatide API. However, if the API is a salt form, its counter-ion identity and content must be characterized and controlled, regardless of whether it's ammonium or another ion. As per the guidelines name: FDA-1997-D-0005-0001_content.	At API level, the DS manufacturer has set impurity limits of individual impurity as not more than 0.5% while Draft Guidelines on synthetic peptides by EMA states that peptide-related impurities should be reported above 0.1%, identified above 0.5% and qualified above 1.0%.
.	Details of reports of comparative tests of Finished product with Innovator product?	Not Submitted	Not Submitted
.	Details of manufacturing section, in which FPP is manufactured? Provide report of regulatory authority instead of a layout plan?	Firm has submitted GMP Certificate and Certificate of Renewal of Licence to Manufacture Drugs.	Peptide manufacturing is not indicated in any of these documents.
.	Please provide the details of Tirzepatide reference standard used in Cell based Bio-assay study?		Not Submitted
.	In revised Specifications, there is still difference in limits of impurities in Drug Substance and FPP. Moreover, the impurity limits in API are more relaxed as compared to Finished product. Please justify in light of RRA guidelines?	The observed differences in impurity limits between the API and FPP are justified based on regulatory risk assessment principles. The more relaxed limits in the API are acceptable because the downstream manufacturing process either controls, removes, or does not allow the concentration of these impurities to exceed the tighter limits set in the FPP. All impurity limits are established based on safety data, process capability, and product stability, in alignment with ICH and RRA guidelines.	
.	You were asked about the justification/ scientific rational of identifying critical steps and intermediates of manufacturing process, instead of submitting critical steps and intermediates of manufacturing process?	The critical steps and intermediates of finished product (FP) manufacturing are well described in the process validation. These critical steps and intermediates are defined by our Subject Matter Experts (SMEs) and Quality Assurance (QA) team, who have extensive experience in the relevant field.	
.	Raw data sheets & chromatograms of stability study data?	The chromatograms submitted are of March, May & June 2025 while stability time points are of 2021 & 2022.	

.	Raw data sheets of Drug Excipient compatibility study?	Chromatograms provided are of Tirzepatide + Sodium Chloride only.	The Drug Excipient compatibility study submitted against point 6 is of year 2021 while the chromatograms submitted are of year 2023.

Decision

Deferred

Registration Board decided to provide one last opportunity to applicant to furnish following documents/clarifications. In case the applicant fails to complete the application this time, the application shall be disposed of by the Board in its next meeting.

- i. Clarification of 280.0% peptide content in Peptide content studies.
- ii. Clarification of submitting same document for Peptide content studies as submitted in other application Tirzep manufactured by M/s Advance Chemical.
- iii. List of product specific impurities in Drug Substance, their inclusion in API specifications & evidence of performance by API manufacturer.
- iv. Risk Assessment Report and API COA verification by Finished Product Manufacturer are still not submitted.
- v. Raw data sheets & chromatograms of Purity & HMWS testing performed during stability studies of API of batches manufactured in 2021 for which stability data is submitted.
- vi. The limit of HMWS in API is mentioned as not more than 0.8% while in stability data Finished product it is mentioned as not more than 3.0%? Please justify the increase in HMWS in light of RRA guidelines?
- vii. Please clarify that applied product being synthetic peptide is manufactured by manufacturer in which section either Biological or non-biological section.
- viii. The provided evidence of Tirzi Injection of 350th meeting has an autoinjector with PFS, what is the status of your applied product.
- ix. In Drug Excipient compatibility performed by DSC, the curve should be a sum of individual components. However, DSC curves of single components are not performed to verify the compatibility.
- x. Peptide mapping of finished product by LC-MS is still not performed instead RP-HPLC is used. Please justify.
- xi. High Molecular Weight Species Testing of Finished product by SEC is not submitted, only general chapter is provided? The provided document is same as submitted in application of Tirzep manufactured by M/s Advance Chemical at pages-79-80 of response tracking ID: S56-LDG-R1DU dated 23-09-2025.
- xii. Please explain that the report submitted for syringe functionality is the copy of report submitted in another dossier of your firm Tyzepa wherein this report was attached for pen injector test report of M/s Jiangsu Wanhai Medical Instruments Co., Ltd. The name of that company has been removed and manufacturer's name is written on it.
- xiii. Please submit revised specs including Dose accuracy (volume by weight), visual/functional inspection (inspection), and injection time (timing) tests for your PFS. Also submit evidence of performance of these tests on finished product.

xiv. Raw data sheets & chromatograms of Purity, HMWS, container closure integrity, break loose and glide force Testing of Finished product testing performed during stability studies of batches manufactured in 2021 for which stability data is submitted.

xv. Ammonium counter ions are not tested by API manufacturer.

xvi. Details of reports of comparative tests of Finished product with Innovator product.

xvii. Please provide any official document from USA confirming that M/s Quality Control Chemicals Inc., USA is authorized to manufacture and sale Reference standards.

xviii. Raw data sheets & chromatograms of stability study data as the chromatograms submitted are of March, May & June 2025 while stability time points are of 2021 & 2022.

xix. Please explain that Drug Excipient Compatibility study is performed by DSC while you have submitted Chromatograms of Tirzepatide + Sodium Chloride.

20	Case Category		Routine (M. Zubair Masood)	
	Name, address of Applicant.		HIMMEL PHARMACEUTICALS (PVT.) LTD Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Zazaria e Pakistan Lahore (05-352-0065)	
	Application Form Dy. No / Tracking ID & date of submission		(EY1-MYJ-MS2A, 2025-07-22)	
	Detail of Fee Submitted		300000.0, 2025-04-16,	
	The proposed proprietary name / brand name		Tirzix 7.5mg Injection	
	Label Claim		Each 0.5 mL solution contains: Tirzepatide.....7.5 mg	
	Reference to Finished product specifications		As per Innovators Specification	
	Proposed Pack Size		1s-As per SRO	
	Shelf Life (Unit)		2 Year(s)ore between 2-8°C. Do not freeze or shake	
	For generic drugs (me-too Status)		Not available	
	Pharmacotherapeutic Group of (API)		GLP-1 & GIP Receptor Agonist	
	Name, address of Manufacturing site:		Beacon Pharmaceuticals PLC.-Kathali, Bhaluka , Mymensingh,-Bangladesh	
	Pharmaceutical Equivalence and Comparative Dissolution Profile		Not Provided.	
	Name, address of Marketing Authorization Holder:		Beacon Pharmaceuticals PLC., Kathali, Bhaluka , Mymensingh,, Bangladesh	
	Details of Certificates (CoPP/FSC/cGMP):		Copy of legalized CoPP No. DA/6-110/2016/16020 dated 08-09-2024.	
	Details of Authorization Letter :		Copy of letter of authorization dated 02-10-2024.	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		Real Time: -20C for 03 batches till 24 months. Accelerated: 2-8C for 03 batches till 06 months. Batch numbers: D20210915, D20210608 and D20210706	
	The status in reference regulatory authorities		ounjaro 7.5mg solution for injection in Prefilled pen	
Evaluation Remarks				
The case was deferred in 350th meeting, the firm submitted the response which was again evaluated and shortcomings were communicated and the firm again submitted the response which is evaluated as follows. The firm has already been granted three opportunities to complete the application.				
	Query	Response	Remarks	
	Peptide content studies are still not provided?	The firm submitted that The result of Peptide Content between 97-103%.	No studies are submitted, only limits	

			provided.
	Purity Testing of API is performed by by RP-HPLC-UV instead of RP-LC-MS?	The RP-LC-UV testing, a single peak of a non-specific impurity exceeds 0.5%. This is done to determine whether the peak represents a single impurity or multiple co-eluting impurities. If it is a single impurity exceeding the limit, the product is considered non-compliant. If it consists of multiple impurities, each impurity is reported individually, and if all are below 0.5%, the product is compliant. Harbin Jixianglong's related substances testing method sets a limit of 0.5% for any single impurity.	In no later stages, firm has performed this testing.
	The provided COA is of finished product while the COA Verification and risk assessment performed by DP manufacturer was required to support omission of repeat testing of Sodium ions & Microbial limit of API at DP manufacturer site?	A formal risk assessment was conducted by the DP Quality Assurance team (Report No. RA-TIR-API2025-01) to evaluate whether repeat testing for sodium ions and microbial limits was necessary at the DP site.	Risk Assessment Report and API COA verification by Finished Product Manufacturer are still not submitted?
	Submit fee of Rs. 9400/- for update in API Bacterial Endotoxin specifications?	Challan No. 7542955762	
	Please explain that Purity & HMWS testing of API were not included in initially submitted stability data of API, now you have submitted the stability data of same batches manufactured in 2021 and included these tests at each time point?	in alignment with the expectations of the importing country and to support the ongoing registration process, we have now submitted updated stability data for the same API batches manufactured in 2021. This updated data includes both Purity and HMWS testing conducted at each designated time point. As these tests had already been performed as part of their internal quality protocols, they were able to furnish the necessary results upon our request.	
	Complete drug-excipient compatibility studies are still not submitted. Moreover, submitted document against this point states the following: "This document is prepared by Quality Control department of Beacon Pharmaceuticals PLC, Punjab Pakistan".	Firm has again submitted report by omitting Punjab Pakistan.	There is no detailed report and results in a table showing no compatibility of excipient and API.
	Peptide mapping of finished product by LC-MS is still not performed instead RP-HPLC is used?	Peptide mapping is a crucial analytical technique used for the structural characterization and identity confirmation of peptides and proteins. This process typically involves enzymatic digestion followed by separation of the resulting peptides. According to the European Pharmacopoeia, Peptide Mapping, various techniques—such as ion-exchange HPLC, hydrophobic interaction HPLC, and capillary electrophoresis—can be employed for	Peptide mapping of finished product by LC-MS is required.

		peptide separation. However, reversed-phase HPLC (RP-HPLC) is identified as the most commonly used method for peptide map analysis. While the innovator may have utilized LC-MS during drug development for detailed structural elucidation, it is important to recognize that, for identification of already established products, HPLC alone is adequate for comparing peptide maps with reference standards. Furthermore, the use of RP-HPLC for peptide mapping is well-supported by multiple monographs in recognized Pharmacopeias.	
	High Molecular Weight Species Testing of Finished product by SEC is not submitted, only general chapter is provided?	The firm has submitted a raw calculation sheet without any batch details along with chromatograms.	The areas in chromatogram of sample (5.9743 + 21923.1018) are slightly different from calculation sheet (5.9644+21824.1017).
	Osmolality testing as part of finished product testing is still not submitted, instead general chapter on Osmolality & Osmolarity is submitted?	The firm has submitted SOP of Osmolality along with COA of one batch showing results of osmolality.	
	Syringe Functionality Test of Finished product is still not submitted, instead general chapter is provided.	The firm has submitted a report	The submitted report is the copy of report submitted in another dossier of firm Tyzepa wherein this report was attached for pen injector test report of M/s Jiangsu Wanhai Medical Instruments Co., Ltd. The firm has removed the name of that company and manufacturer's name is written on it.
	Dose accuracy (volume by weight), visual/functional inspection (inspection), and injection time (timing) tests for its device are still not submitted instead general chapter is provided.	The firm has submitted the SOPs.	Only SOPs are submitted. The firm has neither submitted revised specs with these test nor submitted any evidence of performance.
	Please explain that Purity, HMWS, container closure integrity, break loose and glide force Testing of Finished product were not included in initially submitted stability data of finished product, now you have submitted the	Initially, there is no requirement for the Importer to perform tests such as purity, HMWS, container closure integrity, break-loose, and glide force. However, upon Importer request, we have provided updated stability data, including these tests, as part of the Accelerated and Long-term Stability Studies.	Purity, HMWS, container closure integrity, break loose and glide force Testing of Finished product were not included in initially submitted stability data of finished product, now

	stability data of same batches manufactured in 2021 and included these tests at each time point?		you have submitted the stability data of same batches manufactured in 2021 and included these tests at each time point
.	The limit of HMWS in API is mentioned as not more than 0.8% while in stability data Finished product it is mentioned as not more than 3.0%? Please justify the increase in HMWS in light of RRA guidelines?	No response submitted.	Not Submitted.
.	Evidence of availability of prefilled syringe in RRAs as provided reference Mounjaro is a pre-filled pen?	In DRB Meeting No. 350, the Tirzi Injection 2.5 mg/0.5 mL Solution for Injection in a Pre-filled Syringe, manufactured by GETZ Pharma, was approved. GETZ Pharma provided a reference to Mounjaro, a product by Novartis, to support their submission.	The provided reference is of pre-filled syringe with autoinjector while no such device is mentioned for instant application.
.	Valid GMP Certificate of Drug Substance Manufacturer is issued by Pharmaceutical Profession Association instead of regulatory authority of country of origin?	The firm submitted justification that GMP is not issued by NMPA now.	
.	Ammonium counter ions are not tested by API manufacturer?	No International pharmaceutical quality guidelines do not specifically require ammonium counter-ions for the testing of Tirzepatide API. However, if the API is a salt form, its counter-ion identity and content must be characterized and controlled, regardless of whether it's ammonium or another ion. As per the guidelines name: FDA-1997-D-0005-0001_content.	At API level, the DS manufacturer has set impurity limits of individual impurity as not more than 0.5% while Draft Guidelines on synthetic peptides by EMA states that peptide-related impurities should be reported above 0.1%, identified above 0.5% and qualified above 1.0%.
.	Details of reports of comparative tests of Finished product with Innovator product?	Not Submitted	Not Submitted
.	Details of manufacturing section, in which FPP is manufactured? Provide report of regulatory authority instead of a layout plan?	Firm has submitted GMP Certificate and Certificate of Renewal of Licence to Manufacture Drugs.	Peptide manufacturing is not indicated in any of these documents.
.	Please provide the details of Tirzepatide reference standard used in Cell based Bio-assay study?		Not Submitted

.	In revised Specifications, there is still difference in limits of impurities in Drug Substance and FPP. Moreover, the impurity limits in API are more relaxed as compared to Finished product. Please justify in light of RRA guidelines?	The observed differences in impurity limits between the API and FPP are justified based on regulatory risk assessment principles. The more relaxed limits in the API are acceptable because the downstream manufacturing process either controls, removes, or does not allow the concentration of these impurities to exceed the tighter limits set in the FPP. All impurity limits are established based on safety data, process capability, and product stability, in alignment with ICH and RRA guidelines.	
.	You were asked about the justification/ scientific rational of identifying critical steps and intermediates of manufacturing process, instead of submitting critical steps and intermediates of manufacturing process?	The critical steps and intermediates of finished product (FP) manufacturing are well described in the process validation. These critical steps and intermediates are defined by our Subject Matter Experts (SMEs) and Quality Assurance (QA) team, who have extensive experience in the relevant field.	
.	Raw data sheets & chromatograms of stability study data?	The chromatograms submitted are of March, May & June 2025 while stability time points are of 2021 & 2022.	
.	Raw data sheets of Drug Excipient compatibility study?	Chromatograms provided are of Tirzepatide + Sodium Chloride only.	The Drug Excipient compatibility study submitted against point 6 is of year 2021 while the chromatograms submitted are of year 2023.

Decision

Deferred

Registration Board decided to provide one last opportunity to applicant to furnish following documents/ clarifications. In case the applicant fails to complete the application this time, the application shall be disposed of by the Board in its next meeting.

- Clarification of 280.0% peptide content in Peptide content studies.
- Clarification of submitting same document for Peptide content studies as submitted in other application Tirzep manufactured by M/s Advance Chemical.
- List of product specific impurities in Drug Substance, their inclusion in API specifications & evidence of performance by API manufacturer.
- Risk Assessment Report and API COA verification by Finished Product Manufacturer are still not submitted.
- Raw data sheets & chromatograms of Purity & HMWS testing performed during stability studies of API of batches manufactured in 2021 for which stability data is submitted.
- The limit of HMWS in API is mentioned as not more than 0.8% while in stability data Finished product it is mentioned as not more than 3.0%? Please justify the increase in HMWS in light of RRA guidelines?

- vii. Please clarify that applied product being synthetic peptide is manufactured by manufacturer in which section either Biological or non-biological section.
- viii. The provided evidence of Tirzi Injection of 350th meeting has an autoinjector with PFS, what is the status of your applied product.
- ix. In Drug Excipient compatibility performed by DSC, the curve should be a sum of individual components. However, DSC curves of single components are not performed to verify the compatibility.
- x. Peptide mapping of finished product by LC-MS is still not performed instead RP-HPLC is used. Please justify.
- xi. High Molecular Weight Species Testing of Finished product by SEC is not submitted, only general chapter is provided? The provided document is same as submitted in application of Tirzep manufactured by M/s Advance Chemical at pages-79-80 of response tracking ID: S56-LDG-R1DU dated 23-09-2025.
- xii. Please explain that the report submitted for syringe functionality is the copy of report submitted in another dossier of your firm Tyzepa wherein this report was attached for pen injector test report of M/s Jiangsu Wanhai Medical Instruments Co., Ltd. The name of that company has been removed and manufacturer's name is written on it.
- xiii. Please submit revised specs including Dose accuracy (volume by weight), visual/functional inspection (inspection), and injection time (timing) tests for your PFS. Also submit evidence of performance of these tests on finished product.
- xiv. Raw data sheets & chromatograms of Purity, HMWS, container closure integrity, break loose and glide force Testing of Finished product testing performed during stability studies of batches manufactured in 2021 for which stability data is submitted.
- xv. Ammonium counter ions are not tested by API manufacturer.
- xvi. Details of reports of comparative tests of Finished product with Innovator product.
- xvii. Please provide any official document from USA confirming that M/s Quality Control Chemicals Inc., USA is authorized to manufacture and sale Reference standards.
- xviii. Raw data sheets & chromatograms of stability study data as the chromatograms submitted are of March, May & June 2025 while stability time points are of 2021 & 2022.
- xix. Please explain that Drug Excipient Compatibility study is performed by DSC while you have submitted Chromatograms of Tirzepatide + Sodium Chloride.

21	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Hilton Pharma (Pvt) Limited. Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area (000136)
	Application Form Dy. No / Tracking ID & date of submission	(JA6-SZ4-ZRQP, 2025-07-10)
	Detail of Fee Submitted	75000.0, 2025-05-26,
	The proposed proprietary name / brand name	Semhil 2mg/3mL Injection
	Label Claim	Each vial contains: Semaglutide 2mg/3mL
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C in a refrigerator. Protect from heat & sunlight . Do not Freeze
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	GLP-1 receptor agonist

Name, address of Manufacturing site:	Self Manufacturing				
Name & address of API manufacturer	Hangzhou Zhongmeihuadong Pharmaceutical Jiangdong Co., Ltd., No. 7278 Meilin Avenue, Dajiangdong Industrial Cluster Zone, Hangzhou				
Detail of stability batches of drug product	Three Batches: Batch #: SEM-1283-04/24 Batch #: SEM-1284-05/24 Batch #: SEM-1285-06/24 Conditions: Real Time Stability Study Temperature: 5°C ± 3°C Accelerated Stability Study Temperature: 25°C ± 2°C Humidity: 60% ± 5%RH Size: 200 Vials each				
Documents for the procurement of API with approval from DRAP (in case of Import)	License No. K-2896224265276 dated 15-01-2024.				
Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted				
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: 203520AJ, 220601AJ, 220602AJ Conditions: -20C Realtime, 5°C±3°C Accelerated Size: Around 800g Each				
The status in reference regulatory authorities	FDA Approved - OZEMPIC 2MG/3ML (0.68MG/ML) BY NOVO NORDISK				
GMP status of the firm	GMP certificate dated 20-01-2025.				
Evidence of approval of manufacturing facility	Copy of Section Approval dated 18-02-2023				
Evaluation Remarks					
Decision					
Approved					
Approved as per innovator's specifications with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA&LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP. 4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. 5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022. 6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.					
22	<table> <tr> <td>Case Category</td><td>Routine (M. Zubair Masood)</td></tr> <tr> <td>Name, address of Applicant.</td><td>Hilton Pharma (Pvt) Limited. Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area (000136)</td></tr> </table>	Case Category	Routine (M. Zubair Masood)	Name, address of Applicant.	Hilton Pharma (Pvt) Limited. Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area (000136)
Case Category	Routine (M. Zubair Masood)				
Name, address of Applicant.	Hilton Pharma (Pvt) Limited. Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area (000136)				

Application Form Dy. No / Tracking ID & date of submission	(4JZ-3VQ-5HHB, 2025-07-10)
Detail of Fee Submitted	37000.0, 2025-05-26,
The proposed proprietary name / brand name	Semhil 4mg/3mL Injection
Label Claim	Each vial contains: Semaglutide 4mg/3mL
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's-De-Controlled
Shelf Life (Unit)	2 Year(s)Store at 2-8°C in a refrigerator. Protect from heat & sunlight . Do not Freeze
For generic drugs (me-too Status)	Seglutide 4mg/3ml Injection by Macter International Ltd (Reg No. 120536)
Pharmacotherapeutic Group of (API)	GLP-1 receptor agonist
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd.
Detail of stability batches of drug product	Three Batches: Batch #: SEM-1280-04/24 Batch #: SEM-1281-05/24 Batch #: SEM-1282-06/24 Conditions: Real Time Stability Study Temperature: 5°C ± 3°C Accelerated Stability Study Temperature: 25°C ± 2°C Humidity: 60% ± 5%RH Size: 200 Vials each
Documents for the procurement of API with approval from DRAP (in case of Import)	License No. K-2896224265276 dated 15-01-2024.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: 203520AJ, 220601AJ, 220602AJ Conditions: -20C Realtime, 5°C±3°C Accelerated Size: Around 800g Each
The status in reference regulatory authorities	FDA Approved - OZEMPIC 4MG/3ML (1.34MG/ML) BY NOVO NORDISK
GMP status of the firm	GMP certificate dated 20-01-2025.
Evidence of approval of manufacturing facility	Copy of Section Approval dated 18-02-2023

Evaluation Remarks

The firm has already been granted 03 opportunities to complete the application, yet, following shortcomings are still present:1. The initially submitted stability data was of 06 months till Feb 2025, you are advised to provide updated data with Inclusion of tests i.e. identification by peptide mapping, bacterial endotoxins and sterility in the stability.2. In use stability studies of drug product i.e. after first opening.3. The provided chromatograms of impurity testings are of dates August 2024 and March 2025 while stability data provided is of time points Aug-2024, Nov-2024 & Feb-2024.

Decision

Approved

Approved as per innovator's specifications with following conditions:

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.
2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference

products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA&LT.

3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.

4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.

6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

23	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Getz Pharma (Pvt) Limited 29-30/27,Korangi Industrial Area karachi (000284)
	Application Form Dy. No / Tracking ID & date of submission	(339-V1T-743M, 2025-01-31)
	Detail of Fee Submitted	300000.0, 2024-11-05,
	The proposed proprietary name / brand name	Liraglid 18mg/3mL Pre-Filled Pen Solution for Injection
	Label Claim	Each 3mL Pre-Filled Pen contains: Liraglutide.....18mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3mL x 1Pre-Filled Pe-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a refrigerator at 2~8°C (do not close to freezing chamber) do not freeze.
	For generic drugs (me-too Status)	Victoza Injection in Pre-Filled Pen 6mg/mL by M/s Novonordisk, Pakistan
	Pharmacotherapeutic Group of (API)	GLP-1 receptor agonist
	Name, address of Manufacturing site:	Self Manufacturing
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Biosimilarity data provided
	Name, address of Marketing Authorization Holder:	, ,
	Details of Certificates (CoPP/FSC/cGMP):	Copy of Apostille CoPP No. Zhejiang20250343 dated 27-06-2025 valid till 26-06-2027.
	Details of Authorization Letter :	Copy of LETTER OF AUTHORIZATION dated 01-07-2025
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Long term stability data for 36 months at -20C ±5 and accelerated testing 2-8C.
	The status in reference regulatory authorities	Victoza (Liraglutide) Solution for Injection in Pre-filled Pen 18mg/3mL by M/s Novo Nordisk Inc., USA (USFDA approved)

Evaluation Remarks

Decision of 347th Meeting:The Registration Board deferred the case for the submission of the following documents: The firm has applied under the Head of "Bulk Import and Local manufacturing" the dosage form is pre-filled pen in application.Module 3.2.P.4, (3.2.P.4.1 to 3.2.P.4.4) not provided.Module 3.2.S.2.3, 3.2.S.2.4, 3.2.S.2.5 and 3.2.S.2.6 not provided in Substance part.Submit BPR.Stability studies not performed at secondary packaging site. Clarification is required.All parameters are not tested in stability studies of the product as mentioned in FP specifications.All commitments required under Module should be submitted by applicant instead of DP

manufacturer. Submit in-use stability studies of drug product. Remarks: Firm has submitted following documents: The product will be imported in bulk labelled pens and will be secondary packaged locally. 3.2.P.4.1 to 3.2.P.4.4 provided. Module 3.2.S.2.3, 3.2.S.2.4, 3.2.S.2.5 and 3.2.S.2.6. Firm has submitted batch packaging protocol. For stability studies, the firm submitted that they will import labelled pens and only secondary packaging will be done locally. The already submitted stability data is of finally packaged pens packed in country of origin and batches are simulating the packaging that will be done locally. The firm submitted the evidence that all the tests as per shelf life specifications are performed during stability studies. The firm submitted all commitments required under Module by M/s Getz. The firm has submitted in use-stability data of three batches upto 5 weeks storage at 2-8C after opening. The firm submitted that name of manufacturer has changed and submitted revised CoPP & LOA. Shortcoming: Fee for pre-registration change in name of manufacturer is required.

Decision

Not Applicable

Keeping in view COPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs subject to submission of fee for pre-registration change in name of bulk labelled Pens manufacturer. M/s Getz Pharma (Pvt.) Ltd., Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi shall be responsible for final batch release.

24	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	M & M Pharma Javaid Plaza, Gurumangat Road, Gulberg II, Lahore (05-352-0065)
	Application Form Dy. No / Tracking ID & date of submission	(8JH-1ZA-NAU9, 2025-04-24)
	Detail of Fee Submitted	300000.0, 313500 2025-01-15, 2025-09-11
	The proposed proprietary name / brand name	Recombinant Human Papillomavirus Bivalent (Types 16, 18) Vaccine
	Label Claim	Each dose (0.5 mL) of the vaccine contains: Human Papillomavirus type 16 L1 protein 40 micrograms Human Papillomavirus type 18 L1 protein 20 micrograms
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	0.5ml x 10's-Controlled
	Shelf Life (Unit)	2 Years Store at +2°C to +8°C. DO NOT FREEZE
	For generic drugs (me-too Status)	GlaxoSmithKline Biologicals SA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Yuxi Zerun Biotechnology Co., Ltd-No. 83 South Dongfeng Road, High-tech Zone, Yuxi, Yunnan Province, 653100, P.R. -China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	M&M Pharma, Javaid Plaza, Gurumangt road, Gulberg II, Lahore, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	HPV-2_China

Evaluation Remarks

Decision of 348th Meeting: The Registration Board deferred the case for the submission of the following documents: ☐ Hard copy of original, legalized and valid COPP and original or notarized copy of LOA. ☐ Submit Form 5 F as per final guidance document for biological products. ☐ Submit evidence of already registered vaccine with same concentration, dose and container closure system with DRAP. ☐ The pharmacotherapeutic group

of applied vaccine. □ References to the relevant specifications. □ Provide the Summary of Product Characteristics (SmPC). □ Data on the prevalence of the applied strains in Pakistan. □ Separate drug substance part for each antigen included in the product. □ The container closure system and stability data are for a vial presentation, whereas the applied product is a pre-filled syringe (PFS). □ The applied vaccine is in PFS form, while the WHO-prequalified (PQ) product is in a vial; a justification for this difference is required. □ Non-clinical and clinical studies provided are based on the vial presentation instead of the PFS; justification is needed in line with applicable reference guidelines. □ Submit the Periodic Safety Update Report (PSUR) and Adverse Events Following Immunization (AEFI) data for the pre-filled syringe presentation. Remarks: Response of the firm had confirmed that the product applied by the firm is WHO PQ vaccine. Initially the firm mentioned PFS in its dossier while the WHO PQ vaccine is in Vial. Now, the firm has revised its presentation to vial as per WHO PQ vaccine. The firm has also submitted fee of Rs. 313500 vide challan no. 78358351534.

Decision

Approved

Keeping in view the prequalification of product by WHO; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.

25	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	HIMMEL PHARMACEUTICALS (PVT.) LTD Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Zazaria e Pakistan Lahore (05-352-0065)
	Application Form Dy. No / Tracking ID & date of submission	(ATW-94U-VGLS, 2025-04-21)
	Detail of Fee Submitted	300000.0, 2025-04-10,
	The proposed proprietary name / brand name	Tirzep 2.5 SC Injection
	Label Claim	Each PFS contains: Tirzepatide.....2.5 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	24 Year(s)Store between 2-8°C.
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	GLP-1 and GIP Receptor Agonist
	Name, address of Manufacturing site:	Advanced Chemical Industries Limited. -7 Hajeegonj Road, Godnyl, Narayanganj, -Bangladesh
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not Provided
	Name, address of Marketing Authorization Holder:	Advanced Chemical Industries Limited. , 7 Hajeegonj Road, Godnyl, Narayanganj, , Bangladesh
	Details of Certificates (CoPP/FSC/cGMP):	Copy of legalized CoPP No. DA/6-31/2000/21531 dated 15-12-2024
	Details of Authorization Letter :	Copy of letter of authorization dated 19-02-2025.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	three new batches CP-027-20240901, CP-027-20240902 & CP-027-20241001 Realtime -20C & Accelerated 2-8C
	The status in reference regulatory authorities	Mounjaro 2.5 mg solution for injection in Pre-filled pen. Eli Lilly by Italy

Evaluation Remarks

The case was deferred in 350th meeting, the firm submitted the response which was again evaluated and shortcomings were communicated and the firm again submitted the response which is evaluated as follows. The firm has already been granted three opportunities to complete the application.

	Query	Response	Remarks
o.			

	Peptide content studies are still not provided?	The firm submitted that The result of Peptide Content between 97-103%.	No studies are submitted, only limits provided.
	Purity Testing of API is performed by by RP-HPLC-UV instead of RP-LC-MS?	The RP-LC-UV testing, a single peak of a non-specific impurity exceeds 0.5%. This is done to determine whether the peak represents a single impurity or multiple co-eluting impurities. If it is a single impurity exceeding the limit, the product is considered non-compliant. If it consists of multiple impurities, each impurity is reported individually, and if all are below 0.5%, the product is compliant. Harbin Jixianglong's related substances testing method sets a limit of 0.5% for any single impurity.	
	Residual solvent and inorganic impurity testing by API manufacturer?	The submitted study is by Finished product manufacturer instead of DS manufacturer.	Not performed by DS manufacturer.
	Trifluoroacetic acid is being used in manufacturing of API why it is not being tested as residual solvent?	Trifluoroacetic acid (TFA) is not tested as a residual solvent because it is not classified as one under ICH Q3C guidelines. However, since it is a process-related reagent with potential toxicity, its residual levels must be controlled and justified under ICH Q3A(R2).	The firm admitted that it has potential toxicity, yet firm did not submit any controls.
	You are again advised to clarify that Which DMF of API should be considered as one provided with applications of M/s Beacon Pharmaceuticals has different testing parameters and limits as compared to the one submitted now by the firm as API manufacturer is same in both cases?	Again submitted the same DS part.	No clarification provided. List of impurities in API along with their specification limits are required as firm mentioned only individual unknown, individual known & Total Impurities?
	The Innovator has performed Purity Testing & High Molecular Weight Testing during stability studies of API while your API manufacturer has not performed these test during stability studies of API?	The firm has submitted stability data of three new batches CP-027-20240901, CP-027-20240902 & CP-027-20241001 wherein tests of HMWS is included.	Purity test is still not included in stability studies. Moreover, realtime stability data provided is of 9 months only.
	Justification of Impurities Acceptance criteria mentioned by API manufacturer?	In justification, the firm has submitted performance results of three batches.	
	The initial submitted application was of pre-filled pen while now you have revised it to Pre filled Syringe?	The firm submitted that it was a typo error	Typo error
	Ammounium counter ions are not tested by API manufacturer?	No International pharmaceutical quality guidelines do not specifically require ammonium counter-ions for the testing of Tirzepatide API. However, if the API is a salt	Ammounium counter ions tested and validated by Innovator.

		form, its counter-ion identity and content must be characterized and controlled, regardless of whether it's ammonium or another ion. As per the guidelines name: FDA-1997-D-0005-0001_content.	
.	Following tests are required to be performed by API manufacturer: i. Enantiomeric purity by GC-MS, ii. Identity of potential counter ion by RP-HPLC	Not Submitted.	
.	Valid GMP Certificate of Drug Substance Manufacturer issued by regulatory authority of country of origin?	The firm submitted that NMPA does not issue GMP Certificate now.	
.	Details of reports of comparative tests of Finished product with Innovator product are still not provided? Results are provided only for Appearance, pH & Assay?	Not Submitted	
.	Details of manufacturing section, in which FPP is manufactured?	Firm has submitted GMP Certificate.	Peptide manufacturing is not indicated this document.
.	As per EMA draft guidelines, peptide-related impurities should be reported above 0.1%, identified above 0.5% and qualified above 1.0%. Your provided limit 2% is well above quantification limit. Please explain?	The provided 2% impurity limit exceeds the EMA qualification threshold of 1.0% for peptide-related impurities and may only be acceptable if comprehensive toxicological qualification data are available. Otherwise, Your provided limit 2% is well above quantification limit. Please explain? the limit should be adjusted to comply with EMA guidelines (i.e., report >0.1%, identify >0.5%, and qualify >1.0%).	No Justification submitted.
.	Syringe Functionality Test of Finished product is still not submitted, instead general chapter is provided.	The firm again submitted General Chapter	Not Submitted.
.	Evidence of availability of PFS in RRAs?	In DRB Meeting No. 350, the Tirzi Injection 2.5 mg/0.5 mL Solution for Injection in a Pre-filled Syringe, manufactured by GETZ Pharma, was approved. GETZ Pharma provided a reference to Mounjaro, a product by Novartis, to support their submission.	The provided reference is of pre-filled syringe with autoinjector while no such device is mentioned for instant application.
.	Tirzepatide has dual agonist of GIP and GLP-1 receptors. So, cell based bioassay GIP and cell based bioassay GLP-1 is part of API specifications of innovator. Same is required by the API and	Report Submitted	Details of Reference standard used in BioAssay are required.

	finished product manufacturer of applied product. As provided document is a general protocol instead of report?		
.	Please explain how FPP manufacturer identified critical steps and intermediates of manufacturing process?	Critical steps and intermediates of FP manufacturing are well described in process validation; these critical steps & intermediates are set by our SME & QA having a long experience in the relevant filed. However, in future process validation a QRM will be performed for critical steps and intermediates identification.	
.	You have mentioned commercial batch size as 2000 PFS while as per your dossier it is 909 PFS?	The firm submitted that In Certificate of Analysis the commercial batch size is 2000.	The commercial batch as per firm is of 2000 PFS while stability data and process validation provided is of batch size 909 PFS.
.	The working standard used in finished product is provided by M/s Beijing Sjar Technology Development Co., Ltd., China. Please explain, against which reference standard, the working standard is prepared?	The firm submitted COA of reference standard received from M/s Quality Control Chemicals Inc., USA.	
.	Purity, HMWS, container closure integrity, break loose and glide force during stability studies of finished product.	Not responded.	
.	Stress testing of finished product in stress degradation conditions with respect to thermal, pH, and oxidative stress is required?	Submitted.	

Decision

Deferred

Registration Board decided to provide one last opportunity to applicant to furnish following documents/ clarifications. In case the applicant fails to complete the application this time, the application shall be disposed of by the Board in its next meeting.

i. Clarification of 280.0% peptide content in Peptide content studies.

ii. Clarification of submitting same document for Peptide content studies as submitted in other application Tirzix manufactured by M/s Beacon Pharmaceuticals.

iii. Residual solvent and inorganic impurity testing by Drug Substance manufacturer?

- iv. List of product specific impurities in Drug Substance, their inclusion in API specifications & evidence of performance by API manufacturer.
- v. Trifluoroacetic acid is being used in manufacturing of API why it is not being tested as residual solvent?
- vi. The Innovator has performed Purity Testing & High Molecular Weight Testing during stability studies of API while your API manufacturer has not performed these test during stability studies of API?
- vii. Full fee of Registration for changing application from pre-filled pen to PFS.
- viii. Ammonium counter ions are not tested by API manufacturer.
- ix. Following tests are required to be performed by API manufacturer:
- Enantiomeric purity by GC-MS,
 - Identity of potential counter ion by RP-HPLC
- x. Please clarify that the chromatograms submitted in support of Comparative study are of Tirzix Injection manufactured by another manufacturer M/s Beacon Pharmaceuticals. Moreover, all the chromatograms are signed by same personnels which indicates that they all are of Beacon Pharmaceuticals and not of this application. Moreover, the firm has also provided chromatogram of Phenol detection while phenol is not an API in this application.
- xi. Please clarify that applied product being synthetic peptide is manufactured by manufacturer in which section either Biological or non-biological section.
- xii. As per EMA draft guidelines, peptide-related impurities should be reported above 0.1%, identified above 0.5% and qualified above 1.0%. Your provided limit 2% is well above quantification limit. Please explain?
- xiii. Syringe Functionality Test of Finished product is still not submitted, instead general chapter is provided.
- xiv. The provided evidence of Tirzi Injection of 350th meeting has an autoinjector with PFS, what is the status of your applied product.
- xv. API manufacturer has not performed cell based bioassay GIP and cell based bioassay GLP-1 of API.
- xvi. Please provide any official document from USA confirming that M/s Quality Control Chemicals Inc., USA is authorized to manufacture and sale Reference standards.
- xvii. The provided commercial batch as per firm is 2000 PFS while stability data and process validation provided is of batch size 909 PFS.
- xviii. Purity, HMWS, container closure integrity, break loose and glide force during stability studies of finished product. If available, then submit complete evidence of performance including raw data sheets and chromatograms.

26	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	HIMMEL PHARMACEUTICALS (PVT.) LTD Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Zazaria e Pakistan Lahore (05-352-0065)
	Application Form Dy. No / Tracking ID & date of submission	(GT1-HEP-7M88, 2025-07-22)
	Detail of Fee Submitted	300000.0, 2025-04-10,
	The proposed proprietary name / brand name	Tirzep 5mg SC Injection
	Label Claim	Each PFS contains: Tirzepatide.....5 mg
	Reference to Finished product specifications	As per Innovators Specification

Proposed Pack Size	1's-As per SRO
Shelf Life (Unit)	24 Year(s)Store between 2-8°C.
For generic drugs (me-too Status)	Not Applicable
Pharmacotherapeutic Group of (API)	GLP-1 and GIP Receptor Agonist
Name, address of Manufacturing site:	Advanced Chemical Industries Limited. -7 Hajeegonj Road, Godnyl, Narayanganj, -Bangladesh
Pharmaceutical Equivalence and Comparative Dissolution Profile	Not Provided
Name, address of Marketing Authorization Holder:	Advanced Chemical Industries Limited. , 7 Hajeegonj Road, Godnyl, Narayanganj, , Bangladesh
Details of Certificates (CoPP/FSC/cGMP):	Copy of legalized CoPP No. DA/6-31/2000/21532 dated 15-12-2024
Details of Authorization Letter :	Copy of letter of authorization dated 19-02-2025.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	three new batches CP-027-20240901, CP-027-20240902 & CP-027-20241001 Realtime -20C & Accelerated 2-8C
The status in reference regulatory authorities	Mounjaro 5mg solution for injection in Pre-filled pen (Eli Lilly, Italy)

Evaluation Remarks

The case was deferred in 350th meeting, the firm submitted the response which was again evaluated and shortcomings were communicated and the firm again submitted the response which is evaluated as follows. The firm has already been granted three opportunities to complete the application.

Q. No.	Query	Response	Remarks
	Peptide content studies are still not provided?	The firm submitted that The result of Peptide Content between 97-103%.	No studies are submitted, only limits provided.
	Purity Testing of API is performed by by RP-HPLC-UV instead of RP-LC-MS?	The RP-LC-UV testing, a single peak of a non-specific impurity exceeds 0.5%. This is done to determine whether the peak represents a single impurity or multiple co-eluting impurities. If it is a single impurity exceeding the limit, the product is considered non-compliant. If it consists of multiple impurities, each impurity is reported individually, and if all are below 0.5%, the product is compliant. Harbin Jixianglong's related substances testing method sets a limit of 0.5% for any single impurity.	
	Residual solvent and inorganic impurity testing by API manufacturer?	The submitted study is by Finished product manufacturer instead of DS manufacturer.	Not performed by DS manufacturer.
	Trifluoroacetic acid is being used in manufacturing of API why it is not being tested as residual solvent?	Trifluoroacetic acid (TFA) is not tested as a residual solvent because it is not classified as one under ICH Q3C guidelines. However, since it is a process-related reagent with potential toxicity, its residual levels must be controlled and justified under ICH Q3A(R2).	The firm admitted that it has potential toxicity, yet firm did not submit any controls.
	You are again advised to clarify that Which DMF of API should be considered as one provided with applications of M/s Beacon Pharmaceuticals has different testing parameters and limits as compared to	Again submitted the same DS part.	No clarification provided. List of impurities in API along with their specification limits are required as firm mentioned only individual unknown,

	the one submitted now by the firm as API manufacturer is same in both cases?		individual known & Total Impurities?
	The Innovator has performed Purity Testing & High Molecular Weight Testing during stability studies of API while your API manufacturer has not performed these test during stability studies of API?	The firm has submitted stability data of three new batches CP-027-20240901, CP-027-20240902 & CP-027-20241001 wherein tests of HMWS is included.	Purity test is still not included in stability studies. Moreover, realtime stability data provided is of 9 months only.
	Justification of Impurities Acceptance criteria mentioned by API manufacturer?	In justification, the firm has submitted performance results of three batches.	
	The initial submitted application was of pre-filled pen while now you have revised it to Pre filled Syringe?	The firm submitted that it was a typo error	Typo error
	Ammounium counter ions are not tested by API manufacturer?	No International pharmaceutical quality guidelines do not specifically require ammonium counter-ions for the testing of Tirzepatide API. However, if the API is a salt form, its counter-ion identity and content must be characterized and controlled, regardless of whether it's ammonium or another ion. As per the guidelines name: FDA-1997-D-0005-0001_content.	Ammounium counter ions tested and validated by Innovator.
.	Following tests are required to be performed by API manufacturer: i. Enantiomeric purity by GC-MS, ii. Identity of potential counter ion by RP-HPLC	Not Submitted.	
.	Valid GMP Certificate of Drug Substance Manufacturer issued by regulatory authority of country of origin?	The firm submitted that NMPA does not issue GMP Certificate now.	
.	Details of reports of comparative tests of Finished product with Innovator product are still not provided? Results are provided only for Appearance, pH & Assay?	Not Submitted	
.	Details of manufacturing section, in which FPP is manufactured?	Firm has submitted GMP Certificate.	Peptide manufacturing is not indicated this document.
.	As per EMA draft guidelines, peptide-related impurities should be reported above 0.1%.	The provided 2% impurity limit exceeds the EMA qualification threshold of 1.0% for peptide-related impurities and may only be acceptable if comprehensive toxicological	No Justification submitted.

	identified above 0.5% and qualified above 1.0%. Your provided limit 2% is well above quantification limit. Please explain?	qualification data are available. Otherwise, Your provided limit 2% is well above quantification limit. Please explain? the limit should be adjusted to comply with EMA guidelines (i.e., report >0.1%, identify >0.5%, and qualify >1.0%).	
.	Syringe Functionality Test of Finished product is still not submitted, instead general chapter is provided.	The firm again submitted General Chapter	Not Submitted.
.	Evidence of availability of PFS in RRAs?	In DRB Meeting No. 350, the Tirzi Injection 2.5 mg/0.5 mL Solution for Injection in a Pre-filled Syringe, manufactured by GETZ Pharma, was approved. GETZ Pharma provided a reference to Mounjaro, a product by Novartis, to support their submission.	The provided reference is of pre-filled syringe with autoinjector while no such device is mentioned for instant application.
.	Tirzepatide has dual agonist of GIP and GLP-1 receptors. So, cell based bioassay GIP and cell based bioassay GLP-1 is part of API specifications of innovator. Same is required by the API and finished product manufacturer of applied product. As provided document is a general protocol instead of report?	Report Submitted	Details of Reference standard used in BioAssay are required.
.	Please explain how FPP manufacturer identified critical steps and intermediates of manufacturing process?	Critical steps and intermediates of FP manufacturing are well described in process validation; these critical steps & intermediates are set by our SME & QA having a long experience in the relevant filed. However, in future process validation a QRM will be performed for critical steps and intermediates identification.	
.	You have mentioned commercial batch size as 2000 PFS while as per your dossier it is 909 PFS?	The firm submitted that In Certificate of Analysis the commercial batch size is 2000.	The commercial batch as per firm is of 2000 PFS while stability data and process validation provided is of batch size 909 PFS.
.	The working standard used in finished product is provided by M/s Beijing Sjar Technology Development Co., Ltd., China. Please explain, against which reference standard, the working standard is prepared?	The firm submitted COA of reference standard received from M/s Quality Control Chemicals Inc., USA.	
.	Purity, HMWS, container closure integrity, break loose and glide force	Not responded.	

	during stability studies of finished product.		
.	Stress testing of finished product in stress degradation conditions with respect to thermal, pH, and oxidative stress is required?	Submitted.	

Decision

Deferred

Registration Board decided to provide one last opportunity to applicant to furnish following documents/clarifications. In case the applicant fails to complete the application this time, the application shall be disposed of by the Board in its next meeting.

- i. Clarification of 280.0% peptide content in Peptide content studies.
- ii. Clarification of submitting same document for Peptide content studies as submitted in other application Tirzix manufactured by M/s Beacon Pharmaceuticals.
- iii. Residual solvent and inorganic impurity testing by Drug Substance manufacturer?
- iv. List of product specific impurities in Drug Substance, their inclusion in API specifications & evidence of performance by API manufacturer.
- v. Trifluoroacetic acid is being used in manufacturing of API why it is not being tested as residual solvent?
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- ix. Following tests are required to be performed by API manufacturer:
 - a. Enantiomeric purity by GC-MS,
 - b. Identity of potential counter ion by RP-HPLC
- x. Please clarify that the chromatograms submitted in support of Comparative study are of Tirzix Injection manufactured by another manufacturer M/s Beacon Pharmaceuticals. Moreover, all the chromatograms are signed by same personnels which indicates that they all are of Beacon Pharmaceuticals and not of this application. Moreover, the firm has also provided chromatogram of Phenol detection while phenol is not an API in this application.
- xi. Please clarify that applied product being synthetic peptide is manufactured by manufacturer in which section either Biological or non-biological section.
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27	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	HIMMEL PHARMACEUTICALS (PVT.) LTD Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Zazaria e Pakistan Lahore (05-352-0065)
	Application Form Dy. No / Tracking ID & date of submission	(3EZ-T3V-1SHN, 2025-09-02)
	Detail of Fee Submitted	300000.0, 2025-04-23,
	The proposed proprietary name / brand name	Tirzep 7.5 SC Injection
	Label Claim	Each PFS contains: Tirzepatide.....7.5 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	24 Month(s)Store between 2-8°C.
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	GLP-1 and GIP Receptor Agonist
	Name, address of Manufacturing site:	Advanced Chemical Industries Limited. -7 Hajeegonj Road, Godnyl, Narayanganj, -Bangladesh
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not Provided
	Name, address of Marketing Authorization Holder:	Advanced Chemical Industries Limited. , 7 Hajeegonj Road, Godnyl, Narayanganj, , Bangladesh
	Details of Certificates (CoPP/FSC/cGMP):	Copy of legalized CoPP No. DA/6-31/2000/21531 dated 15-12-2024
	Details of Authorization Letter :	Copy of letter of authorization dated 19-02-2025.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	three new batches CP-027-20240901, CP-027-20240902 & CP-027-20241001 Realtime -20C & Accelerated 2-8C
	The status in reference regulatory authorities	Mounjaro 7.5mg solution for injection in Pre-filled pen (Eli Lilly, Italy)

Evaluation Remarks

The case was deferred in 350th meeting, the firm submitted the response which was again evaluated and shortcomings were communicated and the firm again submitted the response which is evaluated as follows. The firm has already been granted three opportunities to complete the application.

Q. No.	Query	Response	Remarks
	Peptide content studies are still not provided?	The firm submitted that The result of Peptide Content between 97-103%.	No studies are submitted, only limits provided.
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		is a single impurity exceeding the limit, the product is considered non-compliant. If it consists of multiple impurities, each impurity is reported individually, and if all are below 0.5%, the product is compliant. Harbin Jixianglong's related substances testing method sets a limit of 0.5% for any single impurity.	
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	The Innovator has performed Purity Testing & High Molecular Weight Testing during stability studies of API while your API manufacturer has not performed these test during stability studies of API?	The firm has submitted stability data of three new batches CP-027-20240901, CP-027-20240902 & CP-027-20241001 wherein tests of HMWS is included.	Purity test is still not included in stability studies. Moreover, realtime stability data provided is of 9 months only.
	Justification of Impurities Acceptance criteria mentioned by API manufacturer?	In justification, the firm has submitted performance results of three batches.	
	The initial submitted application was of pre-filled pen while now you have revised it to Pre filled Syringe?	The firm submitted that it was a typo error	Typo error
	Ammonium counter ions are not tested by API manufacturer?	No International pharmaceutical quality guidelines do not specifically require ammonium counter-ions for the testing of Tirzepatide API. However, if the API is a salt form, its counter-ion identity and content must be characterized and controlled, regardless of whether it's ammonium or another ion. As per the guidelines name: FDA-1997-D-0005-0001_content.	Ammonium counter ions tested and validated by Innovator.
.	Following tests are required to be performed	Not Submitted.	

	by API manufacturer: i. Enantiomeric purity by GC-MS, ii. Identity of potential counter ion by RP-HPLC		
.	Valid GMP Certificate of Drug Substance Manufacturer issued by regulatory authority of country of origin?	The firm submitted that NMPA does not issue GMP Certificate now.	
.	Details of reports of comparative tests of Finished product with Innovator product are still not provided? Results are provided only for Appearance, pH & Assay?	Not Submitted	
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.	Syringe Functionality Test of Finished product is still not submitted, instead general chapter is provided.	The firm again submitted General Chapter	Not Submitted.
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.	Please explain how FPP manufacturer identified	Critical steps and intermediates of FP manufacturing are well described in process	

	critical steps and intermediates of manufacturing process?	validation; these critical steps & intermediates are set by our SME & QA having a long experience in the relevant filed. However, in future process validation a QRM will be performed for critical steps and intermediates identification.	
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.	Purity, HMWS, container closure integrity, break loose and glide force during stability studies of finished product.	Not responded.	
.	Stress testing of finished product in stress degradation conditions with respect to thermal, pH, and oxidative stress is required?	Submitted.	

Decision

Deferred

Registration Board decided to provide one last opportunity to applicant to furnish following documents/ clarifications. In case the applicant fails to complete the application this time, the application shall be disposed of by the Board in its next meeting.

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- Enantiomeric purity by GC-MS,
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- x. Please clarify that the chromatograms submitted in support of Comparative study are of Tirzix Injection manufactured by another manufacturer M/s Beacon Pharmaceuticals. Moreover, all the chromatograms are signed by same personnels which indicates that they all are of Beacon Pharmaceuticals and not of this application. Moreover, the firm has also provided chromatogram of Phenol detection while phenol is not an API in this application.
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- xvi. Please provide any official document from USA confirming that M/s Quality Control Chemicals Inc., USA is authorized to manufacture and sale Reference standards.
- xvii. The provided commercial batch as per firm is 2000 PFS while stability data and process validation provided is of batch size 909 PFS.
- xviii. Purity, HMWS, container closure integrity, break loose and glide force during stability studies of finished product. If available, then submit complete evidence of performance including raw data sheets and chromatograms.

28	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan (01-374-0006)
	Application Form Dy. No / Tracking ID & date of submission	(2YG-ZZ5-4WE6, 2024-05-08)
	Detail of Fee Submitted	300000.0, 2024-03-08,
	The proposed proprietary name / brand name	Rituxiver 500mg Injection Concentrate solution for infusion
	Label Claim	Each vial (50ml) contains: Rituximab.....500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's vial packing-As per SRO
	Shelf Life (Unit)	24 Month(s)Store at 2-8°C, protecting from light.
	For generic drugs (me-too Status)	MabThera 500mg/vial Manufactured by Roche
	Pharmacotherapeutic Group of (API)	Monoclonal Antibody

Name, address of Manufacturing site:	Actoverco Biotech Pharmaceutical Company -4th Golestan Blv.,Baharestan Industrail Zone, Karaj,Iran.-Iran
Pharmaceutical Equivalence and Comparative Dissolution Profile	Biosimilarity provided.
Name, address of Marketing Authorization Holder:	Actero Middle East, On the corner of 8th Golestan, Sarvestan Blvd., Baharestan Industrial Zone, Karaj, Iran., Iran
Details of Certificates (CoPP/FSC/cGMP):	CoPP No. 665/60346 dated 15-10-2023.
Details of Authorization Letter :	Copy of Distribution certificate dated 29-05-2024.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: 30221001, 30221002, 30221003 Real time at -20C and Accelerated at 2-8C
The status in reference regulatory authorities	MabThera By Roche USFDA Approved
Evaluation Remarks	
The case was deferred in 345th meeting. The firm submitted the response which was evaluated and still following are required:1. The provided comparative clinical trial data is of Mabxience, the firm submitted the following:"We respectfully submit that Rituxiver is developed using the working cell bank sourced from mAbxience, which has already been clinically validated. The manufacturing process of Actoverco has been designed and validated to ensure comparability with the reference Mabxience product. Based on the same cell bank origin, analytical comparability, and biosimilarity exercise performed, Rituxiver is demonstrated to be similar in quality, safety, and efficacy. In line with WHO guidelines for biosimilars, reliance on existing clinical data of the cell bank originator (Mabxience) is acceptable, provided robust analytical comparability is established, which has been submitted."2. Complete detailed quality comparison as provided are only results of tests?3. Complete non-clinical study reports as provided are only study introduction?	
Decision	
Deferred	
Registration Board deferred the product for submission of complete biosimilarity data performed by finished product manufacturer.	
29	Case Category
	Routine (M. Zubair Masood)
	Name, address of Applicant.
	Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan (01-374-0006)
	Application Form Dy. No / Tracking ID & date of submission
	(YGN-7HQ-2MH7, 2024-05-14)
	Detail of Fee Submitted
	300000.0, 2024-03-08,
	The proposed proprietary name / brand name
	Rituxiver vial 10mg/1ml Concentrate for solution for infusion
	Label Claim
	Each vial (10ml) contains: Rituximab.....100mg
	Reference to Finished product specifications
	As per Innovators Specification
	Proposed Pack Size
	1's vial packing-As per SRO
	Shelf Life (Unit)
	24 Month(s)Store at 2-8°C, protecting from light.
	For generic drugs (me-too Status)
	MabThera 100mg/vial Manufactured by Roche
	Pharmacotherapeutic Group of (API)
	Monoclonal Antibody
	Name, address of Manufacturing site:
	Actoverco Biotech Pharmaceutical Company -4th Golestan Blv.,Baharestan Industrail Zone, Karaj,Iran.-Iran
	Pharmaceutical Equivalence and Comparative Dissolution Profile
	Biosimilarity provided.

Name, address of Marketing Authorization Holder:	Actero Middle East, On the corner of 8th Golestan, Sarvestan Blvd., Baharestan Industrial Zone, Karaj, Iran., Iran
Details of Certificates (CoPP/FSC/cGMP):	CoPP No. 665/60349 dated 15-10-2023.
Details of Authorization Letter :	Copy of Distribution certificate dated 29-05-2024.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: 30221001, 30221002, 30221003 Real time at -20C and Accelerated at 2-8C
The status in reference regulatory authorities	MabThera By Roche USFDA Approved

Evaluation Remarks

The case was deferred in 345th meeting. The firm submitted the response which was evaluated and still following are required:1. The provided comparative clinical trial data is of Mabxience, the firm submitted the following:"We respectfully submit that Rituxiver is developed using the working cell bank sourced from mAbxience, which has already been clinically validated. The manufacturing process of Actoverco has been designed and validated to ensure comparability with the reference Mabxience product. Based on the same cell bank origin, analytical comparability, and biosimilarity exercise performed, Rituxiver is demonstrated to be similar in quality, safety, and efficacy. In line with WHO guidelines for biosimilars, reliance on existing clinical data of the cell bank originator (Mabxience) is acceptable, provided robust analytical comparability is established, which has been submitted."2. Complete detailed quality comparison as provided are only results of tests?3. Complete non-clinical study reports as provided are only study introduction?

Decision

Deferred

Registration Board deferred the product for submission of complete biosimilarity data performed by finished product manufacturer.

30

Case Category	Routine (Muneeb Ahmed Cheema)
Name, address of Applicant.	Eli Lilly Pakistan (Pvt) Ltd 5A, 5th Office Floor, 10th Building Floor, Al-Tijarah Centre 32-1-A, Block 6, PECHS, Main Shahra-e-Faisal (0478)
Application Form Dy. No / Tracking ID & date of submission	(1B6-AYB-EXVJ, 2025-08-30)
Detail of Fee Submitted	313500.0, 2025-08-18,
The proposed proprietary name / brand name	Mounjaro 2.5 mg/dose KwikPen solution for injection in pre filled pen
Label Claim	Each 0.6ml contains: Tirzepatide.....2.5mg
Reference to Finished product specifications	Manufacturer Specification
Proposed Pack Size	1's-De-Controlled
Shelf Life (Unit)	2 Year(s)2-8°C
For generic drugs (me-too Status)	This is Innovative Drug
Pharmacotherapeutic Group of (API)	Dual glucose-dependent insulintropic polypeptide (GIP) and glucagon-like peptide-1 (GLP-1) receptor agonist
Name, address of Manufacturing site:	Eli Lilly Italia-Eli Lilly Italia S.p.A., Via Gramsci 731-733, Sesto Fiorentino, 50019 Florence, Italy.-Italy
Pharmaceutical Equivalence and Comparative Dissolution Profile	Not Applicable
Name, address of Marketing Authorization Holder:	Eli Lilly Nederland B.V, Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands, Netherlands
Details of Certificates (CoPP/FSC/cGMP):	CoPP No. 01/24/007183 dated 03.07.2024
Details of Authorization Letter :	Letter of Authorisation dated 24.07.2025

Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Data of DS & DP is submitted
The status in reference regulatory authorities	EMA Approved
Evaluation Remarks	
Moujaro is an innovator product containing Tirzepatide and approved by EMA. Tirzepatide (Mounjaro) is indicated for the treatment of adults with type 2 diabetes mellitus as an adjunct to diet and exercise – as monotherapy when metformin is considered inappropriate due to intolerance or contraindications – in addition to other medicinal products for the treatment of diabetes.	
Decision	
Approved	
Keeping in view the approval of product by EMA; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
31	Case Category
Name, address of Applicant.	Routine (Muneeb Ahmed Cheema) Eli Lilly Pakistan (Pvt) Ltd 5A, 5th Office Floor, 10th Building Floor, Al-Tijarah Centre 32-1-A, Block 6, PECHS, Main Shahra-e-Faisal (0478)
Application Form Dy. No / Tracking ID & date of submission	(2D2-H4Z-YUEL, 2025-08-30)
Detail of Fee Submitted	313500.0, 2025-08-18,
The proposed proprietary name / brand name	Mounjaro 10 mg/dose KwikPen solution for injection in pre filled pen
Label Claim	Each 0.6ml contains: Tirzepatide.....10mg
Reference to Finished product specifications	Manufacturer Specification
Proposed Pack Size	1's-De-Controlled
Shelf Life (Unit)	2 Year(s)2-8°C
For generic drugs (me-too Status)	Innovator
Pharmacotherapeutic Group of (API)	Long acting GIP and GLP-1 receptor agonist
Name, address of Manufacturing site:	Eli Lilly Italia-Eli Lilly Italia S.p.A., Via Gramsci 731-733, Sesto Fiorentino, 50019 Florence, Italy.-Italy
Pharmaceutical Equivalence and Comparative Dissolution Profile	NA
Name, address of Marketing Authorization Holder:	Eli Lilly Nederland B.V, Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands, Netherlands
Details of Certificates (CoPP/FSC/cGMP):	CoPP issued by EMA vide No. 01/24/007186 dated 03.07.2024
Details of Authorization Letter :	NA
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	2900 L manufacturing process for multiple-dose tirzepatide injection 2.5 mg/0.6 mL, 5 mg/0.6 mL, 7.5 mg/0.6 mL, 10 mg/0.6 mL, 12.5 mg/0.6 mL, and 15 mg/0.6 mL at Eli Lilly Italia S.p.A., Sesto Fiorentino, Italy (Sesto). Three process performance qualification (PPQ) batches, two of the lowest strength (2.5 mg/0.6 mL) and one of the highest strength (15 mg/0.6 mL) were manufactured to bracket the six multiple-dose tirzepatide injection dosages (2.5 mg/0.6 mL, 5 mg/0.6 mL, 7.5 mg/0.6 mL, 10 mg/0.6 mL, 12.5 mg/0.6 mL, 15 mg/0.6 mL). The PPQ batches were placed on stability at the 5°C (2°C - 8°C) long-term storage condition for at least 24

		months and on stability at accelerated conditions (25°C and 30°C) for 6 months, per the protocol provided
	The status in reference regulatory authorities	EMA Approved
	Evaluation Remarks	
	Mounjaro is innovator product approved by EMA and is indicated for Type 2 diabetes mellitus and weight management	
	Decision	
	Approved	
	Keeping in view the approval of product by EMA; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
32	Case Category	Routine (Muneeb Ahmed Cheema)
	Name, address of Applicant.	Eli Lilly Pakistan (Pvt) Ltd 5A, 5th Office Floor, 10th Building Floor, Al-Tijarah Centre 32-1-A, Block 6, PECHS, Main Shahra-e-Faisal (0478)
	Application Form Dy. No / Tracking ID & date of submission	(6AZ-NWP-MDJ2, 2025-08-30)
	Detail of Fee Submitted	313500.0, 2025-08-18,
	The proposed proprietary name / brand name	Mounjaro 12.5 mg/dose KwikPen solution for injection in pre filled pen
	Label Claim	Each 0.6ml contains: Tirzepatide.....12.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	2 Year(s)2-8°C
	For generic drugs (me-too Status)	Innovator
	Pharmacotherapeutic Group of (API)	Long acting GIP and GLP-1 receptor agonist
	Name, address of Manufacturing site:	Eli Lilly Italia-Eli Lilly Italia S.p.A., Via Gramsci 731-733, Sesto Fiorentino, 50019 Florence, Italy.-Italy
	Pharmaceutical Equivalence and Comparative Dissolution Profile	NA
	Name, address of Marketing Authorization Holder:	Eli Lilly Nederland B.V, Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands, Netherlands
	Details of Certificates (CoPP/FSC/cGMP):	CoPP issued by EMA vide No. 01/24/007187 dated 03.07.2024
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	2900 L manufacturing process for multiple-dose tirzepatide injection 2.5 mg/0.6 mL, 5 mg/0.6 mL, 7.5 mg/0.6 mL, 10 mg/0.6 mL, 12.5 mg/0.6 mL, and 15 mg/0.6 mL at Eli Lilly Italia S.p.A., Sesto Fiorentino, Italy (Sesto). Three process performance qualification (PPQ) batches, two of the lowest strength (2.5 mg/0.6 mL) and one of the highest strength (15 mg/0.6 mL) were manufactured to bracket the six multiple-dose tirzepatide injection dosages (2.5 mg/0.6 mL, 5 mg/0.6 mL, 7.5 mg/0.6 mL, 10 mg/0.6 mL, 12.5 mg/0.6 mL, 15 mg/0.6 mL). The PPQ batches were placed on stability at the 5°C (2°C - 8°C) long-term storage condition for at least 24 months and on stability at accelerated conditions (25°C and 30°C) for 6 months, per the protocol provided

The status in reference regulatory authorities		EMA Approved
Evaluation Remarks		
Mounjaro is innovator product approved by EMA and is indicated for Type 2 diabetes mellitus and weight management		
Decision		
Approved		
Keeping in view the approval of product by EMA; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.		
33	Case Category	Routine (Muneeb Ahmed Cheema)
	Name, address of Applicant.	Eli Lilly Pakistan (Pvt) Ltd 5A, 5th Office Floor, 10th Building Floor, Al-Tijarah Centre 32-1-A, Block 6, PECHS, Main Shahra-e-Faisal (0478)
	Application Form Dy. No / Tracking ID & date of submission	(7AA-6RT-8V3P, 2025-08-30)
	Detail of Fee Submitted	313500.0, 2025-08-18,
	The proposed proprietary name / brand name	Mounjaro 7.5 mg/dose KwikPen solution for injection in pre filled pen
	Label Claim	Each 0.6ml contains: Tirzepatide.....7.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	2 Year(s)2-8°C
	For generic drugs (me-too Status)	Innovator
	Pharmacotherapeutic Group of (API)	Long acting GIP and GLP-1 receptor agonist
	Name, address of Manufacturing site:	Eli Lilly Italia-Eli Lilly Italia S.p.A., Via Gramsci 731-733, Sesto Fiorentino, 50019 Florence, Italy.-Italy
	Pharmaceutical Equivalence and Comparative Dissolution Profile	NA
	Name, address of Marketing Authorization Holder:	Eli Lilly Nederland B.V, Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands, Netherlands
	Details of Certificates (CoPP/FSC/cGMP):	CoPP issued by EMA vide No. 01/24/007185 dated 03.07.2024
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	2900 L manufacturing process for multiple-dose tirzepatide injection 2.5 mg/0.6 mL, 5 mg/0.6 mL, 7.5 mg/0.6 mL, 10 mg/0.6 mL, 12.5 mg/0.6 mL, and 15 mg/0.6 mL at Eli Lilly Italia S.p.A., Sesto Fiorentino, Italy (Sesto). Three process performance qualification (PPQ) batches, two of the lowest strength (2.5 mg/0.6 mL) and one of the highest strength (15 mg/0.6 mL) were manufactured to bracket the six multiple-dose tirzepatide injection dosages (2.5 mg/0.6 mL, 5 mg/0.6 mL, 7.5 mg/0.6 mL, 10 mg/0.6 mL, 12.5 mg/0.6 mL, 15 mg/0.6 mL). The PPQ batches were placed on stability at the 5°C (2°C - 8°C) long-term storage condition for at least 24 months and on stability at accelerated conditions (25°C and 30°C) for 6 months, per the protocol provided
The status in reference regulatory authorities		EMA Approved
Evaluation Remarks		

Mounjaro is innovator product approved by EMA and is indicated for Type 2 diabetes mellitus and weight management

Decision

Approved

Keeping in view the approval of product by EMA; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.

34	Case Category	Routine (Muneeb Ahmed Cheema)
	Name, address of Applicant.	Eli Lilly Pakistan (Pvt) Ltd 5A, 5th Office Floor, 10th Building Floor, Al-Tijarah Centre 32-1-A, Block 6, PECHS, Main Shahra-e-Faisal (0478)
	Application Form Dy. No / Tracking ID & date of submission	(TTW-X49-UP61, 2025-08-30)
	Detail of Fee Submitted	313500.0, 2025-08-18,
	The proposed proprietary name / brand name	Mounjaro 15 mg/dose KwikPen solution for injection in pre filled pen
	Label Claim	Each 0.6ml contains: Tirzepatide.....15mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	2 Year(s)2-8°C
	For generic drugs (me-too Status)	Innovator
	Pharmacotherapeutic Group of (API)	Long acting GIP and GLP-1 receptor agonist
	Name, address of Manufacturing site:	Eli Lilly Italia-Eli Lilly Italia S.p.A., Via Gramsci 731-733, Sesto Fiorentino, 50019 Florence, Italy.-Italy
	Pharmaceutical Equivalence and Comparative Dissolution Profile	NA
	Name, address of Marketing Authorization Holder:	Eli Lilly Nederland B.V, Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands, Netherlands
	Details of Certificates (CoPP/FSC/cGMP):	CoPP issued by EMA vide No. 01/24/007188 dated 03.07.2024
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	2900 L manufacturing process for multiple-dose tirzepatide injection 2.5 mg/0.6 mL, 5 mg/0.6 mL, 7.5 mg/0.6 mL, 10 mg/0.6 mL, 12.5 mg/0.6 mL, and 15 mg/0.6 mL at Eli Lilly Italia S.p.A., Sesto Fiorentino, Italy (Sesto). Three process performance qualification (PPQ) batches, two of the lowest strength (2.5 mg/0.6 mL) and one of the highest strength (15 mg/0.6 mL) were manufactured to bracket the six multiple-dose tirzepatide injection dosages (2.5 mg/0.6 mL, 5 mg/0.6 mL, 7.5 mg/0.6 mL, 10 mg/0.6 mL, 12.5 mg/0.6 mL, 15 mg/0.6 mL). The PPQ batches were placed on stability at the 5°C (2°C - 8°C) long-term storage condition for at least 24 months and on stability at accelerated conditions (25°C and 30°C) for 6 months, per the protocol provided
	The status in reference regulatory authorities	EMA Approved
	Evaluation Remarks	
	Mounjaro is innovator product approved by EMA and is indicated for Type 2 diabetes mellitus and Weight management	

Decision																																					
Approved																																					
Keeping in view the approval of product by EMA; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.																																					
35	<table> <tr> <td>Case Category</td><td>Routine (Muneeb Ahmed Cheema)</td></tr> <tr> <td>Name, address of Applicant.</td><td>Eli Lilly Pakistan (Pvt) Ltd 5A, 5th Office Floor, 10th Building Floor, Al-Tijarah Centre 32-1-A, Block 6, PECHS, Main Shahra-e-Faisal (0478)</td></tr> <tr> <td>Application Form Dy. No / Tracking ID & date of submission</td><td>(XQM-YA1-BX5Y, 2025-08-30)</td></tr> <tr> <td>Detail of Fee Submitted</td><td>313500.0, 2025-08-18,</td></tr> <tr> <td>The proposed proprietary name / brand name</td><td>Mounjaro 5 mg/dose KwikPen solution for injection in pre filled pen</td></tr> <tr> <td>Label Claim</td><td>Each 0.6ml contains: Tirzepatide.....5mg</td></tr> <tr> <td>Reference to Finished product specifications</td><td>Manufacturer Specification</td></tr> <tr> <td>Proposed Pack Size</td><td>1's-De-Controlled</td></tr> <tr> <td>Shelf Life (Unit)</td><td>2 Year(s)2-8°C</td></tr> <tr> <td>For generic drugs (me-too Status)</td><td>Innovator</td></tr> <tr> <td>Pharmacotherapeutic Group of (API)</td><td>Long acting GIP and GLP-1 receptor agonist</td></tr> <tr> <td>Name, address of Manufacturing site:</td><td>Eli Lilly Italia-Eli Lilly Italia S.p.A., Via Gramsci 731-733, Sesto Fiorentino, 50019 Florence, Italy.-Italy</td></tr> <tr> <td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>NA</td></tr> <tr> <td>Name, address of Marketing Authorization Holder:</td><td>Eli Lilly Nederland B.V, Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands, Netherlands</td></tr> <tr> <td>Details of Certificates (CoPP/FSC/cGMP):</td><td>CoPP issued by EMA vide No. 01/24/007184 dated 03.07.2024</td></tr> <tr> <td>Details of Authorization Letter :</td><td>NA</td></tr> <tr> <td>Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)</td><td>2900 L manufacturing process for multiple-dose tirzepatide injection 2.5 mg/0.6 mL, 5 mg/0.6 mL, 7.5 mg/0.6 mL, 10 mg/0.6 mL, 12.5 mg/0.6 mL, and 15 mg/0.6 mL at Eli Lilly Italia S.p.A., Sesto Fiorentino, Italy (Sesto). Three process performance qualification (PPQ) batches, two of the lowest strength (2.5 mg/0.6 mL) and one of the highest strength (15 mg/0.6 mL) were manufactured to bracket the six multiple-dose tirzepatide injection dosages (2.5 mg/0.6 mL, 5 mg/0.6 mL, 7.5 mg/0.6 mL, 10 mg/0.6 mL, 12.5 mg/0.6 mL, 15 mg/0.6 mL). The PPQ batches were placed on stability at the 5°C (2°C - 8°C) long-term storage condition for at least 24 months and on stability at accelerated conditions (25°C and 30°C) for 6 months, per the protocol provided</td></tr> <tr> <td>The status in reference regulatory authorities</td><td>EMA Approved</td></tr> </table>	Case Category	Routine (Muneeb Ahmed Cheema)	Name, address of Applicant.	Eli Lilly Pakistan (Pvt) Ltd 5A, 5th Office Floor, 10th Building Floor, Al-Tijarah Centre 32-1-A, Block 6, PECHS, Main Shahra-e-Faisal (0478)	Application Form Dy. No / Tracking ID & date of submission	(XQM-YA1-BX5Y, 2025-08-30)	Detail of Fee Submitted	313500.0, 2025-08-18,	The proposed proprietary name / brand name	Mounjaro 5 mg/dose KwikPen solution for injection in pre filled pen	Label Claim	Each 0.6ml contains: Tirzepatide.....5mg	Reference to Finished product specifications	Manufacturer Specification	Proposed Pack Size	1's-De-Controlled	Shelf Life (Unit)	2 Year(s)2-8°C	For generic drugs (me-too Status)	Innovator	Pharmacotherapeutic Group of (API)	Long acting GIP and GLP-1 receptor agonist	Name, address of Manufacturing site:	Eli Lilly Italia-Eli Lilly Italia S.p.A., Via Gramsci 731-733, Sesto Fiorentino, 50019 Florence, Italy.-Italy	Pharmaceutical Equivalence and Comparative Dissolution Profile	NA	Name, address of Marketing Authorization Holder:	Eli Lilly Nederland B.V, Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands, Netherlands	Details of Certificates (CoPP/FSC/cGMP):	CoPP issued by EMA vide No. 01/24/007184 dated 03.07.2024	Details of Authorization Letter :	NA	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	2900 L manufacturing process for multiple-dose tirzepatide injection 2.5 mg/0.6 mL, 5 mg/0.6 mL, 7.5 mg/0.6 mL, 10 mg/0.6 mL, 12.5 mg/0.6 mL, and 15 mg/0.6 mL at Eli Lilly Italia S.p.A., Sesto Fiorentino, Italy (Sesto). Three process performance qualification (PPQ) batches, two of the lowest strength (2.5 mg/0.6 mL) and one of the highest strength (15 mg/0.6 mL) were manufactured to bracket the six multiple-dose tirzepatide injection dosages (2.5 mg/0.6 mL, 5 mg/0.6 mL, 7.5 mg/0.6 mL, 10 mg/0.6 mL, 12.5 mg/0.6 mL, 15 mg/0.6 mL). The PPQ batches were placed on stability at the 5°C (2°C - 8°C) long-term storage condition for at least 24 months and on stability at accelerated conditions (25°C and 30°C) for 6 months, per the protocol provided	The status in reference regulatory authorities	EMA Approved
Case Category	Routine (Muneeb Ahmed Cheema)																																				
Name, address of Applicant.	Eli Lilly Pakistan (Pvt) Ltd 5A, 5th Office Floor, 10th Building Floor, Al-Tijarah Centre 32-1-A, Block 6, PECHS, Main Shahra-e-Faisal (0478)																																				
Application Form Dy. No / Tracking ID & date of submission	(XQM-YA1-BX5Y, 2025-08-30)																																				
Detail of Fee Submitted	313500.0, 2025-08-18,																																				
The proposed proprietary name / brand name	Mounjaro 5 mg/dose KwikPen solution for injection in pre filled pen																																				
Label Claim	Each 0.6ml contains: Tirzepatide.....5mg																																				
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Proposed Pack Size	1's-De-Controlled																																				
Shelf Life (Unit)	2 Year(s)2-8°C																																				
For generic drugs (me-too Status)	Innovator																																				
Pharmacotherapeutic Group of (API)	Long acting GIP and GLP-1 receptor agonist																																				
Name, address of Manufacturing site:	Eli Lilly Italia-Eli Lilly Italia S.p.A., Via Gramsci 731-733, Sesto Fiorentino, 50019 Florence, Italy.-Italy																																				
Pharmaceutical Equivalence and Comparative Dissolution Profile	NA																																				
Name, address of Marketing Authorization Holder:	Eli Lilly Nederland B.V, Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands, Netherlands																																				
Details of Certificates (CoPP/FSC/cGMP):	CoPP issued by EMA vide No. 01/24/007184 dated 03.07.2024																																				
Details of Authorization Letter :	NA																																				
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	2900 L manufacturing process for multiple-dose tirzepatide injection 2.5 mg/0.6 mL, 5 mg/0.6 mL, 7.5 mg/0.6 mL, 10 mg/0.6 mL, 12.5 mg/0.6 mL, and 15 mg/0.6 mL at Eli Lilly Italia S.p.A., Sesto Fiorentino, Italy (Sesto). Three process performance qualification (PPQ) batches, two of the lowest strength (2.5 mg/0.6 mL) and one of the highest strength (15 mg/0.6 mL) were manufactured to bracket the six multiple-dose tirzepatide injection dosages (2.5 mg/0.6 mL, 5 mg/0.6 mL, 7.5 mg/0.6 mL, 10 mg/0.6 mL, 12.5 mg/0.6 mL, 15 mg/0.6 mL). The PPQ batches were placed on stability at the 5°C (2°C - 8°C) long-term storage condition for at least 24 months and on stability at accelerated conditions (25°C and 30°C) for 6 months, per the protocol provided																																				
The status in reference regulatory authorities	EMA Approved																																				
Evaluation Remarks																																					
Mounjaro is innovator product approved by EMA and is indicated for Type 2 diabetes mellitus and Weight management																																					
Decision																																					

Approved

Keeping in view the approval of product by EMA; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.

36	Case Category	Priority As Per 257-M of RB (Muneeb Ahmed Cheema)
	Name, address of Applicant.	Amson Vaccines & Pharma (Pvt.) Ltd 115, Industrial Triangle Kahuta Road (DHO-ISB-135)
	Application Form Dy. No / Tracking ID & date of submission	(VQ3-ZS6-A1ZT, 2025-08-20)
	Detail of Fee Submitted	300000.0, 2025-07-21,
	The proposed proprietary name / brand name	BEVAC® 5 ml vaccine (10 Paediatric doses)
	Label Claim	Each Dose of 0.5 mL contains: Purified HBsAg 10 µg Aluminium Hydroxide gel equivalent to Al+++ .. 0.25 mg Preservative: Thiomersal BP 0.025 mg Recombinant HBs antigen produced in Pichia Pastoris (Yeast)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	24's x 5ml-As per SRO
	Shelf Life (Unit)	36 Month(s) 2-8 °C
	For generic drugs (me-too Status)	Product Name: ENGERIX-B [Hepatitis B Vaccine (Recombinant)] Registration No: 012370 Company Name: GSK Pakistan Limited
	Pharmacotherapeutic Group of (API)	Recombinant Vaccine
	Name, address of Manufacturing site:	M/s Biological E. Limited-Plot No. 1, Biotech Park, Phase II, Kolthur Village, Shameerpet, Medchal – Malkajgiri (District), Telangana, -India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	NA
	Name, address of Marketing Authorization Holder:	M/s. Amson Vaccines & Pharma Pvt. Ltd., 115, Industrial Triangle ,Kahuta Rd Islamabad, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	CoPP issued by Drugs Control Administration, Govt. of Telangana vide No. 4365091/TS/2025 valid upto 16.01.2026 for Hepatitis B Vaccine (rDNA) BP (For Paediatric use) Ten Dose Vial 5mL BEVAC. The CoPP indicates that aforesaid product is registered and is
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches of Hepatitis B Vaccine (rDNA), 5 mL presentation (B. No's: 19167A14, 19168A14 and 19169A14) were charged for stability studies at accelerated conditions (25±2°C) for 6 months and at real time conditions (2-8°C) for 42 months. Based on stability studies conducted and results, it is evident that Hepatitis B Vaccine (rDNA) is stable up to 36 months at real time storage conditions (2-8°C). Based on the available stability data, shelf life 36 months is proposed when stored at 2-8°C.
	The status in reference regulatory authorities	BEVAC® WHO Prequalified Link: https://extranet.who.int/prequal/vaccines/p/bevacr-2

Evaluation Remarks

Hepatitis B Vaccine (rDNA) is indicated for active immunization against infection caused by Hepatitis B virus and its common sub-types. It can also be given to hepatitis C and D virus infected patients to protect them against co-
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infection with hepatitis B virus. Hepatitis B vaccine (rDNA) BP is recommended primarily for neonates, infants and young adults not only for the prevention of disease but also to protect them from probable hepatitis B virus - induced carrier state, cirrhosis and hepatocellular carcinoma. Pediatric dose (0.5mL) is recommended for neonates, infants and children at and below 10 years of age. WHO prequalified vaccine
<https://extranet.who.int/prequal/vaccines/p/bevacr-2>

Decision

Approved

Keeping in view the prequalification of product by WHO; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.

37	Case Category	Priority As Per 257-M of RB (Muneeb Ahmed Cheema)
	Name, address of Applicant.	Amson Vaccines & Pharma (Pvt.) Ltd 115, Industrial Triangle Kahuta Road (DHO-ISB-135)
	Application Form Dy. No / Tracking ID & date of submission	(WVM-EAZ-5T2L, 2025-08-20)
	Detail of Fee Submitted	300000.0, 2025-07-22,
	The proposed proprietary name / brand name	BEVAC® 10 ml vaccine (10 adult doses)
	Label Claim	Each Dose of 1 mL contains: Purified HBsAg 20 µg Aluminium Hydroxide gel equivalent to Al+++ .. 0.5 mg Preservative: Thiomersal BP 0.05 mg Recombinant HBs antigen produced in Pichia Pastoris (Yeast)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	24's x 10ml-As per SRO
	Shelf Life (Unit)	36 Month(s)2-8 °C
	For generic drugs (me-too Status)	Product Name: Amvax-B [Hepatitis B Vaccine (Recombinant)] Registration No: 018727 Company Name: M/s. Amson Vaccines & Pharma Pvt. Ltd
	Pharmacotherapeutic Group of (API)	Recombinant Vaccine
	Name, address of Manufacturing site:	M/s Biological E. Limited-Plot No. 1, Biotech Park, Phase II, Kolthur Village, Shameerpet, Medchal – Malkajgiri (District), Telangana, -India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	NA
	Name, address of Marketing Authorization Holder:	M/s. Amson Vaccines & Pharma Pvt. Ltd., 115, Industrial Triangle ,Kahuta Rd Islamabad, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	CoPP issued by Drugs Control Administration, Govt. of Telangana vide No. 4365094/TS/2025 valid upto 16.01.2026 for Hepatitis B Vaccine (rDNA) BP (For Adult use)-Ten Dose Vial 10 mL - BEVAC. The CoPP indicates that aforesaid product is registered and is o
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches of Hepatitis B Vaccine (rDNA), 10 mL presentation (B.No's: 220500417A, 220500517A, 220500617A) were charged also charged for for stability studies at real time conditions (2-8°C) for 42 months and for accelerated stability condition (25±2°C) for 6 months. Based on stability studies conducted and results, it is evident that Hepatitis B Vaccine (rDNA) is stable up to 36 months at real time storage conditions (2-8°C).

The status in reference regulatory authorities	BEVAC® WHO Prequalified Link: https://extranet.who.int/prequal/vaccines/p/bevacr

Evaluation Remarks

Hepatitis B Vaccine (rDNA) is indicated for active immunization against infection caused by Hepatitis B virus and its common sub-types. It can also be given to hepatitis C and D virus infected patients to protect them against co-infection with hepatitis B virus. Hepatitis B vaccine (rDNA) BP is recommended primarily for neonates, infants and young adults not only for the prevention of disease but also to protect them from probable hepatitis B virus - induced carrier state, cirrhosis and hepatocellular carcinoma. Adult dose (1mL) is for adults and children above ten years of age.

Decision

Approved

Keeping in view the prequalification of product by WHO; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.

38	Case Category	Priority As Per 257-M of RB (Muneeb Ahmed Cheema)
	Name, address of Applicant.	ASTER LIFE SCIENCES 32-BABAR BLOCK NEW GARDEN TOWN LAHORE (05352006501)
	Application Form Dy. No / Tracking ID & date of submission	(L9S-YUE-1R3Q, 2025-08-31)
	Detail of Fee Submitted	300000.0, 2025-07-29,
	The proposed proprietary name / brand name	Euvax B Vaccine 10ml /10 doses
	Label Claim	Hepatitis B vaccine (rDNA) (Adult) Each dose of 1ml contains: 20mcg of purified Hepatitis B Surface Antigen (rDNA) [Host: Saccharomyces cerevisiae AB110. Vector: pYLBC-A/G-UB-HBs].....20µg Aluminum Hydroxide Gel (as aluminum) 0.5mg Thimerosal as preservative 0.01w/v% Potassium Phosphate Monobasic q.s. Sodium Phosphate Dibasic q.s Sodium Chloride.....8.5mg Water for Injection.....q.s.
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	Box of 10 vials -Controlled
	Shelf Life (Unit)	36 Month(s)2-8°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Recombinant vaccine
	Name, address of Manufacturing site:	LG Chem Ltd.-151, Osongsaengmyeong 1-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Korea-South Korea
	Pharmaceutical Equivalence and Comparative Dissolution Profile	NA
	Name, address of Marketing Authorization Holder:	LG Chem Ltd., 151 Osangsaengmyeong 1 – ro, Osang-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea, South Korea
	Details of Certificates (CoPP/FSC/cGMP):	DML issued by MFDS Korea vide No. 2025-GI-1163 dated 23.07.2025 Apostilled GMP Certificate issued by MFDS Korea dated 02.05.2025 Apostilled Free Sale Certificate issued by MFDS Korea vide No. 2024-A1-1204 dated 23.05.2024 indicates that 10ml vial is per
	Details of Authorization Letter :	Authorisation letter issued by the firm LG Chem., Ltd Korea to M/s Aster Life Sciences, Korea dated

	28.07.2025.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Based on the stability data, the shelf-life of Euvax B is claimed as 36 months when stored at the recommended storage temperature of 5±3°C in the original container (Type I glass vial)
The status in reference regulatory authorities	WHO PQ: https://extranet.who.int/prequal/vaccines/p/euvax-b-0

Evaluation Remarks

Immunization against infection caused by known subtypes of Hepatitis B virus. Euvax B is for intramuscular use only. One pediatric dose (neonates, infants and children aged up to and including 15 years of age) is 0.5 ml containing 10 micrograms of HBsAg. One adult dose (from 16 years of age) is 1.0 ml containing 20 micrograms of HBsAg.

Decision

Approved

Keeping in view the prequalification of product by WHO; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.

39	Case Category	Priority As Per 257-M of RB (Muneeb Ahmed Cheema)
	Name, address of Applicant.	ASTER LIFE SCIENCES 32-BABAR BLOCK NEW GARDEN TOWN LAHORE (05352006501)
	Application Form Dy. No / Tracking ID & date of submission	(33H-G8W-14A6, 2025-08-31)
	Detail of Fee Submitted	300000.0, 2025-07-29,
	The proposed proprietary name / brand name	Euvax B Vaccine 5ml /10 doses
	Label Claim	Purified Hepatitis B Surface Antigen (rDNA) Strength: 5ml / 10 doses Each dose of 0.5ml contains: 10mcg of purified Hepatitis B Surface Antigen (rDNA) [Host: Saccharomyces cerevisiae AB110. Vector: pYLBC-A/G-UB-HBs].....10µg Aluminum Hydroxide Gel (as aluminum) 0.25mg Thimerosal as preservative 0.01w/v% Potassium Phosphate Monobasic q.s. Sodium Phosphate Dibasic q.s. Sodium Chloride.....4.25mg Water for Injection.....q.s.
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	Box of 10 vials -Controlled
	Shelf Life (Unit)	36 Month(s)2-8°C
	For generic drugs (me-too Status)	Available in single dose vial
	Pharmacotherapeutic Group of (API)	Recombinant vaccine
	Name, address of Manufacturing site:	LG Chem Ltd.-151, Osongsaengmyeong 1-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Korea-South Korea
	Pharmaceutical Equivalence and Comparative Dissolution Profile	NA
	Name, address of Marketing Authorization Holder:	LG Chem Ltd., 151 Osangsaengmyeong 1 – ro, Osang-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea, South Korea
	Details of Certificates (CoPP/FSC/cGMP):	DML issued by MFDS Korea vide No. 2025-GI-1163 dated 23.07.2025 Apostilled GMP Certificate issued by (23rd – 24th September, 2025)

	MFDS Korea dated 02.05.2025 Apostilled Free Sale Certificate issued by MFDS Korea vide No. 2024-A1-1721 dated 24.07.2025 indicates that 5ml vial is perm
Details of Authorization Letter :	Authorization letter issued by the firm LG Chem., Ltd Korea to M/s Aster Life Sciences, Korea dated 28.07.2025.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	WVX14501, WVX14502, WVX14501, (Process Validation Batches) Accelerated Stability 25±2°C and long term stability 5□3°C. WVX19501, WVX19502, WVX19503 (Commercial Batches) Accelerated Stability 25±2°C and long term stability 5□3°C.
The status in reference regulatory authorities	Product is WHO PQ: https://extranet.who.int/prequal/vaccines/p/euvax-b-0
Evaluation Remarks	
Immunization against infection caused by known subtypes of Hepatitis B virus. Euvax B is for intramuscular use only. One pediatric dose (neonates, infants and children aged up to and including 15 years of age) is 0.5 ml containing 10 micrograms of HBsAg. One adult dose (from 16 years of age) is 1.0 ml containing 20 micrograms of HBsAg.	
Decision	
Approved	
Keeping in view the prequalification of product by WHO; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
40	Case Category
	Contract Manufacturing (Muneeb Ahmed Cheema)
	Name, address of Applicant.
	The Searle Company Limited Plot No. F-319, Sindh Industrial Trading Estate (SITE) (000016)
	Application Form Dy. No / Tracking ID & date of submission
	(RQ1-YV2-U3YL, 2025-04-14)
	Detail of Fee Submitted
	93000.0, 2025-02-14,
	The proposed proprietary name / brand name
	Semavi-S 0.25mg/0.188ml Pre-filled Syringe
	Label Claim
	Each 0.188ml contains: Semaglutide 0.25mg
	Reference to Finished product specifications
	As per Innovators Specification
	Proposed Pack Size
	1's PFS as per SRO 2-As per SRO
	Shelf Life (Unit)
	2 Year(s)2°C-8°C
	For generic drugs (me-too Status)
	Ozempic Injection by Novo Nordisk Pharma (Private) Limited Karachi
	Pharmacotherapeutic Group of (API)
	GLP-I Analogue
	Name, address of Manufacturing site:
	M/s. Nextar Pharma (Pvt) Ltd-Plot No. E-58, North Western Industrial Zone, Port Qasim, Karachi, Pakistan.-
	The status in reference regulatory authorities
	Ozempic 0.25 mg solution for injection in pre-filled pen Novo Nordisk A/S (Denmark)
	Detail of previous approval
Evaluation Remarks	
SEMAVI-PFS 0.25mg/0.188ml (Semaglutide) was approved by Registration Board in its 350th meeting and letter was issued on 28.08.2025	
Decision	
Approved	

The Registration Board approved application for contract manufacturing from M/s. Nextar Pharma (Pvt) Ltd, Plot No. E-58, North Western Industrial Zone, Port Qasim, Karachi, Pakistan with following conditions:

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.
2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA&LT.
3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.
4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.
5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.
6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

41	Case Category	Contract Manufacturing (Muneeb Ahmed Cheema)
	Name, address of Applicant.	The Searle Company Limited Plot No. F-319, Sindh Industrial Trading Estate (SITE) (000016)
	Application Form Dy. No / Tracking ID & date of submission	(Z5P-VRV-EERZ, 2025-08-06)
	Detail of Fee Submitted	93000.0, 2025-02-14,
	The proposed proprietary name / brand name	Semavi-S 1mg/0.75ml pre-filled Syringe (Semaglutide 1mg/0.75ml)
	Label Claim	Each 0.75 ml contains: Semaglutide 1mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO 228-As per SRO
	Shelf Life (Unit)	2 Year(s) 2°C-8°C
	For generic drugs (me-too Status)	Ozempic Injection by Novo Nordisk Pharma (Private) Limited Karachi
	Pharmacotherapeutic Group of (API)	GLP-I Analogue
	Name, address of Manufacturing site:	M/s. Nextar Pharma (Pvt) Ltd-Plot No. E-58, North Western Industrial Zone, Port Qasim, Karachi, Pakistan.-
	The status in reference regulatory authorities	Ozempic 1mg solution for injection in pre-filled pen Novo Nordisk A/S (Denmark)
	Detail of previous approval	
Evaluation Remarks		
SEMAVI-PFS 1mg/0.75ml (Semaglutide) was approved by Registration Board in its 350th meeting and letter was issued on 28.08.2025		
Decision		
Approved		

The Registration Board approved application for contract manufacturing from M/s. Nextar Pharma (Pvt) Ltd, Plot No. E-58, North Western Industrial Zone, Port Qasim, Karachi, Pakistan with following conditions:

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.
2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA&LT.
3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.
4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.
5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.
6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

42	Case Category	Contract Manufacturing (Muneeb Ahmed Cheema)
	Name, address of Applicant.	The Searle Company Limited Plot No. F-319, Sindh Industrial Trading Estate (SITE) (000016)
	Application Form Dy. No / Tracking ID & date of submission	(Z6G-89H-7QLL, 2025-04-14)
	Detail of Fee Submitted	93000.0, 2025-02-14,
	The proposed proprietary name / brand name	Semavi-S 0.5mg/0.375ml pre-filled Syringe
	Label Claim	Each 0.375ml contains: Semaglutide 0.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO 228-As per SRO
	Shelf Life (Unit)	2 Year(s)(2 °C- 8 °C)
	For generic drugs (me-too Status)	Ozempic Injection, Novo Nordisk Pharma
	Pharmacotherapeutic Group of (API)	GLP-I Analogue
	Name, address of Manufacturing site:	Nextar Pharam (Pvt.) Limited-Plot No. E-58, North Western Industrial Zone, Port Qasim, Karachi, Pakistan.-
	The status in reference regulatory authorities	Ozempic 0.5 mg solution for injection in pre-filled pen, Denmark
	Detail of previous approval	
Evaluation Remarks		
SEMAVI-PFS 0.5mg/0.375ml (Semaglutide) was approved by Registration Board in its 350th meeting and letter was issued on 28.08.2025		
Decision		
Approved		
The Registration Board approved application for contract manufacturing from M/s. Nextar Pharma (Pvt) Ltd, Plot No. E-58, North Western Industrial Zone, Port Qasim, Karachi, Pakistan with following conditions:		

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.
2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA&LT.
3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.
4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.
5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.
6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

43	Case Category	Priority As Per 257-M of RB (Muneeb Ahmed Cheema)
	Name, address of Applicant.	HOSPITAL SERVICES & SALES 13-C Annexe, Block 6, PECHS, Shahrah e Faisal (0398)
	Application Form Dy. No / Tracking ID & date of submission	(9VX-UR4-URQ5, 2025-08-06)
	Detail of Fee Submitted	300000.0, 2025-02-04,
	The proposed proprietary name / brand name	ROTASIIL-Liquid
	Label Claim	Each dose of 2 ml contains: Live Attenuated Bovine - Human Rotavirus Reassortant [G1, G2, G3, G4 and G9]* $\geq 10(5.6)$ FFU / Serotype. *Grown on vero cells. Excipients: Citric Acid Anhydrous, Potassium Phosphate Dibasic Anhydrous, Sucrose, Hydrolyzed Gelatin, Zinc Chloride, Calcium Chloride Dihydrate, Sodium citrate tribasic dihydrate, Eagle's MEM (Minimum Essential Medium) with Hank's Salts, Glutamine, Sodium Bicarbonate and Water for injection. This vaccine contains no Preservatives.
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	Box of 50 Vials + Adapters and Sterile Disposable - Controlled
	Shelf Life (Unit)	24 Month(s) 2 to 8°C
	For generic drugs (me-too Status)	ROTARIX by GSK
	Pharmacotherapeutic Group of (API)	Rotavirus diarrhoea vaccines, ATC code: J07BH02
	Name, address of Manufacturing site:	Serum Institute of India Pvt. Ltd.-212/2 Hadapsar, Pune-411 0028, INDIA.-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	NA
	Name, address of Marketing Authorization Holder:	Hospital Services & Sales, 13-C Annexe, Block 6, PECHS, Karachi, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Original CoPP issued by FDA Maharashtra State Mumbai vide No.

	CoPP/CERT/PD/141484/2024/11/52086/248986 dated 10.10.2024 and is valid upto 21.08.2027.
Details of Authorization Letter :	Letter of authorization by Serum Institute of India valid till 30.09.2025
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Studies at accelerated temperature conditions (25±2°C; 60±5% RH) were done to study the impact of different temperature zones on vaccine stability for up to 6 months' time-point for commercial batches
The status in reference regulatory authorities	WHO PQ Vaccine https://extranet.who.int/prequal/vaccines/p/rotasiil-liquid-1
Evaluation Remarks	
Rotavirus Vaccine, Live Attenuated (Oral), Liquid is indicated for active immunization of healthy infants from the age of 6 weeks for the prevention of gastroenteritis due to rotavirus infection when administered as a 3-dose series. The three dose regimen should be completed by one year of age. It is WHO PQ Vaccine https://extranet.who.int/prequal/vaccines/p/rotasiil-liquid-1	
Decision	
Approved	
Keeping in view the prequalification of product by WHO; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	

SUPPLEMENTARY MINUTES OF 351ST MEETING

Case No. 01: Veterinary Biologicals discussed in 6th meeting of Sub-Committee on veterinary drugs.

Sr. No.	Name of Importer & Manufacturer	Brand Name, Composition, Pack Size, Shelf Life & Storage Conditions	Decision of RB in previous meetings	Recommendations of Sub-Committee	Decision of RB
1.	M/s Hivet Animal Health Business, 1st Floor,667-P. MA, Johar Town, Lahore, Pakistan PT. VAKSINDO SATWA NUSANTARA Jl. Mercedes Benz No. 12, Cicadas, Gunung Putri, Bogor, West Java 16964, Indonesia.	Vaksimune ND Inaktif 0.1 Each dose (0.5 ml) contains: ND virus of lasota strain at least ≥ 108.1 EID50 2000 doses bottle (200ml) / Decontrolled 5000 dose bottle (500ML) / Decontrolled 24 months (2-8°C)	The Registration Board deferred the case for rectification of following deficiencies in the application; ☐ ☐ As the product is available in multiple pack sizes, applied pack size needs to be specified. ☐ ☐ The label of the product does not bear name of the importer. ☐ ☐ Original, legalized, GMP certificate of foreign manufacturer is required. ☐ ☐ Original, legalized and valid LOA from MAH, is required as the LOA has expired. ☐ ☐ Safety & Efficacy studies data is required. (M-344)	Recommended.	Keeping in view the recommendation of Sub-Committee and FSC indicating product availability in country of origin; Registration Board approved the product subject to rectification of following deficiencies in the application: • As the product is available in multiple pack sizes, applied pack size needs to be specified. • The label of the product does not bear name of the importer. • Original, legalized GMP certificate of foreign manufacturer is required. • Original, legalized and valid LOA from MAH, is required as the LOA has expired. • Safety & Efficacy studies data is required.
2.	M/s Lucky Core Industries Limited, 5 West Wharf, Karachi Intervet International B.V. Wim de Korverstraat 35, 5831 AN Boxmeer, the Netherlands.	Bovilis Lumpyvax-E Lyophilisate and Solvent for Suspension for Injection for Cattle Each 1ml dose of reconstituted vaccine contains; Live attenuated lumpy skin disease virus (Neethling)... $\geq 1 \times 10^4$ and $\leq 5.0 \times 10^5$ TCID50 20 doses of lyophilisate + 20ml solvent/Decontrolled	The Registration Board referred the case to sub-committee on veterinary drugs for the expert opinion of expert working group (EWG) on veterinary drugs for comments regarding immunological relevance and need of applied strain in Pakistan. Moreover, the Board directed to ask the applicant for	Recommended.	Keeping in view the recommendation of Sub-Committee and FSC indicating product availability in country of origin; Registration Board approved the product subject to rectification of following deficiencies in the application: • Evidence of registration of product in other countries as the product is not available in country of origin as per submitted CoPP.

		100 doses of lyophilisate + 100ml solvent/Decontrolled 24 Months (2 – 8oC)	rectification of following deficiencies in their application; □□It has been mentioned in the CoPP that the product is not licensed to be placed on the market of country of origin since the disease has never occurred there. □□The GMP certificate of foreign manufacturer, has expired in July-2023. □□As the product is available in multiple pack sizes, the applied pack size needs to be specified. □□The name of importer has not been mentioned on the label. □□Stability studies data of three large scale batches at intended storage conditions, is required. (M-344)		• Valid GMP Certificate. • As the product is available in multiple pack sizes, the applied pack size needs to be specified. • The name of importer has not been mentioned on the label. • Stability studies data of three large scale batches at intended storage conditions, is required.
3.	M/s Hilton Pharma (Pvt.) Ltd., Plot No.13 & 14, Sector 15, Korangi Industrial Area, Karachi. PT. MEDION FARMA JAYA, JI, Raya Batujajar No.29, Cimareme, Ngamprah, Bandung Barat, Indonesia	Medivac IBH Emulsion Each dose contains: Inactivated Fowl Adenovirus, 8b Serotype...at least 106.5 TCID50 Inactivated Fowl Adenovirus, 11 Serotype...at least 106.5 TCID50 500ml/ Decontrolled 24 months (2-8°C)	The Registration Board referred the case to sub-committee on veterinary drugs for the expert opinion of expert working group (EWG) on veterinary drugs for comments regarding immunological relevance and need of applied strains in Pakistan. Moreover, the Board directed to ask the applicant for rectification of following deficiencies in their application;	Recommended.	Keeping in view the recommendations of Sub-Committee on Veterinary Drugs; Registration Board approved the product subject to compliance of current Import Policy for finished drugs and submission of valid Letter of Authorization from Product License Holder.

			☐ Legalized LOA from MAH, is required. (M-344)		
4.	M/s Innovegic Pharmaceuticals, Plot No.C-19, 2nd Floor, Main Road RCCI, Industrial Area, Rawat, Islamabad. Veterinary Serum and Vaccine Research Institute (VSVRI). E1-Sekka E1-Beda St. Abbassia, Cairo, Arab Republic of Egypt.	Servac Polyvalent Inactivated FMD Oil Vaccine Each 1ml vaccine contains; FMD virus serotypes : Type O subtype panasia2...108.5 TCID50 Type A (Iran 05)...108.5 TCID50 SAT2 Egypt 12...108.5 TCID50 SAT2 Egypt 18...108.5 TCID50 Decontrolled/Not Specified-Multiple packs 12 Months (4-8 oC)	The Registration Board deferred the case for rectification of following deficiencies in the application; ☐ The DSL of the firm has expired on 16-09-2023. ☐ Copy of Letter of Authorization from MAH submitted, is not legalized. ☐ The address of manufacturer is not mentioned on the product registration letter issued by regulatory body of country of origin. ☐ Legalized, valid GMP certificate of manufacturer is required to be submitted. ☐ The FSC provided, has been issued by the manufacturer, not the regulatory body of country of origin and the same has also not been legalized. ☐ Stability studies data of the product is required to be submitted. ☐ Safety & efficacy studies data of the product is required to be submitted. ☐ Finished product specifications and testing methods are required to be submitted. ☐ The label of the product does not bear name of the importer.	The Committee did not recommend the registration of applied vaccine as strains SAT2 Egypt 12 and SAT2 Egypt 18 are not immunologically relevant to Pakistan.	Keeping in view the recommendations of Sub-Committee on Veterinary Drugs regarding non-relevance of SAT2 Egypt 12 and SAT2 Egypt 18 strains; Registration Board rejected the application.

			☐ ☐ As the product is available in multiple pack sizes, the applied pack size needs to be specified. ☐ ☐ Information regarding international availability of the product is required to be submitted. (M-344)		
5.	M/s Innovegic Pharmaceuticals, Plot No.C-19, 2nd Floor, Main Road RCCI, Industrial Area, Rawat, Islamabad. Veterinary Serum and Vaccine Research Institute (VSVRI). E1-Sekka E1-Beda St. Abbassia, Cairo, Arab Republic of Egypt.	Servac BEF Attenuated Vaccine Each dose contains; Bovine Ephemeral Fever virus (BEF/Abasya/2000) not less than 5.5 log10 TCID50 10 dose Vial/Decontrolled 24 Months (-20 oC)	The Registration Board referred the case to sub-committee on veterinary drugs for the expert opinion of expert working group (EWG) on veterinary drugs for comments regarding immunological relevance and need of applied strains in Pakistan. Moreover, the Board directed to ask the applicant for rectification of following deficiencies in their application; ☐ ☐ The DSL of the firm has expired on 16-09-2023. ☐ ☐ Copy of Letter of Authorization from MAH submitted, is not legalized. ☐ ☐ The address of manufacturer is not mentioned on the product registration letter issued by regulatory body of country of origin. ☐ ☐ Legalized, valid GMP certificate of manufacturer is required to be submitted. ☐ ☐ The FSC provided, has been	Recommended.	Keeping in view the recommendation of Sub-Committee and FSC indicating product availability in country of origin; Registration Board approved the product subject to rectification of following deficiencies in the application: • Copy of valid DSL. • Copy of Letter of Authorization from MAH submitted, is not legalized. • The address of manufacturer is not mentioned on the product registration letter issued by regulatory body of country of origin. • Legalized, valid GMP certificate of manufacturer is required to be submitted. • The FSC provided, has been issued by the manufacturer, not the regulatory body of country of origin and the same has also not been legalized. • Stability studies data of the product is required to be submitted. • Safety & efficacy studies data of the product is required to be submitted.

			issued by the manufacturer, not the regulatory body of country of origin and the same has also not been legalized. ☐☐Stability studies data of the product is required to be submitted. ☐☐Safety & efficacy studies data of the product is required to be submitted. ☐☐Finished product specifications and testing methods are required to be submitted. ☐☐The label of the product does not bear name of the importer. ☐☐Information regarding international availability of the product is required to be submitted. (M-344)		• Finished product specifications and testing methods are required to be submitted. • The label of the product does not bear name of the importer. • Information regarding international availability of the product is required to be submitted.
6.	M/s Huzaifa International, Commercial Area, Aziz Bhatti Town, Sargodha. VETAL HAYVAN SAGLIGI URUNLERI A.S. Petrol Mah. 14 Cad. No: 1 Adiyaman, Turkey.	Poxvac Each 0.5ml dose of vaccine contains; Freez dried, live attenuated sheep & goat pox virus not less than 102.5 TCID₅₀ Decontrolled/50 doses 36 Months (2 - 8 oC)	The Registration Board referred the case to sub-committee on veterinary drugs for the expert opinion of expert working group (EWG) on veterinary drugs for comments regarding immunological relevance and need of applied strain in Pakistan. Moreover, the Board directed to ask the applicant for rectification of following deficiencies in their application; ☐☐Differential fee of Rs. 50,000/-, is	Recommended.	Keeping in view the recommendation of Sub-Committee and FSC indicating product availability in country of origin; Registration Board approved the product subject to rectification of following deficiencies in the application: • Differential fee of Rs. 50,000/-, is required to be deposited. • LOA submitted is not legalized. • Copy of legalized GMP certificate dated 08-05-2018 has been submitted. Fresh, Legalized, valid GMP certificate of the foreign manufacturer, is required.

			required to be deposited. ☐☐LOA submitted is not legalized. ☐☐Copy of legalized GMP certificate dated 08-05-2018 has been submitted. Fresh, Legalized, valid GMP certificate of the foreign manufacturer, is required. ☐☐Stability studies data of three batches of the product with same pack size is required. ☐☐As multiple pack sizes of the vaccine have been mentioned on FSC, the applied pack size is needed to be specified. ☐☐Information regarding international availability of the product is required to be submitted. (M-344)		- Stability studies data of three batches of the product with same pack size is required. - As multiple pack sizes of the vaccine have been mentioned on FSC, the applied pack size is needed to be specified. - Information regarding international availability of the product is required to be submitted.
7.	M/s Huzaifa International, Commercial Area, Aziz Bhatti Town, Sargodha. VETAL HAYVAN SAGLIGI URUNLERI A.S. Petrol Mah. 14 Cad. No: 1 Adiyaman, Turkey	Aborvac S Cow vaccine with Diluent Composition (Lyophilized vaccine): Each 1m dose of lyophilized vaccine contains; Live attenuated freeze dried <i>Brucella abortus</i> (S19 strain..... ≥ 1-3x10⁹ CFU Diluent Composition: Each 1000 ml contains: Sodium chloride (NaCl)....8000 mg Potassium chloride (KCl)....200 mg Disodium phosphate (Na₂HPO₄).....1140 mg	The Registration Board referred the case to sub-committee on veterinary drugs for the expert opinion of expert working group (EWG) on veterinary drugs for comments regarding immunological relevance and need of applied strain in Pakistan. Moreover, the Board directed to ask the applicant for rectification of following deficiencies in their application;	Recommended.	Keeping in view the recommendation of Sub-Committee and FSC indicating product availability in country of origin; Registration Board approved the product subject to rectification of following deficiencies in the application: - Differential fee of Rs. 75,000/-, is required to be deposited. - Safety & efficacy studies data of applied vaccine is required. - The copy of GMP certificate of foreign manufacturer provided, is not legalized. Moreover, GMP

		Potassium dihydrogen phosphate (KH₂PO₄)....200 mg Distilled water.....upto 1000 ml 2 doses with 2ml diluent 5 doses with 5ml diluent 10 doses with 10ml diluent 20 doses with 20ml diluent 50 doses with 50ml diluent Price is decontrolled. Vaccine: 12 Months (2 – 8oC) Diluent: 24 Months (25oC)	☐☐ Differential fee of Rs. 75,000/-, is required to be deposited. ☐☐ Safety & efficacy studies data of applied vaccine is required. ☐☐ The copy of GMP certificate of foreign manufacturer provided, is not legalized. Moreover, GMP certificate has expired on 11-04-2024. ☐☐ As multiple pack sizes of the vaccine have been mentioned on FSC, the applied pack size is needed to be specified. ☐☐ Original, legalized LOA from MAH, is required. ☐☐ LOA submitted is not legalized (M-344)		certificate has expired on 11-04-2024. - As multiple pack sizes of the vaccine have been mentioned on FSC, the applied pack size is needed to be specified. - Original, legalized LOA from MAH, is required. - LOA submitted is not legalized.
8.	M/s QAS International, Address Opposite Marian Hotel Near Grace Marque Subhan Ceramics Main GT Road, Gujranwala. Valid till: 24-Nov-2022 Manufacturer: M/s. PHARMAGAL BIO, s.r.o. Murgasova 5, 949 01 Nitra Slovak Republic.	COLUMBA Emulsion for injection One dose of the vaccine 0.3 ml contains: Inactivated pigeon paramyxovirus 1 strain 988M-ca inducing ≥ 5.8 log₂ HI unit in chickens 50doses: Decontrolled 30 Months	i. Registration Board referred the case for the detailed comments/recommendations of Animal Husbandry Commissioner regarding need of vaccine, prevalence of disease and immunological relevance of the strain in Pakistan. ii. The Board also advised firm to apply for change in address of Drug Sale License along with requisite fee.	Recommended.	Keeping in view the recommendations of Sub-Committee on Veterinary Drugs; Registration Board approved the product subject to compliance of current Import Policy for finished drugs and submission of application for change in address of Importer along with requisite fee.

			(M-344)		
9.	M/s QAS International, Address Opposite Marian Hotel Near Grace Marque Subhan Ceramics Main GT Road, Gujranwala. Valid till: 24-Nov-2022 Manufacturer: M/s. PHARMAGAL BIO, s.r.o. Murgasova 5, 949 01 Nitra Slovak Republic.	PHARMAVAC COLUMBI 2 Emulsion for injection for pigeons Each dose of vaccine (0.3ml) contains: Poultry paramyxovirus type I (strain LaSota) inactivated.....min. 7 log ₂ HI* Pigeon Herpes virus strain (V298/70) inactivated...min. 1 log ₂ VN* ELIZA units in chicken 100 doses: Decontrolled Shelf-life of the veterinary medicinal product as packaged for sale: 2 years	i. Registration Board referred the case for the detailed comments/recommendations of Animal Husbandry Commissioner regarding need of vaccine, prevalence of disease and immunological relevance of the strain in Pakistan. ii. The Board also advised firm to apply for change in address of Drug Sale License along with requisite fee. (M-334)	Recommended.	Keeping in view the recommendations of Sub-Committee on Veterinary Drugs; Registration Board approved the product subject to compliance of current Import Policy for finished drugs and submission of application for change in address of Importer along with requisite fee.
10.	M/s. QAS International, Address/premises situated at: Opposite Marian Hotel Near Grace Marque Subhan Ceramics Main GT Road, Gujranwala Valid till: 24-Nov-2022. Manufacturer: M/s. PHARMAGAL BIO, s. r. o. Murgasova 5 949 01 Nitra Slovak Republic	PHARMAVAC PHA (Emulsion for Injection for pigeons) Each dose of vaccine (0.3 ml) contains: Inactivated Pigeon Paramyxovirus type 1 (PPMV1), strain 988M ≥ 6.9 log ₂ HIU* Inactivated Pigeon Herpesvirus 1 (PHV1), strain V298/70 ≥ 38.1 EU** Inactivated Fowl Adenovirus type 8 (FAdV-8), strain M2/E ≥ 24.7 EU** * Haemagglutination inhibition units in chicken ** ELISA units in chicken 24 months doses per Vial: Decontrolled	i. Registration Board referred the case for the detailed comments/recommendations of Animal Husbandry Commissioner regarding need of vaccine, prevalence of disease and immunological relevance of the strain in Pakistan. ii. The Board also advised firm to apply for change in address of Drug Sale License along with requisite fee. (M-334)	Recommended.	Keeping in view the recommendations of Sub-Committee on Veterinary Drugs; Registration Board approved the product subject to compliance of current Import Policy for finished drugs and submission of application for change in address of Importer along with requisite fee.

Case No. 2: Registration of Imported Biological Product applied by M/s Revive Healthcare deferred in 350th meeting.

Teriparatide is a recombinant human parathyroid hormone analog (PTH 1-34). It has an identical sequence to the 34 N-terminal amino acids (the biological active region) of the 84-amino acid human parathyroid hormone. It is used in the treatment of postmenopausal women with osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy.	
Name, address of Applicant / Importer	M/s Revive Healthcare, Office 503, 5 th Floor, 6 Main Gulberg Jail Road, Lahore.
Details of Drug Sale License of importer	Address: Office 503, 5th Floor, Eden Heights, 6 Main Gulberg Jail Road, Lahore. Validity: 21-05-2027 Status: License to sell drugs as distributor
Name and address of marketing authorization holder (abroad)	Virchow Biotech Private Limited Survey No.172 Part, Gagillapur(V), Dundigal Gandimaisamma (M), Medchal- Malkajgiri (D), Telangana-500043, India
Name, address of manufacturer(s)	Virchow Biotech Private Limited Survey No.172 Part, Gagillapur(V), Dundigal Gandimaisamma (M), Medchal- Malkajgiri (D), Telangana-500043, India
Name of exporting country	India
Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	Firm has submitted original valid legalized CoPP Certificate No. 4222631/TS/2023 Valid upto 11-12-2025 issued by by Drug Control Administration, Government of Telangana State, India. The COPP confirms free sale status of the product (Osteotide Injection 750mcg/3mL, prefilled cartridge with pen device) in exporting country as well as GMP status of the manufacturing site. The submitted legalized GMP is valid upto 11-12-2025
Details of letter of authorization / sole agency agreement	Firm has submitted letter of authorization from Virchow Biotech Private Limited . The letter species that the manufacturer appoints M/s Revive Healthcare Lahore to register their products in Pakistan. The authorization letter is issued on 13-03- 2023
Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
Dy. No. and date of submission	Dy. No.1298 : dated 08-11-2023
Details of fee submitted	PKR 75,000/-: 26-10-2023
The proposed proprietary name / brand	OSTEOTIDE INJECTION 750 mcg/3mL

name	
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each mL of prefilled pen device contains: Teriparatide 250mcg
Pharmaceutical form of applied drug	Solution for injection
Pharmacotherapeutic Group of (API)	Antineoplastic agent ATC Code: H05AA02
Reference to Finished product specifications	USP
Proposed Pack size	1's
Proposed unit price	AS PER SRO
The status in reference regulatory authorities	FORSTEO INJECTION (250mcg/mL) by Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands MHRA Approved
For generic drugs (me-too status)	Not applicable
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	Virchow Biotech Private Limited Survey No.172 Part, Gagillapur(V), Dundigal Gandimaisamma (M), Medchal- Malkajgiri (D), Telangana-500043, India
Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis 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 DS stability study data of 3 batches of API Batch # 4- BOST00120 5- BOST00220 6- BOST00320 at accelerated as well as real time conditions. The real time stability data provided for claimed shelf life of 18 months.
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Pharmaceutical Equivalence and	Firm has submitted complete data of formulation development

Comparative Dissolution Profile	process. Firm has submitted comparative quantitative composition of applied product along with reference product. Firm has also submitted results of pharmaceutical equivalence against the reference product which is Forteo Injection by Lilly, France.
Analytical method validation/verification of product	Firm has submitted analytical verification validation studies for the applied product.
Container closure system of the drug product	The drug product is filled into 3.0 mL sterile USP Type-I siliconized glass cartridges closed with lined seals, followed by solid plunger.
Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Batch No. 1- 5400119 2- 5400219 3- 5400319 The accelerated stability study data is conducted at 25oC ±2oC / 60% ± 5% RH and real time stability study data conducted at 5oC ±3oC for 36 months with the claimed shelf life of 24 months.
Non-clinical (Module-IV)	The firm has submitted non-clinical data following study reports: Pharmacology • Primary pharmacodynamics • Secondary pharmacodynamics • Safety pharmacology Pharmacokinetics • Absorption • Distribution • Metabolism • Excretion Toxicology • Single dose toxicity • Repeated dose toxicity
Clinical (Module-V)	Firm has submitted clinical data of • Reports of Biopharmaceutic Studies • Reports of Studies Pertinent to Pharmacokinetics using Human Biomaterials • Reports of Human Pharmacokinetic (PK) Studies • Reports of Human Pharmacodynamic (PD) Studies • Reports of Efficacy and Safety Studies
Evaluator's remarks: The firm has provided incomplete data of non-clinical and clinical studies.	
Decision of 344th RB meeting: After detailed discussion and deliberation, the Board decided to defer the case for provision of following: i. Documented study reports and non-clinical data of pharmacological, pharmacokinetics, toxicology including single-dose and repeat dose toxicity studies, genotoxicity, carcinogenicity, reproductive and developmental toxicity (including range-finding studies and supportive toxicokinetics evaluations), local tolerance and other toxicological studies:	

- ii. Documented and published clinical studies, biosimilarity studies including In vitro-In vivo Correlation Study Reports, Reports of Bioanalytical and Analytical Methods for Human Studies, Human Pharmacokinetic and Pharmacodynamics studies, Study Reports of Controlled Clinical Studies Pertinent to the claimed indication:
- iii. Documented and published study reports of pre-clinical, Clinical trial reports establishing the safety and efficacy of the product:
- iv. Post-marketing surveillance (Pharmacovigilance) study reports.

Evaluation by BE&R:

Now the firm has submitted a reply as under:

In non-clinical part, firm has submitted following;

- Comparative pharmacodynamic study conducted in White Albino Rabbits.
- In Repeat-Dose toxicity, following studies are performed:
- To investigate the acute and Sub-chronic toxicity effects when administered intravenously and subcutaneously to Sprague Dawley Rats.
- To assess the safety and local effects when administered subcutaneously to male and female New Zealand white albino rabbits

In clinical part, firm has submitted following studies;

- A phase I study was conducted to assess the safety and pharmacokinetic profile of rhPTH (1-34) drug product. The objective of the study was to assess pharmacokinetics profile of Osteotide of Virchow Biotech, containing 20 µg of rhPTH following subcutaneous injection in healthy, adult, human subjects.
- A phase II comparative study was conducted to compare the safety bioavailability and pharmacodynamic effects of rhPTH (1-34) drug product (test drug) and a reference product (Forteo®). The objective of the study was to assess and compare the pharmacodynamic profile and bioavailability of Osteotide of Virchow Biotech, with that of Forteo of Eli Lilly containing 20µg of rhPTH following subcutaneous injection.
- Phase 3 study title: Safety and Efficacy of **OSTEOFORM** (rhParathyroid Hormone (1-34)) in increasing Bone Mineral Density in Osteoporosis -A Randomised control open-label multicenter study in India VB006/09/05 Prot.3 Dated 04/09/2005
- Phase IV study: A Non-inferiority, multicenter, comparative study between **Bonista** and Forteo in the treatment of osteoporosis;
- PERIODIC SAFETY UPDATE REPORT on TERIPARATIDE (rhParathyroid Hormone) of every year from 2010 to 2017 is attached.

Decision of 350th meeting:

Deferred for submission of bio similarity data in accordance with WHO guidelines or other relevant guidelines from Stringent Regulatory Authorities (SRAs) for the applied product.

Evaluation by BE&R:

Teriparatide is a rDNA peptide of 34 amino acids sequence and evaluated as per decision of the Board for peptide drugs. Following is submitted by the applicant;

- Physico-chemical and biological characterization of Teriparatide (rhPTH (1-34)) USP drug substance and Teriparatide Injection (rhPTH (1-34)) USP drug product which is manufactured at Virchow Biotech Private limited, Hyderabad.
- Comparative study results of Osteotide with Forteo (reference product).
- Comparative pharmacodynamic study conducted in White Albino Rabbits.
- A phase II comparative study to compare the safety bioavailability and pharmacodynamic effects of rhPTH (1-34) drug product (test drug) and a reference product (Forteo®). The objective of the study was to assess and compare the pharmacodynamic profile and bioavailability of Osteotide of Virchow Biotech, with that of Forteo of Eli Lilly containing 20µg of rhPTH following subcutaneous injection.

Remarks:

- Peptide mapping is done by HPLC.
- Comparative impurity testing of applied product with innovator is required including product related and process related impurities.
- Innovator product Forteo is available as 600µg/2.4ml (the strength 750µg/3ml is discontinued) while the applied product is 750µg/3ml.

Decision:

Registration Board deferred the case for submission of following by the firm:

- Justification of performing Peptide mapping by HPLC instead of LC-MS.
- Comparative impurity testing of applied product with innovator including product related and process related impurities.
- Reason of discontinuation of Innovator in applied strength in USFDA.
- Evidence of availability of formulation in applied strength in Reference Regulatory Authorities.

Case No. 3: Application for permission to Import 220,000 Packs of Vaxigrip Tetra (Reg. No.105066) with previous name of MAH.

M/s Hoechst Pakistan Limited, Karachi applied for grant of permission to Import 220,000 Packs of Batch No. 5DF57D1 of Vaxigrip Tetra (Reg. No.105066) with previous name of MAH.

It is submitted that the firm has already got approval of change in MAH from “M/s Sanofi Pasteur 14 Espace Henry Vallée, 69007 Lyon, France” to “M/s Sanofi Winthrop Industrie 82 Avenue Raspail 94250 Gentilly, France” vide E-App letter dated 17-May, 2025. The firm submitted that all other quality attributes including manufacturer & batch release shall be the same as per current approval i.e. “M/s Sanofi Winthrop Industrie, Parc Industriel D’ Incarville, Voie De L Institut, P. O. Box 101, Val De Reuil, 27100, France.”

Decision:

Registration Board acceded to request of the firm and granted one-time permission to Import 220,000 packs of Batch No. 5DF57D1 of Vaxigrip Tetra with previous Market Authorization Holder i.e. M/s Sanofi Pasteur 14 Espace Henry Vallée, 69007 Lyon, France and updated manufacturing site i.e. M/s Sanofi Winthrop Industrie, Parc Industriel D’ Incarville, Voie De L Institut, P. O. Box 101, Val De Reuil, 27100, France.

Case No. 4: Imported Veterinary Biologicals applied by M/s Better Traders International, Faisalabad approved in 313th, 316th & 344th meeting of Registration Board.

Following products of M/s Better Traders International, Faisalabad were approved in 313th, 316th & 344th meetings of Registration Board as per following details:

Sr. NO.	Name of MAH & Manufacturer	Brand Name & Composition	Decision of RB
1.	M/s AVAC Vietnam Co., Ltd., Highway A, Ngoc Lick, Trung Tac Province, Hung Yen City Vietnam	AVAC IB- H120 Infectious Bronchitis Vaccine, Live Each dose contains: Attenuated IB Virus strain H120.....Not less than 10 ² EID ⁵⁰ Manufacturer’s Specifications	<i>Keeping in view legalized GMP and FSC indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. The firm shall submit valid legalized FSC indicating diluent in combopack before issuance of registration letter. Chairman Registration</i>

			<i>Board is authorized for issuance of letter. (M-313)</i>
2.		AVAC ND- Lasota Newcastle Disease Vaccine, Live Each 0.1ml contains: Each dose contains: Newcastle Virus strain Lasota.... Not less than 10^6EID_{50} Manufacturer's Specifications	<i>Keeping in view legalized GMP and FSC indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. The firm shall submit valid legalized FSC indicating diluent in combopack before issuance of registration letter. Chairman Registration Board is authorized for issuance of letter. (M-313)</i>
3.		Avac ND -IB Live Newcastle and Infectious Bronchitis Vaccine, Live Each dose contains: Newcastle Disease Virus, Hitchner B1 strain..... not less than 10^6EID_{50} infectious Bronchitis Virus, H120 strain..... not less than 10^2EID_{50} BP Specifications	<i>Keeping in view legalized GMP and FSC indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. The firm shall submit valid legalized Free Sale Certificate indicating diluent in combopack before issuance of registration letter. Chairman Registration Board is authorized for issuance of letter after submission of said FSC. (M-316)</i>
4.		Avac ND -IB K Newcastle and Infectious Bronchitis Vaccine, Inactivated Each dose contains: Newcastle Disease Virus, LaSota strain..... not less than 10^6EID_{50} infectious Bronchitis Virus, H120 strain..... not less than 10^2EID_{50} BP Specifications	<i>Keeping in view legalized GMP and FSC indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. The firm shall submit valid legalized Free Sale Certificate indicating diluent in combopack before issuance of registration letter. Chairman Registration Board is authorized for issuance of letter after submission of said FSC. (M-316)</i>
5.		Avac Gumboro INT Infectious Bursal Disease Vaccine, Live Each dose contains: attenuated Infectious Bursal (IBD) Disease Virus, strain W2512.....not less than 10^3TCID_{50} BP Specifications	<i>Keeping in view legalized GMP and FSC indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. The firm shall submit valid legalized Free Sale Certificate indicating diluent in combopack before issuance of registration letter. Chairman Registration Board is authorized for issuance of letter after submission of said FSC. (M-316)</i>
6.	M/s Avac Vietnam Joint Stock Company, Highway 5A, Ngoc Lich Village, Trung	Avac LSD Lumpy Skin Disease Vaccine, Live Each dose contains: Attenuated LSD Virus (Neethling Strain).....NLT $10^{3.5}\text{TCID}_{50}$	<i>Keeping in view the legalized FSC indicating product availability in the country of origin, the Registration Board approved the product subject to compliance to the current Import</i>

	Trac Commune, Van Lam District, Hung Yen Province, Vietnam.	Manufacturer's Specifications	<i>Policy for finished drugs and rectification of following deficiencies in the application;</i> • <i>Legalized LOA from MAH is required.</i> • <i>Copy of Valid DSL is required.</i> • <i>The name of importer has not been mentioned on the label.</i> (M-344)

During processing of Registration Letter, it was observed that in Free Sale Certificate submitted by the firm, following statement was mentioned:

“Can be freely sold in Viet Nam and overseas market”.

As the clear statement was not mentioned, hence, it was decided to ask regulatory authority of country of origin to confirm the status of Free Sale of above products in country of import. Accordingly, email was forwarded twice once on 19-08-2025 & then on 02-09-2025 to the email address mentioned on one of the FSCs. However, no response is yet received.

Decision:

Registration Board deferred the applications for submission of valid Free Sale Certificate of each product indicating actual status of availability of product in country of origin.



Drug Regulatory Authority of Pakistan

(Biological Evaluation & Research Division)



Additional/Supplementary Minutes:

Sr. No	Title	Description
1	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Hakimsons (Impex) (Pvt.) Ltd. Hakimsons Building, 19 West Wharf Road, Karachi 74000, Pakistan. (030)
	Application Form Dy. No / Tracking ID & date of submission	(4PA-X8M-25B7, 2024-09-13)
	Detail of Fee Submitted	75000.0, 225000.0 2024-06-13, 2024-07-25
	The proposed proprietary name / brand name	Rhoclone
	Label Claim	Each ml contains; Anti Rho-D Immunoglobulin 300mcg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	3 Year(s)2-8 °C
	For generic drugs (me-too Status)	-
	Pharmacotherapeutic Group of (API)	Immunoglobulin
	Name, address of Manufacturing site:	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 Maharashtra State, India-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Name, address of Marketing Authorization Holder:	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 Maharashtra State, India, India
	Details of Certificates (CoPP/FSC/cGMP):	COPP: Legalized COPP has been submitted and product is available freely in the country of Export. GMP: Valid, legalized GMP of manufacturer, has been submitted.
	Details of Authorization Letter :	LOA: Valid, legalized LOA from MAH, has been submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted accelerated stability studies data of 3 batches of drug substance at 25°C ± 2°C /60 % ± 5% RH of 6 months and real time studies data of 3 batches at 2-8 °C of 12 months
	The status in reference regulatory authorities	Rhophylac by CSL Behring AG-USFDA (It is not recombinant)
Evaluation Remarks		
Decision of 345th meeting of RB:The Registration Board deferred the case for rectification of following deficiencies in the application; • Justification of in-house specification ranges of different tests given for drug product, has not been provided. • The real time stability studies data of three batches, of only 12 months, has been submitted with a claimed shelf-life of 36 months. • Only protocol of Phase-III clinical studies, has been submitted.		

Findings & conclusion has not been submitted. Evaluation by BE&R: The firm has submitted a reply as under; We will follow the In-House specifications for product Rhoclone 300mcg (Anti Rho-D Immunoglobulin Injection (Monoclonal) (Liquid injection) as product is not appeared in any official published pharmacopoeia. Stability data of Batch# A23121001, 23121002, 23121003 at accelerated conditions $25^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $60\% \pm 5\%\text{RH}$ till 6 months and at real time conditions $5 \pm 3^{\circ}\text{C}$ till 36 months is attached. "A Prospective, Randomized, Open Label, Phase III, Multicentric Clinical Trial to Compare the Efficacy and Safety of Monoclonal Anti RHO(D) Immunoglobulin with Polyclonal Anti RHO(D) Immunoglobulin in Prevention of Hemolytic Disease of Newborn" was conducted in 206 subjects. Clinical report attached. Decision of 347th meeting of RB: Registration Board deferred the case for further deliberation. Evaluation by BE&R: Following is required from the applicant; Evidence of availability of recombinant Anti Rho-D immunoglobulin in vial container closure system in any reference country as approved by Registration Board.

Decision

Rejected

Registration Board rejected the application as the rDNA-origin Anti Rho-D Immunoglobulin has not been approved by any of the Reference Regulatory Authorities as designated by the Board.

2

Case Category	Routine (Anam Saeed)
Name, address of Applicant.	SIR-BIO Pharma SF 09, 4th Floor, Shahnaz Arcade, Main Shaheed e Millat Road (0782)
Application Form Dy. No / Tracking ID & date of submission	(GUN-P8U-WJ75, 2024-02-21)
Detail of Fee Submitted	300000.0, 2024-02-19,
The proposed proprietary name / brand name	Hepsir
Label Claim	Heparin Injection BP, 25000IU/5mL
Reference to Finished product specifications	British Pharmacopoeia
Proposed Pack Size	25-As per SRO
Shelf Life (Unit)	3 Year(s) Store below 30°C
For generic drugs (me-too Status)	Vasparin 25000Iu/5ml by M/s Bristol Mayer (Reg.#11169)
Pharmacotherapeutic Group of (API)	Heparin
Name, address of Manufacturing site:	Gland Pharma Limited-Unit-II, Plot no: 42-52, Survey. No. 166, 171, 172 & 177, Phase III, TSIIC, Pashamylaram Village, Patancheru Mandal, Sangareddy District, Hyderabad, Telangana - 502307, India.-India
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
Name, address of Marketing Authorization Holder:	Gland Pharma Limited, Unit-II, Plot no: 42-52, Survey. No. 166, 171, 172 & 177, Phase III, TSIIC, Pashamylaram Village, Patancheru Mandal, Sangareddy District, Hyderabad, Telangana - 502307, India., India
Details of Certificates (CoPP/FSC/cGMP):	CoPP Certificate No.: 4280510/TS/2024 Valid Up To : 16/06/2025
Details of Authorization Letter :	LOA dated 28-03-2024 has been provided. According to LOA, the product shall be supplied through M/s Wanbang Biopharmaceuticals South of Dongshan, Comprehensive area, Jinshanqiao development zone, Xuzhou, Jiangsu, China.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of drug substance is incomplete.
The status in reference regulatory authorities	Heparin Leo, France

Evaluation Remarks

The case was deferred in 345th meeting.

Decision of 345th meeting: After detailed discussion and deliberation on the matter, the Board decided to defer the case for provision of valid and legalized CoPP, indicating the availability of applied brand in the country of origin.

Evaluation by BE&R: The firm has submitted a statement as under; "It is requested to kindly keep the name "Heparin Fosun." as the brand name mentioned on submitted CoPP. We are not insisting to have a separate brand name." Remarks: · Address of manufacturer/MAH in COPP is different from that on LOA. · The COPP submitted is not legalized and expired also. · GMP certificate of manufacturer is not legalized and expired also. · Brand name is not mentioned in LOA. · The supplier mentioned in LOA is M/s Wanbang Biopharmaceuticals South of Dongshan, Comprehensive area, Jinshanqiao development zone, Xuzhou, Jiangsu, China. Clarification required as the exporting country recorded in minutes is India. · Stability data of drug substance at real time and accelerated storage conditions is required. Incomplete data submitted. · Real time stability data of drug product is submitted till 24 months while the claimed shelf life is 36 months.

Decision:

Decision

Deferred

Registration Board deferred the case for submission of following clarifications/documents;

i. Address of manufacturer/MAH in COPP is different from that on Letter of Authorization (LOA)

ii. The submitted COPP & GMP is both expired and not legalized.

iii. Brand name is not mentioned in LOA.

iv. The supplier mentioned in LOA is M/s Wanbang Biopharmaceuticals South of Dongshan, comprehensive area, Jinshanqiao Development Zone, Xuzhou, Jiangsu, China. Clarification required as the exporting country recorded in minutes is India.

v. Complete stability data of drug substance at real time and accelerated storage conditions is required as incomplete data submitted.

vi. Real-time stability data of the drug product has been provided only up to 24 months, whereas the claimed shelf life is 36 months.

3

Case Category	Routine (Anam Saeed)
Name, address of Applicant.	Hakimsons (Impex) (Pvt.) Ltd. Hakimsons Building, 19 West Wharf Road, Karachi 74000, Pakistan. (030)
Application Form Dy. No / Tracking ID & date of submission	(32X-P4B-HGQZ, 2024-12-24)
Detail of Fee Submitted	300000.0, 2024-11-12,
The proposed proprietary name / brand name	STPASE Injection
Label Claim	Each Vial contains..... Streptokinase concentrate 1500000 IU
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	1's-Controlled
Shelf Life (Unit)	24 Month(s)Store between 2-8 °C. Protect from Light
For generic drugs (me-too Status)	Dicclair-ST Gene Tech Laboratories BBT Biotech , Germany Registration No. 059023
Pharmacotherapeutic Group of (API)	Thrombolytic protein ATC Code: B01AD01

Name, address of Manufacturing site:	Cadila Pharmaceuticals Limited-1389,Trasad Road, Dholka – 382 225, District: Ahmedabad Gujarat State, INDIA-India
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
Name, address of Marketing Authorization Holder:	Cadila Pharmaceuticals Limited, 1389,Trasad Road, Dholka – 382 225, District: Ahmedabad Gujarat State, INDIA, India
Details of Certificates (CoPP/FSC/cGMP):	COPP: Firm has submitted the legalized COPP and Product is available freely in the country of Export [Certificate No. MFG/WHO/GMP COPP/2024/4550243710 Issuance Date: 15-02-2024 Validity: 16.11-2025 Name and address of Issuing Regulatory Authority: Foo
Details of Authorization Letter :	Firm has submitted Legalized letter of distribution certificate from Cadila Pharmaceuticals Limited. The letter species that the manufacturer appoints M/s Hakimsons (Impex) (Pvt.) Ltd. to register their products in Pakistan issued on 03-05-2024.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted the 3 batches data 14019, 14020, 14021 Accelerated 2-8°C (6Months) & Long Term (Real Time) Studies - 20° C ± 2° C (12Months)
The status in reference regulatory authorities	Streptokinase Karma 1,500,000 IU (MHRA approved)

Evaluation Remarks

The case was deferred in 348th meeting. Decision of 349th Meeting: The Registration Board after thorough deliberation deferred the case for the submission of the following documents:

- Evidence of approval of biological section from concerned regulatory authority.
- Documented study reports and non-clinical data of pharmacological, pharmacokinetics, toxicology including single-dose and repeat dose toxicity studies, genotoxicity, carcinogenicity, reproductive and developmental toxicity (including range-finding studies and supportive toxicokinetics evaluations), local tolerance and other toxicological studies:
- Documented and published clinical studies, In vitro-In vivo Correlation Study Reports, Reports of Bioanalytical and Analytical Methods for Human Studies, Human Pharmacokinetic and Pharmacodynamics studies, Study Reports of Controlled Clinical Studies Pertinent to the claimed indication:
- Documented and published Clinical trial reports establishing the safety and efficacy of the product.

Evaluation by BE&R: i. Firm has submitted a legalized GMP certificate issued by National Pharmaceutical Regulatory Agency, Ministry of Health Malaysia which is PIC/s participating authority. However, the GMP certificate states that it only applies to small volume parenteral production area on main pharma block and dry powder injection on the cephalosporin block. Firm has submitted a justification regarding production of streptokinase in pharmaceutical production area as under; “With reference to registration Application of STPase. We would like to provide the following compliance confirmation regarding the manufacturing of Streptokinase. Streptokinase, a protein enzyme, is manufactured in a fully segregated and dedicated injectable area located within our main pharmaceutical block. While the facility is multi-product. this specific manufacturing area is both physically and operationally isolated, functioning under validated closed system processes with robust containment, decontamination, and cleaning procedures, all aligned with Quality Risk Management (QRM) principles. In accordance with the WHO Good Manufacturing Practices (GMP) for Biological Products - Replacement of Annex I of WHO Technical Report Series No. 822 (Annex 2, Section 9.1). Link below "https://*www.who.int/docs/default-source/biological/gmp/annex-2-who-goodmanufacturing-ptactices-for-biological-producers.pdf?it=stipulated it is stipulated that preparations containing live microorganisms or live viruses should not be manufactured in areas utilized for other pharmaceutical processing. However, the guideline also states that such use of multi-product facilities is acceptable if effective containment and validated decontamination measures are implemented. We confirm that our facility is fully compliant with these international GMP requirements. All relevant aspects including facility and equipment design, personnel and material flow, microbiological controls, and cleaning validation are established and validated to the highest international standards.” ii. Regarding submission of clinical and non-clinical data, the firm has submitted studies form already published literatures and submit justification as under; “As per USFDA “Generic medicines tend to cost less than their brand-name counterparts because they do not have to repeat animal and clinical (human)

studies that were required of the brand-name medicines to demonstrate safety and effectiveness.” For More information, click on below Link [Annexure 6] <https://www.fda.gov/drugs/generic-drugs/generic-drug-facts>. Further, please refer to the case discussed in the 295th Meeting of the Registration Board regarding the brand “BioFactor,” imported from Germany and approved by both the German Regulatory Authority and the MHRA. In this case, DRAP had requested clinical trial data (Point C, Page 2270). However, the applicant submitted only published literature-based data of the originator product. Since the product has been marketed for a long period with no evidence of an impaired risk–benefit balance, and considering the submission of published data, the Registration Board approved the product for registration. [Annexure-7]”Concluding remarks:· The finished product manufacturer does not have biological section and the manufacturer informed that the product will be manufactured in general section.· The firm has submitted studies from already published literature in place of clinical and non-clinical data.· The storage conditions of the reference product (approved by MHRA) is “Do not store above 25°C” while the storage conditions of applied product is 2-8°C.· The manufacturer and MA Holder is same as per COPP while different is mentioned in Module 1 in the dossier which is M/s Firmlink Pvt Limited., India.

Decision

Deferred

The Registration Board, after detailed deliberation, decided to defer the case and granted the applicant a final opportunity to clarify and provide evidence on whether the area where Streptokinase is being manufactured is included under the GMP issued by NPRA Malaysia for the Small Volume Parenterals Production Area in the Main Pharma Block.

4	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Macter International Limited F-216,S.I.T.E.,Karachi-Pakistan (000141)
	Application Form Dy. No / Tracking ID & date of submission	(97S-UYP-AHR5, 2025-09-04)
	Detail of Fee Submitted	37000.0, 1700.0 2025-05-29, 2025-09-03
	The proposed proprietary name / brand name	Zepatide (Tirzepatide) 2.5 mg per 0.5 ml strength (single dose vial) solution for injection
	Label Claim	Each 0.5ml contains: Tirzepatide 2.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a refrigerator at 2°C to 8°C.
	For generic drugs (me-too Status)	Yurpeak 2.5mg/0.5mL by Eli Lilly Pakistan (Private) Limited
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhejiang Peptides Biotech Co., Ltd. Address: No. 8, Hengyizhi Road, Sanjie Town, Shengzhou City, Shaoxing City, Zhejiang Province, China
	Detail of stability batches of drug product	Stability study was conducted at real time storage condition 5°C ± 3°C and accelerated condition 25°C ± 2°C; 60%RH ± 5%RH and data of 2 batches (TZV-02A and TZV-03A) are submitted till 2 months while one batch (TZV-01A) till 06 months.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Commercial invoice No.ZPCW20241025 dated Nov.18th, 2024 which is not DRAP attested.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A

Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	In stability data of drug substance, accelerated and long term stability studies are performed on one lab batch (G271-2403121P4-F-1) and three pilot batches (ZG271240301, ZG271240302, ZG271240701). Accelerated data of lab batch is till 6 months and long term data is till 12 months. Accelerated and long term stability data of pilot batches are till 6 months. Stability data of 3 commercial batches of drug substance is provided till 3 months only.
The status in reference regulatory authorities	Mounjaro US-FDA approved
GMP status of the firm	GMP certificate valid till 30th June, 2027.
Evidence of approval of manufacturing facility	Liquid and Lyophilized recombinant DNA technology products (biological) section granted on 19th July 2012
Evaluation Remarks	
The case was evaluated and found deficient for the following; i. Stability data provided for the drug substance covers only up to 3 months. Remaining data is required. ii. Peptide mapping by LC-MS should be a part of finished product specifications. iii. Individual impurities are not performed in comparative testing of applied product with innovator. iv. Stability data has been provided for only one batch up to 6 months, while the remaining two batches have data up to 3 months. Complete stability data for all three batches is required.	
Decision	
Deferred	
Registration Board deferred the case for submission of following documents/ clarifications;	
i. Stability data provided for the drug substance covers only up to 3 months.	
Remaining data is required.	
ii. Peptide mapping by LC-MS should be a part of finished product specifications.	
iii. Individual impurities are not performed in comparative testing of applied product with innovator.	
iv. Stability data has been provided for only one batch up to 6 months, while the remaining two batches have data up to 3 months. Complete stability data for all three batches is required.	
5	Case Category
	Routine (Anam Saeed)
	Name, address of Applicant.
	Macter International Limited F-216,S.I.T.E.,Karachi-Pakistan (000141)
	Application Form Dy. No / Tracking ID & date of submission
	(EUH-PPQ-E948, 2025-09-04)
	Detail of Fee Submitted
	37000.0, 1700.0 2025-05-30, 2025-09-03
	The proposed proprietary name / brand name
	Zepatide (Tirzepatide) 15 mg per 0.5 ml strength (single dose vial) solution for injection
	Label Claim
	Each 0.5ml contains: Tirzepatide 15mg
	Reference to Finished product specifications
	As per Innovators Specification
	Proposed Pack Size
	1's-As per SRO
	Shelf Life (Unit)
	2 Year(s)Store in a refrigerator at 2°C to 8°C.
	For generic drugs (me-too Status)
	Yurpeak 15 mg / 0.5 mL by Eli Lilly Pakistan (Private) Limited
	Pharmacotherapeutic Group of (API)
	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16

Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Zhejiang Peptides Biotech Co., Ltd. Address: No. 8, Hengyizhi Road, Sanjie Town, Shengzhou City, Shaoxing City, Zhejiang Province, China
Detail of stability batches of drug product	Stability study was conducted at real time storage condition $5^{\circ}\text{C} \pm 3^{\circ}\text{C}$ and accelerated condition $25^{\circ}\text{C} \pm 2^{\circ}\text{C}$; 60%RH $\pm$ 5%RH and data of 2 batches (TZV-03F and TZV-01F) are submitted till 3 months while one batch (TZV-02F) till 06 months.
Documents for the procurement of API with approval from DRAP (in case of Import)	Commercial invoice No.ZPCW20241025 dated Nov.18th, 2024 which is not DRAP attested.
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	In stability data of drug substance, accelerated and long term stability studies are performed on one lab batch (G271-2403121P4-F-1) and three pilot batches (ZG271240301, ZG271240302, ZG271240701). Accelerated data of lab batch is till 6 months and long term data is till 12 months. Accelerated and long term stability data of pilot batches are till 6 months. Stability data of 3 commercial batches of drug substance is provided till 3 months only.
The status in reference regulatory authorities	Mounjaro US-FDA approved
GMP status of the firm	GMP certificate valid till 30th June, 2027.
Evidence of approval of manufacturing facility	Liquid and Lyophilized recombinant DNA technology products (biological) section granted on 19th July 2012
Evaluation Remarks	
The case was evaluated and found deficient for the following; i. Stability data provided for the drug substance covers only up to 3 months.Remaining data is required.ii. Peptide mapping by LC-MS should be a part of finished product specifications.iii. Individual impurities are not performed in comparative testing of applied product with innovator. iv. Stability data has been provided for only one batch up to 6 months, while the remaining two batches have data up to 3 months. Complete stability data for all three batches is required.	
Decision	
Deferred	
Registration Board deferred the case for submission of following documents/ clarifications;	
i. Stability data provided for the drug substance covers only up to 3 months. Remaining data is required.	
ii. Peptide mapping by LC-MS should be a part of finished product specifications.	
iii. Individual impurities are not performed in comparative testing of applied product with innovator.	
iv. Stability data has been provided for only one batch up to 6 months, while the remaining two batches have data up to 3 months. Complete stability data for all three batches is required.	
6	Case Category
	Routine (Anam Saeed)
	Name, address of Applicant.
	Macter International Limited F-216,S.I.T.E.,Karachi-Pakistan (000141)

Application Form Dy. No / Tracking ID & date of submission	(GDZ-EG5-HES5, 2025-09-04)
Detail of Fee Submitted	37000.0, 1700.0 2025-05-29, 2025-09-03
The proposed proprietary name / brand name	Zepatide
Label Claim	Each 0.5ml contains: Tirzepatide 5mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's-As per SRO
Shelf Life (Unit)	2 Year(s)Store in a refrigerator at 2°C to 8°C
For generic drugs (me-too Status)	Yurpeak Solution for injection by Eli Lilly Pakistan (Private) Limited
Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Zhejiang Peptides Biotech Co., Ltd. Address: No. 8, Hengyizhi Road, Sanjie Town, Shengzhou City, Shaoxing City, Zhejiang Province, China
Detail of stability batches of drug product	Not performed
Documents for the procurement of API with approval from DRAP (in case of Import)	Commercial invoice No.ZPCW20241025 dated Nov.18th, 2024 which is not DRAP attested.
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	In stability data of drug substance, accelerated and long term stability studies are performed on one lab batch (G271-2403121P4-F-1) and three pilot batches (ZG271240301, ZG271240302, ZG271240701). Accelerated data of lab batch is till 6 months and long term data is till 12 months. Accelerated and long term stability data of pilot batches are till 6 months. Stability data of 3 commercial batches of drug substance is provided till 3 months only.
The status in reference regulatory authorities	Mounjaro US-FDA approved
GMP status of the firm	GMP certificate valid till 30th June, 2027.
Evidence of approval of manufacturing facility	Liquid and Lyophilized recombinant DNA technology products (biological) section granted on 19th July 2012

Evaluation Remarks

The case was evaluated and found deficient for the following;

- Stability data provided for the drug substance covers only up to 3 months.Remaining data is required.
- Peptide mapping by LC-MS should be a part of finished product specifications.
- Individual impurities are not performed in comparative testing of applied product with innovator.
- Firm has not performed stability studies on applied product and submitted justification of following ICH guidelines. However, ICH guidelines on BRACKETING AND MATRIXING DESIGNS FOR STABILITY TESTING OF NEW DRUG SUBSTANCES AND PRODUCTS Q1D states that: With justification, bracketing can be applied to studies with multiple strengths where the relative amounts of drug substance and excipients change in a formulation. Such justification can include a demonstration of comparable stability profiles among the different strengths of clinical or development batches.

Decision

Deferred

Registration Board deferred the case for submission of following documents/clarifications;

i. Stability data provided for the drug substance covers only up to 3 months.

Remaining data is required.

ii. Peptide mapping by LC-MS should be a part of finished product specifications.

iii. Individual impurities are not performed in comparative testing of applied product with innovator.

iv. Submit Justification of not performing stability studies on applied product including a demonstration of comparable stability profiles among the different strengths of clinical or development batches as per ICH Guidelines Q1D on "BRACKETING AND MATRIXING DESIGNS FOR STABILITY TESTING OF DRUG SUBSTANCES AND DRUG PRODUCTS".

7	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Macter International Limited F-216,S.I.T.E.,Karachi-Pakistan (000141)
	Application Form Dy. No / Tracking ID & date of submission	(QVL-2S5-3615, 2025-09-04)
	Detail of Fee Submitted	37000.0, 1700.0 2025-05-29, 2025-09-03
	The proposed proprietary name / brand name	Zepatide (Tirzepatide) 7.5 mg per 0.5 ml strength (single dose vial) solution for injection
	Label Claim	Each 0.5ml contains: Tirzepatide 7.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a refrigerator at 2°C to 8°C.
	For generic drugs (me-too Status)	Yurpeak 7.5 mg / 0.5mL by Eli Lilly Pakistan (Private) Limited
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhejiang Peptides Biotech Co., Ltd. Address: No. 8, Hengyizhi Road, Sanjie Town, Shengzhou City, Shaoxing City, Zhejiang Province, China
	Detail of stability batches of drug product	Not performed
	Documents for the procurement of API with approval from DRAP (in case of Import)	Commercial invoice No.ZPCW20241025 dated Nov.18th, 2024 which is not DRAP attested.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	In stability data of drug substance, accelerated and long term stability studies are performed on one lab batch (G271-2403121P4-F-1) and three pilot batches (ZG271240301, ZG271240302, ZG271240701). Accelerated data of lab batch is till 6 months and long term data is till 12 months. Accelerated and long term stability data of pilot batches are till 6 months. Stability data of 3 commercial batches of drug substance is provided till 3 months only.
	The status in reference regulatory authorities	Mounjaro US-FDA approved
	GMP status of the firm	GMP certificate valid till 30th June, 2027.
	Evidence of approval of manufacturing facility	Liquid and Lyophilized recombinant DNA technology products (biological) section granted on 19th July 2012

Evaluation Remarks

The case was evaluated and found deficient for the following; i. Stability data provided for the drug substance covers only up to 3 months. Remaining data is required. ii. Peptide mapping by LC-MS should be a part of finished product specifications. iii. Individual impurities are not performed in comparative testing of applied product with innovator. iv. Firm has not performed stability studies on applied product and submitted justification of following ICH guidelines. However, ICH guidelines on BRACKETING AND MATRIXING DESIGNS FOR STABILITY TESTING OF NEW DRUG SUBSTANCES AND PRODUCTS Q1D states that: With justification, bracketing can be applied to studies with multiple strengths where the relative amounts of drug substance and excipients change in a formulation. Such justification can include a demonstration of comparable stability profiles among the different strengths of clinical or development batches.

Decision**Deferred**

Registration Board deferred the case for submission of following documents/clarifications;

i. Stability data provided for the drug substance covers only up to 3 months. Remaining data is required.

ii. Peptide mapping by LC-MS should be a part of finished product specifications.

iii. Individual impurities are not performed in comparative testing of applied product with innovator.

iv. Submit Justification for not performing stability studies on applied product including a demonstration of comparable stability profiles among the different strengths of clinical or development batches as per ICH Guidelines Q1D on "Bracketing and Matrixing Designs for Stability Testing of Drug Substances and Drug Products".

8	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Macter International Limited F-216,S.I.T.E.,Karachi-Pakistan (000141)
	Application Form Dy. No / Tracking ID & date of submission	(EQA-SAE-2LPS, 2025-09-04)
	Detail of Fee Submitted	37000.0, 1700.0 2025-05-30, 2025-09-03
	The proposed proprietary name / brand name	Zepatide (Tirzepatide) 12.5 mg per 0.5 ml strength (single dose vial) solution for injection
	Label Claim	Each 0.5ml contains: Tirzepatide 12.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a refrigerator at 2°C to 8°C.
	For generic drugs (me-too Status)	Yurpeak 12.5 mg / 0.5 mL by Eli Lilly Pakistan (Private) Limited
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhejiang Peptides Biotech Co., Ltd. Address: No. 8, Hengyizhi Road, Sanjie Town, Shengzhou City, Shaoxing City, Zhejiang Province, China
	Detail of stability batches of drug product	Not performed
	Documents for the procurement of API with approval from DRAP (in case of Import)	Commercial invoice No.ZPCW20241025 dated Nov.18th, 2024 which is not DRAP attested.

Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	In stability data of drug substance, accelerated and long term stability studies are performed on one lab batch (G271-2403121P4-F-1) and three pilot batches (ZG271240301, ZG271240302, ZG271240701). Accelerated data of lab batch is till 6 months and long term data is till 12 months. Accelerated and long term stability data of pilot batches are till 6 months. Stability data of 3 commercial batches of drug substance is provided till 3 months only.
The status in reference regulatory authorities	Mounjaro US-FDA approved
GMP status of the firm	GMP certificate valid till 30th June, 2027.
Evidence of approval of manufacturing facility	Liquid and Lyophilized recombinant DNA technology products (biological) section granted on 19th July 2012
Evaluation Remarks	
The case was evaluated and found deficient for the following; i. Stability data provided for the drug substance covers only up to 3 months. Remaining data is required. ii. Peptide mapping by LC-MS should be a part of finished product specifications. iii. Individual impurities are not performed in comparative testing of applied product with innovator. iv. Firm has not performed stability studies on applied product and submitted justification of following ICH guidelines. However, ICH guidelines on BRACKETING AND MATRIXING DESIGNS FOR STABILITY TESTING OF NEW DRUG SUBSTANCES AND PRODUCTS Q1D states that: With justification, bracketing can be applied to studies with multiple strengths where the relative amounts of drug substance and excipients change in a formulation. Such justification can include a demonstration of comparable stability profiles among the different strengths of clinical or development batches.	
Decision	
Deferred	
Registration Board deferred the case for submission of following documents/clarifications;	
i. Stability data provided for the drug substance covers only up to 3 months. Remaining data is required.	
ii. Peptide mapping by LC-MS should be a part of finished product specifications.	
iii. Individual impurities are not performed in comparative testing of applied product with innovator.	
iv. Submit Justification for not performing stability studies on applied product including a demonstration of comparable stability profiles among the different strengths of clinical or development batches as per ICH Guidelines Q1D on "Bracketing and Matrixing Designs for Stability Testing of Drug Substances and Drug Products".	
9	Case Category
	Routine (Anam Saeed)
	Name, address of Applicant.
	Macter International Limited F-216,S.I.T.E.,Karachi-Pakistan (000141)
	Application Form Dy. No / Tracking ID & date of submission
	(H7Y-NS9-J2Q4, 2025-09-04)
	Detail of Fee Submitted
	37000.0, 1700.0 2025-05-29, 2025-09-03
	The proposed proprietary name / brand name
	Zepatide (Tirzepatide) 10 mg per 0.5 ml strength (single dose vial) solution for injection
	Label Claim
	Each 0.5ml contains: Tirzepatide 10mg
	Reference to Finished product specifications
	As per Innovators Specification

Proposed Pack Size	1-As per SRO
Shelf Life (Unit)	2 Year(s)Store in a refrigerator at 2°C to 8°C.
For generic drugs (me-too Status)	Yurpeak 10 mg / 0.5mL by Eli Lilly Pakistan (Private) Limited
Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Zhejiang Peptides Biotech Co., Ltd. Address: No. 8, Hengyizhi Road, Sanjie Town, Shengzhou City, Shaoxing City, Zhejiang Province, China
Detail of stability batches of drug product	Not performed
Documents for the procurement of API with approval from DRAP (in case of Import)	Commercial invoice No.ZPCW20241025 dated Nov.18th, 2024 which is not DRAP attested.
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	In stability data of drug substance, accelerated and long term stability studies are performed on one lab batch (G271-2403121P4-F-1) and three pilot batches (ZG271240301, ZG271240302, ZG271240701). Accelerated data of lab batch is till 6 months and long term data is till 12 months. Accelerated and long term stability data of pilot batches are till 6 months. Stability data of 3 commercial batches of drug substance is provided till 3 months only.
The status in reference regulatory authorities	Mounjaro US-FDA approved
GMP status of the firm	GMP certificate valid till 30th June, 2027.
Evidence of approval of manufacturing facility	Liquid and Lyophilized recombinant DNA technology products (biological) section granted on 19th July 2012

Evaluation Remarks

The case was evaluated and found deficient for the following;

- Stability data provided for the drug substance covers only up to 3 months.Remaining data is required.
- Peptide mapping by LC-MS should be a part of finished product specifications.
- Individual impurities are not performed in comparative testing of applied product with innovator.
- Firm has not performed stability studies on applied product and submitted justification of following ICH guidelines. However, ICH guidelines on BRACKETING AND MATRIXING DESIGNS FOR STABILITY TESTING OF NEW DRUG SUBSTANCES AND PRODUCTS Q1D states that: With justification, bracketing can be applied to studies with multiple strengths where the relative amounts of drug substance and excipients change in a formulation. Such justification can include a demonstration of comparable stability profiles among the different strengths of clinical or development batches.

Decision

Deferred

Registration Board deferred the case for submission of following documents/clarifications;

- Stability data provided for the drug substance covers only up to 3 months. Remaining data is required.
- Peptide mapping by LC-MS should be a part of finished product specifications.
- Individual impurities are not performed in comparative testing of applied product with innovator.
- Submit Justification for not performing stability studies on applied product including a demonstration of comparable stability profiles among the different strengths of clinical or development batches as per ICH

10	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Macter International Limited F-216,S.I.T.E.,Karachi-Pakistan (000141)
	Application Form Dy. No / Tracking ID & date of submission	(U4E-DX1-GVND, 2025-09-04)
	Detail of Fee Submitted	37000.0, 1700.0 2025-05-30, 2025-09-03
	The proposed proprietary name / brand name	Zepatide (Tirzepatide) 20 mg / 2.4 ml ((8.33 mg/ml) solution for injection, Pre-filled Pen (Multi Dose)
	Label Claim	Each 2.4 ml pre-filled pen (multi dose) contains 20 mg of tirzepatide (8.33 mg/ml) Each pen delivers 4 doses of 5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a refrigerator at 2°C to 8°C.
	For generic drugs (me-too Status)	Yurpeak by Eli Lilly Pakistan (Private) Limited
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhejiang Peptides Biotech Co., Ltd. Address: No. 8, Hengyizhi Road, Sanjie Town, Shengzhou City, Shaoxing City, Zhejiang Province, China
	Detail of stability batches of drug product	Stability study was conducted on the three batches at real time storage condition 5°C ± 3°C and accelerated condition 25°C ± 2°C; 60%RH ± 5%RH Stability data of 2 batches (TZC02A, TZC-03A) of 20mg strength and 2 batches (TZC-01C & TZC-03C) of 60mg strength are submitted till 3 months at real time and accelerated storage conditions. While stability data of 01 batch (TZC-01A) of 20mg strength and 01 batch(TZC-02C) of 60mg strength is submitted till 6 months at real time and accelerated storage conditions.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Commercial invoice No.ZPCW20241025 dated Nov.18th, 2024 which is not DRAP attested.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	In stability data of drug substance, accelerated and long term stability studies are performed on one lab batch (G271-2403121P4-F-1) and three pilot batches (ZG271240301, ZG271240302, ZG271240701). Accelerated data of lab batch is till 6 months and long term data is till 12 months. Accelerated and long term stability data of pilot batches are till 6 months. Stability data of 3 commercial batches of drug substance is provided till 3 months only.
	The status in reference regulatory authorities	Mounjaro 5 mg/dose KwikPen solution for injection in pre-filled pen ☐ Each dose contains 5 mg of tirzepatide in 0.6 ml solution. Each multi-dose pre-filled pen

	contains 20 mg of tirzepatide in 2.4 ml (8.33 mg/ml), registered product of Eli Lilly, The Netherlands. approved by European Medicines Agency (EMA) in 15 September 2022
GMP status of the firm	GMP certificate valid till 30th June, 2027.
Evidence of approval of manufacturing facility	Pre-Filled Syringe (PFS) and Cartridge Pen Filling Area (in already approved licensed Biotech facility) granted on 18th June 2025

Evaluation Remarks

The case was evaluated and found deficient for the following; i. Stability data provided for the drug substance covers only up to 3 months. Remaining data is required. ii. Peptide mapping by LC-MS should be a part of finished product specifications. iii. Individual impurities are not performed in comparative testing of applied product with innovator. iv. Stability data has been provided for only one batch up to 6 months, while the remaining two batches have data up to 3 months. Complete stability data for all three batches is required.

Decision

Deferred

Registration Board deferred the case for submission of following documents/clarifications;

i. Stability data provided for the drug substance covers only up to 3 months.

Remaining data is required.

ii. Peptide mapping by LC-MS should be a part of finished product specifications.

iii. Individual impurities are not performed in comparative testing of applied product with innovator.

iv. Stability data has been provided for only one batch up to 6 months, while the remaining two batches have data up to 3 months. Complete stability data for all three batches is required.

11	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Macter International Limited F-216, S.I.T.E., Karachi-Pakistan (000141)
	Application Form Dy. No / Tracking ID & date of submission	(2RG-A21-LV3R, 2025-08-15)
	Detail of Fee Submitted	37000.0, 1700.0 2025-05-30, 2025-09-03
	The proposed proprietary name / brand name	Zepatide (Tirzepatide) 60 mg / 2.4 ml (25 mg/ml) solution for injection, Pre-filled Pen (Multi Dose)
	Label Claim	Each 2.4 ml pre-filled pen (multi dose) contains 60 mg of tirzepatide (25 mg/ml). Each pen delivers 4 doses of 15mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s) Store in a refrigerator at 2°C to 8°C.
	For generic drugs (me-too Status)	Yurpeak Solution for injection by Eli Lilly Pakistan (Private) Limited
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhejiang Peptides Biotech Co., Ltd. Address: No. 8, Hengyizhi Road, Sanjie Town, Shengzhou City, (23rd – 24th September, 2025)

	Shaoxing City, Zhejiang Province, China
Detail of stability batches of drug product	Stability study was conducted on the three batches at real time storage condition $5^{\circ}\text{C} \pm 3^{\circ}\text{C}$ and accelerated condition $25^{\circ}\text{C} \pm 2^{\circ}\text{C}$; $60\%\text{RH} \pm 5\%\text{RH}$. Stability data of 2 batches (TZC02A, TZC-03A) of 20mg strength and 2 batches (TZC-01C & TZC-03C) of 60mg strength are submitted till 3 months at real time and accelerated storage conditions. While stability data of 01 batch (TZC-01A) of 20mg strength and 01 batch (TZC-02C) of 60mg strength is submitted till 6 months at real time and accelerated storage conditions.
Documents for the procurement of API with approval from DRAP (in case of Import)	Commercial invoice No.ZPCW20241025 dated Nov.18th, 2024 which is not DRAP attested.
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	In stability data of drug substance, accelerated and long term stability studies are performed on one lab batch (G271-2403121P4-F-1) and three pilot batches (ZG271240301, ZG271240302, ZG271240701). Accelerated data of lab batch is till 6 months and long term data is till 12 months. Accelerated and long term stability data of pilot batches are till 6 months. Stability data of 3 commercial batches of drug substance is provided till 3 months only.
The status in reference regulatory authorities	Mounjaro 15 mg/dose KwikPen solution for injection in pre-filled pen □ Each dose contains 15 mg of tirzepatide in 0.6 ml solution. Each multi-dose pre-filled pen contains 60 mg of tirzepatide in 2.4 ml (25 mg/ml), registered product of Eli Lilly, The Netherlands. approved by European Medicines Agency (EMA) in 15 September 2022
GMP status of the firm	GMP certificate valid till 30th June, 2027.
Evidence of approval of manufacturing facility	Pre-Filled Syringe (PFS) and Cartridge Pen Filling Area (in already approved licensed Biotech facility) granted on 18th June 2025

Evaluation Remarks

The case was evaluated and found deficient for the following; i. Stability data provided for the drug substance covers only up to 3 months. Remaining data is required. ii. Peptide mapping by LC-MS should be a part of finished product specifications. iii. Individual impurities are not performed in comparative testing of applied product with innovator. iv. Stability data has been provided for only one batch up to 6 months, while the remaining two batches have data up to 3 months. Complete stability data for all three batches is required.

Decision

Deferred

Registration Board deferred the case for submission of following documents/clarifications;

i. Stability data provided for the drug substance covers only up to 3 months.

Remaining data is required.

ii. Peptide mapping by LC-MS should be a part of finished product specifications.

iii. Individual impurities are not performed in comparative testing of applied product with innovator.

iv. Stability data has been provided for only one batch up to 6 months, while the remaining two batches have data up to 3 months. Complete stability data for all three batches is required.

12	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Macter International Limited F-216,S.I.T.E.,Karachi-Pakistan (000141)
	Application Form Dy. No / Tracking ID & date of submission	(ZE8-ASJ-PPT8, 2025-09-04)
	Detail of Fee Submitted	37000.0, 1700.0 2025-05-30, 2025-09-03
	The proposed proprietary name / brand name	Zepatide (Tirzepatide) 40 mg / 2.4 ml (16.7 mg/ml) solution for injection, Pre-filled Pen (Multi Dose)
	Label Claim	Each 2.4 ml pre-filled pen (multi dose) contains 40 mg of tirzepatide (16.7 mg/ml). Each pen delivers 4 doses of 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a refrigerator at 2°C to 8°C.
	For generic drugs (me-too Status)	Yurpeak Solution for injection by Eli Lilly Pakistan (Private) Limited
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhejiang Peptides Biotech Co., Ltd. Address: No. 8, Hengyizhi Road, Sanjie Town, Shengzhou City, Shaoxing City, Zhejiang Province, China
	Detail of stability batches of drug product	Not performed
	Documents for the procurement of API with approval from DRAP (in case of Import)	Commercial invoice No.ZPCW20241025 dated Nov.18th, 2024 which is not DRAP attested.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	In stability data of drug substance, accelerated and long term stability studies are performed on one lab batch (G271-2403121P4-F-1) and three pilot batches (ZG271240301, ZG271240302, ZG271240701). Accelerated data of lab batch is till 6 months and long term data is till 12 months. Accelerated and long term stability data of pilot batches are till 6 months. Stability data of 3 commercial batches of drug substance is provided till 3 months only.
	The status in reference regulatory authorities	Mounjaro 10 mg/dose KwikPen solution for injection in pre-filled pen □ Each dose contains 10 mg of tirzepatide in 0.6 ml solution. Each multi-dose pre-filled pen contains 40 mg of tirzepatide in 2.4 ml (16.7 mg/ml), registered product of Eli Lilly, The Netherlands. approved by European Medicines Agency (EMA) in 15 September 2022
	GMP status of the firm	GMP certificate valid till 30th June, 2027.
	Evidence of approval of manufacturing facility	Pre-Filled Syringe (PFS) and Cartridge Pen Filling Area (in already approved licensed Biotech facility) granted on

Evaluation Remarks

The case was evaluated and found deficient for the following; i. Stability data provided for the drug substance covers only up to 3 months. Remaining data is required. ii. Peptide mapping by LC-MS should be a part of finished product specifications. iii. Individual impurities are not performed in comparative testing of applied product with innovator. iv. Firm has not performed stability studies on applied product and submitted justification of following ICH guidelines. However, ICH guidelines on BRACKETING AND MATRIXING DESIGNS FOR STABILITY TESTING OF NEW DRUG SUBSTANCES AND PRODUCTS Q1D states that: With justification, bracketing can be applied to studies with multiple strengths where the relative amounts of drug substance and excipients change in a formulation. Such justification can include a demonstration of comparable stability profiles among the different strengths of clinical or development batches.

Decision**Deferred**

Registration Board deferred the case for submission of following documents/clarifications;

i. Stability data provided for the drug substance covers only up to 3 months. Remaining data is required.

ii. Peptide mapping by LC-MS should be a part of finished product specifications.

iii. Individual impurities are not performed in comparative testing of applied product with innovator.

iv. Submit Justification for not performing stability studies on applied product including a demonstration of comparable stability profiles among the different strengths of clinical or development batches as per ICH Guidelines Q1D on "Bracketing and Matrixing Designs for Stability Testing of Drug Substances and Drug Products".

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Case Category	Routine (Anam Saeed)
Name, address of Applicant.	HIGHNOON LABORATORIES LIMITED 17.5 KM, MULTAN ROAD, LAHORE (05-352-0066)
Application Form Dy. No / Tracking ID & date of submission	(QAG-U7X-NGD9, 2025-01-30)
Detail of Fee Submitted	300000.0, 2024-10-09,
The proposed proprietary name / brand name	Reglutide
Label Claim	Each ml of solution contains: Semaglutide 1.34mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	3mL Cartridge-As per SRO
Shelf Life (Unit)	2 Year(s)2-8°C
For generic drugs (me-too Status)	Ozempic 1mg Reg. No.: 107914 Novo Nordisk Pharma (Pvt.) Ltd.
Pharmacotherapeutic Group of (API)	Pharmacotherapeutic group: Drugs used in diabetes, glucagon-like peptide- 1 (GLP-1) analogues, ATC code: A10BJ06
Name, address of Manufacturing site:	Beximco Pharmaceuticals Ltd.-126 Kathaldia, Auchpara, Tongi, Gazipur, Bangladesh.-Bangladesh
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
Name, address of Marketing Authorization Holder:	Beximco Pharmaceuticals Ltd., 19 Dhanmondi R/A, Road No. 7, Dhaka 1205, Bangladesh., Bangladesh
Details of Certificates (CoPP/FSC/cGMP):	Scanned Copy of Legalized COPP Certificate No: DA/6-3/96/16986 Certifying Authority: Directorate General of Drug Administration, Mohakhali, Dhaka'-1212.

	Bangladesh Is this product licensed to be placed on the, market for use in the exporting country? YES
Details of Authorization Letter :	Scanned copy of Letter of Authorization M/s Beximco Pharmaceuticals Ltd. 19 Dhanmondi R/A, Road No. 7, Dhaka 1205, Bangladesh. Dated: 26-09-2024.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability testing has been performed on accelerated -20°C ± 5°C and long-term 5°C ± 3° condition
The status in reference regulatory authorities	Ozempic 1 mg solution for injection in pre-filled pen MHRA

Evaluation Remarks

The case was deferred in 345th meeting. Decision of 345th Meeting: The Registration Board deferred the case for the submission of the following documents: i. Hard copy of original, legalized and valid COPP. ii. Hard copy of original or notarized sole agency agreement is required. iii. Certificate of renewal of DML of manufacturer mentions semaglutide will be manufactured in non-biological facility. Clarification is required. iv. Documents/evidence for acceptable shipping conditions for finished product and & proof of shipping validation. v. Prescribing Information (PI) along with patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP) including instructions on how to use. vi. The data should be submitted in relevant sections instead of referring to DMF. vii. Clarification is required whether it is a synthetic peptide or manufactured by rDNA technology along with biological origin. viii. Specify the hydrophobic and hydrophilic impurities. ix. Justification of specification is required. x. Justification for overage is required on scientific basis, as content of semaglutide is within specification without overage. xi. The stability data also represents due to addition of overage trend of assay content towards higher limit 105% to 110%. xii. 3.2. S.4.5: Justification of Specification is not provided. xiii. Test of protein content, specific activity (by invitro bioassay), HMWP and related substances not performed. xiv. The copies of complete analysis of at least two batches shall be provided. xv. The justification of specification(s) for non-pharmacopeia products must be provided. Justification of specification of non-pharmacopeia product shall be based on batch analysis results. xvi. Stability data of drug product of at least three batches till claimed shelf life is required. xvii. Clarification for non-performance of test of protein content, specific activity (by invitro bioassay, HMWP and related substances. xviii. Data of stability batches to be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. xix. Compliance Record of HPLC software 21CFR & audit trail reports on product testing. xx. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated). xxi. A list of manufacturing and testing facilities / equipment available with reference to the applied drug product shall be provided along with evidence of RP-UHPLC, SEC-UHPL, LCMS. xxii. Justification is required as comparability protocol doesn't provide information of the following: Test of protein content, specific activity (by invitro bioassay, HMWP and related substances. xxiii. Bio similarity studies or evidence of reference guidelines for following justification for not performing bio similarity studies that states: "Bio-similarity applies to large complex biomolecules owing to the size and complexity of molecules which has primary, secondary/ tertiary and quaternary structures which cannot be fully elucidated by analytical means that's why clinical evidence are required to prove the efficacy and safety." xxiv. Complete clinical or non-clinical studies for rDNA origin or justification in case of "Not applicable" in the light of reference guidelines. xxv. For synthetic peptides data in the light of guidelines for "Synthetic Peptide That Refer to Drugs of rDNA Origin". xxvi. Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3. Evaluation by BE&R: The firm has submitted a reply as under:

Sr.No.	Observations	Query Response	Remarks
1	Hard copy of original, legalized and valid COPP.	Hard copy submitted. Acknowledgement attached.	-
2	Hard copy of original or notarized sole agency agreement is required.	Hard copy submitted. Acknowledgement attached.	-
3	Certificate of renewal of DML of manufacturer mentions semaglutide will be manufactured in non-	Semaglutide is not considered a biological. It is categorized as a synthetic peptide because it has a chain of 40 or fewer amino acids (protein building blocks). It is approved and regulated through the same pathway as other medications.	Semaglutide will be manufactured in a non-biological facility.

	biological facility. Clarification is required.	That's why it is mentioned in renewal DML that Semaglutide will be manufactured in a non-biological facility.	
4	Documents/evidence for acceptable shipping conditions for finished product and & proof of shipping validation.	Transport validation is a country-specific requirement. We will conduct transport validation of Reglutide Injection during commercial shipment. Commitment letter has been shared in Annex 1. As this is a cool chain product, transport validation of similar cold chain shipment (Annex 2) for South Africa has been shared.	
5	Prescribing Information (PI) along with patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP) including instructions on how to use.	The revised PIL is included in Annex 3.	Attached
6	The data should be submitted in relevant sections instead of referring to DMF.	The restricted part of the DMF will be shared directly to DRAP by API Manufacturer on these emails: nafees.rehman@dra.gov.pk	Not shared yet
8	Clarification is required whether it is a synthetic peptide or manufactured by rDNA technology.	It is categorized as a synthetic peptide because it has a chain of 40 or fewer amino acids (protein building blocks). It is approved and regulated through the same pathway as other medications. The restricted part of the DMF will be shared directly to DRAP by API Manufacturer on these emails: nafees.rehman@dra.gov.pk	Not shared yet
9	Specify the hydrophobic and hydrophilic impurities.	The restricted part of the DMF will be shared directly to DRAP by API Manufacturer on these emails: nafees.rehman@dra.gov.pk	Not shared yet
10	Justification of specification is required.	The restricted part of the DMF will be shared directly to DRAP by API Manufacturer on these emails: nafees.rehman@dra.gov.pk	Not shared yet
11	Justification for overage is required on scientific basis, as content of semaglutide is within specification without overage.	Formulation and process development data at lab scale supports 5% active overage due to filter adsorption. Considering small batch size (2 L) at commercial scale & process loss due to filter adsorption during aseptic processing 5% overage is considered for process optimization and validation.	The overage is to be optimized based on results of long term stability data of process validation batches.
12	The stability data also represents due to addition of overage trend of assay content towards higher limit 105% to 110%.	This product is under process validation. Based on the long-term stability data of process validation batches, this active overage to be optimized if required.	
13	3.2. S.4.5: Justification of Specification is not Minutes of 351st Meeting	The restricted part of the DMF will be shared directly to DRAP by API Manufacturer on these of Registration Board (23rd – 24th September, 2025)	Not shared yet

	provided.	emails: nafees.rehman@dra.gov.pk	
14	Test of protein content, specific activity (by invitro bioassay), HMWP and related substances not performed.	Semaglutide is a polypeptide that contains a linear sequence of 31 amino acids joined together by peptide linkages. It is an analog of human glucagon like peptide-1 (GLP-1) (residues 7-37) and act as a long acting GLP-1 receptor agonist. Molecular Formula is C187H291N45O59 and Molecular Weight is 4113.6 Da. Semaglutide is as classified as Highly Purified Synthetic Peptide. Synthetic peptides considered to differ from products of recombinant DNA technology in two structural aspects: 1. They are usually small, typically below 5000 Da; 2. They may have chemical structures that do not occur naturally in proteins or peptides. Protein content refers to the total amount of protein present in a large, complex molecules made up of long chains of amino acids (typically 50 or more) where peptide content is specifically to smaller chains of amino acids, usually consisting of 2 to about 50 amino acids. As Semaglutide consists of 31 amino acids together by peptide linkages, peptide content is determined by the Kjeldahl method by measuring its total nitrogen content in drug substances. Assays for synthetic peptides are generally comparative chromatographic procedures, performed using a defined chemical reference substance as the standard. As the structural identification confirmed by the mass spectroscopy, amino acid ratio and reversed-phase LC method, chromatographic procedures for assay are justified than functional assays (e.g. bio-assay). High molecular weight peptide/protein impurities encountered in peptide drug substances of rDNA source may arise from several aggregation or self-association mechanisms. For synthetic peptide, oligomer is determined and controlled by reversed-phase LC	Peptide mapping and cell based bio-assay are not a part of drug substance specifications.

		method as related substances in drug substances not necessarily in drug product.	
15	The copies of complete analysis of at least two batches shall be provided.	As there is no change in specifications, please consider submitting COA for submission. Complete analysis was done for all the shared three-batch COA. Attached again. Please see Annex 4	Peptide content, tests for impurities/related substances, dose accuracy, phenol content is not performed.
16	The justification of specification(s) for non-pharmacoepial products must be provided. Justification of specification of non-pharmacoepial product shall be based on batch analysis results.	Justification of specification has been shared in Annex 5	
17	a) Stability data of drug product of at least three batches till claimed shelf life is required.	Stability Protocol & full shelf-life data i.e. 24 months long-term stability data of 02 batches has been shared in Annex 6 & Annex 7.	Data in tabular form of 2 batches till 24 months while one batch till 12 months is provided.
		12 months data of 3rd batch along with commitment letter has been shared in Annex 8 & Annex 9. Accelerated stability has been shared in Annex 10.	Raw data and chromatograms not provided.
18	b) Test of protein content, specific activity (by invitro bioassay, HMWP and related substances not performed.	Semaglutide is a polypeptide that contains a linear sequence of 31 amino acids joined together by peptide linkages. It is an analog of human glucagon like peptide-1 (GLP-1) (residues 7-37) and act as a long acting GLP-1 receptor agonist. Molecular Formula is C187H291N45O59 and Molecular Weight is 4113.6 Da. Semaglutide is as classified as Highly Purified Synthetic Peptide. Synthetic peptides considered to differ from products of recombinant DNA technology in two structural aspects:	Peptide content, tests for impurities/related substances, dose accuracy, phenol content is not performed in finished product.
		1. They are usually small, typically below 5000 Da;	
		2. They may have chemical structures that do not occur naturally in proteins or peptides.	
		Protein content refers to the total amount of protein present in a large, complex molecules made up of long chains of amino acids (typically 50 or more) where peptide content is specifically to smaller chains of amino acids, usually consisting of 2 to about 50 amino acids. As	

		Semaglutide consists of 31 amino acids together by peptide linkages, peptide content is determined by the Kjeldahl method by measuring its total nitrogen content in drug substances.	
		Assays for synthetic peptides are generally comparative chromatographic procedures, performed using a defined chemical reference substance as the standard. As the structural identification confirmed by the mass spectroscopy, amino acid ratio and reversed-phase LC method, chromatographic procedures for assay is justified than functional assays (e.g. bio-assay).	
		High molecular weight peptide/protein impurities encountered in peptide drug substances of rDNA source may arise from several aggregation or self-association mechanisms. For synthetic peptide, oligomer is determined and controlled by reversed-phase LC method as related substances in drug substances not necessarily in drug product.	
19	c) Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Annex 11: COA, Raw data, Chromatograms of BN-12100231 (Accelerated condition)	
		Annex 12: COA, Raw data, Chromatograms of BN-12100231 (Long term condition)	
		Annex 13: COA, Raw data, Chromatograms of BN-12200221 (Accelerated condition)	
		Annex 14: COA, Raw data, Chromatograms of BN-12200221 (Long term condition)	
		Annex 15: COA, Raw data, Chromatograms of BN-12300011 (Accelerated condition)	
		Annex 16: COA, Raw data, Chromatograms of BN-12300011 (Long term condition)	
20	d) Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Compliance Record of HPLC software 21CFR has been shared in Annex 17. Audit trail reports on product testing: response for 3.2.P.8.3 (c) is also applicable here.	Empower 3.6.1 software was installed.
21	e) Record of Digital data logger for temperature and humidity monitoring Minutes of 351st Meeting	Records of Digital data logger for temperature and humidity monitoring of stability chambers has been shared in Annex 18 & Annex 19.	

	of stability chambers (real time and accelerated).		
22	A list of manufacturing and testing facilities / equipment available with reference to the applied drug product shall be provided along with evidence of RP-UHPLC, SEC-UHPL, LCMS.	Attached Please see Annex 20.	Manufacturer does not have LC-MS as per attached list of equipment.
23	Comparability protocol doesn't provide information of the following:	Semaglutide is a polypeptide that contains a linear sequence of 31 amino acids joined together by peptide linkages. It is an analog of human glucagon like peptide-1 (GLP-1) (residues 7-37) and act as a long acting GLP-1 receptor agonist. Molecular Formula is C187H291N45O59 and Molecular Weight is 4113.6 Da. Semaglutide is as classified as Highly Purified Synthetic Peptide. Synthetic peptides considered to differ from products of recombinant DNA technology in two structural aspects:	
		1. They are usually small, typically below 5000 Da;	
	a) Test of protein content, specific activity (by in-vitro bioassay, HMWP and related substances.	2. They may have chemical structures that do not occur naturally in proteins or peptides.	
		Protein content refers to the total amount of protein present in a large, complex molecules made up of long chains of amino acids (typically 50 or more) where peptide content is specifically to smaller chains of amino acids, usually consisting of 2 to about 50 amino acids. As Semaglutide consists of 31 amino acids together by peptide linkages, peptide content is determined by the Kjeldahl method by measuring its total nitrogen content in drug substances.	
		Assays for synthetic peptides are generally comparative chromatographic procedures, performed using a defined chemical reference substance as the standard. As the structural identification confirmed by the mass spectroscopy, amino acid ratio and reversed-phase LC method, chromatographic procedures for assay is justified than functional assays (e.g. bio-assay).	
		High molecular weight peptide/protein impurities encountered in peptide drug substances of rDNA source may arise from several aggregation or self-association mechanisms. For synthetic peptide, oligomer is determined and controlled by reversed-phase LC	

		method as related substances in drug substances not necessarily in drug product.	
	b) Bio similarity studies or evidence of reference guidelines for following justification for not performing bio similarity studies that states:		Only appearance, pH, density and assay is performed in comparative testing with innovator product.
24	“Bio-similarity applies to large complex biomolecules owing to the size and complexity of molecules which has primary, secondary/tertiary and quaternary structures which cannot be fully elucidated by analytical means that’s why clinical evidence are required to prove the efficacy and safety.”	The in vitro comparative study is shared in Annex 21 Along with the in vitro comparative study, literature reference-based safety and efficacy data are shared in Annex 22, Annex 23, Annex 24 & Annex 25.	Complete comparative testing is required on all parameters including impurities/related substances as well.
25	Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3.	Executed BMR BPR of stability batches has been shared in Annex 26, Annex 27 & Annex 28.	Submitted

Concluding remarks:· The manufacturer informed that semaglutide will be manufactured in non-biological facility.· The firm informed that overage in drug product will be optimized based on results of long term stability data of process validation batches.· The firm informed that drug substance part will be shared directly to the official email but data is not shared yet.· Peptide mapping and cell based bio-assay are not a part of drug substance specifications.· Peptide content, tests for impurities/related substances, dose accuracy, phenol content is not performed in drug product.· Manufacturer does not have LC-MS as per attached list of equipment.· Only appearance, pH, density and assay is performed in comparative testing with innovator product.· Complete comparative testing is required on all parameters including impurities/related substances as well.· Stability data in tabular form of 2 batches till 24 months while one batch till 12 months is provided. Raw data and chromatograms not provided.

Decision

Rejected

Proceedings:

The Registration Board reviewed the manufacturer’s statement, wherein it was conveyed that Semaglutide is not considered a biological product but rather categorized as a synthetic peptide, as it comprises a chain of 40 or fewer amino acids (protein building blocks) and is produced in a non-biological facility. However, the Board noted that peptides are highly sensitive biopharmaceutical products, and therefore, their manufacturing must be carried out in dedicated and segregated facilities to ensure product integrity and prevent cross-contamination. Accordingly, it was decided that local manufacturing of peptides shall be undertaken only in biological/biotechnological sections duly approved and licensed by the Central Licensing Board (CLB) and same policy shall be applicable to imported applications as well

Decision:

The Registration Board rejected the application as applied product is being manufactured in non-biological facility.

14	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Getz Pharma (Pvt) Limited 29-30/27,Korangi Industrial Area karachi (000284)
	Application Form Dy. No / Tracking ID & date of submission	(648-JNQ-ZBEQ, 2025-04-29)
	Detail of Fee Submitted	300000.0, 2024-11-18,
	The proposed proprietary name / brand name	ENERCEPT Solution for Injection in Pre-filled Syringe 25mg
	Label Claim	Each pre-filled syringe contains: Etanercept.....25mg/0.5mL
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	36 Month(s)Store in a refrigerator (2°C - 8°C).
	For generic drugs (me-too Status)	ENBREL Pre-Filled Syringe 50mg/PFS (1ml) (Reg. No. 062228) by M/s Wyeth (Pakistan) Ltd., Pakistan.
	Pharmacotherapeutic Group of (API)	Tumor necrosis factor alpha (TNF- α) inhibitors ATC Code: L04AB01
	Name, address of Manufacturing site:	Self Manufacturing
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Name, address of Marketing Authorization Holder:	, ,
	Details of Certificates (CoPP/FSC/cGMP):	Firm has submitted Apostile COPP Certificate No.Shanghai 20230264 issued by Shanghai Municipal Medical Product Administration China on 02-11-2023. Validity: 01-11-2025 The CoPP specifies that the product is licensed to be placed for use in the exporting
	Details of Authorization Letter :	Firm has attached Letter of Authorization with the application on e-app. The letter was issued on 17-10-2023 and valid for two years from the date of signature.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	6 months Accelerated and 36 months long term stability data of 3 batches of drug substance is submitted.
	The status in reference regulatory authorities	Enbrel 25mg Solution for Injection in pre-filled syringe by M/s Pfizer Limited, UK.
	Evaluation Remarks	
	The case was deferred in 347th meeting of Registration Board.Decision of 347th meeting: Registration Board deferred for submission of the following documents/clarifications; i. Letter of Authorization does not show that the product will be imported in primary packaging and secondary packaging will performed by the importer i.e. M/s Getz Pharma. Submit revised LOA. ii. Legalized COPP is required in hard copy also. iii. Details of Secondary packaging material and the procedure to be followed by M/s Getz Pharma is required. iv. The commitment by M/s Getz Pharma is also required that they will perform stability after secondary packaging. v. Stability data of Drug Substance is required mentioning batch size, batch number and stability conditions. vi. Stability data of applied product i.e. Pre-filled syringe by the manufacturer is required at long term and accelerated stability conditions mentioning batch size also and all parameters should be tested as mentioned in Certificate of Analysis of Drug product. vii. Bio similarity data of applied product in pre-filled syringe, as per WHO Bio similarity guidelines in tabular form is required including; Comparative structural and functional characterization with the Reference product. Comparative in vitro bioassays for receptor affinity and activation. Comparative in-vivo potency. Impurity testing (product related and process related). Comparative Pharmacokinetic studies. Comparative Toxicology studies (single dose and repeat dose). Comparative Clinical trial data	
	Evaluation by BE&R: Minutes of 351st Meeting of Registration Board (23rd – 24th September, 2025)	

S. No.	Shortcomings	Getz Pharma Response	Remarks
1	Letter of Authorization does not show that the product will be imported in primary packaging and secondary packaging will performed by the importer i.e. M/s Getz Pharma. Submit revised LOA.	Please refer to Annexure 1 for updated Letter of Authorization / Statement Letter wherein it is mentioned that the secondary packaging will be done by M/s Getz Pharma (Pvt.) Ltd.	Brand name is not mentioned in LOA.
2	Legalized COPP is required in hard copy also.	Please refer to Annexure 2 for updated scan copy of Legalized COPP of ENERCEPT Solution for Injection in Pre-filled Syringe 25mg. Hard copy will be submitted to your good office via cover letter.	-
3	Details of Secondary packaging material and the procedure to be followed by M/s Getz Pharma is required.	This is to inform you that the secondary packaging material is unit carton in which labelled pre-filled syringe will be packed along with leaflet & for packaging operation of sterile products in production packaging area, please refer to Annexure 3 for detailed SOP.	SOP is required for secondary packaging of labelled PFS. Detail about QC release of finished product is required that who will be responsible for QC release.
4	The commitment by M/s Getz Pharma is also required that they will perform stability after secondary packaging.	Please refer to Annexure 4 for commitment letter that we will perform stability studies of ENERCEPT Solution for Injection in Pre-filled Syringe 25mg till the assigned shelf life of product after secondary packaging.	-
5	Stability data of Drug Substance is required mentioning batch size, batch number and stability conditions.	Please refer to Annexure 5 for Summary of Stability Study Information for Drug Substance mentioning batch size, batch number and stability conditions.	Submitted
6	Stability data of applied product i.e. Pre-filled syringe by the manufacturer is required at long term and accelerated stability conditions mentioning batch size also and all parameters should be tested as mentioned in Certificate of Analysis of Drug product.	Please refer to Annexure 6 for Summary of Stability Study Information for Drug Product of ENERCEPT Solution for Injection in Pre-Filled Syringe 25mg mentioning batch size, batch number and stability conditions. Further, please note that all parameters tested in Stability Studies are as per Certificate of Analysis (COA) of Drug Product.	Stability data does not indicate container closure system of the batches kept at stability whether in secondary packaging or otherwise.
7	Bio similarity data of applied product in pre-filled syringe, as per WHO Bio similarity guidelines in tabular form is required including; · Comparative structural and functional characterization with the Reference product. · Comparative in vitro bioassays for receptor affinity and activation. · Comparative in-vivo potency. · Impurity testing (product related and process related).	Please refer to Annexure 7 for Biosimilarity data of product as per WHO Bio similarity guidelines including; · Comparative structural and functional characterization with the Reference product. · Comparative in vitro bioassays for receptor affinity and activation. · Comparative in-vivo potency. · Impurity testing (product related and process related). · Comparative Pharmacokinetic studies · Comparative Toxicology studies (single dose and repeat dose). · Comparative Clinical trial data. Please	Firm has performed following comparative studies with Innovator product Enbrel; · Physicochemical properties · Analysis of primary structure · N-glycan analysis · Analysis of High order structure · Analysis of affinity and activity Firm has performed comparative impurity testing with its lyophilized product. Regarding

· Comparative Pharmacokinetic studies · Comparative Toxicology studies (single dose and repeat dose). · Comparative Clinical trial data

note that in clinical trials, manufacturer has performed comparison studies of Etanercept Lyophilized Powder with Innovator product ‘Enbrel’ and then manufacturer has performed comparison studies of Etanercept Lyophilized Powder with ENERCEPT Solution for Injection in Pre-filled Syringe since the only difference in the manufacturer formulation is the change in dosage form / dispensing mode of products.

toxicology studies, the firm has submitted reference of studies performed on Etanercept lyophilized product. In clinical data, the firm has submitted following comparative study with lyophilized product; Bioequivalence study between the Recombinant Human Tumour Necrosis Factor- α Receptor II:IgG Fc Fusion Protein Injection (Prefilled Syringe) (test product, T) and the Recombinant Human Tumour Necrosis Factor- α Receptor II:IgG Fc Fusion Protein Powder for Injection (reference product, R) in healthy volunteers, which were developed by Sunshine Guojian Pharmaceutical (Shanghai) Co., Ltd. “A randomized, double-blind, multi-centred phase III clinical study to evaluate the efficacy and safety of Recombinant Human Tumour Necrosis Factor- α Receptor II:IgG Fc Fusion Protein Injection (Prefilled Syringe) in the treatment of ankylosing spondylitis (AS) with nonsteroidal anti-inflammatory drugs (NSAIDs) as basic treatment and marketed powder for injection as control”.

Concluding remarks:Ø Brand name is not mentioned in LOA.Ø SOP is required for secondary packaging of labelled PFS.Ø Detail about QC release of finished product is required that who will be responsible for QC release. Ø Stability data does not indicate container closure system of the batches kept at stability whether in secondary packaging or otherwise.

Decision

Approved

Registration Board decided to approve the product subject to submission of following;

i. SOP for secondary packaging of labelled PFS.

ii. Letter of Authorization (LOA)

iii. QC release of finished product.

15	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Leven Medical Care 8-C STREET 3 (05-352-0063)
	Application Form Dy. No / Tracking ID & date of submission	(XZX-DEQ-BJN1, 2025-03-27)
	Detail of Fee Submitted	300000.0, 2025-03-13,
	The proposed proprietary name / brand name	CINNAL-F
	Label Claim	Each Prefilled Pen contains; Recombinant Human Follicle stimulating Hormone (Follitropin Alfa)..... 300IU in 0.5ml
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	1-As per SRO
	Shelf Life (Unit)	2 Year(s)2C to 8C
	For generic drugs (me-too Status)	Gonal-F Pen 3000 IU /0.5ml Solution for Injection in a pre-filled pen Imported by Martin Dow Specialities Pvt.Limited, Karachi.
	Pharmacotherapeutic Group of (API)	Gonadotropins Code ATC: G03GA05
	Name, address of Manufacturing site:	CinnaGen Co.-Plot 72,74,87,88, 3rd Sq, Simin Dasht Non-Governmental Industrial Area, Fardis County, Alborz Province Iran-Iran
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Name, address of Marketing Authorization Holder:	CinnaGen Co., Plot 72,74,87,88, 3rd Sq, Simin Dasht Non-Governmental Industrial Area, Fardis County, Alborz Province Iran, Iran
	Details of Certificates (CoPP/FSC/cGMP):	CoPP: Firm has attached CoPP (665/89275) issued by Iran Food & Drug Administration on 09-12-2024. The CoPP specifies that the product is licensed to be placed for use in the exporting country as well as the product is actually in the market in exporting
	Details of Authorization Letter :	Firm has attached Letter of Authorization No.1403-007526 with the application on e-app. The letter was issued on 06-11-2024 and valid for one year from the date of signature.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted Stability data of Follitropin Alfa drug substance of 6 pilot scale batches and 3 commercial scale batches at real time (below -20 °C) storage condition for 24 months and accelerated (5 ± 3 °C) storage condition for 6 months.
	The status in reference regulatory authorities	Gonal-F Pen 300 IU /0.5ml Solution for Injection in a pre-filled pen M/s. Merck Serono S.P.A. VIA Delle Magnolie (LOC. FrazioneZona Industriale), Italy.

Evaluation Remarks

The case was deferred in 347th meeting. Decision of 347th meeting: Registration Board deferred the case for submission of the following documents/clarifications: i. Valid Legalized COPP is required in hard copy also. ii. Manufacturing details of drug substance is required. iii. In 3.2.P.6 Reference standard or material, Certificate of analysis of Reference standard is required. iv. Adventitious agent safety evaluation is required in section 3.2.A.2. v. Analytical method verification reports of drug product is required in Section 3.2.P.5.3. vi. Compatibility studies is required under Module 3.2.P.2.6. vii. Bio similarity data as per WHO Bio similarity guidelines in tabular form is required including; Ø Comparative structural and functional characterization with the Reference product. Ø Comparative in vitro bioassays for receptor affinity and activation. Ø Comparative in-vivo potency. Ø Impurity testing (product related and process related). Ø Comparative Pharmacokinetic studies Ø Comparative Toxicology studies (single dose and repeat dose). Ø Clinical trial data. Evaluation by BE&R:

Sr.No.	Observations	Response of the firm	Remarks
1	Valid Legalized COPP is required in hard copy also.	Submitted	Submitted
2	Manufacturing details of drug substance is required.	Quality overall summary attached	Submitted
3	In 3.2.P.6 Reference standard or material, Certificate of analysis of Reference standard is required.	As mentioned in section 3.2.P.6 of the dossier, the reference standards utilized, including those obtained from CRS and NIBSC, are handled in accordance with the information provided in section 3.2.S.5. With respect to the CoAs for Metacresol and L-methionine, which are used as working standards in the manufacturing process, the relevant documentation has been provided. You may refer to the folder titled "Annex 1", which includes: · Certificate of Analysis for L-methionine Working Standard · Certificate of Analysis for Metacresol Working Standard	-
4	Adventitious agent safety evaluation is required in section 3.2.A.2.	TSE/ BSE certificates of raw materials and excipients of non-biological origins are presented in figure 3.2.A.2 1 to 3.2.A.2 4. Viral Clearance Study for the Manufacturing Process of CHO cell derived recombinant Cinnal-f (FSH) is attached.	Submitted
5	Analytical method verification reports of drug product is required in Section 3.2.P.5.3.	Attached as Annexure 5	Submitted
6	Compatibility studies is required under Module 3.2.P.2.6.	It is important to highlight that the formulation of Cinnal-f is identical to that of the reference medicinal product (RMP), GONAL-f. As such, CinnaGen Co. has not conducted any comprehensive formulation development for this product, given that the biosimilar was developed to match the RMP in both qualitative and quantitative composition, as well as in dosage form and route of administration. Considering that comprehensive compatibility studies have already been conducted on the RMP during its development, it is not scientifically necessary to replicate all of those studies for the biosimilar. Furthermore, as part of our studies, long-term (24 months) and accelerated (6 months) stability studies were performed on the Cinnal-f drug product. The results	-

		of these studies showed no formation of degradation products or impurities related to excipient interactions. Additionally, there were no significant changes observed in the quality, safety, or efficacy attributes of the drug product throughout the study periods. Based on the alignment with the RMP formulation and the robust data from the stability studies of Cinnal-f, we consider that additional compatibility studies are not required.	
7	Bio similarity data as per WHO Bio similarity guidelines in tabular form is required including; Ø Comparative structural and functional characterization with the Reference product. Ø Comparative in vitro bioassays for receptor affinity and activation. Ø Comparative in-vivo potency. Ø Impurity testing (product related and process related). Ø Comparative Pharmacokinetic studies Ø Comparative Toxicology studies (single dose and repeat dose). Ø Clinical trial data	Attached as Annex 7	Firm has submitted following comparative studies; Protein content, primary structure analysis, higher order structure, product related variants and impurities, particulate matter, functional activity (Cell-based assay for the determination of FSH activity, Biological Activity by Rat ovary weight gain assay). Firm has also submitted following non-clinical and clinical (PK and efficacy) study; “Comparative analysis of Biological Activity of FSH in Cinnal f® and GONAL-f®.” “A randomized, double-blind, cross over clinical trial which was conducted on 30 healthy female and compared the pharmacokinetics of a single dose administration of Cinnal-f® to Gonol-f®.” “A prospective, non-inferiority, randomized, triple-blind, and phase 3 clinical trial comparing efficacy and safety of Cinnal-f® versus Gonol-f® in 200 women undergoing ovarian stimulation for Intracytoplasmic sperm injection”.

Decision

Approved

Registration Board approved the product subject to compliance of current Import Policy for Finished Drugs.

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Case Category	Routine (Anam Saeed)		
Name, address of Applicant.	Leven Medical Care 8-C STREET 3 (05-352-0063)		
Application Form Dy. No / Tracking ID & date of submission	(5B9-4LX-7YQH, 2025-03-27)		
Detail of Fee Submitted	300000.0, 2025-03-13,		
The proposed proprietary name / brand name	CINNAL-F		
Label Claim	Each Prefilled Pen contains; Recombinant Human Follicle stimulating Hormone (Follitropin Alfa)..... 450IU (equivalent to 33 micrograms) in 0.75ml		
Reference to Finished product specifications	European Pharmacopeia		
Proposed Pack Size	1-As per SRO		
Shelf Life (Unit)	2 Year(s)2C to 8C		
For generic drugs (me-too Status)	Gonal-F Pen 450 IU (33 ug)/0.75ml Solution for Injection in a pre-filled pen Imported by Martin Dow Specialities Pvt.Limited, Karachi.		
Pharmacotherapeutic Group of (API)	Gonadotropins Code ATC: G03GA05		
Name, address of Manufacturing site:	CinnaGen Co.-Plot 72,74,87,88, 3rd Sq, Simin Dasht Non-Governmental Industrial Area, Fardis County, Alborz Province Iran-Iran		
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A		
Name, address of Marketing Authorization Holder:	CinnaGen Co., Plot 72,74,87,88, 3rd Sq, Simin Dasht Non-Governmental Industrial Area, Fardis County, Alborz Province Iran, Pakistan		
Details of Certificates (CoPP/FSC/cGMP):	CoPP: Firm has attached CoPP (665/70260) issued by Iran Food & Drug Administration on 13-10-2024. The CoPP specifies that the product is licensed to be placed for use in the exporting country as well as the product is actually in the market in exporting		
Details of Authorization Letter :	Firm has attached Letter of Authorization No.1403-007526 with the application on e-app. The letter was issued on 06-11-2024 and valid for one year from the date of signature.		
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted Stability data of Follitropin Alfa drug substance of 6 pilot scale batches and 3 commercial scale batches at real time (below -20 °C) storage condition for 24 months and accelerated (5 ± 3 °C) storage condition for 6 months.		
The status in reference regulatory authorities	Gonal-F Pen 450 IU (33 ug)/0.75ml Solution for Injection in a pre-filled pen M/s. Merck Serono S.P.A. VIA Delle Magnolie (LOC. FrazioneZona Industriale), Italy.		
Evaluation Remarks			
Evaluation by BE&R:			
Sr.No.	Observations in 347th meeting	Response of the firm	Remarks
1	Valid Legalized COPP is required in hard copy also.	Submitted	Submitted
2	Manufacturing details of drug substance is required.	Quality overall summary attached	Submitted
3	In 3.2.P.6 Reference standard or material, Certificate of analysis	As mentioned in section 3.2.P.6 of the dossier, the reference standards utilized, including those obtained	-

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	of Reference standard is required.	from CRS and NIBSC, are handled in accordance with the information provided in section 3.2.S.5. With respect to the CoAs for Metacresol and L-methionine, which are used as working standards in the manufacturing process, the relevant documentation has been provided. You may refer to the folder titled “Annex 1”, which includes: · Certificate of Analysis for L-methionine Working Standard · Certificate of Analysis for Metacresol Working Standard	
4	Adventitious agent safety evaluation is required in section 3.2.A.2.	TSE/ BSE certificates of raw materials and excipients of non-biological origins are presented in figure 3.2.A.2 1 to 3.2.A.2 4. Viral Clearance Study for the Manufacturing Process of CHO cell derived recombinant Cinnal-f (FSH) is attached.	Attached
5	Analytical method verification reports of drug product is required in Section 3.2.P.5.3.	Attached as Annexure 5	Submitted
6	Compatibility studies is required under Module 3.2.P.2.6.	It is important to highlight that the formulation of Cinnal-f is identical to that of the reference medicinal product (RMP), GONAL-f. As such, CinnaGen Co. has not conducted any comprehensive formulation development for this product, given that the biosimilar was developed to match the RMP in both qualitative and quantitative composition, as well as in dosage form and route of administration. Considering that comprehensive compatibility studies have already been conducted on the RMP during its development, it is not scientifically necessary to replicate all of those studies for the biosimilar. Furthermore, as part of our studies, long-term (24 months) and accelerated (6 months) stability studies were performed on the Cinnal-f drug product. The results of these studies showed no formation of degradation products or impurities related to excipient interactions. Additionally, there were no significant changes observed in the quality, safety, or efficacy attributes of the drug product throughout the study	-

		periods. Based on the alignment with the RMP formulation and the robust data from the stability studies of Cinnal-f, we consider that additional compatibility studies are not required.	
7	Bio similarity data as per WHO Bio similarity guidelines in tabular form is required including; Ø Comparative structural and functional characterization with the Reference product. Ø Comparative in vitro bioassays for receptor affinity and activation. Ø Comparative in-vivo potency. Ø Impurity testing (product related and process related). Ø Comparative Pharmacokinetic studies Ø Comparative Toxicology studies (single dose and repeat dose). Ø Clinical trial data	Attached as Annex 7	Firm has submitted following comparative studies; Protein content, primary structure analysis, higher order structure, product related variants and impurities, particulate matter, functional activity (Cell-based assay for the determination of FSH activity, Biological Activity by Rat ovary weight gain assay). Firm has also submitted following non-clinical and clinical (PK and efficacy) study; “Comparative analysis of Biological Activity of FSH in Cinnal f® and GONAL-f®.” “A randomized, double-blind, cross over clinical trial which was conducted on 30 healthy female and compared the pharmacokinetics of a single dose administration of Cinnal-f® to Gonol-f®.” “A prospective, non-inferiority, randomized, triple-blind, and phase 3 clinical trial comparing efficacy and safety of Cinnal-f® versus Gonol-f® in 200 women undergoing ovarian stimulation for Intracytoplasmic sperm injection”.

Concluding remarks:Firm has not performed stability of applied product and submitted justification of following ICH guidelines. However, ICH guidelines on BRACKETING AND MATRIXING DESIGNS FOR STABILITY TESTING OF DRUG SUBSTANCES AND DRUG PRODUCTS Q1D states that: With justification, bracketing can be applied to studies with multiple strengths where the relative amounts of drug substance and excipients change in a formulation. Such justification can include a demonstration of comparable stability profiles among the different strengths of clinical or development batches.

Decision

Approved

Registration Board approved the product subject to compliance of current Import Policy for Finished Drugs. However, the waiver of stability testing for applied strength shall be evaluated in the light of ICH Guidelines Q1D

on “Bracketing and Matrixing Designs for Stability Testing of Drug Substances and Drug Products” before issuance of registration letter.

17	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Leven Medical Care 8-C STREET 3 (05-352-0063)
	Application Form Dy. No / Tracking ID & date of submission	(E1M-DNY-WZEL, 2025-03-27)
	Detail of Fee Submitted	75000.0, 2025-03-11,
	The proposed proprietary name / brand name	CINNAL-F
	Label Claim	Each Prefilled Pen contains; Recombinant Human Follicle stimulating Hormone (Follitropin Alfa)..... 900IU in 1.5ml
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	1-As per SRO
	Shelf Life (Unit)	2 Year(s)2C to 8C
	For generic drugs (me-too Status)	Gonal-F Pen 900 IU/1.5ml Solution for Injection in a pre-filled pen Imported by Martin Dow Specialities Pvt.Limited, Karachi.
	Pharmacotherapeutic Group of (API)	Gonadotropins Code ATC: G03GA05
	Name, address of Manufacturing site:	CinnaGen Co.-Plot 72,74,87,88, 3rd Sq, Simin Dasht Non-Governmental Industrial Area, Fardis County, Alborz Province Iran-Iran
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Name, address of Marketing Authorization Holder:	CinnaGen Co., Plot 72,74,87,88, 3rd Sq, Simin Dasht Non-Governmental Industrial Area, Fardis County, Alborz Province Iran, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	CoPP: Firm has attached CoPP (665/70257) issued by Iran Food & Drug Administration on 13-10-2024. The CoPP specifies that the product is licensed to be placed for use in the exporting country as well as the product is actually in the market in exporting
	Details of Authorization Letter :	Firm has attached Letter of Authorization No.1403-007526 with the application on e-app. The letter was issued on 06-11-2024 and valid for one year from the date of signature.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted Stability data of Follitropin Alfa drug substance of 6 pilot scale batches and 3 commercial scale batches at real time (below -20 °C) storage condition for 24 months and accelerated (5 ± 3 °C) storage condition for 6 months.
	The status in reference regulatory authorities	Gonal-F Pen 900 IU/1.5ml Solution for Injection in a pre-filled pen M/s. Merck Serono S.P.A. VIA Delle Magnolie (LOC. FrazioneZona Industriale), Italy.

Evaluation Remarks

The case was deferred in 347th meeting. Decision of 347th meeting: Registration Board deferred the case for submission of the following documents/clarifications: i. Valid Legalized COPP is required in hard copy also. ii. Manufacturing details of drug substance is required. iii. In 3.2.P.6 Reference standard or material, Certificate of analysis of Reference standard is required. iv. Adventitious agent safety evaluation is required in section 3.2.A.2. v. Analytical method verification reports required in Section 3.2.P.5.3 vi. Compatibility studies with excipients is required. vii. Real time stability data of Batch# H019DR at 24 months' time interval is required. viii. Bio similarity data as per WHO Bio similarity guidelines in tabular form is required including; Ø Comparative structural and functional characterization with the Reference product. Ø Comparative in vitro

bioassays for receptor affinity and activation. Ø Comparative in-vivo potency. Ø Impurity testing (product related and process related). Ø Comparative Pharmacokinetic studies Ø Comparative Toxicology studies (single dose and repeat dose). Ø Clinical trial data Evaluation by BE&R:

Sr.No.	Observations	Response of the firm	Remarks
1	Valid Legalized COPP is required in hard copy also.	Submitted	Submitted
2	Manufacturing details of drug substance is required.	Quality overall summary attached	Submitted
3	In 3.2.P.6 Reference standard or material, Certificate of analysis of Reference standard is required.	As mentioned in section 3.2.P.6 of the dossier, the reference standards utilized, including those obtained from CRS and NIBSC, are handled in accordance with the information provided in section 3.2.S.5. With respect to the CoAs for Metacresol and L-methionine, which are used as working standards in the manufacturing process, the relevant documentation has been provided. You may refer to the folder titled "Annex 1", which includes: · Certificate of Analysis for L-methionine Working Standard · Certificate of Analysis for Metacresol Working Standard	-
4	Adventitious agent safety evaluation is required in section 3.2.A.2.	TSE/ BSE certificates of raw materials and excipients of non-biological origins are presented in figure 3.2.A.2 1 to 3.2.A.2 4. Viral Clearance Study for the Manufacturing Process of CHO cell derived recombinant Cinnal-f (FSH) is attached.	-
5	Analytical method verification reports of drug product is required in Section 3.2.P.5.3.	Attached as Annexure 5	Submitted
6	Compatibility studies is required under Module 3.2.P.2.6.	It is important to highlight that the formulation of Cinnal-f is identical to that of the reference medicinal product (RMP), GONAL-f. As such, CinnaGen Co. has not conducted any comprehensive formulation development for this product, given that the biosimilar was developed to match the RMP in both qualitative and quantitative composition, as well as in dosage form and route of administration. Considering that comprehensive compatibility studies have already been conducted on the RMP during its development, it is not scientifically necessary to replicate all of those studies for the biosimilar. Furthermore, as part of our studies, long-term (24 months)	-

		and accelerated (6 months) stability studies were performed on the Cinnal-f drug product. The results of these studies showed no formation of degradation products or impurities related to excipient interactions. Additionally, there were no significant changes observed in the quality, safety, or efficacy attributes of the drug product throughout the study periods. Based on the alignment with the RMP formulation and the robust data from the stability studies of Cinnal-f, we consider that additional compatibility studies are not required.	
7	Real time stability data of Batch# H019DR at 24 months' time interval is required.	Attached as Annex 8	Submitted
8	Bio similarity data as per WHO Bio similarity guidelines in tabular form is required including; Ø Comparative structural and functional characterization with the Reference product. Ø Comparative in vitro bioassays for receptor affinity and activation. Ø Comparative in-vivo potency. Ø Impurity testing (product related and process related). Ø Comparative Pharmacokinetic studies Ø Comparative Toxicology studies (single dose and repeat dose). Ø Clinical trial data	Attached as Annex 7	Firm has submitted following comparative studies; Protein content, primary structure analysis, higher order structure, product related variants and impurities, particulate matter, functional activity (Cell-based assay for the determination of FSH activity, Biological Activity by Rat ovary weight gain assay). Firm has also submitted following non-clinical and clinical (PK and efficacy) study; "Comparative analysis of Biological Activity of FSH in Cinnal f® and GONAL-f®." "A randomized, double-blind, cross over clinical trial which was conducted on 30 healthy female and compared the pharmacokinetics of a single dose administration of Cinnal-f® to Gonol-f®." "A prospective, non-inferiority, randomized, triple-blind, and phase 3 clinical trial comparing efficacy and safety of Cinnal-f® versus Gonol-f® in 200 women undergoing ovarian stimulation for

Decision**Approved**

Registration Board approved the product subject to compliance of current Import Policy for Finished Drugs.

18	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan (01-374-0006)
	Application Form Dy. No / Tracking ID & date of submission	(12X-JLL-LWVD, 2025-01-30)
	Detail of Fee Submitted	300000.0, 2025-01-02,
	The proposed proprietary name / brand name	TETAVIN
	Label Claim	Each ml contains: Enzyme Refined, Equine Tetanus Antitoxic Immunoglobulin fragments not less than 1500 I.U.
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	20 ampoules of 1 mL -As per SRO
	Shelf Life (Unit)	24 Month(s)Store at 2°C-8°C.Do not freeze.
	For generic drugs (me-too Status)	TETANUS ANTITOXIN ATS 1500I.U/AMPOULE MAH: RYAN PHARMA UK Manufacturer: JIANGSI INSTITUTE OF BIOLOGICAL PRODUCTS MFG. LIC. NO. S10970021 NMPA APPROVED
	Pharmacotherapeutic Group of (API)	Antitoxins
	Name, address of Manufacturing site:	VINS Bioproducts Limited -Survey No.117, Thimmapur (V) Kothur (M), Rangareddy Dist.,509325 Telangana, India. -India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Name, address of Marketing Authorization Holder:	VINS Bioproducts Limited , Survey No.117, Thimmapur (V) Kothur (M), Rangareddy Dist.,509325 Telangana, India. , India
	Details of Certificates (CoPP/FSC/cGMP):	Ministry of Foreign Affairs attested COPP is provided.
	Details of Authorization Letter :	-
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of three batches accelerated conditions 25°C±2°C and 60% + 5% RH for 6 months and long -term stability studies of three batches at 2° C-8° C for 24 months.
	The status in reference regulatory authorities	Tetanus Antitoxin 1500 I.U/ml BP, MAH: Amson Vaccines & Pharma (Pvt) Ltd, Islamabad, Manufacturer: Biological E. Ltd, 18 / 1 & 3, Azamabad, Hyderabad, India

Evaluation Remarks

The case was deferred in 348th meeting. Decision of 348th RB meeting: Registration Board after detailed deliberation deferred the case for clarification from the applicant as the applied product is already approved in the name of M/s Bristol Mayer Biotech Pakistan in 339th meeting of Registration Board. The Board advised the applicant to submit valid product specific letter of authorization and further clarification from MAH about the marketing rights given to M/s Bristol Mayer Biotech Pakistan. Evaluation by BE&R: An email was forwarded to the manufacturer “Vins Bioproducts Limited, India” for clarification regarding letter of authorization. The manufacturer replied as under; “With reference to the below communication, we would like to confirm that M/s Bristol Mayer Biotech Pakistan, Lahore, Pakistan is our exclusive authorized agent for the registration, import, and

sale of Tetanus Antitoxin 1500 I.U. Ampoule in Pakistan. For your reference, please find attached the Authorization Letter issued in their favor.” In attached LOA, Tetanus Antitoxin, Vinrab and Snake Venom Anti serum are mentioned.

Decision

Deferred

Registration Board directed the BE&R Division to issue a Show Cause Notice to M/s Lab Diagnostic Systems (SMC), Taxila, for rejection of their registration application of Tetavin (Tetanus Anti Toxin 1500IU) Ampoule as the authenticity of the Letter of Authorization (LoA) submitted by the applicant could not be verified. This decision was based on the communication received from M/s VINS Bioproducts Limited, India, wherein it was confirmed via email to DRAP that M/s Bristol Mayer Biotech, Pakistan, is the sole authorized entity to register, import, and market their product Tetanus Antitoxin 1500 IU Ampoule in Pakistan.

19	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan (01-374-0006)
	Application Form Dy. No / Tracking ID & date of submission	(D9J-N52-7Z6U, 2025-01-31)
	Detail of Fee Submitted	300000.0, 2024-12-18,
	The proposed proprietary name / brand name	Globurab (Rabies Antiserum 1000 I.U)
	Label Claim	Rabies Antiserum 1000 I.U I.H.S (5ml Liquid Vial) Each ml contains: Enzyme refined, Equine Antirabies Immunoglobulin fragments not less than 200 I.U. Preservatives: Cresol B.P. 0.25% v/v Stabilizer: Glycine B.P. Excipients: Sodium Chloride
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's (5ml Vial)-As per SRO
	Shelf Life (Unit)	24 Month(s)Store between 2-8°C. Do not freeze.
	For generic drugs (me-too Status)	Rabies Anti-serum (Equine Immunoglobulin) Registration Number: 003847 Manufactured by: Biological Production Division National Institute of Health , Islamabad, Pakistan
	Pharmacotherapeutic Group of (API)	Rabies antiserum
	Name, address of Manufacturing site:	VINS Bioproducts Limited-Survey No.117, Thimmapur (V) Kothur (M), Rangareddy Dist., Telangana, India.- India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Name, address of Marketing Authorization Holder:	VINS Bioproducts Limited, Survey No.117, Thimmapur (V) Kothur (M), Rangareddy Dist., Telangana, India., India
	Details of Certificates (CoPP/FSC/cGMP):	Ministry of Foreign Affairs attested COPP is provided.
	Details of Authorization Letter :	-
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of three batches at accelerated conditions 25°C±2°C and 60% + 5% RH for 6 months and long -term stability studies data of three batches at 2° C-8° C for 24 months.
	The status in reference regulatory authorities	FAVIRAB 1000IU/5ml (Rabies Immunoglobulin) MAH: Sanofi Pasteur SA ANSM APPROVED

Evaluation Remarks

The case was deferred in 348th meeting. Decision of 348th RB meeting: Registration Board after detailed deliberation deferred the case for clarification from the applicant as the applied product is already approved in the Minutes of 351st Meeting of Registration Board (23rd – 24th September, 2025)

name of M/s Bristol Mayer Biotech Pakistan in 339th meeting of Registration Board. The Board advised the applicant to submit valid product specific letter of authorization and further clarification from MAH about the marketing rights given to M/s Bristol Mayer Biotech Pakistan. Evaluation by BE&R: An email was forwarded to the manufacturer "Vins Bioproducts Limited, India" for clarification regarding letter of authorization. The manufacturer replied as under; "With reference to the below communication, we would like to confirm that M/s Bristol Mayer Biotech Pakistan, Lahore, Pakistan is our exclusive authorized agent for the registration, import, and sale of Tetanus Antitoxin 1500 I.U. Ampoule in Pakistan. For your reference, please find attached the Authorization Letter issued in their favor." In attached Letter of Authorization, Tetanus Antitoxin, Vinrab and Snake Venom Anti serum are mentioned. Registration Letter to M/s Bristol Mayer Biotech Pakistan for Vinrab has already been issued.

Decision

Rejected

Registration Board rejected the application on the grounds that the product is already registered in the name of M/s Bristol Mayer Biotech, Pakistan Lahore. Furthermore, the manufacturer i.e., M/s VINS Bioproducts Limited, India, through an email to DRAP, confirmed the authorization for Rabies Antiserum in favor of M/s Bristol Mayer Biotech, Pakistan.

20	Case Category	Priority As Per 257-M of RB (Anam Saeed)
	Name, address of Applicant.	Bristol Mayer Biotech Pakistan 73 B Guldasht Town Zarrar Shaheed Lahore (05-352-0068)
	Application Form Dy. No / Tracking ID & date of submission	(XYA-Q92-B4HX, 2025-08-13)
	Detail of Fee Submitted	300000.0, 2025-05-26,
	The proposed proprietary name / brand name	SUYA-FIX
	Label Claim	Each vial contains Human coagulation factor IX 500 IU (10ml after reconstitution)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 vial/box-As per SRO
	Shelf Life (Unit)	36 Month(s)Store at 2-8°C. Protect from light
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Anti-haemorrhagics: blood coagulation factor IX ATC code: B02BD04.
	Name, address of Manufacturing site:	Grand Shuyang Life Sciences (Chengdu) Co., Ltd-Address: No. 888, Antai 5th Road, Hi-Tech Zone, Chengdu, Sichuan, P.R. China-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Name, address of Marketing Authorization Holder:	Grand Shuyang Life Sciences (Chengdu) Co., Ltd, Address: No. 888, Antai 5th Road, Hi-Tech Zone, Chengdu, P.R. China, China
	Details of Certificates (CoPP/FSC/cGMP):	Firm has submitted Apostile COPP No. Sichuan 20250108 issued by Sichuan Medical Products Administration, China valid till 09-04-2027. The certificate confirms that the product is actually on the market in the exporting country and facilities and operation
	Details of Authorization Letter :	Firm has submitted Apostile Letter of Authorization dated 29-04-2025. Brand name is not mentioned in the Letter.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	The Human Coagulation Factor IX bulk is not stored. To assess the stability of the active components during the brief storage period of the bulk before preparation, three

	batches (202303F01, 202303F02 and 202303F03) of thawed bulk are kept for 10 hours and tested at 0,4,6,8 and 10 hours intervals.
The status in reference regulatory authorities	MHRA approved (ALPHANINE 500 I.U. POWDER AND SOLVENT FOR SOLUTION FOR INJECTION)

Evaluation Remarks

The case was evaluated and found deficient for the following;

- The applied product is lyophilized powder for Injection. Is it combo pack with diluent or otherwise? The innovator is available in combo pack.
- Detail regarding plasma regulatory body and certificate/approval granted to plasma collection centers is required.
- Total protein, Factor VIII content, Parvovirus B19 NAT, HAV, ALT are not performed on human plasma. Submit justification.
- 3 types of plasma are mentioned in application: Single donor plasma, Small sample mixed plasma and pooled plasma. Submit collection details of all the plasma and tests performed
- Thrombogenicity / Thrombogenic potential of applied product in Pharmacodynamics studies using animal models in Module 4 is required.
- Drug substance structural characterization detail is required.
- Complete virus removal/inactivation procedure is required.
- Process and product related impurities are required including testing details.
- Complete Stability data of drug substance is required till claimed shelf life/retest date.
- In-use stability data of drug product is not provided.
- Batch size of stability batches of drug product is not mentioned in stability data.

Decision

Deferred

Registration Board deferred the application for submission of following documents/ clarification;

- The applied product is lyophilized powder for Injection. Is it combo pack with diluent or otherwise? The innovator is available in combo pack.
- Detail regarding plasma regulatory body and certificate/approval granted to plasma collection centers is required.
- Total protein, Factor VIII content, Parvovirus B19 NAT, HAV, ALT are not performed on human plasma. Submit justification.
- 3 types of plasma are mentioned in application: Single donor plasma, Small sample mixed plasma and pooled plasma. Submit collection details of all the plasma and tests performed
- Thrombogenicity / Thrombogenic potential of applied product in Pharmacodynamics studies using animal models in Module 4 is required.
- Drug substance structural characterization detail is required.
- Complete virus removal/inactivation procedure is required.
- Process and product related impurities are required including testing details.
- Complete Stability data of drug substance is required till claimed shelf life/retest date.
- In-use stability data of drug product is not provided.
- Batch size of stability batches of drug product is not mentioned in stability data.

21	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	SAMI Pharmaceuticals Pvt. Ltd. F-95 Hub River Road S.I.T.E Karachi (000072)
	Application Form Dy. No / Tracking ID & date of submission	(1U1-ZUA-QUNB, 2025-08-25)
	Detail of Fee Submitted	38700.0, 2025-08-06,

The proposed proprietary name / brand name	SEGLUTA 2mg/1.5ml Injection
Label Claim	Each ml of solution contains: Semaglutide 1.34 mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's-De-Controlled
Shelf Life (Unit)	2 YearsStore between 2°C to 8°C
For generic drugs (me-too Status)	Seglutide
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Hangzhou Zhongmeihuadong Pharmaceutical Jiangdong Co., Ltd. No.7278 Meilin Avenue, Dajiangdong Industrial Cluster Zone, Hangzhou, 311228, China.
Detail of stability batches of drug product	
Documents for the procurement of API with approval from DRAP (in case of Import)	
Pharmaceutical Equivalence and Comparative Dissolution Profile	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
The status in reference regulatory authorities	OZEMPIC FDA approved
GMP status of the firm	
Evidence of approval of manufacturing facility	

Evaluation Remarks

The case was evaluated and found deficient for the following;1. 2 sites are involved in manufacturing of drug substance as under;“Hangzhou Zhongmeihuadong Pharmaceutical Jiangdong Co., Ltd. No.7278 Meilin Avenue, Dajiangdong Industrial Cluster Zone, Hangzhou, 311228, China” is responsible for Manufacturing, packaging, labeling for Semaglutide and release testing for intermediates of Semaglutide.“Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd. No. 866 Moganshan Road, Hangzhou, 310011, China” is responsible for Release testing, stability testing and storage for Semaglutide.GMP and DML of both sites are required.2. Module 3.2.S.2.3 to 3.2.S.2.6 are not provided.3. Evidence of procurement of API is required.4. Complete quality comparison of API with Reference product is not performed by API manufacturer.5. In batch analysis of API, all tests are not performed as mentioned in drug substance specifications under Module 3.2. S.4.1.6. Results of Stress testing of API is not provided.7. Risk assessment of presence of nitrosamine impurities in drug substance is not provided.8. Testing detail of residual reagent and cell related impurities are not provided in drug substance part.9. Complete Analytical method validation of drug substance of all parameters is required.10. Real time stability data of drug substance is till 9 months only while retest/expiry date is 24 months.11. Process validation report of drug product is required. Only protocol attached.12. Peptide mapping is not a part of finished product specifications.13. Comparative testing of applied product with Seglutide of M/s Macter is provided, which is not innovator product. Complete Comparative testing with innovator is required.14. Compatibility with container closure system is required under Module 3.2.P.2.6.

Decision

Deferred

Registration Board deferred the application for submission of following documents/ clarification;

i. Two sites are involved in manufacturing of drug substance as under;

a. “Hangzhou Zhongmeihuadong Pharmaceutical Jiangdong Co., Ltd. No.7278 Meilin Avenue, Dajiangdong Industrial Cluster Zone, Hangzhou, 311228, China” is responsible for Manufacturing, packaging, labeling for Semaglutide and release testing for intermediates of Semaglutide.

- b. "Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd. No. 866 Moganshan Road, Hangzhou, 310011, China" is responsible for Release testing, stability testing and storage for Semaglutide.
- ii. GMP and DML of both sites are required.
- iii. Module 3.2.S.2.3 to 3.2.S.2.6 are not provided.
- iv. Evidence of procurement of API is required.
- v. Complete quality comparison of API with Reference product is not performed by API manufacturer.
- vi. In batch analysis of API, all tests are not performed as mentioned in drug substance specifications under Module 3.2. S.4.1.
- vii. Results of Stress testing of API is not provided.
- viii. Risk assessment of presence of nitrosamine impurities in drug substance is not provided.
- ix. Testing detail of residual reagent and cell related impurities are not provided in drug substance part.
- x. Complete Analytical method validation of drug substance of all parameters is required.
- xi. Real time stability data of drug substance is till 9 months only while retest/expiry date is 24 months.
- xii. Process validation report of drug product is required. Only protocol attached.
- xiii. Peptide mapping is not a part of finished product specifications.
- xiv. Comparative testing of applied product with Seglutide of M/s Macter is provided, which is not innovator product. Complete Comparative testing with innovator is required.
- xv. Compatibility with container closure system is required under Module 3.2.P.2.6.

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Case Category	Routine (Anam Saeed)
Name, address of Applicant.	SAMI Pharmaceuticals Pvt. Ltd. F-95 Hub River Road S.I.T.E Karachi (000072)
Application Form Dy. No / Tracking ID & date of submission	(SSA-71U-U9MS, 2025-08-25)
Detail of Fee Submitted	38700.0, 2025-08-06,
The proposed proprietary name / brand name	SEGLUTA 4mg/3ml Injection
Label Claim	Each ml of solution contains: Semaglutide 1.34 mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's-De-Controlled
Shelf Life (Unit)	2 YearsStore between 2°C to 8°C
For generic drugs (me-too Status)	Seglutide
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	"Hangzhou Zhongmeihuadong Pharmaceutical Jiangdong Co., Ltd. No.7278 Meilin Avenue, Dajiangdong Industrial Cluster Zone, Hangzhou, 311228, China"
Detail of stability batches of drug product	
Documents for the procurement of API with approval from DRAP (in case of Import)	

Pharmaceutical Equivalence and Comparative Dissolution Profile	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
The status in reference regulatory authorities	OZEMPIC FDA approved
GMP status of the firm	
Evidence of approval of manufacturing facility	

Evaluation Remarks

The case was evaluated and found deficient for the following; 1. 2 sites are involved in manufacturing of drug substance as under; “Hangzhou Zhongmeihuadong Pharmaceutical Jiangdong Co., Ltd. No.7278 Meilin Avenue, Dajiangdong Industrial Cluster Zone, Hangzhou, 311228, China” is responsible for Manufacturing, packaging, labeling for Semaglutide and release testing for intermediates of Semaglutide. “Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd. No. 866 Moganshan Road, Hangzhou, 310011, China” is responsible for Release testing, stability testing and storage for Semaglutide. GMP and DML of both sites are required. 2. Module 3.2.S.2.3 to 3.2.S.2.6 are not provided. 3. Evidence of procurement of API is required. 4. Complete quality comparison of API with Reference product is not performed by API manufacturer. 5. In batch analysis of API, all tests are not performed as mentioned in drug substance specifications under Module 3.2. S.4.1. 6. Results of Stress testing of API is not provided. 7. Risk assessment of presence of nitrosamine impurities in drug substance is not provided. 8. Testing detail of residual reagent and cell related impurities are not provided in drug substance part. 9. Complete Analytical method validation of drug substance of all parameters is required. 10. Real time stability data of drug substance is till 9 months only while retest/expiry date is 24 months. 11. Process validation report of drug product is required. Only protocol attached. 12. Peptide mapping is not a part of finished product specifications. 13. Comparative testing of applied product with Seglutide of M/s Macter is provided, which is not innovator product. Complete Comparative testing with innovator is required. 14. Compatibility with container closure system is required under Module 3.2.P.2.6.

Decision

Deferred

Registration Board deferred the application for submission of following documents/ clarification;

i. 2 sites are involved in manufacturing of drug substance as under;

a. “Hangzhou Zhongmeihuadong Pharmaceutical Jiangdong Co., Ltd. No.7278 Meilin Avenue, Dajiangdong Industrial Cluster Zone, Hangzhou, 311228, China” is responsible for Manufacturing, packaging, labeling for Semaglutide and release testing for intermediates of Semaglutide.

b. “Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd. No. 866 Moganshan Road, Hangzhou, 310011, China” is responsible for Release testing, stability testing and storage for Semaglutide.

GMP and DML of both sites are required.

ii. Module 3.2.S.2.3 to 3.2.S.2.6 are not provided.

iii. Evidence of procurement of API is required.

iv. Complete quality comparison of API with Reference product is not performed by API manufacturer.

v. In batch analysis of API, all tests are not performed as mentioned in drug substance specifications under Module 3.2. S.4.1.

vi. Results of Stress testing of API is not provided.

vii. Risk assessment of presence of nitrosamine impurities in drug substance is not provided.

viii. Testing detail of residual reagent and cell related impurities are not provided in drug substance part.

- ix. Complete Analytical method validation of drug substance of all parameters is required.
- x. Real time stability data of drug substance is till 9 months only while retest/expiry date is 24 months.
- xi. Process validation report of drug product is required. Only protocol attached.
- xii. Peptide mapping is not a part of finished product specifications.
- xiii. Comparative testing of applied product with Seglutide of M/s Macter is provided, which is not innovator product. Complete Comparative testing with innovator is required.
- xiv. Compatibility with container closure system is required under Module 3.2.P.2.6.

23	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Organs Pharma Block A, 6th Floor Plot No. FD-35-36-A7, National Industrial Park, Korangi Creek (0616)
	Application Form Dy. No / Tracking ID & date of submission	(1Q2-D8P-8J7X, 2024-11-04)
	Detail of Fee Submitted	300000.0, 2024-09-18,
	The proposed proprietary name / brand name	FOLISURGE 75 [Recombinant Human Follicle Stimulating Hormone (Follitropin Alfa) Solution for Injection 75 IU/0.12 mL] Pre-filled Syringe
	Label Claim	Each single use pre-filled syringe contains: Recombinant Human Follicle Stimulating Hormone (Follitropin Alfa) Solution for Injection..... 75 IU/0.12 mL
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	Single-use, pre-fill-As per SRO
	Shelf Life (Unit)	24 Month(s)Store between 2°C to 8°C
	For generic drugs (me-too Status)	Brand name: Follitrope 75 IU Pre-filled syringe Injection, Reg no. – 069574, Composition: Recombinant Human Follicle Stimulating Hormone 75 IU, Registration holder: Galaxy Pharma Private Limited, Pack
	Pharmacotherapeutic Group of (API)	Hormone
	Name, address of Manufacturing site:	Intas Pharmaceuticals Limited -Plot No. 423/P/A Sarkhej – Bavla Highway, Village: Moraiya, Taluka: Sanand, Ahmedabad – 382213, Gujarat State. India.-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Name, address of Marketing Authorization Holder:	Intas Pharmaceuticals Limited, Plot No. 423/P/A, Sarkhej-Bavla Highway, Village- Moraiya, Taluka-Sanand, Dist. Ahmedabad – 382213. Gujarat State, India., India
	Details of Certificates (CoPP/FSC/cGMP):	CoPP: Firm has attached CoPP (MFG/WHO-COPP/INTAS/2023/009752) valid up to 10-03-2025 issued by Food & Drugs Control Administration, Gujrat State, India attested by Ministry of Foreign Affairs. The CoPP specifies that the product is licensed to be place
	Details of Authorization Letter :	Firm has submitted notarized copy of Letter of Authorization The letter was issued on February 29th, 2024 and valid for five (5) years from the date of signature.

Stability Studies of Drug Substance/Product
(Conditions & duration of Stability studies)

Firm has submitted stability study data on Following batches: Stability Study – R&D Batches: Batch no. P7-CB-D01, P7-CB-D02 and P7-CB-D03 Real Time Stability: The intended storage condition of $-20^{\circ}\text{C} \pm 5^{\circ}\text{C}$ for 18 months. Accelerated Stability: The accelerated condition of $5^{\circ}\text{C} \pm 3^{\circ}\text{C}$ for 6 months. Stressed Stability: The stressed condition of $25^{\circ}\text{C} \pm 2^{\circ}\text{C}$ for 15 days. Stability Study – Clinical Trial Batch: Batch no. P7- BM-CT- 0001 Real Time Stability: At $-20^{\circ}\text{C} \pm 5^{\circ}\text{C}$ for 18 Months. Accelerated Stability: The accelerated condition of $5^{\circ}\text{C} \pm 3^{\circ}\text{C}$ for 6 Months. Stressed Stability: The stressed condition of $25^{\circ}\text{C} \pm 2^{\circ}\text{C}$ for 15 Days. An 18 months shelf life is proposed for Intas rHu FSH Drug Substance at the intended storage condition of $-20^{\circ}\text{C} \pm 5^{\circ}\text{C}$.

The status in reference regulatory authorities

RRA: European Medicine Agency, Brand name: GONAL-f®, Composition: Each vial contains 5.5 micrograms of follitropin alfa* equivalent to 75 IU. Each mL of the reconstituted solution contains 75 IU Recombinant human follicle stimulating hormone (r-hFSH), Marketing Authorization no. in EU EU/1/95/001/026 and EU/1/95/001/027, Manufacturer/Registration holder: Merck Serono S.p.A, Italy / Merck Specialties Pvt. Ltd Pack Size 1or 5 vials + 1 or 5 pre-filled syringes

Evaluation Remarks

Sr.No.	Queries as per decision of 345th meeting	Response of the firm	Remarks
1	Evidence for availability of applied product in pre-filled syringe in reference regulatory authorities as approved by Registration Board is not provided.	Please refer to Response 1 in attached query responses	Firm informed that the product is registered in Kenya, Cambodia, Nigeria, Uganda in PFS.
2	Address of manufacturer and Marketing Authorization Holder in LOA is different from that in COPP.	Applicant acknowledges agency's comment. The address in LOA is of our Corporate (Head) office. Whereas in COPP it's of plant. Because COPP is product and plant specific.	-
3	Finished product specifications in the light of 267th meeting of the Registration Board and in the light of "Guidance document regarding application of drug product specifications" conveyed vide Letter No. 9- 2/2022-PEC dated 18-12-2023.	Applicant acknowledges agency's comment. The applicant would like to clarify that the no official monograph for FSH is currently available in the USP or the European Pharmacopoeia. Moreover, the product is not approved in the Reference Regulatory Authorities mentioned on the "Guidance Document Regarding Application of Drug Product Specifications". The provided specification is based on currently available batch release and stability data.	-
4	Compatibility studies with container closure system	Applicant acknowledges agency's comment. Container closure	Compatibility studies were performed in pre-filled pen

	and with excipients.	compatibility study of Intas rHu FSH (Follitropin alfa) drug product was carried out with prefilled cartridge. The study was carried out using USP Type-I Glass cartridges and rubber plungers having different MOCs (Chlorobutylated and Bromobutylated) and lined seals. This study was carried for 30 days at real time ($5^{\circ}\text{C} \pm 3^{\circ}\text{C}$) and accelerated conditions ($25^{\circ}\text{C} \pm 2^{\circ}\text{C}$) and for 15 days at stress condition ($40^{\circ}\text{C} \pm 2^{\circ}\text{C}$). The following analytical tests were performed to confirm the compatibility of the container closure with the drug product: • Physical appearance • pH • Osmolality • Protein Concentration • Purity determination by RP-HPLC • Oligomer determination by SE-HPLC • Free protein subunits determination by SDS PAGE.	while applied product is pre-filled syringe.
5	Stability data of process validation batches of drug product is submitted. Clarification required regarding batch size.	Applicant acknowledges agency's comment. Applicant would like to clarify that the batch sizes of process validation batches for upstream scale 150 L and for downstream scale 400 mg.)	Stability data of commercial batches is required.
6	Potency testing by in-vivo bioassay is outsource (by M/s BIONEEDS (GLP Certified) Devarahosally, Sompura Hobli, Nelamangala Taluka, Bangalore Rural District). Details of the agreement with the other party and testing method and validation is required.	Applicant acknowledges agency's comment. The agreement with the BIONEEDS (GLP Certified) Davarahosally, Sompura Hobli, Nelamangala Taluka, Bangalore Rural District) is enclosed as Annexure 3.)	Only template attached. Contract/agreement for Potency testing is not provided.
7	The finished product manufacturer does not have biological section as per GMP certificate. Clarification required.	Please be noted that the GMP certificate has classification according to the Dosage forms (Tablets, Capsules - Hard & soft, Oral Liquids, Injection- Lyo, Parenterals- Liquid vial, prefilled syringe etc.).	SVP (rDNA) is mentioned in GMP certificate.
8	The firm has claimed the product to be biosimilar to Gonal-F which is powder for injection in vial dosage form while the applied product is prefilled syringe. Clarification and justification of selecting Gonal-F as comparator in	Applicant acknowledges agency's comment. The formulation of Reference Medicinal Product being patent protected cannot be used in the in-house product. Intas rHU FSH drug product is developed as a non-infringing formulation. Excipients are different from the innovators recipe and their quantities are selected on the basis of a number of experiments carried out during the screening study	The innovator is in vial while the applied product is PFS.

	the light of reference guidelines is required.	for non-infringing formulation development. To develop the new formulation, an extensive study was conducted to select new sets of excipients which make the formulation stable and non-infringing. Different sets of excipients were tried to make the formulation stable physically, chemically as well as physiologically, and the composition was finalized on the basis of accelerated and stress studies of selected formulation.)	
9	Complete Bio similarity studies as per WHO Bio similarity guidelines is required in tabular form including; a) Comparative structural and functional characterization with the Reference product. b) Comparative in vitro bioassays for receptor affinity and activation. c) Comparative in-vivo potency. d) Impurity testing (product related and process related). e) Comparative pharmacokinetics. f) Comparative Toxicology studies (single dose and repeat dose). g) Comparative Phase III clinical trial data of the applied product with reference product.	Applicant acknowledges agency's comment. Applicant would like to clarify that the complete bio similarity studies are provided in the section 3.2.R.1 and in the module 5. However, we are resubmitting the sections in Annexure 2.)	Intas follitropin alfa drug substance and drug product lots have been compared with Gonal- .f for their structural properties, product related impurities and biological activity. Both the products have identical primary structure, and show high similarity in their secondary and tertiary structures, as demonstrated by peptide mapping, western blot, CD and fluorescence analysis. Product related impurities like oligomers, dissociated subunits and oxidized follitropin alfa were studied using SE HPLC, SDS PAGE and RP HPLC. Impurities present in Intas follitropin alfa DS and DP lots were same as that observed in all three lots of Gonal-:f. No new impurities were observed in Intas follitropin alfa. Sialylation was studied using IEF. The isoform distribution in both the products is highly comparable. Moles of sialic acid per mole of follitropin alfa in both the products are also comparable. Biological activity of both the products was compared using an in-vitro and an in-vivo assay. In in-vivo assay, Intas follitropin lots showed potency 100 % against Gonal-:JID. In invitro assay, both the products showed comparable activity when tested against NIBSC standard. Overall, both the products show high similarity in terms of their structures, sialylation, impurities and biological efficacy. Firm

has also submitted: “A Prospective, Comparative, Randomized, Open label, Multicenteric Phase III Study to Compare the Safety and Efficacy of rHu FSH (Follitropin alfa) of Intas Pharmaceuticals Ltd. against GONAL F of EMD Serono, Inc. for the induction of ovulation in infertile female subjects. Total 104 patients randomized in this Phase III study, were assessed for efficacy and safety analysis.

Decision

Rejected

Registration Board rejected the application due to non-availability of evidence of approval of applied product in Pre-filled Syringe in any of the reference regulatory authorities as approved by Registration Board.

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Case Category	Routine (Anam Saeed)
Name, address of Applicant.	Organs Pharma Block A, 6th Floor Plot No. FD-35-36-A7, National Industrial Park, Korangi Creek (0616)
Application Form Dy. No / Tracking ID & date of submission	(4AN-SJ3-U78L, 2025-02-17)
Detail of Fee Submitted	300000.0, 2024-09-18,
The proposed proprietary name / brand name	FOLISURGE 150 [Recombinant Human Follicle Stimulating Hormone (Follitropin Alfa) Solution for Injection 150 IU/0.24 mL] Pre-filled Syringe
Label Claim	Each single use pre-filled syringe contains: Recombinant Human Follicle Stimulating Hormone (Follitropin Alfa) Solution for Injection..... 150 IU/0.24 mL
Reference to Finished product specifications	Manufacturer Specification
Proposed Pack Size	single-use, PFS-As per SRO
Shelf Life (Unit)	24 Month(s)Store between 2°C to 8°C
For generic drugs (me-too Status)	Brand name: Follitrope 150 IU Pre-filled syringe Injection, Reg no. – 069575, Composition: Recombinant Human Follicle Stimulating Hormone 150 IU, Registration holder: Galaxy Pharma Private Limited, Pa
Pharmacotherapeutic Group of (API)	Hormone
Name, address of Manufacturing site:	Intas Pharmaceuticals Limited-Plot No. 423/P/A, Sarkhej-Bavla Highway, Village - Moraiya, Taluka-Sanand, Dist. Ahmedabad – 382213. Gujarat State, India.-India
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
Name, address of Marketing Authorization Holder:	Intas Pharmaceuticals Limited, Plot No. 423/P/A, Sarkhej-Bavla Highway, Village - Moraiya, Taluka-Sanand, Dist. Ahmedabad – 382213. Gujarat State, India., India
Details of Certificates (CoPP/FSC/cGMP):	CoPP: Firm has attached CoPP (MFG/WHO-COPP/INTAS/2023/009753) valid up to 10-03-2025

	issued by Food & Drugs Control Administration, Gujrat State, India attested by Ministry of Foreign Affairs. The CoPP specifies that the product is licensed to be place
Details of Authorization Letter :	Firm has submitted notarized copy of Letter of Authorization The letter was issued on February 29th, 2024 and valid for five (5) years from the date of signature.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data on Following batches of drug substance: Stability Study – R&D Batches: Batch no. P7-CB-D01, P7-CB-D02 and P7-CB-D03 Real Time Stability: The intended storage condition of -20°C ± 5°C for 18 months. Accelerated Stability: The accelerated condition of 5 °C ± 3 °C for 6 months. Stressed Stability: The stressed condition of 25°C ± 2°C for 15 days. Stability Study – Clinical Trial Batch: Batch no. P7- BM-CT- 0001 Real Time Stability: At -20 °C ± 5 °C for 18 Months. Accelerated Stability: The accelerated condition of 5 °C ± 3 °C for 6 Months. Stressed Stability: The stressed condition of 25 °C ± 2 °C for 15 Days. An 18 months shelf life is proposed for Intas rHu FSH Drug Substance at the intended storage condition of -20°C ± 5°C.
The status in reference regulatory authorities	RRA: European Medicine Agency, Brand name: GONAL-f ®, Composition: Each pre-filled multidose pen contains 150 IU (equivalent to 11 micrograms) of follitropin alfa* in 0.24 mL solution Recombinant human follicle stimulating hormone. Marketing Authorization no. in EU EU/1/95/001/036. Manufacturer/Registration holder: Merck Serono S.p.A, Italy / Merck Specialties Pvt. Ltd Pack Size 1 pre-filled pen + 4 needles

Evaluation Remarks

Sr.No.	Queries asked in 345th meeting	Response of the firm	Remarks
1	Evidence for availability of applied product in pre-filled syringe in reference regulatory authorities as approved by Registration Board is not provided.	Applicant acknowledges agency's comments. rHu FSH Drug Product, the medicinal product applied for, has been developed as a proposed "similar biological medicinal product". The chosen reference medicinal product is GONAL f®, which is manufactured and marketed by Merck Serono S.p.A, Italy/Perck Specialties Pvt Ltd., India. The r-Hu FSH Product formulation was established based on knowledge of GONAL-f®, formulation excipients and concentrations. Intas Recombinant Human Follicle Stimulating Factor (rHu FSH, follitropin alfa) Drug Product is a sterile,	PFS is not available in any RRA.

		clear and colorless liquid formulation in a single-use, single dose pre-filled syringe for subcutaneous administration in strength of 150 IU/0.24 mL. Applicant would like to clarify that the formulation of Reference Medicinal Product (Multidose Gonal-f® Injection in Pen) being patent, protected, cannot be used in the in-house product. Intas rHu FSH drug product is developed as a non-infringing formulation. Excipients are different from the innovators recipe and their quantities are selected on the basis of a number of experiments carried out during the screening study for non-infringing formulation development. To develop the new formulation, an extensive study was conducted to select new sets of excipients which make the formulation stable and non-infringing. Different sets of excipients were tried to make the formulation stable physically, chemically as well as physiologically, and the composition was finalized on the basis of accelerated and stress studies of selected formulation. The dosing and route of administration used for clinical trials and commercial purpose are similar to GONAL-f®	
2	Address of manufacturer and Marketing Authorization Holder in LOA is different from that in COPP.	Applicant acknowledges agency's comment. The address in LOA is of our Corporate (Head) office. Whereas in COPP it's of plant. Because COPP is product and plant specific.	-
3	Finished product specifications in the light of 267th meeting of the Registration Board and in the light of "Guidance document regarding application of drug	Applicant acknowledges agency's comment. The applicant would like to clarify that the no official monograph for FSH is	-

	product specifications” conveyed vide Letter No. 9- 2/2022-PEC dated 18-12-2023.	currently available in the USP or the European Pharmacopoeia. Moreover, the product is not approved in the Reference Regulatory Authorities mentioned on the “Guidance Document Regarding Application of Drug Product Specifications”. The provided specification is based on currently available batch release and stability data.	
4	Compatibility studies with container closure system and with excipients.	Applicant acknowledges agency’s comment. Container closure compatibility study of Intas rHu FSH (Follitropin alfa) drug product was carried out with prefilled cartridge. The study was carried out using USP Type-I Glass cartridges and rubber plungers having different MOCs (Chlorobutylated and Bromobutylated) and lined seals. This study was carried for 30 days at real time (5 °C ± 3 °C) and accelerated conditions (25 °C ± 2 °C) and for 15 days at stress condition (40 °C ± 2 °C). The following analytical tests were performed to confirm the compatibility of the container closure with the drug product: • Physical appearance • pH • Osmolality • Protein Concentration • Purity determination by RP-HPLC • Oligomer determination by SE-HPLC • Free protein subunits determination by SDS PAGE.	Compatibility studies were performed in pre-filled pen while applied product is pre-filled syringe.
5	Stability data of process validation batches of drug product is submitted. Clarification required regarding batch size.	Applicant would like to clarify that the batch sizes of process validation batches is 5L.	Stability data of commercial batches is required.
6	Potency testing by in-vivo bioassay is outsource (by M/s BIONEEDS (GLP Certified) Devarahosally, Sompura Hobli, Nelamangala Taluka, Bangalore Rural District). Details of the	Applicant acknowledges agency’s comment. The agreement with the BIONEEDS (GLP Certified) Davarahosally, Sompura Hobli, Nelamangala Taluka,	Only template attached. Contract/agreement for Potency testing is not provided.

	agreement with the other party and testing method and validation is required.	Bangalore Rural District) is enclosed as Annexure 6.	
7	The finished product manufacturer does not have biological section as per GMP certificate. Clarification required.	Please be noted that the GMP certificate has classification according to the Dosage forms (Tablets, Capsules - Hard & soft, Oral Liquids, Injection- Lyo, Parentrals- Liquid vial, prefilled syringe etc.).	SVP (rDNA) is mentioned in GMP certificate.
8	The firm has claimed the product to be biosimilar to Gonal-F which is powder for injection in vial dosage form while the applied product is prefilled syringe. Clarification and justification of selecting Gonal-F as comparator in the light of reference guidelines is required.	Applicant acknowledges agency's comment. The formulation of Reference Medicinal Product being patent protected cannot be used in the in-house product. Intas rHU FSH drug product is developed as a non-infringing formulation. Excipients are different from the innovators recipe and their quantities are selected on the basis of a number of experiments carried out during the screening study for non-infringing formulation development. To develop the new formulation, an extensive study was conducted to select new sets of excipients which make the formulation stable and non-infringing. Different sets of excipients were tried to make the formulation stable physically, chemically as well as physiologically, and the composition was finalized on the basis of accelerated and stress studies of selected formulation.	The innovator is in vial and pre-filled pen while the applied product is PFS.
9	Complete Bio similarity studies as per WHO Bio similarity guidelines is required in tabular form including; a) Comparative structural and functional characterization with the Reference product. b) Comparative in vitro bioassays for receptor affinity and activation. c) Comparative in-vivo potency. d) Impurity testing (product related and	Applicant acknowledges agency's comments. Applicant would like to clarify that the complete bio similarity studies are provided in the section 3.2.R.1 and in the module 5. However we are resubmitting the sections in Annexure 09.	Intas follitropin alfa drug substance and drug product lots have been compared with Gonal-f for their structural properties, product related impurities and biological activity. Both the products have identical primary structure, and show high similarity in their secondary and tertiary structures, as demonstrated by peptide mapping, western blot, CD and

process related). e) Comparative pharmacokinetics. f) Comparative Toxicology studies (single dose and repeat dose). g) Comparative Phase III clinical trial data of the applied product with reference product.

fluorescence analysis. Product related impurities like oligomers, dissociated subunits and oxidized follitropin alfa were studied using SE HPLC, SDS PAGE and RP HPLC. Impurities present in Intas follitropin alfa DS and DP lots were same as that observed in all three lots of Gonal-f. No new impurities were observed in Intas follitropin alfa. Sialylation was studied using IEF. The isoform distribution in both the products is highly comparable. Moles of sialic acid per mole of follitropin alfa in both the products are also comparable. Biological activity of both the products was compared using an in-vitro and an in-vivo assay. In in-vivo assay, Intas follitropin lots showed potency 100 % against Gonal-JID. In invitro assay, both the products showed comparable activity when tested against NIBSC standard. Overall, both the products show high similarity in terms of their structures, sialylation, impurities and biological efficacy. Firm has also submitted: "A Prospective, Comparative, Randomized, Open label, Multicenteric Phase III Study to Compare the Safety and Efficacy of rHu FSH (Follitropin alfa) of Intas Pharmaceuticals Ltd. against GONAL F of EMD Serono, Inc. for the induction of ovulation in infertile female subjects. Total 104 patients randomized in this Phase III study, were assessed for efficacy and safety analysis.

Concluding Remarks: · Pre-filled syringe is not available in any RRA. · Compatibility studies were performed in pre-filled pen while applied product is pre-filled syringe. · Stability data of commercial batches of drug product till claimed shelf life is required. · Contract/agreement with third party for Potency testing is required along with testing method and its validation. · Evidence of approval of pre-filled syringe section by manufacturer. · The innovator is in vial and pre-filled pen while the applied product is PFS. · Clarification of the drug product, whether pre-filled syringe or otherwise, used in quality comparison of the applied product with the innovator. · Comparative Toxicology studies (single dose and repeat dose) and Comparative Phase III clinical trial data of the applied product with reference product.

Decision:

Decision

Rejected

The Registration Board rejected the application due to non-availability of evidence of approval of applied product in Pre-filled syringe in any of the reference regulatory authorities as approved by Registration Board.

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Case Category	Routine (Anam Saeed)		
Name, address of Applicant.	Medicorp Life Sciences Medicorp Lifesciences, Office No 301, 3rd Floor, Sky Mark tower Plot No A-13, Block 7/8, K.C.H.S Off Sharah-e-Faisal Karachi. (0498)		
Application Form Dy. No / Tracking ID & date of submission	(AWM-1DR-5AUZ, 2025-04-30)		
Detail of Fee Submitted	300000.0, 2025-02-07,		
The proposed proprietary name / brand name	STREPTOLEV		
Label Claim	Each Lyophilized vial contains: Recombinant Streptokinase for Injection..... 1500,000IU		
Reference to Finished product specifications	Manufacturer Specification		
Proposed Pack Size	1's (1.5 MIU) -As per SRO		
Shelf Life (Unit)	24 Month(s)2°C -8°C		
For generic drugs (me-too Status)	Diclair-ST of M/s Gene-Tech Laboratories Karachi Registration No. 059023		
Pharmacotherapeutic Group of (API)	Thrombolytic protein ATC Code: B01AD01		
Name, address of Manufacturing site:	M/s. Levim Biotech LLP-M/s. Levim Biotech LLP, NAGARJUNASAGAR, NALGONDA DISTRICT, TELEGANA, 508202,TELANGANA, INDIA.-India		
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A		
Name, address of Marketing Authorization Holder:	M/s. Levim Biotech LLP, M/s. Levim Biotech LLP, NAGARJUNASAGAR, NALGONDA DISTRICT, TELEGANA, 508202,TELANGANA, INDIA., India		
Details of Certificates (CoPP/FSC/cGMP):	CoPP: The firm has submitted copy of CoPP (Certificate No 4271127/TS/2024) by Drug Control Administration, Telangana State India.The certificate confirms that the product is actually on the market in the exporting country and facilities and operations c		
Details of Authorization Letter :	A copy of product specific Letter of Authorization is attached.		
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3-month stress, 6 months accelerated and 12 months long term stability data for the following batches are provided; > RSKUF19018 > RSKUF19019 > RSKUF19020 Test conditions and schedule: Stress Stability • Storage conditions: 25±2°C/ 60±5% RH • Test points: Initial ,15 days, 1 month & 3 months Accelerated Stability • Storage conditions: 5±3°C • Test points: Initial ,1,3 & 6 months Long -term stability • Storage conditions: -20±5°C • Test points: Initial,1,3,6,9 &12 months		
The status in reference regulatory authorities	Streptase by M/s CSL Behring, Germany Streptase®, Streptokinase, is a sterile, purified preparation of a bacterial protein elaborated by group C (beta) -hemolytic streptococci. So, it is of natural origin while applied product is of rDNA origin.		

Evaluation Remarks

Sr.No.	Queries in 349th meeting	Response of the firm	Remarks

1	Original legalized COPP is required as the submitted document is not legalized.	COPP enclosed.	COPP submitted is not legalized.
2	Brand name is not mentioned in COPP.	GMP certificate mentions the Brand name. However, due to company name change under process, addition of brand name – STREPTOLEV in COPP is not initiated. We will provide the same soon.	Brand name and pack size is not mentioned in COPP.
3	Original or notarized product specific LOA in hard copy is required.	Notarized LOA enclosed.	LOA attached is not notarized.
4	Module 1.4.1 to 1.4.3 is not provided.	Attached:updated: Module-1 Administrative with inclusion of Sections 1.4.1 to 1.4.3.	Submitted
5	Updated Module 1 as per final guidance document for biological products is required.		Submitted
6	Evidence of availability of recombinant streptokinase in any reference country is required. The product “Streptase” mentioned in the application as reference is of natural origin.	5.1 EVIDENCE OF REGISTRATION BY DRAP PAKISTAN: Approval of Eptase Injection (Streptokinase): In the 340th Meeting of the Registration Board held on 1st–2nd October 2024, the product Eptase Injection (Streptokinase), manufactured by M/s. Beacon Pharmaceuticals Limited, Bangladesh, was approved by the Drug Regulatory Authority of Pakistan (DRAP). Relevant excerpt from the meeting minutes is attached (5.1-Page-713-715). Levim Biotech, India is the bulk drug substance manufacturer for EPTASE Injection. Additionally, Levim Biotech also serves as the finished dosage form manufacturer for our product, Streptolev Injection, utilizing the same bulk drug substance source. 5.2 EVIDENCE OF REGISTRATION FROM ABBOTT HEALTHCARE PVT LTD, INDIA: ABBOTT Healthcare Pvt Ltd, India is marketing Icikinase Injection (Recombinant Streptokinase) which is manufactured by Levim Biotech, India & is being exported to 15 countries namely, Singapore, Turkey, Saudi Arabia, United Arab Emirate, Jordan, Russia, Tajikistan, Egypt, Bhutan, Mali, Kenya, Venezuela, Afghanistan, Myanmar, Somalia, 5.2 - (Icikinase –All Country search report (Volza): Jan 2024-25- Volzaglobal export import competitive intelligence, enclosed) 5.2 - Attached product brochure of Icikinase Inj as an evidence of availability in India and export to 15 countries. 5.3 EVIDENCE OF REGISTRATION FROM CUBA:	Recombinant streptokinase is not available in any reference country as approved by registration board.

		Heberkinasa is a recombinant streptokinase available in Cuba. 5.3 - Attached product brochure as evidence for availability of recombinant streptokinase. PRODUCTS ALREADY REGISTERED WITH DRAP FROM CUBA MFG WITH RECOMBINANT TECHNOLOGY: 1. Heberbiovac 10mcg HB Inj (Vaccine) Registration No: 020648 Composition: Hepatitis B Virus recombinant DNA Surface Antigen 2. Heberbiovac 20mcg HB Injection (Vaccine) Registration No: 020647 Mfg: Heberbiotec S.A. Cuba 3. HEBERVITAL G-CSF. Registration No: 053836 Composition: FILGRASTIM (G-CSF)30MIU. CIGB, Cuba(The Center for Genetic Engineering and Biotechnology (CIGB).	
7	All registered streptokinase products with DRAP are natural in origin as per available data.	Refer Anex 5-1, regarding the approval of Eptase Inj (Streptokinase) by DRAP (340th - Meeting). This approval highlights the registration of Streptokinase with RECOMBINANT TECHNOLOGY, therefore, all registered streptokinase with DRAP are not natural in origin.	-
8	Proposed Label of the product attached in module 1 does not show recombinant word in composition.	Attached updated Composition in the proposed product label.	Submitted
9	Finished product specifications as per DRAP guidance document.	With reference to the guidance for specification as per DRAP, Recombinant Streptokinase falls under C-ii. Attached the physico chemical characterization comparability report for Levim's Recombinant Streptokinase Injection and Streptase (Natural streptokinase).	Finished product specifications is In-House mentioned on proposed label.
10	Stability data of Drug Substance submitted till 12 months however the product shelf life is 24 months.	As per the stability data provided, the recombinant streptokinase bulk solution (drug substance) demonstrated stability for a period of 12 months under the defined storage conditions -20+5°C. The drug substance was formulated with excipients including glycine - bulking/ stabilizing agent, contributing to the maintenance of its physicochemical and biological properties of the formulated streptokinase bulk solution. Further, the formulated drug substance was subjected to a lyophilization (freeze-drying) process which shall also support the stabilization of the drug product by reducing the moisture content and minimizing the product degradation. The lyophilized Recombinant Streptokinase for Injection 1500000 IU. Drug Product stored at 5+3°C .was found to be stable for 24 months as per	-

		the stability report provided in the dossier as attachment-20. SUPPORTING REFERENCES FOR DRUG PRODUCT SHELF LIFE LONGER THAN THE DRUG SUBSTANCE: A. FDA Guidance- ICH Q1A(R2): Stability Testing of New drug substance and drug product. Shelf life of drug product is based on formal stability studies, not solely on the drug substance's retest period.(p9(2.2.6) https://www.fda.gov/regulatory-information/search-fda-guidancedocuments/q1ar2-stability-testing-new-drug-substances-andproducts B. Guidance for Industry Q1E Evaluation of Stability Data. Specifically addresses when and how extrapolation can be used to propose a shelf life for a drug product that extends beyond the period covered by real-time stability data which may include periods longer than supported for the drug substance.(page2,sec.2.1,p4 2.4). https://www.fda.gov/regulatory-information/search-fda-guidancedocuments/q1e-evaluation-stability-data C. ICH Topic Q1E: Evaluation of Stability data: Note for Guidance on Evaluation of Stability Data. EMEA. (p1(2.1) Includes detailed decision trees and statistical approaches for extending shelf life based on available stability data-even beyond the timeframe covered by long-term studies. These tools are helpful for scientifically justifying longer shelf lives for finished products under stated conditions. https://www.ema.europa.eu/en/documents/scientific-guideline/ichq1e-evaluation-stability-data-step-5_en.pdf D. WHO GMP Annex 10 Stability testing of active pharmaceutical ingredients and finished pharmaceutical product.p315(2.1.6) Stability data including formulation effects or packaging to consider when setting or extending shelf life of drug product. https://www.who.int/publications/m/item/annex-10-stability-testingof-active-pharmaceutical-ingredients-and-finished-pharmaceuticalproducts	
11	Process related and host cell related impurity testing is not provided.	As described in the drug substance characterization Module 3 section (3.2.S.3.2), the expected process-related and host-cell-related impurities include host cell proteins (HCP), host cell DNA, and endotoxins. These test parameters were part of the drug substance lot release specification till Jun 2022 (Refer Process	Impurity testing is not a part of Finished product specifications.

Validation Protocol Report in Attachment 7 provided in dossier) Considering the robustness of the purification process, which has consistently demonstrated effective clearance of impurities from the drug substance, as evidenced by quality trend analysis and sustained compliance with established specifications it is justified and removed host cell protein and host cell DNA test parameters from the routine lot release specification whereas endotoxin is still existing in the lot release specification. Clearance of host cell protein (HCP) and residual host cell DNA (HCDNA) has been demonstrated through process validation studies using worst case spiking and multiple consecutive production scale lots. Both impurities were consistently reduced to well below their respective qualified acceptance criteria. SUPPORTING REFERENCES: A. Guideline on Real Time Release Testing (formerly guideline on parametric release). Routine lot-release tests to be omitted when sufficient process understanding and validation exist. p5(5.2.1) https://www.ema.europa.eu/en/documents/scientificguideline/guideline-real-time-release-testing-formerly-guideline-parametric-release-revision-1_en.pdf B. EMA Q&A for biologicals (2024-2025). It is acceptable not to routinely test for process-related impurities if consistent elimination has been demonstrated by validation studies and sufficient batch data is available” (Q&A: Process validation, removal of processrelated impurities, Sept 2023).p2 (under “Process validation, removal of process related impurities...” and “Active substance specification: Host cell proteins testing) <https://www.ema.europa.eu/en/human-regulatory-overview/researchand-development/scientific-guidelines/biological-guidelines/questionsanswers-biological-medicinal-products> C. EMA CPMP Position Statement on DNA & HCP impurities, routine testing versus validation studies. (conclusion p2) Validation approach appears to be an acceptable way for residual host cell DNA whereas host cell proteins (HCP) impurities depends ‘case by case’ based on available data. <https://www.ema.europa.eu/en/documents/scientificguideline/position-statement-dna-and-host-cell-proteins-hcpimpurities->

		routine-testing-versus-validation-studies-partly-superseded_en.pdf D. ICH Q6B-Specifications for Biotechnological/Biological products (EMA). (p12(4.2.3)) https://www.ema.europa.eu/en/documents/scientific-guideline/ich-q-6-b-test-procedures-and-acceptance-criteria-biotechnologicalbiologicalproducts-step-5_en.pdf	
12	Immunogenicity testing is required as recombinant products have a potential to induce an immune response.	Recombinant streptokinase is intended for acute, single-use administration (e.g., thrombolytic therapy in myocardial infarction), rather than chronic or repeated dosing. Immunogenicity concerns are generally associated with long-term or repeated administration of biotherapeutics. Streptokinase, both native and recombinant, has a long history of clinical use with well characterized immunogenicity profiles documented in published literature. Existing data indicates that anti-streptokinase antibodies may develop after treatment, but these are typically not clinically relevant for single-dose therapies. The product is manufactured under a validated process with stringent control of impurities (e.g., Host Cell Proteins, DNA), which minimizes potential immunogenicity risks from process-related contaminants. Immunogenicity test is a part of clinical and post-marketing assessment, not as a quality-control release test. Lot-release specifications for biologics are defined around identity, purity/impurities, potency, and general tests-not patient immunogenicity. SUPPORTING REFERENCES FOR IMMUNOGENICITY IS NOT A LOT-RELEASE TEST: A. ICH Q6B — Specifications for Biotechnological/Biological Products. Test Procedures and Acceptance Criteria for Biotechnological/ Biological Products” Immunogenicity testing not included among lot release tests. p5(2.1.3) https://www.ema.europa.eu/en/documents/scientific-guideline/ich-q-6-b-test-procedures-and-acceptance-criteria-biotechnologicalbiologicalproducts-step-5_en.pdf B. EMA Guideline on Immunogenicity Assessment of Therapeutic Proteins- Immunogenicity assessment of therapeutic proteins. Immunogenicity is a part of clinical development, assay strategy, and pharmacovigilance and not included as batch release tests. (p9.section 6)	

		https://www.ema.europa.eu/en/documents/scientificguideline/guideline-immunogenicity-assessment-therapeutic-proteinsrevision-1_en.pdf C. FDA Guidance: Immunogenicity Testing of Therapeutic Protein Products-Developing and Validating Assays for Anti-Drug Antibody Detection. (p1-4) Immunogenicity recommended during clinical trials. https://www.fda.gov/regulatory-information/search-fda-guidancedocuments/immunogenicity-testing-therapeutic-protein-productsdeveloping-and-validating-assays-anti-drug .	
13	GMP of drug substance manufacturer is required.	GMP is scheduled to be issued in September 2025.	GMP of drug substance not provided.
14	In-use stability data is required.	As Recombinant Streptokinase for Injection 1,500,000 IU is presented as A SINGLE-USE VIAL, THEREFORE AN IN-USE STABILITY STUDY IS NOT REQUIRED. SUPPORTING REFERENCES: REFERENCES FOR IN-USE STABILITY ARE MEANT FOR MULTI-DOSE PRODUCT AND NOT EXPECTED FOR SINGLE DOSE PRODUCT. A. EMA — “Note for Guidance on In-Use Stability Testing of Human Medicinal Products” (CPMP/QWP/2934/99)(p1,1-2) The purpose of in-use stability testing is to establish - where applicable - a period of time during which a multidose product can be used whilst retaining quality within an accepted specification once the container is opened, indication that in-use stability testing is specifically designed for multi-dose products to ensure they maintain quality after opening https://www.ema.europa.eu/en/documents/scientific-guideline/noteguidance-use-stability-testing-human-medicinal-products_en.pdf B. WHO GMP Annex 10 Stability testing of active pharmaceutical ingredients and finished pharmaceutical product. Given the product’s single-use presentation & the absence of post-opening handling or storage, in-use stability testing is not required. p315(2.1.6) https://www.who.int/publications/m/item/trs-1010-annex10 C. FDA Guidance – ICH Q1A(R2): Stability Testing of New drug substance and drug product. https://www.fda.gov/media/102469/download In-use studies are only required if applicable, such as for reconstituted or	-

		multidose products. p4(2.1.6) https://www.fda.gov/media/71707/download D. Guidance for Industry ANDAs: Stability Testing of Drug Substances and Products Questions and Answers. In-use stability testing is required only “if applicable,” meaning it applies to products requiring constitution, dilution, or extended use, but not to single-use vials used immediately upon opening.(p4L3Q7) https://www.fda.gov/files/drugs/published/ANDAs--StabilityTesting-of-Drug-Substances-and-Products--Questions-andAnswers.pdf	
15	Complete Module 4 and Module 5 on CTD format is required including PK and PD studies.		

Decision

Deferred

Registration Board deferred the application for submission of following documents/ clarifications;

- i. COPP submitted is not legalized.
- ii. Brand name and pack size is not mentioned in COPP.
- iii. Original or notarized LOA is required.
- iv. GMP of drug substance not provided.
- v. Impurity testing is not a part of finished product specifications.

Registration Board noted that the applied formulation of Streptokinase of recombinant DNA (rDNA) origin is not approved by any of the Reference Regulatory Authorities designated by the Board. In view of the applicant's statement that a product from the same API source is already registered in the name of M/s Himmel Pharmaceuticals (Pvt.) Ltd., Lahore, under the brand name Eptase Injection (Registration No. 120575), the Board directed the BE&R Division to issue a Show Cause Notice to M/s Himmel Pharmaceuticals (Pvt.) Ltd., Lahore, under Section 7(11)(a) & (d) and Section 42 of the Drugs Act, 1976, read with Rule 24(17) of the Drugs (Licensing, Registering & Advertising) Rules, 1976, requiring them to explain why the registration of Eptase Injection (Registration No. 120575) should not be cancelled. Till the decision on the aforesaid registered product of M/s Himmel Pharmaceuticals (Pvt.) Ltd., Lahore, the application of M/s Medicorp Life Sciences Karachi shall remain deferred.

26	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	SacBio Pharma Model town b bahawalpur (03-312-0162)
	Application Form Dy. No / Tracking ID & date of submission	(QQG-QDV-U5N2, 2024-01-22)
	Detail of Fee Submitted	150000.0, 150000.0 2023-12-29, 2025-02-18
	The proposed proprietary name / brand name	CHORIOTEC 5000

Label Claim	Each vial contains Chorionic Gonadotrophin BP 5000IU Excipients q.s. Each ampoule of solvent contains Sterile water for Injection BP....2ml
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	White to off-white l-De-Controlled
Shelf Life (Unit)	24 Month(s)Store below 25 Degrees Celsius. Protect from light.
For generic drugs (me-too Status)	IVF-C 5000 IU (Galaxy Pharma (Pvt) Ltd., Karachi) Reg. No.: 039811
Pharmacotherapeutic Group of (API)	Hormone. Code ATC: G03GA01
Name, address of Manufacturing site:	M/s United Biotech (P) Ltd.-Bagbania, Baddi-Nalagarh Road, Distt. Solan, Himachal Pradesh (174 101), India.- India
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
Name, address of Marketing Authorization Holder:	M/s United Biotech (P) Limited, Bagbania, Baddi-Nalagarh Road, Distt. Solan, Himachal Pradesh (174 101), India., India
Details of Certificates (CoPP/FSC/cGMP):	Firm has attached CoPP (HFW-H(DRUGS) 427/05/25-95) valid up to 21-02-2026 issued by Office of State Drug Controller, Licensing and Controlling Authority, Health and Family Welfare Department, Himachal Pardesh, India. The CoPP specifies that the product
Details of Authorization Letter :	The firm has provided LOA dated 25-07-2023 which is valid for 05 years.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as under; Long term testing conditions: Batch No: 010401, 010402, 010403 at 2-8oC for 36 months.
The status in reference regulatory authorities	Pregnyl 5000IU of M/s Merk Sharp & Dohme, UK.

Evaluation Remarks

Decision of 345th meeting	Response of the Firm
Fee challan is of Rs.150000 instead of Rs.30000 as per SRO 1872(I)/2023 dated 29-12-2023. Differential fee is required to be submitted by the applicant.	The remaining amount of Rs. 150,000 has been paid. Receipt No. 6495426958, dated 18-02-2025
COPP is not legalized and was valid till 22-02-2024. Valid legalized COPP is required.	We have Attached the new copp with Pakistan embassy receipt and we have also given the new COPP for legalization at the Pakistan Embassy. As soon as we receive it from the Pakistan Embassy, we will send it to you.
Product specific LOA is not provided.	The letter of Authorization, because we have to submit other products to the regulatory authority to import them, that's why they have given us All products Authorization letter. Letter of authorization is attached
Evidence of approval of applied product in any reference regulatory authority is not provided.	Evidence of approval of product in India, Sri Lanka, Nepal and Turkmenistan have been provided.
The diluent is Sodium Chloride in already approved products of chorionic gonadotropin while the applied product is with WFI. Clarification required.	No clarification has been provided. The firm has attached COAs and Stability Studies Data of sodium chloride 0.9%

GMP certificate of Drug product manufacturer is not legalized and was valid till 22-02-2024. Valid legalized GMP certificate is required.	The firm has provided GMP Certificate of M/s United Biotech valid till 21-02-2026 however the Biological Section is not mentioned on the said Certificate.
The finished product manufacturer does not have biological section as per GMP certificate. Clarification required.	The firm has provided evidence of approval of Biological Section dated 22-02-2021.
Module 1 is not as per CTD guidelines/format. Complete Module 1 as per CTD format is required.	The firm has provided Module 1 as per CTD Guidelines
All other already approved products of chorionic gonadotropin are stored at 2-8°C. while the storage condition of applied product is below 25°C. Clarification required.	The firm has given the statement that their product has good stability at 25 °C
GMP certificate of drug substance manufacturer is required.	The firm has provided GMP Certificate of M/s Shanghai Techwell Biopharmaceuticals valid till 25-12-2027
Process development of DS and its validation is not provided.	The firm has provided Process development of DS and its validation
20% overage is added in the formulation. Proper justification is required in comparison with the Innovator.	The firm has provided justification letter from manufacturer which is reproduced as under: Subject: Registration of CHORIOTEC 5000(Chorionic Gonadotrophin for Injection BP 5000IU) Regarding: Justification for taking overage '20%' in formulation We, United Biotech (P) Limited presented our formulation of CHORIOTEC 5000(Chorionic Gonadotrophin for Injection BP 5000IU) for registration in which 20% overage has been used, for which justification is needed. So we are hereby clarifying reason for taking overage '20%' in formulation. Amount of Overage: 20.0% Reason for Overage: There were processing losses during many steps of manufacturing process i.e. weighing, mixing, solution preparation, filtration, filling which results in potency loss of in final formulated product. Justification for Overage: To compensate the loss during formulation processing and to maintain the potency of final formulated product, inclusion of 20.0% overage was necessary. Hence, 20.0% overage was added in order to compensate for degradation. Thanking You. For United Biotech (P) Limited
Real time and accelerated stability data of 3 commercial batches of drug substance is required.	Stability data has been provided with storage condition of 2 – 8 °C
Adventitious agent safety evaluation under Module 3.2.A.2 is not provided.	The firm has provided following clarification from the manufacturer: Dear Sir, We certify that the material, CHORIOTEC 5000: Chorionic Gonadotrophin for Injection BP 5000IU (Lyophilized) supplied from our site contains no ingredients of animal's origin and no material derived from, or exposed to animals affected by, or under quarantine for Transmitting Animal Spongiform Encephalopathy (TSE) / Bovine Spongiform Encephalopathy (BSE), GMO

	(Genetically Modified Organism). The product is produced in facility where no animal, animal products, animal byproducts, veterinary vaccines or animal pathogens are maintained and are packed in a packaging that can be identified as to the nature of the products and the country of origin.
Analytical method verification of drug product is required under Module 3.2.P.5.3.	Provided
Diluent COA and stability is not provided.	COA of WFI 2ml has been provided
In-use stability data is not provided.	Provided
Compatibility of product with container closure system is required under Module 3.2.P.2.6.	Only specifications have been provided
Virus removal/inactivation studies is not provided.	The firm has provided following justification: Subject: Justification for not providing virus removal / inactivation studies We United Biotech (P) Limited established in Bagbania Baddi-Nalagarh Road District Solan (HP) INDIA; hereby declare that our productt: Chorionic Gonadotrophin for Injection BP 5000IU (Lyophilized) (CHORIOTEC 5000) is a gonadotrophin with its primary mode of action as: 1. It stimulates the production of gonadal steroid hormones by stimulating the interstitial cells (Leydig cells) of the testis to produce androgens and the corpus luteum of the ovaries to produce progesterone. 2. In males its action is predominantly steroidogenic while in female it is predominantly luteinizing. They have no mechanism of action to inactivate or kill or eliminate any virus, therefore any study related to the same could not be provided.
Toxicological data including single dose and repeat dose toxicity studies are not provided in Module 4.	Only summary has been provided
Genotoxicity, carcinogenicity, reproductive and developmental toxicity not provided.	Only summary has been provided
Clinical trial data of the product in Module 5 is required	References of clinical studies conducted on products of other manufacturers have been provided.

Decision of 348th meeting: The Registration deferred the case for submission of above-mentioned shortcoming documents/information. Evaluation by BE&R: Following is required from the applicant: In-use stability data of applied product. Single dose and repeat dose toxicity studies of applied product. Phase III clinical trial data of applied product.

Decision

Deferred

Registration Board deferred the case for submission of following documents/ clarifications;

- i. In-use stability data of applied product.
- ii. Single dose and repeat dose toxicity studies of applied product as required under non clinical data.
- iii. Phase III clinical trial data of applied product.

Case Category	Routine (Anam Saeed)

Name, address of Applicant.	Organs Pharma Block A, 6th Floor Plot No. FD-35-36-A7, National Industrial Park, Korangi Creek (0616)
Application Form Dy. No / Tracking ID & date of submission	(RZA-H5Z-Y289, 2024-11-20)
Detail of Fee Submitted	300000.0, 2024-09-30,
The proposed proprietary name / brand name	FOLISURGE 900 [Recombinant Human Follicle Stimulating Hormone (Follitropin Alfa) Solution for Injection 900 IU/1.44 mL] Pre-filled Cartridge
Label Claim	Each multi-dose pre-filled cartridge contains: r-Hu FSH (Follitropin Alfa) 900 IU/1.44 mL
Reference to Finished product specifications	Manufacturer Specification
Proposed Pack Size	Multi-dose pre-fille-As per SRO
Shelf Life (Unit)	24 Month(s)Store between 2°C to 8°C
For generic drugs (me-too Status)	Gonal-f Pen 900 IU (66ug)/1.5ml Solution for Injection, Reg no. – 103995, Composition: Recombinant Human Follicle Stimulating Hormone 900 IU, Registration holder: Martin Dow Specialities (Private) Lim
Pharmacotherapeutic Group of (API)	Gonadotropins (Code ATC: G03GA05)
Name, address of Manufacturing site:	Intas Pharmaceuticals Limited-Plot No. 423/P/A, Sarkhej-Bavla Highway, Village- Moraiya, Taluka-Sanand, Dist. Ahmedabad – 382213 Gujarat State, India.- India
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
Name, address of Marketing Authorization Holder:	Intas Pharmaceuticals Limited, Plot No. 423/P/A, Sarkhej-Bavla Highway, Village- Moraiya, Taluka-Sanand, Dist. Ahmedabad – 382213 Gujarat State, India., India
Details of Certificates (CoPP/FSC/cGMP):	Firm has attached copy of CoPP certificate(MFG/WHO-COPP/INTAS/2023/009755) valid up to 10-03-2025 issued by Food & Drugs Control Administration, Gujrat State, India. The CoPP specifies that the product is licensed to be placed for use in the exporting c
Details of Authorization Letter :	Firm has submitted notarized copy of Letter of Authorization The letter was issued on February 29th, 2024 and valid for five (5) years from the date of signature.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data on Following batches of drug substance: Stability Study – R&D Batches: Batch no. P7-CB-D01, P7-CB-D02 and P7-CB-D03 Real Time Stability: The intended storage condition of -20°C ± 5°C for 18 months. Accelerated Stability: The accelerated condition of 5 °C ± 3 °C for 6 months. Stressed Stability: The stressed condition of 25°C ± 2°C for 15 days. Stability Study – Clinical Trial Batch: Batch no. P7- BM-CT- 0001 Real Time Stability: At -20 °C ± 5 °C for 18 Months. Accelerated Stability: The accelerated condition of 5 °C ± 3 °C for 6 Months. Stressed Stability: The stressed condition of 25 °C ± 2 °C for 15 Days. An 18 months shelf life is proposed for Intas rHu FSH Drug Substance at the intended storage condition of -20°C ± 5°C.

The status in reference regulatory authorities

RRA: European Medicine Agency Approved, Brand name: GONAL-f®, Composition: Each pre-filled multidose pen contains 900 IU (equivalent to 66 micrograms) of follitropin alfa* in 1.44 mL solution Recombinant human follicle stimulating hormone, Marketing Authorization no. in EU EU/1/95/001/035, Manufacturer/Registration holder: Merck Serono S.p.A, Italy / Merck Specialties Pvt. Ltd, Pack Size 1 pre-filled pen + 20 needles

Evaluation Remarks

Sr.No.	Decision of 345th meeting	Remarks	Evaluation
1	COPP is not legalized. Submit valid legalized COPP.	Submitted	-
2	Address of manufacturer and Marketing Authorization Holder in LOA is different from that in COPP.	The address in LOA is of our Corporate (Head) office. Whereas in COPP it's of plant. Because COPP is product and plant specific.	-
3	Finished product specifications in the light of 267th meeting of the Registration Board and in the light of "Guidance document regarding application of drug product specifications" conveyed vide Letter No. 9- 2/2022-PEC dated 18-12-2023 is required	Applicant acknowledges agency's comment. Applicant would like to clarify that no official monograph for FSH is currently available in the USP or the European Pharmacopoeia. Moreover, the product is not approved in the Reference Regulatory Authorities mentioned on the "Guidance Document Regarding Application of Drug Product Specifications". The provided specification is based on currently available batch release and stability data.	-
4	Compatibility studies with excipients is not provided although excipients are different from reference product Gonal-F.	Applicant acknowledges agency's comment. Applicant would like to clarify that the formulation of Reference Medicinal Product being patent, protected, cannot be used in the in-house product. Intas rHu FSH drug product is developed as a non-infringing formulation. Excipients are different from innovator's recipe and their quantities are selected on the basis of a number of experiments carried out during the screening study for no infringing formulation development. To develop the new formulation, an extensive study was conducted to select new sets of excipients which make the formulation stable and non-infringing. Different sets of excipients were tried to make the	Container closure compatibility attached.

		formulation stable physically, chemically as well as physiologically, and the composition was finalized on the basis of accelerated and stress studies of selected formulation.	
5	Firm has informed that stability studies of drug product in final container are on-going. Stability data of drug product in final container till claimed shelf life is required.	Applicant acknowledges agency's comment. Stability data is enclosed as Annexure 1.	Stability of drug substance attached. Stability data of drug product is still not provided.
6	Potency testing by in-vivo bioassay is outsource (by M/s BIONEEDS (GLP Certified) Devarahosally, Sompura Hobli, Nelamangala Taluka, Bangalore Rural District). Details of the agreement with the other party and testing method and validation is required.	Applicant acknowledges agency's comment. The agreement with the BIONEEDS (GLP Certified) Davarahosally, Sompura Hobli, Nelamangala Taluka, Bangalore Rural District) is enclosed as Annexure 4.	Only template attached. Contract/agreement for Potency testing is not provided.
7	The finished product manufacturer does not have biological section as per GMP certificate. Clarification required.	Applicant acknowledges agency's comment. Please be noted that the GMP certificate has classification according to the dosage form (Tablet, Capsule – Hard & soft, Oral Liquids, Injection- Lyo, Parenteral – Liquid vial, prefilled syringe etc.)	SVP (rDNA) is mentioned in GMP certificate.
8	Phase III clinical trial is open label while Double-blind trials are recommended by the guidelines. Provide justification in the reference of guidelines of not performing double blind Phase III clinical trial.	Not provided.	No response submitted.
9	The firm has not performed following in Biosimilarity studies; - Comparative structural and functional characterization with the Reference product. - Comparative in vitro bioassays for receptor affinity and activation. - Comparative in-vivo	Applicant acknowledges agency's comment. Applicant would like to clarify that the complete bio similarity studies are provided in the section 3.2.R.1 and in the module 5. However, we are resubmitting the sections in Annexure 3	Firm has submitted following; Intas follitropin alfa drug substance and drug product lot have been compared with Gon for their structural properties, product related impurities and biological activity. Both the products have identical primary structure, and show high similarity in their secondary and tertiary structures, as demonstrated by peptide

potency. · Impurity testing (product related and process related). · Comparative Toxicology studies (single dose and repeat dose). · Immunogenicity in efficacy studies using validated antibody assays of adequate sensitivity and specificity.

mapping, western blot, CD and fluorescence analysis. Product related impurities like oligomeric dissociated subunits and oxidized follitropin alfa were studied using SE HPLC, SDS PAGE and RP HPLC. Impurities present in In follitropin alfa DS and DP lots were same as that observed in three lots of Gonal-f. No new impurities were observed in In follitropin alfa. Sialylation was studied using IEF. The isoform distribution in both the products is highly comparable. Moles of sialic acid per mole of follitropin alfa in both the products are also comparable. Biological activity of both the products was compared using an in-vitro and an in-vivo assay. In in-vivo assay, Intas follitropin lots showed potency 100 % against Gonal-JID. In invitro assay, both the products showed comparable activity when tested against NIBSC standard. Overall, both the products show high similarity in terms of their structures, sialylation, impurities and biological efficacy. Drug product used in comparative studies is not mentioned whether it is prefilled pen or otherwise.

Concluding remarks: Following is still required from the applicant: · Stability data of applied product till claimed shelf life. · Contract/agreement with third party for Potency testing including method of testing and validation. · Evidence of approval of cartridge/pre-filled pen section by manufacturer. · Data of comparative toxicology and phase 3 clinical trial studies with the innovator. · Clarification of the drug product, whether pre-filled pen or otherwise, used in quality comparison of the applied product with the innovator.

Decision

Deferred

Registration Board deferred the case and granted final opportunity to the applicant for submission of following documents/ clarifications;

- i. Stability data of applied product till claimed shelf life.
- ii. Contract/agreement with third party for Potency testing including method of testing and its validation.
- iii. Approval of cartridge/pre-filled pen manufacturing facility by manufacturer.
- iv. Data of comparative toxicology and phase 3 clinical trial studies with the innovator.
- v. Clarification of the drug product, whether pre-filled pen or otherwise, used in quality comparison of the applied product with the innovator.

Case Category	Routine (Anam Saeed)
Name, address of Applicant.	Organs Pharma Block A, 6th Floor Plot No. FD-35-36-A7, National Industrial Park, Korangi Creek (0616)
Application Form Dy. No / Tracking ID & date of submission	(U7L-W7D-3H3Q, 2024-11-20)
Detail of Fee Submitted	300000.0, 2024-09-30,
The proposed proprietary name / brand name	FOLISURGE 300 [Recombinant Human Follicle Stimulating Hormone (Follitropin Alfa) Solution for Injection 300 IU/0.48 mL] Pre-filled Cartridge
Label Claim	Each multi-dose pre-filled cartridge contains: r-Hu FSH (Follitropin Alfa) 300 IU/0.48 mL
Reference to Finished product specifications	Manufacturer Specification
Proposed Pack Size	Multi-dose pre-fille-As per SRO
Shelf Life (Unit)	24 Month(s)Store between 2°C to 8°C
For generic drugs (me-too Status)	Brand name: Gonal-f Pen 300 IU (22ug)/0.5ml Solution for Injection, Reg no. – 0103993, Composition: Recombinant Human Follicle Stimulating Hormone 300 IU, Registration holder: Martin Dow Specialities
Pharmacotherapeutic Group of (API)	Gonadotropins Code ATC: G03GA05
Name, address of Manufacturing site:	Intas Pharmaceuticals Limited-Plot No. 423/P/A, Sarkhej-Bavla Highway, Village- Moraiya, Taluka-Sanand, Dist. Ahmedabad – 382213. Gujarat State, India.-India
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
Name, address of Marketing Authorization Holder:	Intas Pharmaceuticals Limited, Plot No. 423/P/A, Sarkhej-Bavla Highway, Village- Moraiya, Taluka-Sanand, Dist. Ahmedabad – 382213. Gujarat State, India., India
Details of Certificates (CoPP/FSC/cGMP):	Firm has attached CoPP (MFG/WHO-COPP/INTAS/2023/009754) valid up to 10-03-2025 issued by Food & Drugs Control Administration, Gujrat State, India attested by Ministry of Foreign Affairs. The CoPP specifies that the product is licensed to be placed for u
Details of Authorization Letter :	Firm has submitted notarized copy of Letter of Authorization The letter was issued on February 29th, 2024 and valid for five (5) years from the date of signature.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data on Following batches of drug substance: Stability Study – R&D Batches: Batch no. P7-CB-D01, P7-CB-D02 and P7-CB-D03 Real Time Stability: The intended storage condition of -20°C ± 5°C for 18 months. Accelerated Stability: The accelerated condition of 5 °C ± 3 °C for 6 months. Stressed Stability: The stressed condition of 25°C ± 2°C for 15 days. Stability Study – Clinical Trial Batch: Batch no. P7- BM-CT- 0001 Real Time Stability: At -20 °C ± 5 °C for 18 Months. Accelerated Stability: The accelerated condition of 5 °C ± 3 °C for 6 Months. Stressed Stability: The stressed condition of 25 °C ± 2 °C for 15 Days. An

	18 months shelf life is proposed for Intas rHu FSH Drug Substance at the intended storage condition of -20°C ± 5°C.
The status in reference regulatory authorities	RRA: European Medicine Agency, Brand name: GONAL-f®, Composition: Each pre-filled multidose pen contains 300 IU (equivalent to 22 micrograms) of follitropin alfa* in 0.48 mL solution Recombinant human follicle stimulating hormone, Marketing Authorization no. in EU EU/1/95/001/033, Manufacturer/Registration holder: Merck Serono S.p.A, Italy/Merck Specialties Pvt. Ltd, Pack Size 1 pre-filled pen+8 needles

Evaluation Remarks

Sr.No.	Decision of 345th meeting	Remarks	Evaluation
1	Address of manufacturer and Marketing Authorization Holder in LOA is different from that in COPP.	The address in LOA is of our Corporate (Head) office. Whereas in COPP it's of plant. Because COPP is product and plant specific.	-
2	Finished product specifications in the light of 267th meeting of the Registration Board and in the light of "Guidance document regarding application of drug product specifications" conveyed vide Letter No. 9- 2/2022-PEC dated 18-12-2023 is required	Applicant acknowledges agency's comment. Applicant would like to clarify that no official monograph for FSH is currently available in the USP or the European Pharmacopoeia. Moreover, the product is not approved in the Reference Regulatory Authorities mentioned on the "Guidance Document Regarding Application of Drug Product Specifications". The provided specification is based on currently available batch release and stability data.	-
3	Compatibility studies with excipients is not provided although excipients are different from reference product Gonal-F.	Applicant acknowledges agency's comment. Applicant would like to clarify that the formulation of Reference Medicinal Product (Multidose Gonal-f® Injection in Pen) being patent, protected, cannot be used in the in-house product. Intas rHu FSH drug product is developed as a non-infringing formulation. Excipients are different from innovator's recipe and their quantities are selected on the basis of a number of experiments carried out during the screening study for no infringing formulation development. To develop the new formulation, an extensive study was conducted to select new sets of excipients which make the formulation stable and non-infringing. Different sets of excipients were tried to make the formulation stable physically,	Container closure compatibility attached.

		chemically as well as physiologically, and the composition was finalized on the basis of accelerated and stress studies of selected formulation. Compatibility Study: Container closure compatibility study of Intas rHu FSH (Follitropin alfa) drug product was carried out with prefilled cartridge. The study was carried out using USP Type-I Glass cartridges and rubber plungers having different MOCs (Chlorobutylated and Bromobutylated) and lined seals. This study was carried for 30 days at real time ($5^{\circ}\text{C} \pm 3^{\circ}\text{C}$) and accelerated conditions ($25^{\circ}\text{C} \pm 2^{\circ}\text{C}$) and for 15 days at stress condition ($40^{\circ}\text{C} \pm 2^{\circ}\text{C}$). The following analytical tests were performed to confirm the compatibility of the container closure with the drug product: • Physical appearance • pH • Osmolality • Protein Concentration • Purity determination by RP-HPLC • Oligomer determination by SE-HPLC • Free protein subunits determination by SDS PAGE.	
4	Firm has informed that stability studies of drug product in final container are on-going. Stability data of drug product in final container till claimed shelf life is required.	Applicant acknowledges agency's comment. Stability data is enclosed as Annexure 1.	Stability of drug substance attached. Stability data of drug product is still not provided.
5	Potency testing by in-vivo bioassay is outsource (by M/s BIONEEDS (GLP Certified) Devarahosally, Sompura Hobli, Nelamangala Taluka, Bangalore Rural District). Details of the agreement with the other party and testing method and validation is required.	Applicant acknowledges agency's comment. The agreement with the BIONEEDS (GLP Certified) Davarahosally, Sompura Hobli, Nelamangala Taluka, Bangalore Rural District) is enclosed as Annexure 4.	Only template attached. Contract/agreement for Potency testing is not provided.
6	The finished product manufacturer does not have biological section as per GMP certificate. Clarification required.	Applicant acknowledges agency's comment. Please be noted that the GMP certificate has classification according to the dosage form (Tablet, Capsule – Hard & soft, Oral Liquids, Injection- Lyo, Parenteral – Liquid vial, prefilled syringe etc.)	SVP (rDNA) is mentioned in GMP certificate.

7	Phase III clinical trial is open label while Double-blind trials are recommended by the guidelines. Provide justification in the reference of guidelines of not performing double blind Phase III clinical trial.	Not provided.	No response submitted.
8	The firm has not performed following in Biosimilarity studies; · Comparative structural and functional characterization with the Reference product. · Comparative in vitro bioassays for receptor affinity and activation. · Comparative in-vivo potency. · Impurity testing (product related and process related). · Comparative Toxicology studies (single dose and repeat dose). · Immunogenicity in efficacy studies using validated antibody assays of adequate sensitivity and specificity.	Applicant acknowledges agency's comment. Applicant would like to clarify that the complete bio similarity studies are provided in the section 3.2.R.1 and in the module 5. However, we are resubmitting the sections in Annexure 3	Firm has submitted following; Intas follitropin alfa drug substance and drug product lots have been compared with Gonal-f for their structural properties, product related impurities and biological activity. Both the products have identical primary structure, and show high similarity in their secondary and tertiary structures, as demonstrated by peptide mapping, western blot, CD and fluorescence analysis. Product related impurities like oligomers, dissociated subunits and oxidized follitropin alfa were studied using SE HPLC, SDS PAGE and RP HPLC. Impurities present in Intas follitropin alfa DS and DP lots were same as that observed in all three lots of Gonal-f. No new impurities were observed in Intas follitropin alfa. Sialylation was studied using IEF. The isoform distribution in both the products is highly comparable. Moles of sialic acid per mole of follitropin alfa in both the products are also comparable. Biological activity of both the products was compared using an in-vitro and an in-vivo assay. In in-vivo assay, Intas follitropin lots showed potency 100 % against Gonal-JID. In invitro assay, both the products showed comparable activity when tested against NIBSC standard. Overall, both the products show high similarity in terms of their structures, sialylation, impurities and biological efficacy. Drug product used in comparative

studies is not mentioned whether it is prefilled pen or otherwise.

Concluding remarks: Following is still required from the applicant: · Stability data of applied product till claimed shelf life. · Contract/agreement with third party for Potency testing including method of testing and its validation. · Evidence of approval of cartridge/pre-filled pen section by manufacturer. · Data of comparative toxicology and phase 3 clinical trial studies with the innovator. · Clarification of the drug product used in quality comparison of the applied product with the innovator, whether pre-filled pen or otherwise.

Decision

Deferred

Registration Board deferred the case and grant final opportunity to the applicant for submission of following documents/ clarifications;

- Stability data of applied product till claimed shelf life.
- Contract/agreement with third party for Potency testing including method of testing and its validation.
- Approval of cartridge/pre-filled pen manufacturing facility by manufacturer.
- Data of comparative toxicology and phase 3 clinical trial studies with the innovator.
- Clarification of the drug product, whether pre-filled pen or otherwise, used in quality comparison of the applied product with the innovator.

29	Case Category	New Section (Anam Saeed)
	Name, address of Applicant.	Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (000644)
	Application Form Dy. No / Tracking ID & date of submission	(RPA-HR8-A6Y6, 2025-09-03)
	Detail of Fee Submitted	75000.0, 2025-07-26,
	The proposed proprietary name / brand name	TERZA 2.5MG/0.5ML Injection in PreFilled Pen
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....2.5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 2-8°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Hangzhou Patience Chemical Co., Ltd. Address: No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, Hangzhou, ZheJiang, China.
	Detail of stability batches of drug product	Stability is performed at Real condition 5°C + 3°C and Accelerated condition 25°C + 2°C, 60%+5 % RH conditions for Batch#T-19, T-20, T-21 for 6 months.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm informed that "We have imported this material directly and intimated DRAP about this via tracking ID TVQ-HWDJ1WU dated 3rd June, 2025 with the

	undertaking that we shall not import any further material without acquiring DRAP Clearance Certificate. "
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies were performed on Batch# P20210915, P20210608 and P20210706 under accelerated conditions till 6 months and long term conditions till 24 months.
The status in reference regulatory authorities	Mounjaro, EMA Approved
GMP status of the firm	Not provided
Evidence of approval of manufacturing facility	Biological non-rDNA Liquid Injection vial and PFS (new) section granted on 25th June,2025.

Evaluation Remarks

The application was evaluated and some shortcomings were communicated to the applicant. The applicant submitted reply and addressed all queries. However, in comparative data with innovator, impurity testing is not performed and raw data and chromatograms of comparative testing is not provided. Separate impurities are not performed in stability data of drug product also.

Decision

Deferred

Registration Board deferred the case for submission of following documents/ clarifications;

- Impurity profiling was not performed in comparative testing of applied product with innovator
- Raw data and chromatograms supporting the complete comparative testing is required.
- Impurity testing is not performed in stability studies of applied product.

30

Case Category	New Section (Anam Saeed)
Name, address of Applicant.	Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (000644)
Application Form Dy. No / Tracking ID & date of submission	(G2P-NY2-VAGJ, 2025-09-03)
Detail of Fee Submitted	75000.0, 2025-07-26,
The proposed proprietary name / brand name	Terza 5mg/0.5ml Single Dose Prefilled Pen
Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....5mg (Product complies Innovator's Specs)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 Year(s)Store at 2-8°C
For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Hangzhou Patience Chemical Co., Ltd. Address: No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, Hangzhou, ZheJiang, China.
Detail of stability batches of drug product	Stability is performed at Real condition 5°C + 3°C and Accelerated condition 25°C + 2°C, 60%+5 % RH conditions on 3 batches for 6 months.
Documents for the procurement of API with approval from DRAP	The firm informed that "We have imported this material directly and intimated DRAP about this via tracking ID

(in case of Import)	TVQ-HWDJ1WU dated 3rd June, 2025 with the undertaking that we shall not import any further material without acquiring DRAP Clearance Certificate".
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies were performed on Batch# P20210915, P20210608 and P20210706 under accelerated conditions till 6 months and long term conditions till 24 months.
The status in reference regulatory authorities	Mounjaro, EMA Approved
GMP status of the firm	Not provided
Evidence of approval of manufacturing facility	Biological non-rDNA liquid Injection vial and PFS (new) section granted on 25th June,2025.

Evaluation Remarks

The application was evaluated, and certain shortcomings were communicated to the applicant. In response, the applicant submitted a reply addressing all the raised queries. However, the following issues remain unresolved: 1. Comparative Testing with Innovator: o Impurity profiling was not performed in the comparative data with the innovator product. o Raw data and chromatograms supporting the comparative testing have not been provided. 2. Stability Data: o Separate impurity profiling has not been performed in the stability studies of the drug product.

Decision

Deferred

Registration Board deferred the case for submission of following documents/ clarifications;

- Impurity profiling was not performed in comparative testing of applied product with innovator
- Raw data and chromatograms supporting the complete comparative testing is required.
- Impurity testing is not performed in stability studies of applied product.

31	Case Category	New Section (Anam Saeed)
	Name, address of Applicant.	Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (000644)
	Application Form Dy. No / Tracking ID & date of submission	(GVA-T83-EH1N, 2025-09-03)
	Detail of Fee Submitted	75000.0, 2025-07-26,
	The proposed proprietary name / brand name	Terza 7.5mg/0.5ml Single Dose Prefilled Pen
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....7.5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Hangzhou Patience Chemical Co., Ltd. Address: No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, Hangzhou, ZheJiang, China.
	Detail of stability batches of drug product	Stability is performed at Real condition 5°C + 3°C and Accelerated condition 25°C + 2°C, 60%+5 % RH

	conditions on 3 batches for 6 months.
Documents for the procurement of API with approval from DRAP (in case of Import)	The firm informed that "We have imported this material directly and intimated DRAP about this via tracking ID TVQ-HWDJ1WU dated 3rd June, 2025 with the undertaking that we shall not import any further material without acquiring DRAP Clearance Certificate".
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies were performed on Batch# P20210915, P20210608 and P20210706 under accelerated conditions till 6 months and long term conditions till 24 months
The status in reference regulatory authorities	Mounjaro, EMA Approved
GMP status of the firm	Not provided
Evidence of approval of manufacturing facility	Biological non-rDNA Liquid Injection vial and PFS (New) section granted on 25th June 2025.

Evaluation Remarks

The application was evaluated, and certain shortcomings were communicated to the applicant. In response, the applicant submitted a reply addressing all the raised queries. However, the following issues remain unresolved: 1. Comparative Testing with Innovator: o Impurity profiling was not performed in the comparative data with the innovator product. o Raw data and chromatograms supporting the comparative testing have not been provided. 2. Stability Data: o Separate impurity profiling has not been performed in the stability studies of the drug product.

Decision

Deferred

Registration Board deferred the case for submission of following documents/ clarifications;

- i. Impurity profiling was not performed in comparative testing of applied product with innovator
- ii. Raw data and chromatograms supporting the complete comparative testing is required.
- iii. Impurity testing is not performed in stability studies of applied product.

32	Case Category	New Section (Anam Saeed)
	Name, address of Applicant.	Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (000644)
	Application Form Dy. No / Tracking ID & date of submission	(7QB-9P2-V7N5, 2025-09-03)
	Detail of Fee Submitted	75000.0, 2025-07-26,
	The proposed proprietary name / brand name	Terza 10mg/0.5ml Single Dose Prefilled Pen
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....10mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Hangzhou Patience Chemical Co., Ltd. Address: No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, (23rd – 24th September, 2025)

	Hangzhou, ZheJiang, China.
Detail of stability batches of drug product	Stability is performed at Real condition 5°C + 3°C and Accelerated condition 25°C + 2°C, 60%+5 % RH conditions on 3 batches for 6 months.
Documents for the procurement of API with approval from DRAP (in case of Import)	The firm informed that "We have imported this material directly and intimated DRAP about this via tracking ID TVQ-HWDJ1WU dated 3rd June, 2025 with the undertaking that we shall not import any further material without acquiring DRAP Clearance Certificate".
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies were performed on Batch# P20210915, P20210608 and P20210706 under accelerated conditions till 6 months and long term conditions till 24 months.
The status in reference regulatory authorities	EMA Approved
GMP status of the firm	Not provided
Evidence of approval of manufacturing facility	Not provided
Evaluation Remarks	
The application was evaluated, and certain shortcomings were communicated to the applicant. In response, the applicant submitted a reply addressing all the raised queries. However, the following issues remain unresolved: 1. Comparative Testing with Innovator: o Impurity profiling was not performed in the comparative data with the innovator product. o Raw data and chromatograms supporting the comparative testing have not been provided. 2. Stability Data: o Separate impurity profiling has not been performed in the stability studies of the drug product.	
Decision	
Deferred	
Registration Board deferred the case for submission of following documents/ clarifications;	
i. Impurity profiling was not performed in comparative testing of applied product with innovator	
ii. Raw data and chromatograms supporting the complete comparative testing is required.	
iii. Impurity testing is not performed in stability studies of applied product.	
33	Case Category
	New Section (Anam Saeed)
	Name, address of Applicant.
	Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (000644)
	Application Form Dy. No / Tracking ID & date of submission
	(TRE-6JL-P6J7, 2025-09-03)
	Detail of Fee Submitted
	75000.0, 2025-07-26,
	The proposed proprietary name / brand name
	Terza 12.5mg/0.5ml Single Dose Prefilled Pen
	Label Claim
	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....12.5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications
	As per Innovators Specification
	Proposed Pack Size
	As per SRO-As per SRO
	Shelf Life (Unit)
	2 Year(s) Store at 2-8°C
	For generic drugs (me-too Status)
	N/A
	Pharmacotherapeutic Group of (API)
	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:
	Self Manufacturing

Name & address of API manufacturer	Hangzhou Patience Chemical Co., Ltd. Address: No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, Hangzhou, ZheJiang, China.
Detail of stability batches of drug product	Stability is performed at Real condition 5°C + 3°C and Accelerated condition 25°C + 2°C, 60%+5 % RH conditions on 3 batches for 6 months.
Documents for the procurement of API with approval from DRAP (in case of Import)	The firm informed that "We have imported this material directly and intimated DRAP about this via tracking ID TVQ-HWDJ1WU dated 3rd June, 2025 with the undertaking that we shall not import any further material without acquiring DRAP Clearance Certificate".
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies were performed on Batch# P20210915, P20210608 and P20210706 under accelerated conditions till 6 months and long term conditions till 24 months.
The status in reference regulatory authorities	Mounjaro of M/s Eli Lilly (EMA Approved)
GMP status of the firm	Not provided
Evidence of approval of manufacturing facility	Biological non-rDNA Liquid Injection vial and PFS (New) section granted on 25th June 2025.
Evaluation Remarks	
The application was evaluated, and certain shortcomings were communicated to the applicant. In response, the applicant submitted a reply addressing all the raised queries. However, the following issues remain unresolved: 1. Comparative Testing with Innovator: o Impurity profiling was not performed in the comparative data with the innovator product. o Raw data and chromatograms supporting the comparative testing have not been provided. 2. Stability Data: o Separate impurity profiling has not been performed in the stability studies of the drug product.	
Decision	
Deferred	
Registration Board deferred the case for submission of following documents/ clarifications;	
i. Impurity profiling was not performed in comparative testing of applied product with innovator	
ii. Raw data and chromatograms supporting the complete comparative testing is required.	
iii. Impurity testing is not performed in stability studies of applied product.	
34	Case Category
	New Section (Anam Saeed)
	Name, address of Applicant.
	Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (000644)
	Application Form Dy. No / Tracking ID & date of submission
	(LMV-YTQ-JHDS, 2025-09-03)
	Detail of Fee Submitted
	75000.0, 2025-07-26,
	The proposed proprietary name / brand name
	Terza 15mg/0.5ml Single Dose Prefilled Pen
	Label Claim
	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....15mg (Product complies Innovator's Specs)
	Reference to Finished product specifications
	As per Innovators Specification
	Proposed Pack Size
	As per SRO-As per SRO
	Shelf Life (Unit)
	2 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)
	N/A

Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Hangzhou Patience Chemical Co., Ltd. Address: No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, Hangzhou, ZheJiang, China.
Detail of stability batches of drug product	Stability is performed at Real condition 5°C + 3°C and Accelerated condition 25°C + 2°C, 60%+5 % RH conditions on 3 batches for 6 months.
Documents for the procurement of API with approval from DRAP (in case of Import)	The firm informed that "We have imported this material directly and intimated DRAP about this via tracking ID TVQ-HWDJ1WU dated 3rd June, 2025 with the undertaking that we shall not import any further material without acquiring DRAP Clearance Certificate".
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies were performed on Batch# P20210915, P20210608 and P20210706 under accelerated conditions till 6 months and long term conditions till 24 months.
The status in reference regulatory authorities	Mounjaro, EMA Approved
GMP status of the firm	Not provided
Evidence of approval of manufacturing facility	Biological non-rDNA Liquid Injection vial and PFS (New) section granted on 25th June 2025.

Evaluation Remarks

The application was evaluated, and certain shortcomings were communicated to the applicant. In response, the applicant submitted a reply addressing all the raised queries. However, the following issues remain unresolved: 1. Comparative Testing with Innovator: o Impurity profiling was not performed in the comparative data with the innovator product. o Raw data and chromatograms supporting the comparative testing have not been provided. 2. Stability Data: o Separate impurity profiling has not been performed in the stability studies of the drug product.

Decision

Deferred

Registration Board deferred the case for submission of following documents/ clarifications;

- Impurity profiling was not performed in comparative testing of applied product with innovator
- Raw data and chromatograms supporting the complete comparative testing is required.
- Impurity testing is not performed in stability studies of applied product.

35	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	ASTER LIFE SCIENCES 32-BABAR BLOCK NEW GARDEN TOWN LAHORE (05352006501)
	Application Form Dy. No / Tracking ID & date of submission	(SLD-AH4-AH96, 2025-06-28)
	Detail of Fee Submitted	75000.0, 225000.0 2024-09-20, 2024-10-30
	The proposed proprietary name / brand name	Lutrisa 40mg/0.8mL Injection
	Label Claim	Each 0.8ml PFS contains: Adalimumab.....40mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	0.8ML PFS-Controlled

Shelf Life (Unit)	24 Month(s)2-8°C
For generic drugs (me-too Status)	Dalimab
Pharmacotherapeutic Group of (API)	Monoclonal Antibody
Name, address of Manufacturing site:	Bio-Thera Solutions Ltd.-155 Yaotianhe Avenue, Yonghe Development Zone, Huangpu District, Guangzhou, Guangdong, China. -China
Pharmaceutical Equivalence and Comparative Dissolution Profile	Biosimilarity data submitted.
Name, address of Marketing Authorization Holder:	Bio-Thera Solutions Ltd., 155 Yaotianhe Avenue, Yonghe Development Zone, Huangpu District, Guangzhou, Guangdong, China. , China
Details of Certificates (CoPP/FSC/cGMP):	Copy of legalized CoPP No. Guangdong20230106 valid till 07-05-2025.
Details of Authorization Letter :	Not Provided.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: 02S20221204, 02S20230101, 02S20230202 Conditions: Real time at -60C & Accelerated at 2C-8C Batch Size: 3000L
The status in reference regulatory authorities	USFDA
Evaluation Remarks	
The firm has submitted following biosimilarity data:	
Quality Comparison	Primary Structure: · Molecular weight by LC-MS · Peptide mapping by RP-HPLC · Peptide mapping by LC-MS/MS · cISO Electric Focusing' Higher order structure · Disulfide bond by LC-MS/MS · Free thiol (Ellman method) · CD (Circular dichroism) · DSC (Differential scanning Evaluation of thermal stability and determination of calorimetry) · FTIR (Fourier transform infrared spectroscopy) Particles & Aggregates · Sub-visible particles (Light-obscuration method, HIAC) · SEC-MALS · DLS Product related Substances and Impurities · SEC-HPLC* · Reduced CE-SDS · Non-reduced CE-SDS · IEC-HPLC · RP-HPLC · HIC-HPLC Glycosylation · Glycosylation site (LC-MS) · Glycans (HILIC-HPLC) · Sialic acid analysis (HPLC) General Properties · Protein concentration (UV280) · The content of polysorbate 80 (UV) · pH Process Related Impurities · Residual host cell protein (ELISA) · Residual host cell DNA (qPCR)
Potency & Binding	Fab-related Biological Activity · Binding to soluble TNFa (sTNFa) (ELISA) · Binding kinetics to soluble TNFa (SPR) · Binding to transmembrane-TNFa (tmTNFa) Cell-Based ELISA · TNFa neutralizing activity (L929 cells) · Apoptosis inhibition (U-937 cells) Fc Binding Affinity · C I q binding affinity (BLI) · FcRn binding affinity (BLI) · FcyR1a binding affinity (SPR) · FcyR11a(131H) (BLI) · FcyR11a (13 IR) binding affinity (BLI) · FcyR11b binding affinity (BLI) · FcyR11a (158V) binding affinity (BLI) · FcyR11a (158F) binding affinity (BLI) Fab and Fc-related Biological Activity · ADCC using tmTNFa-overexpressing CHO as target cells (tmTNFa ex ressession level, ~ 80% · ADCC using tmTNFa-overexpressing Jurkat as target cells (tmTNFa ex ressession level, ~ 20% · ADCC using tmTNFa-overexpressing Jurkat as target cells (tmTNFa ex ressession level, ~ 2% · ADCC using LPS-stimulated PBMCs from healthy donors as target cells · CDC (Cell-based assay)
Non-Clinical	· In Vitro Hemolysis Test of BAT1406 with Human Red Blood Cells Study Number: O17-S135-2HE · Evaluation of the efficacy of Biothera test article 1406 in preventing arthritic symptoms in the Tg197 transgenic mouse model of arthritis · Test of the effects of the test drug 1406 on the death rate of D-galactose sensitized mice · Test of the effects of the test drug 1406 on the rabbit model of rhTNF-α induced fever · Pharmacokinetic Study of BAT1406 Injection After A Single Subcutaneous Injection Tocynomolgus Monkeys ·

Clinical	A randomized, double-blind, single-dose, three-group parallel (i.e., adalimumab biosimilar BAT1406 A2 injection, adalimumab biosimilar BAT1406 B3 injection, and adalimumab injection) comparative study to compare their pairwise PK similarity as well as their safety, tolerability and immunogenicity in healthy Chinese males. Study of efficacy and safety of BAT1406 in Patients with active ankylosing spondylitis

Remarks: The brand mentioned on submitted CoPP is Qleti while the firm has submitted Lutrisa. Hence, NOC from manufacturer abroad is required for proposed brand name. The CoPP is expired. Hence, valid COPP is required. Letter of Authorization is not provided.

Decision

Approved

Keeping in view COPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs subject to submission of following by the firm:

1. NOC from manufacturer abroad for proposed brand name "Lutrisa".
2. Valid Legalized CoPP.
3. Valid legalized Letter of Authorization.

36	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	QAS INTERNATIONAL PLOT # 153/155, MUSTAFA ABAD TEHSIL KAMOKE (09-341-0134)
	Application Form Dy. No / Tracking ID & date of submission	(XY4-49A-ZEVL, 2025-03-28)
	Detail of Fee Submitted	300000.0, 2025-03-05,
	The proposed proprietary name / brand name	Dou Jing
	Label Claim	Each dose contains; Attenuated goat pox virus strain (CVCC AV41 Strain)...NLT 10 ^{3.5} TCID ₅₀
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	50 ANIMALS/VIAL-De-Controlled
	Shelf Life (Unit)	18 Month(s)Store at 2 ~ 8°C
	For generic drugs (me-too Status)	Not registered
	Pharmacotherapeutic Group of (API)	Veterinary Viral Vaccine
	Name, address of Manufacturing site:	BEIJING SINDER-VET TECHNOLOGY CO, LTD- N0.118, SHUNYU ROAD, BEIJING TIANZHU AIRPORT ECONOMIC DEVELOPMENT ZONE SHUNIYE DISTRICT, BEIJING-China
	Name, address of Marketing Authorization Holder:	BEIJING SINDER-VET TECHNOLOGY CO., LTD, N0.118, SHUNYU ROAD, BEIJING TIANZHU AIRPORT ECONOMIC DEVELOPMENT ZONE SHUNIYE DISTRICT, BEIJING , China
	Details of Certificates (CoPP/FSC/cGMP):	Valid legalized FSC has been submitted. Valid legalized GMP certificate of manufacturer has been submitted.
	Details of Authorization Letter :	LOA from MAH has been submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies data of three batches has been submitted.

Evaluation Remarks

Registration Board in its 349th meeting decided as follows: "The Registration Board referred the case to Expert Working Group on veterinary drugs for opinion regarding immunological relevance and need of applied product in

Pakistan."Sub-Committee on Veterinary Drugs in its 6th meeting recommended the vaccine for grant of Registration.

Decision

Approved

Keeping in view FSC indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.

37	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Dairy heed Pakistan(pvt)Ltd 169 Ahmad block new Garden town Lahore (05-352-0065)
	Application Form Dy. No / Tracking ID & date of submission	(LNQ-84G-SY3D, 2025-06-19)
	Detail of Fee Submitted	300000.0, 2025-06-18,
	The proposed proprietary name / brand name	Bavtox Foot and Mouth Disease Vaccine, Bivalent
	Label Claim	Each dose contains: Foot and Mouth Disease Bivalent (Type O and A) vaccine, Inactivated (strain O/MYA98/BY/2010 + strain Re-A/WH/09).....≥ 6PD50 .
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	50ml bottle -De-Controlled
	Shelf Life (Unit)	24 Month(s)2-8°C
	For generic drugs (me-too Status)	none
	Pharmacotherapeutic Group of (API)	Inactivated Veterinary Vaccine
	Name, address of Manufacturing site:	Shanghai Shen Lian Biomedical Corporation Lanzhou - No. 2398, Middle Section of Kunlunshan Avenue,Lanzhou New Area, Lanzhou City, Gansu Province-China
	Name, address of Marketing Authorization Holder:	Shanghai Shen Lian Biomedical Corporation Lanzhou , No. 2398, Middle Section of Kunlunshan Avenue,Lanzhou New Area, Lanzhou City, Gansu Province, China
	Details of Certificates (CoPP/FSC/cGMP):	Copy of Apostille FSC dated 07-01-2025 valid for 03 years Copy of Apostille GMP No. (2021) GMP 28002 dated 17-11-2023 valid till 25-05-2026
	Details of Authorization Letter :	Copy of Apostille Letter of Authorization.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches (220801 , 220802 , 220803J) at 2-8C for 24 months
	Evaluation Remarks	
	Sub-Committee on veterinary Drugs in its 6th meeting decided as follows:"The Committee deliberated that in Pakistan, trivalent FMD vaccine is required and there is no need of bivalent vaccine, hence, registration is not recommended."	
	Decision	
	Rejected	
	Keeping in view the recommendation of Sub-Committee on Veterinary Drugs; Registration Board rejected the application.	
38	Case Category	Routine (M. Zubair Masood)

Name, address of Applicant.	Dairy heed Pakistan(pvt)Ltd 169 Ahmad block new Garden town Lahore (05-352-0065)
Application Form Dy. No / Tracking ID & date of submission	(Z1E-4E7-JZ9W, 2025-06-19)
Detail of Fee Submitted	300000.0, 2025-06-18,
The proposed proprietary name / brand name	CavtoVax Foot & Mouth Disease Vaccine
Label Claim	Each dose contains Foot and mouth disease trivalent vaccine, inactivated (strain O/MYA98/BY/2010 +Asia1/JSL/ZK/06+Re-A/WH/09) antigen ≥ 6 PD50
Reference to Finished product specifications	Any Other
Proposed Pack Size	50ml bottle -De-Controlled
Shelf Life (Unit)	24 Month(s)2-8°C
For generic drugs (me-too Status)	aftovaxpur
Pharmacotherapeutic Group of (API)	Inactivated Viral Vaccine
Name, address of Manufacturing site:	China Agricultural Veterinary Biological Science a-Xujiaping 1#,Chengguan District, Lanzhou City,Gansu Province -China
Name, address of Marketing Authorization Holder:	Dairy Heed Pakistan (Private) Limited, 169, Ahmad Block, New Garden Town, Lahore, Pakistan, Pakistan
Details of Certificates (CoPP/FSC/cGMP):	Copy of Apostille FSC dated 27-02-2025 valid for 03 years Copy of Apostille GMP No. (2022) GMP 28001 dated 16-02-2022 valid till 15-02-2027
Details of Authorization Letter :	Copy of Apostille Letter of Authorization.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches (M210301J , M180202J , M180303J) at 2-8C for 24 months

Evaluation Remarks

The applied product is not on Free Sale in country of origin as the firm submitted the following:"From July 1 , 2018 , immunization against Asian type 1 foot-and-mouth disease will be suspended nationwide , and the production and sale of vaccines containing Asian type 1 foot-and-mouth disease virus components will be stopped"Moreover, the case was placed in 6th meeting of Sub-Committee on veterinary drugs and following was decided:"The Committee recommended to ask the firm to submit immunological relevance & need of applied strains for Pakistan."

Decision

Approved

Keeping in view FSC indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs subject to submission of Immunological relevance of applied strain & their need for Pakistan and recommendations of Sub-Committee on Veterinary Drugs on provided relevance and need.

39	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Vetline International 939-A, Block-J, Phase-1, LDA Avenue-1, Lahore (05-352-0066)
	Application Form Dy. No / Tracking ID & date of submission	(2YW-DU7-7JN9, 2024-07-23)
	Detail of Fee Submitted	300000.0, 2024-07-22,
	The proposed proprietary name / brand name	Biocan Novel Puppy, lyophilisate and solvent for suspension for injection for dogs
	Label Claim	Each dose (1 ml) contains: Lyophilisate: Canine Distemper virus, strain CDV Bio 11/A 10 ^{4.1} TCID ₅₀ min.

	10 ^{5.5} TCID _{max} , Canine Parvovirus type 2b, strain CPV-2b Bio 12/B 10 ^{5.5} TCID _{min} . 10 ^{7.0} TCID _{max} . Solvent: Water for injection 1 ml
Reference to Finished product specifications	Manufacturer Specification
Proposed Pack Size	1ml x 10-De-Controlled
Shelf Life (Unit)	2 Year(s)2-8°C
For generic drugs (me-too Status)	Not registered
Pharmacotherapeutic Group of (API)	Veterinary Vaccine
Name, address of Manufacturing site:	M/s Bioveta, a.s.-Komenskeho 212/12, Ivanovice na Hané Czech Republic-Czechia
Name, address of Marketing Authorization Holder:	M/s Bioveta, a.s., Komenskeho 212/12, Ivanovice na Hané Czech Republic, Czechia
Details of Certificates (CoPP/FSC/cGMP):	Valid Legalized CoPP has been submitted.
Details of Authorization Letter :	Legalized POA from MAH has been submitted.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies data of three batches has been submitted.
Evaluation Remarks	
Registration Board in its 347th meeting decided as follows:"The Registration Board endorsed the recommendations of sub-committee on veterinary drugs and deferred the case for the opinion of M/o National Food Security & Research regarding immunological relevance and need of applied product in Pakistan."The application was considered in 6th meeting of Sub-Committee on Veterinary Drugs wherein vaccine was recommended for grant of registration.	
Decision	
Approved	
Keeping in view recommendation of Sub-Committee on Veterinary Drugs and COPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
40	Case Category
	Routine (M. Zubair Masood)
	Name, address of Applicant.
	HI TECH PHARMACEUTICALS I-C SHADMAN CHOWK JAIL ROAD LAHORE (037052D)
	Application Form Dy. No / Tracking ID & date of submission
	(49Y-BWQ-33N6, 2024-07-03)
	Detail of Fee Submitted
	300000.0, 2024-06-14,
	The proposed proprietary name / brand name
	Polimun ND EDS IB MAX
	Label Claim
	Each 0.5 ml dose contains: Inactivated Newcastle disease virus, strain La-Sota - $\geq 4,5 \log_2$ HI*; Inactivated Egg drop syndrome virus, strain EDS-76 - $\geq 7,0 \log_2$ HI. Inactivated Avian infectious bronchitis virus strain M-41(group Massachusetts) - $\geq 5,0 \log_2$ HI; strain BK-07 (group 793B) - $\geq 4,0 \log_2$ HI; strain VAR2/V2 (group VAR2) - $\geq 4,0 \log_2$ HI. * HI – antibody titer determined in HAI.1000 dose vial in pack size of 10 x 1000 doses vials.
	Reference to Finished product specifications
	Manufacturer Specification
	Proposed Pack Size
	1000 dose vial in pa-De-Controlled
	Shelf Life (Unit)
	24 Month(s)2-8°C
	For generic drugs (me-too Status)
	Not registered
	Pharmacotherapeutic Group of (API)
	Veterinary Vaccine

	Name, address of Manufacturing site:	M/s “BIOTESTLAB” LLC-Legal address: 57-A Volodymyrska St., Vasylkiv, Kyiv Region, 08600, Ukraine-Ukraine M/s “BIOTESTLAB” LLC-Manufacturing site: 1/3, Listrovoho Oleksandra St., Vasylkiv, Obukhiv District, Kyiv Region, 08600, Ukraine-Ukraine
	Name, address of Marketing Authorization Holder:	M/s “BIOTESTLAB” LLC, Legal address: 57-A Volodymyrska St., Vasylkiv, Kyiv Region, 08600, Ukraine, Ukrain
	Details of Certificates (CoPP/FSC/cGMP):	Valid Legalized FSC & GMP has been submitted.
	Details of Authorization Letter :	Legalized Distribution Agreement from MAH is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies data of three batches has been submitted.
	Evaluation Remarks	
	Registration Board in its 347th meeting decided as follows:The Registration Board deferred the case for the opinion of M/o National Food Security & Research regarding immunological relevance and need of applied product in Pakistan.Sub-Committee on Veterinary Drugs in its 6th meeting recommended the product for grant of registration.	
	Decision	
	Approved	
	Keeping in view recommendation of Sub-Committee on Veterinary Drugs and FSC indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
41	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Vetline International 939-A, Block-J, Phase-1, LDA Avenue-1, Lahore (05-352-0066)
	Application Form Dy. No / Tracking ID & date of submission	(BMV-JLJ-8VGW, 2024-07-26)
	Detail of Fee Submitted	300000.0, 2024-07-24,
	The proposed proprietary name / brand name	Biofel PCHR emulsion for injection for cats
	Label Claim	Each dose (1ml) contains; Inactivated feline panleucopenia virus, strain FPV Bio 7 RP $\geq 1^*$, Inactivated feline calicivirus, strain FCV F9 Bio 8 RP $\geq 1^*$, Inactivated feline herpesvirus, strain FHV-1 Bio 9 RP $\geq 1^*$, Inactivated Rabies virus, strain SAD Vnukovo-32 min 1 IU
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1ml x 10-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in a refrigerator (2 °C – 8 °C).°C
	For generic drugs (me-too Status)	Not registered
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	Bioveta, a.s.-Komenského 212/12, 683 23 Ivanovice na Hané Czech Republic-Czechia
	Name, address of Marketing Authorization Holder:	Bioveta, a.s., Komenského 212/12, 683 23 Ivanovice na Hané Czech Republic, Czechia
	Details of Certificates (CoPP/FSC/cGMP):	Valid legalized CoPP has been submitted.
	Details of Authorization Letter :	Legalized POA from MAH has been submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies data of three natches has been submiited.

Evaluation Remarks

Registration Board in its 347th meeting decided as follows: The Registration Board endorsed the recommendations of sub-committee on veterinary drugs and deferred the case for the opinion of M/o National Food Security & Research regarding immunological relevance and need of applied product in Pakistan. Sub-Committee on Veterinary Drugs in its 6th meeting recommended the product for grant of registration.

Decision**Approved**

Keeping in view recommendation of Sub-Committee on Veterinary Drugs and COPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.

42

Case Category	Routine (M. Zubair Masood)
Name, address of Applicant.	HI TECH PHARMACEUTICALS I-C SHADMAN CHOWK JAIL ROAD LAHORE (037052D)
Application Form Dy. No / Tracking ID & date of submission	(NGR-T8N-Y2SY, 2024-07-04)
Detail of Fee Submitted	300000.0, 2024-06-14,
The proposed proprietary name / brand name	POLIMUN IB VAR2
Label Claim	Each one dose (1 ml) contains: Avian Infectious Bronchitis virus, strain VAR2/V2 ≥ 3.5 lg EID50 ($\geq 10^{3.5}$ EID50). 2500 doses vial in pack size of 10 x 2500 doses vials.
Reference to Finished product specifications	European Pharmacopeia
Proposed Pack Size	2500 doses vial in p-De-Controlled
Shelf Life (Unit)	24 Month(s) 2-8°C
For generic drugs (me-too Status)	Not Registered.
Pharmacotherapeutic Group of (API)	Veterinary Vaccine
Name, address of Manufacturing site:	M/s "BIOTESTLAB" LLC-Legal address: 57-A Volodymyrska St., Vasylkiv, Kyiv Region, 08600, Ukraine-Ukraine M/s "BIOTESTLAB" LLC-Manufacturing site: 1/3, Listrovoho Oleksandra St., Vasylkiv, Obukhiv District, Kyiv Region, 08600, Ukraine-Ukraine
Name, address of Marketing Authorization Holder:	M/s "BIOTESTLAB" LLC, Legal address: 57-A Volodymyrska St., Vasylkiv, Kyiv Region, 08600, Ukraine, Ukraine
Details of Certificates (CoPP/FSC/cGMP):	Valid Legalized FSC & GMP certificate has been submitted.
Details of Authorization Letter :	Legalized distribution agreement with MAH has been submitted.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies data of three batches has been submitted.

Evaluation Remarks

Registration Board in its 347th meeting decided as follows: The Registration Board endorsed the recommendations of sub-committee on veterinary drugs and deferred the case for the opinion of M/o National Food Security & Research regarding immunological relevance and need of applied product in Pakistan. Sub-Committee on Veterinary Drugs in its 6th meeting recommended the product for grant of registration.

Decision**Approved**

Keeping in view recommendation of Sub-Committee on Veterinary Drugs and FSC indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.

43	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Vetline International 939-A, Block-J, Phase-1, LDA Avenue-1, Lahore (05-352-0066)
	Application Form Dy. No / Tracking ID & date of submission	(V66-TLU-DBVX, 2024-07-23)
	Detail of Fee Submitted	300000.0, 2024-07-11,
	The proposed proprietary name / brand name	Biocan Novel DHPPi/L4R, lyophilizate and suspension for injection for dogs
	Label Claim	Each dose (1 ml) contains: Lyophilisate (live attenuated): Canine Distemper virus, strain CDV Bio 11/A $10^{3.1}$ TCIDmin $10^{5.1}$ TCIDmax, Canine Adenovirus type 2, strain CAV-2 Bio 13 $10^{3.6}$ TCIDmin. $10^{5.3}$ TCIDmax, Canine Parvovirus type 2b, strain CPV-2b Bio 12/B $10^{4.3}$ TCIDmin. $10^{6.6}$ TCIDmax, Canine Parainfluenza type 2 virus, strain CPiV-2 Bio 15 $10^{3.1}$ TCIDmin. $10^{5.1}$ TCIDmax. Suspension (inactivated): Leptospira interrogans serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae, strain MSLB 1089 GMT $\geq 1:51$ ALR, Leptospira interrogans serogroup Canicolaserovar Canicola, strain MSLB 1090 GMT $\geq 1:51$ ALR, Leptospira kirschneri serogroup Grippotyphosaserovar Grippotyphosa, strain MSLB 1091 GMT $\geq 1:40$ ALR, Leptospira interrogans serogroup Australis serovar Bratislava, strain MSLB 1088 GMT $\geq 1:51$ ALR, Inactivated rabies virus, strain SAD Vnukovo-32 ≥ 5.0 IU
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1ml x 10-De-Controlled
	Shelf Life (Unit)	2 Year(s) 2 – 8 °C
	For generic drugs (me-too Status)	Not registered
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	Bioveta, a.s.-Komenenského 212/12, 683.23 Ivanovice na Hané Czech Republic-Czechia
	Name, address of Marketing Authorization Holder:	Bioveta, a.s., Komenenského 212/12, 683.23 Ivanovice na Hané Czech Republic, Czechia
	Details of Certificates (CoPP/FSC/cGMP):	Valid legalized CoPP has been submitted.
	Details of Authorization Letter :	Legalized POA from MAH has been submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies data of three batches has been submitted.
	Evaluation Remarks	
	Registration Board in its 347th meeting decided as follows: The Registration Board endorsed the recommendations of sub-committee on veterinary drugs and deferred the case for the opinion of M/o National Food Security & Research regarding immunological relevance and need of applied product in Pakistan. Sub-Committee on Veterinary Drugs in its 6th meeting recommended the product for grant of registration.	
	Decision	
	Approved	

Keeping in view recommendation of Sub-Committee on Veterinary Drugs and COPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.

44	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Vetline International 939-A, Block-J, Phase-1, LDA Avenue-1, Lahore (05-352-0066)
	Application Form Dy. No / Tracking ID & date of submission	(VEB-36M-EYSA, 2024-07-23)
	Detail of Fee Submitted	300000.0, 2024-07-22,
	The proposed proprietary name / brand name	Biocan Novel R, suspension for injection for dogs
	Label Claim	Each 1 ml dose contains; Inactivated rabies virus, strain SAD Vnukovo-32 > 2.0 IU
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1ml x 10-De-Controlled
	Shelf Life (Unit)	2 Year(s) 2 – 8 °C
	For generic drugs (me-too Status)	Not registered
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	Bioveta, a.s.-komenského 212/12, 683.23 Ivanovice na Hané Czech Republic-Czechia
	Name, address of Marketing Authorization Holder:	Bioveta, a.s., komenského 212/12, 683.23 Ivanovice na Hané Czech Republic, Czechia
	Details of Certificates (CoPP/FSC/cGMP):	Valid legalized CoPP has been submitted.
	Details of Authorization Letter :	Legalized POA from MAH has been submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies data of three batches has been submitted.
Evaluation Remarks		
Registration Board in its 347th meeting decided as follows: The Registration Board endorsed the recommendations of sub-committee on veterinary drugs and deferred the case for the opinion of M/o National Food Security & Research regarding immunological relevance and need of applied product in Pakistan. Sub-Committee on Veterinary Drugs in its 6th meeting recommended the product for grant of registration.		
Decision		
Approved		
Keeping in view recommendation of Sub-Committee on Veterinary Drugs and COPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.		
45	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Snam Pharma 61-G, Phase 1, Commercial Area, DHA, Lahore (05-352-0058)
	Application Form Dy. No / Tracking ID & date of submission	(VGR-6M9-ZQ3V, 2024-04-02)
	Detail of Fee Submitted	75000.0, 2024-03-21,
	The proposed proprietary name / brand name	Biocan M inj. ad us. vet.
	Label Claim	Biocan M inj. ad us. vet. Vaccine against Microsporum canis in dogs and cats Vaccine composition - 1 ml (1 dose) contains: Active substance: Microsporum canis inact. min. 500 000 vegetative forms
	Reference to Finished product specifications	As per Innovators Specification

Proposed Pack Size	20 x 1 ml Vial-De-Controlled
Shelf Life (Unit)	2 Year(s)2 - 8°C
For generic drugs (me-too Status)	New Registration in Pakistan
Pharmacotherapeutic Group of (API)	Veterinary Vaccine
Name, address of Manufacturing site:	Bioveta, a.s.-Komenskeho 212/12, 683 23 Ivanovice na Hane-Czechia
Name, address of Marketing Authorization Holder:	Bioveta, a.s., Komenskeho 212/12, 683 23 Ivanovice na Hane, Czechia
Details of Certificates (CoPP/FSC/cGMP):	Valid legalized CoPP has been submitted
Details of Authorization Letter :	Legalized LOA form MAH has been submitted.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies data of three batches has been submitted.
Evaluation Remarks	
Registration Board in its 347th meeting decided as follows:The Registration Board deferred the case for the opinion of M/o National Food Security & Research regarding immunological relevance and need of applied product in Pakistan.Sub-Committee on Veterinary Drugs in its 6th meeting recommended the product for grant of registration.	
Decision	
Approved	
Keeping in view recommendation of Sub-Committee on Veterinary Drugs and COPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
46	Case Category
	Routine (M. Zubair Masood)
	Name, address of Applicant.
	Inouko Animal Health (Private) Limited 3rd Floor, Plaza No. 3, D-Block, DHA Phase 5, Cantt, District Lahore (05-352-0058)
	Application Form Dy. No / Tracking ID & date of submission
	(VHQ-E8B-9VZP, 2025-05-12)
	Detail of Fee Submitted
	225000.0, 2025-03-18,
	The proposed proprietary name / brand name
	Cevac Megamune ND-IB-EDS-SHS K
	Each Dose contains: In activated New Castle Disease Virus, Strain NDV-SZ LaSota min 4log2 HI*titer or min.50 PD50** Avian Infectious Bronchitis virus strain M-41.....min 4.9 log2 HI*titer Avian Infectious Bronchitis virus strain QX Fr.....min 1 RPU*** Inactivated Egg Drop Syndrome virus, strain B8/78.....min 7 log2 HI*titer Inactivated Avian Metapneumovirus strain TRT50 min.20 Antigen ELISA unit *HI-Haemagglutination Inhibition ** PD-Protective Dose *** RPU-Relative Potency Unit
	Label Claim
	Reference to Finished product specifications
	Manufacturer Specification
	Proposed Pack Size
	500ml -De-Controlled
	Shelf Life (Unit)
	21 Month(s)Store at 2-8 C, Protect from Light, don't freeze
	For generic drugs (me-too Status)
	N/A
	Pharmacotherapeutic Group of (API)
	Veterinary Viral Vaccine
	Name, address of Manufacturing site:
	Ceva-Phylaxia Veterinary Biologicals Co.Ltd. -1107 Budapest, Szallas u. 5.,-Hungary

Name, address of Marketing Authorization Holder:	Ceva-Phylaxia Veterinary Biologicals Co.Ltd. , 1107 Budapest, Szallas u. 5.,, Hungary
Details of Certificates (CoPP/FSC/cGMP):	Valid Legalized FSC has been submitted. Valid legalized GMP certificate has been submitted.
Details of Authorization Letter :	Sole Agency agreement submitted but the agreement is with Ceva Sante Animal S.A., France.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Studies data of three batches has been submitted.

Evaluation Remarks

Registration Board in its 349th meeting decided as follows:"The Registration Board referred the case to Expert Working Group on veterinary drugs for opinion regarding immunological relevance and need of applied product in Pakistan. The Board further advised DBE&R to ask the firm to submit the following:1. The sole agency agreement has been signed by Seva Sante Animal Health S.A., France while the product license holder mentioned on the FSC is Ceva-Phylaxia Veterinary Biologicals Co.Ltd., Hungary.2. The me-too product with the applied formulation is not already registered."Sub-Committee on Veterinary Drugs in its 6th meeting recommended the product for grant of registration.Valid Letter of Authorization from Product License Holder i.e. M/s Ceva-Phylaxia Veterinary Biologicals Co.Ltd., Hungary is required.

Decision

Approved

Keeping in view recommendation of Sub-Committee on Veterinary Drugs and FSC indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. and submission of valid legalized Letter of Authorization from Product License Holder i.e. M/s Ceva-Phylaxia Veterinary Biologicals Co.Ltd., Hungary.

47	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Welwink Pharmaceuticals G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751)
	Application Form Dy. No / Tracking ID & date of submission	(V12-3W4-D1S5, 2025-08-19)
	Detail of Fee Submitted	93000.0, 2025-07-08,
	The proposed proprietary name / brand name	Semwink 0.5mg PFS Solution for Injection for Subcutaneous Use)
	Label Claim	Each 0.37 contains: Semaglutide.....0.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	24 Month(s)2°C - 8°C
	For generic drugs (me-too Status)	Sematide 0.5mg Injection (Reg No. 120529)
	Pharmacotherapeutic Group of (API)	GLP-1 Receptor Agonist
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-
	Name & address of API manufacturer	Fuxin Long Rui Pharmaceutical CO., Ltd Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China
	Detail of stability batches of drug product	Data Approved in 350th Meeting
	Documents for the procurement of API with approval from DRAP (in case of Import)	Data Approved in 350th Meeting
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Data Approved in 350th Meeting

Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data Approved in 350th Meeting																						
The status in reference regulatory authorities	EMA Approved																						
GMP status of the firm	Data Approved in 350th Meeting																						
Evidence of approval of manufacturing facility	Data Approved in 350th Meeting																						
Evaluation Remarks																							
The applied formulation is already approved in name of proposed manufacturer in 350th meeting of Registration Board and letter has already been issued vide F. No. 3-1/2021-ADC(BD)(M-350) dated 22-09-2025.																							
Decision																							
Approved																							
The Registration Board approved application for contract manufacturing from M/s Weather Folds Pharmaceuticals Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA&LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP. 4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. 5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022. 6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.																							
48	<table> <tr> <td>Case Category</td><td>Routine (M. Zubair Masood)</td></tr> <tr> <td>Name, address of Applicant.</td><td>Welwink Pharmaceuticals G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751)</td></tr> <tr> <td>Application Form Dy. No / Tracking ID & date of submission</td><td>(3QY-ZL4-RNXJ, 2025-08-15)</td></tr> <tr> <td>Detail of Fee Submitted</td><td>93000.0, 2025-07-08,</td></tr> <tr> <td>The proposed proprietary name / brand name</td><td>Semwink 1mg PFS Solution for Injection for Subcutaneous Use)</td></tr> <tr> <td>Label Claim</td><td>Each 0.74ml contains: Semaglutide.....1mg</td></tr> <tr> <td>Reference to Finished product specifications</td><td>As per Innovators Specification</td></tr> <tr> <td>Proposed Pack Size</td><td>As per SRO-As per SRO</td></tr> <tr> <td>Shelf Life (Unit)</td><td>24 Month(s)2°C - 8°C</td></tr> <tr> <td>For generic drugs (me-too Status)</td><td>Sematide 0.5mg Injection (Reg No. 120530)</td></tr> <tr> <td>Pharmacotherapeutic Group of (API)</td><td>GLP-1 Receptor Agonist</td></tr> </table>	Case Category	Routine (M. Zubair Masood)	Name, address of Applicant.	Welwink Pharmaceuticals G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751)	Application Form Dy. No / Tracking ID & date of submission	(3QY-ZL4-RNXJ, 2025-08-15)	Detail of Fee Submitted	93000.0, 2025-07-08,	The proposed proprietary name / brand name	Semwink 1mg PFS Solution for Injection for Subcutaneous Use)	Label Claim	Each 0.74ml contains: Semaglutide.....1mg	Reference to Finished product specifications	As per Innovators Specification	Proposed Pack Size	As per SRO-As per SRO	Shelf Life (Unit)	24 Month(s)2°C - 8°C	For generic drugs (me-too Status)	Sematide 0.5mg Injection (Reg No. 120530)	Pharmacotherapeutic Group of (API)	GLP-1 Receptor Agonist
Case Category	Routine (M. Zubair Masood)																						
Name, address of Applicant.	Welwink Pharmaceuticals G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751)																						
Application Form Dy. No / Tracking ID & date of submission	(3QY-ZL4-RNXJ, 2025-08-15)																						
Detail of Fee Submitted	93000.0, 2025-07-08,																						
The proposed proprietary name / brand name	Semwink 1mg PFS Solution for Injection for Subcutaneous Use)																						
Label Claim	Each 0.74ml contains: Semaglutide.....1mg																						
Reference to Finished product specifications	As per Innovators Specification																						
Proposed Pack Size	As per SRO-As per SRO																						
Shelf Life (Unit)	24 Month(s)2°C - 8°C																						
For generic drugs (me-too Status)	Sematide 0.5mg Injection (Reg No. 120530)																						
Pharmacotherapeutic Group of (API)	GLP-1 Receptor Agonist																						

Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-	
Name & address of API manufacturer	Fuxin Long Rui Pharmaceutical CO., Ltd Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China	
Detail of stability batches of drug product	Data Approved in 350th Meeting	
Documents for the procurement of API with approval from DRAP (in case of Import)	Data Approved in 350th Meeting	
Pharmaceutical Equivalence and Comparative Dissolution Profile	Data Approved in 350th Meeting	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data Approved in 350th Meeting	
The status in reference regulatory authorities	EMA Approved	
GMP status of the firm	Data Approved in 350th Meeting	
Evidence of approval of manufacturing facility	Data Approved in 350th Meeting	
Evaluation Remarks		
The applied formulation is already approved in name of proposed manufacturer in 350th meeting of Registration Board and letter has already been issued vide F. No. 3-1/2021-ADC(BD)(M-350) dated 22-09-2025.		
Decision		
Approved		
The Registration Board approved application for contract manufacturing from M/s Weather Folds Pharmaceuticals Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK with following conditions:		
1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.		
2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA&LT.		
3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.		
4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.		
5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.		
6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.		
49	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Welwink Pharmaceuticals G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751)
	Application Form Dy. No / Tracking ID & date of submission	(6UE-G9A-QDNN, 2025-08-19)

Detail of Fee Submitted	93000.0, 2025-07-08,
The proposed proprietary name / brand name	Semwink 0.25mg PFS Solution for Injection for Subcutaneous Use)
Label Claim	Each 0.19ml contains: Semaglutide.....0.25mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	24 Month(s)2°C - 8°C
For generic drugs (me-too Status)	Sematide 0.25mg Injection (Reg No. 120528)
Pharmacotherapeutic Group of (API)	GLP-1 Receptor Agonist
Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-
Name & address of API manufacturer	Fuxin Long Rui Pharmaceutical CO., Ltd Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China
Detail of stability batches of drug product	Data Approved in 350th Meeting
Documents for the procurement of API with approval from DRAP (in case of Import)	Data Approved in 350th Meeting
Pharmaceutical Equivalence and Comparative Dissolution Profile	Data Approved in 350th Meeting
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data Approved in 350th Meeting
The status in reference regulatory authorities	EMA Approved
GMP status of the firm	Data Approved in 350th Meeting
Evidence of approval of manufacturing facility	Data Approved in 350th Meeting

Evaluation Remarks

The applied formulation is already approved in name of proposed manufacturer in 350th meeting of Registration Board and letter has already been issued vide F. No. 3-1/2021-ADC(BD)(M-350) dated 22-09-2025.

Decision

Approved

The Registration Board approved application for contract manufacturing from M/s Weather Folds Pharmaceuticals Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK with following conditions:

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.
2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA&LT.
3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.

4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.
5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.
6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

50	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Winbrains Research Laboratories Plot No. 69/1 Block B, Phase I-II Industrial Estate, Hattar, Pakistan (000725)
	Application Form Dy. No / Tracking ID & date of submission	(1W7-ZTT-JQ6T, 2025-08-19)
	Detail of Fee Submitted	93000.0, 2025-07-08,
	The proposed proprietary name / brand name	Semgold 0.5mg PFS (Solution for Injection for Subcutaneous Use)
	Label Claim	Each 0.37ml contains: Semaglutide.....0.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	24 Month(s) 2°C - 8°C
	For generic drugs (me-too Status)	Semtide Injection (Reg No. 120529)
	Pharmacotherapeutic Group of (API)	GLP-1 Receptor Agonist
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK. -
	Name & address of API manufacturer	Fuxin Long Rui Pharmaceutical CO., Ltd Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China
	Detail of stability batches of drug product	Data Already Approved in 350th Meeting
	Documents for the procurement of API with approval from DRAP (in case of Import)	Data Already Approved in 350th Meeting
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Data Already Approved in 350th Meeting
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data Already Approved in 350th Meeting
	The status in reference regulatory authorities	EMA Approved
	GMP status of the firm	Data Already Approved in 350th Meeting
	Evidence of approval of manufacturing facility	Data Already Approved in 350th Meeting
	Evaluation Remarks	
	The applied formulation is already approved in name of proposed manufacturer in 350th meeting of Registration Board and letter has already been issued vide F. No. 3-1/2021-ADC(BD)(M-350) dated 22-09-2025.	
	Decision	
	Approved	
	The Registration Board approved application for contract manufacturing from M/s Weather Folds Pharmaceuticals Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK with following conditions:	
	1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.	

2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA&LT.
3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.
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6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

51	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Winbrains Research Laboratories Plot No. 69/1 Block B, Phase I-II Industrial Estate, Hattar, Pakistan (000725)
	Application Form Dy. No / Tracking ID & date of submission	(5ND-VUP-7VGA, 2025-08-19)
	Detail of Fee Submitted	93000.0, 2025-07-08,
	The proposed proprietary name / brand name	Semgold 1mg PFS (Solution for Injection for Subcutaneous Use)
	Label Claim	Each 0.74ml contains: Semaglutide.....1mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	24 Month(s) 2°C - 8°C
	For generic drugs (me-too Status)	Semtide Injection (Reg No. 120530)
	Pharmacotherapeutic Group of (API)	GLP-1 Receptor Agonist
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK. -
	Name & address of API manufacturer	Fuxin Long Rui Pharmaceutical CO., Ltd Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China
	Detail of stability batches of drug product	Data Already Approved in 350th Meeting
	Documents for the procurement of API with approval from DRAP (in case of Import)	Data Already Approved in 350th Meeting
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Data Already Approved in 350th Meeting
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data Already Approved in 350th Meeting
	The status in reference regulatory authorities	EMA Approved
	GMP status of the firm	Data Already Approved in 350th Meeting
	Evidence of approval of manufacturing facility	Data Already Approved in 350th Meeting
Evaluation Remarks		

The applied formulation is already approved in name of proposed manufacturer in 350th meeting of Registration Board and letter has already been issued vide F. No. 3-1/2021-ADC(BD)(M-350) dated 22-09-2025.

Decision

Approved

The Registration Board approved application for contract manufacturing from M/s Weather Folds Pharmaceuticals Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK with following conditions:

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.
2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA&LT.
3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.
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5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.
6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

52	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Winbrains Research Laboratories Plot No. 69/1 Block B, Phase I-II Industrial Estate, Hattar, Pakistan (000725)
	Application Form Dy. No / Tracking ID & date of submission	(ZAY-B3Z-W7RR, 2025-08-18)
	Detail of Fee Submitted	93000.0, 2025-07-08,
	The proposed proprietary name / brand name	Semgold 0.25mgPFS (Solution for Injection for Subcutaneous Use)
	Label Claim	Each 0.19ml contains: Semaglutide.....0.25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	24 Month(s)2°C - 8°C
	For generic drugs (me-too Status)	Semtide Injection (Reg No. 120528)
	Pharmacotherapeutic Group of (API)	GLP-1 Receptor Agonist
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK. -
	Name & address of API manufacturer	Fuxin Long Rui Pharmaceutical CO., Ltd Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China
	Detail of stability batches of drug product	Data Already Approved in 350th Meeting

Documents for the procurement of API with approval from DRAP (in case of Import)	Data Already Approved in 350th Meeting														
Pharmaceutical Equivalence and Comparative Dissolution Profile	Data Already Approved in 350th Meeting														
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data Already Approved in 350th Meeting														
The status in reference regulatory authorities	EMA Approved														
GMP status of the firm	Data Already Approved in 350th Meeting														
Evidence of approval of manufacturing facility	Data Already Approved in 350th Meeting														
Evaluation Remarks															
The applied formulation is already approved in name of proposed manufacturer in 350th meeting of Registration Board and letter has already been issued vide F. No. 3-1/2021-ADC(BD)(M-350) dated 22-09-2025.															
Decision															
Approved															
The Registration Board approved application for contract manufacturing from M/s Weather Folds Pharmaceuticals Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA&LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP. 4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. 5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022. 6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.															
53	<table> <tr> <td>Case Category</td><td>Routine (M. Zubair Masood)</td></tr> <tr> <td>Name, address of Applicant.</td><td>PUNJAB MEDICAL SERVICES 1st Floor, 6 - Judicial Colony (Extension) Shahrah Nzaria e Pakistan (05-352-0063)</td></tr> <tr> <td>Application Form Dy. No / Tracking ID & date of submission</td><td>(1VM-NZS-5HY4, 2025-08-13)</td></tr> <tr> <td>Detail of Fee Submitted</td><td>300000.0, 2025-07-25,</td></tr> <tr> <td>The proposed proprietary name / brand name</td><td>Tyzepa 2.5mg Injection</td></tr> <tr> <td>Label Claim</td><td>Each 0.5ml contains: Tirzepatide INN.....2.5 mg</td></tr> <tr> <td>Reference to Finished product specifications</td><td>As per Innovators Specification</td></tr> </table>	Case Category	Routine (M. Zubair Masood)	Name, address of Applicant.	PUNJAB MEDICAL SERVICES 1st Floor, 6 - Judicial Colony (Extension) Shahrah Nzaria e Pakistan (05-352-0063)	Application Form Dy. No / Tracking ID & date of submission	(1VM-NZS-5HY4, 2025-08-13)	Detail of Fee Submitted	300000.0, 2025-07-25,	The proposed proprietary name / brand name	Tyzepa 2.5mg Injection	Label Claim	Each 0.5ml contains: Tirzepatide INN.....2.5 mg	Reference to Finished product specifications	As per Innovators Specification
Case Category	Routine (M. Zubair Masood)														
Name, address of Applicant.	PUNJAB MEDICAL SERVICES 1st Floor, 6 - Judicial Colony (Extension) Shahrah Nzaria e Pakistan (05-352-0063)														
Application Form Dy. No / Tracking ID & date of submission	(1VM-NZS-5HY4, 2025-08-13)														
Detail of Fee Submitted	300000.0, 2025-07-25,														
The proposed proprietary name / brand name	Tyzepa 2.5mg Injection														
Label Claim	Each 0.5ml contains: Tirzepatide INN.....2.5 mg														
Reference to Finished product specifications	As per Innovators Specification														

Proposed Pack Size	1s-As per SRO
Shelf Life (Unit)	2 Year(s) store between 2-8°C. Do not freeze or shake
For generic drugs (me-too Status)	Not available
Pharmacotherapeutic Group of (API)	GLP-1 & GIP Receptor Agonist
Name, address of Manufacturing site:	Drug International Limited-31/1 Satrong Road, Gopalpur ,Tongoi I/A, Ghazipur Bangladesh-Bangladesh
Pharmaceutical Equivalence and Comparative Dissolution Profile	Not Provided
Name, address of Marketing Authorization Holder:	Drug International Limited, KHWAJA ENAYETPURI (R:) TOWER 17 Bir Uttam K.M Shafiullah Sarak , (Green Road) Dhaka -1205 Bangladesh, Bangladesh
Details of Certificates (CoPP/FSC/cGMP):	Copy of legalized CoPP No. DGDA/6-235/2019/ 7358 dated 25-05-2025
Details of Authorization Letter :	Copy of Letter of Authorization dated 19-05-2025.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: HXTZ620901V, HXTZ620902V, HXTZ820903V Conditions: -20C Realtime, 2-8 C Accelerated.
The status in reference regulatory authorities	mounjaro 2.5mg solution for injection in Prefilled pen

Evaluation Remarks

The firm has already been granted two opportunities to complete the application. Following are the observations:

Q. No.	Query	Response	Remarks
	Please submit revised API specifications including peptide mapping, cell based bio-assay and sodium content along with results of three batches of API indicating these tests?	The firm has submitted revised API specifications including peptide mapping, cell based bio-assay and sodium content along with results of three batches of API indicating these tests.	No raw data sheets and chromatograms submitted in support of performance.
	Please provide the list of impurities in API along with their specification limits instead of just mentioning individual unknown, individual known & Total Impurities?	The firm provided the list of non-specific impurities and residual solvents.	No API specific impurities have been tested neither by the Drug Substance nor by Drug Product Manufacturer?
	The initially submitted real time stability data of API did not include pH, Specific rotation, Residual Solvents, Sodium Content, Bacterial Endotoxin & TABC tests while now you have revised the stability data of same batches that were manufactured in 2022 and included the results of these tests at each time point?	With reference to the query regarding the initially submitted real-time stability data for the API batches manufactured in 2022, we would like to clarify the following: In the initial submission, the results for pH, Specific Rotation, Residual Solvents, Sodium Content, Bacterial Endotoxin, and Total Aerobic Bacterial Count (TABC) were marked with a dash (“—”) in the stability data tables. This was due to an oversight in documentation and not due to the absence of testing. We confirm that these tests were indeed performed at each stability time point as part of the original real-time stability studies conducted in 2022, in accordance with ICH Q1A(R2) guidelines on Stability Testing of New Drug Substances and Products. The results complied with the predefined specifications at all time points. As per the query raised, we have	No raw data sheets and chromatograms submitted in support of performance of these tests in 2022.

		now revised the stability data to include the actual results of these parameters at each respective time point. No new testing has been conducted retrospectively; the data presented are from the original studies performed in real time in 2022. This update ensures that the stability data set is now complete and compliant with regulatory expectations and ICH guidelines.	
	The Innovator has performed Purity Testing & High Molecular Weight Testing during stability studies of API while your API manufacturer has not performed these test during stability studies of API. Please explain?	The firm has submitted stability data of three more batches with inclusion of these results.	No raw data sheets and chromatograms submitted in support of performance of these tests in 2023.
	Please provide Batch analysis data of three batches including Identification of Finished product by RP-LC-UV & peptide mapping, High Molecular Weight Species Testing of Finished product by using SEC, Purity Testing by RP-LC-UV, Osmolality Test and Syringe Functionality Test?	Batch analysis data of three batches including Identification of Finished product by RP-LC-UV & peptide mapping, High Molecular Weight Species Testing of Finished product.	No raw data sheets and chromatograms submitted in support of performance.
	Please provide the method for syringe functionality as you have mention visual inspection?	The firm has submitted SOPs for Syringe Functionality Tests.	
	The initially submitted stability data of Finished product did not include purity, HMWS, break loose and glide force, and auto injector testing while now you have revised the stability data of same batches that were manufactured in Feb-2021 and included the results of these tests at each time point?	With reference to the query regarding the initially submitted stability data of the finished product, we would like to provide the following clarification: In the original stability data submission for the finished product batches manufactured in February 2021, the results for Purity, High Molecular Weight Species (HMWS), Break Loose Force, Glide Force, and Auto injector Testing were not included in the submitted data tables. These parameters were tested at each scheduled stability time point as part of the original real-time stability program conducted in 2021–2023. However, their omission from the initial submission was due to a documentation oversight, potentially influenced by the then-applicable regulatory requirements of the importing country, which did not mandate the inclusion of these specific parameters for product release or stability evaluation. In response to the current query, we have revised the stability data to include the results for the above tests at all relevant time	No raw data sheets and chromatograms submitted in support of performance of these tests in 2021.

		points for the same batches. These results were generated as part of the original stability studies and are not retrospective in nature. These updates ensure that the stability data now comprehensively address both product quality and device functionality over the intended shelf life, in alignment with ICH Q1A(R2) and relevant product- and device specific regulatory expectations	
	Please explain, why all the tests as per COA are not performed in your in-use stability studies?	The purpose of in-use stability studies is to evaluate the stability and integrity of the drug product under conditions that simulate the actual usage by the end user, such as repeated vial puncturing, room temperature exposure, and duration of use after first opening. In-use studies are conducted based on risk based scientific principles as recommended by ICH Q1A(R2) and WHO Technical Report Series No. 992, Annex 2, focusing on parameters that are most likely to be affected during the in-use period. Therefore, not all CoA tests are repeated during in-use stability studies. Instead, a targeted set of stability-indicating tests are selected to assess potential degradation, contamination, or other risks associated with the intended use. This typically includes: Assay / Potency – to confirm drug content over in-use period. Appearance, pH, and Physical Attributes – to identify any visible or measurable changes. Sterility testing– especially for multi-dose formulations, to assess risk of microbial contamination. Tests such as identity, residual solvents, specific rotation, or elemental impurities, which are part of the initial Certificate of Analysis (CoA), are not repeated during inuse studies because they are not expected to change during normal product use and are not stability-indicating under in-use conditions.	Justification submitted.
	Tirzepatide is not included in the scope of The provided Drug Manufacturing License of Drug Substance Manufacturer?	The firm submitted that The source of API Tirzepatide is FDA approved	No evidence is yet submit that indicates Tirzepatide API is included in Scope of DML issued by country of origin or document issued by by USFDA.
.	Valid GMP Certificate of Drug Substance Manufacturer issued by regulatory authority of country of origin?	The firm submitted that NMPA no longer issues GMP certificate.	
.	Following tests are required to be performed by API manufacturer: i. Enantiomeric purity by GC-MS ii. Identity of	The firm has submitted Purity and Related Substances by HPLC Result Summary and Sodium by HPLC Validation Result Summary	The Purity and Related Substances by HPLC Result Summary provided by the firm has already been submitted in another

	potential counter ion by RP-HPLC		application Tirzix of same firm imported from another manufacturer at pages-4-6 of their response dated 02-09-2025. The submitted validation of Sodium by HPLC is not performed by API manufacturer.
.	Details of reports of comparative tests of Finished product with Innovator product are still not provided? Results are provided only for Appearance, pH & Assay?	Different chromatograms submitted.	The comparative report is still not submitted.
.	In your justification of limits of impurities, you submitted that Tirzepatide is a weekly once taken medication the applied 2% limit for total impurities is well acceptable. While as per dossier, you total impurity limit is NMT 6.0%?	The firm submitted the following: "The proposed limit is supported by impurity levels observed in clinical batches used during Phase 2 and Phase 3 studies. These batches met the proposed specification of NMT 6.0% Total Impurities throughout their shelf life. No safety concerns attributable to impurities were observed in clinical studies. Therefore, the limit is considered clinically qualified."	The firm may be advised to provide the Phase 2 and Phase 3 studies as mentioned by them in their justification.
.	Details of manufacturing section, in which FPP is manufactured?	The firm has submitted copy of GMP Certificate that is indicating Biological Pre-filled/ Cartridge/ pen dosage form.	
.	Syringe Functionality Test of Finished product is still not submitted, instead general chapter is provided.	The firm again submitted General Chapter	Not Submitted.
.	Please provide the justification of Total Impurity limit of 6.0%?	Same as point 13.	

Decision

Deferred

Registration Board decided to provide one last opportunity to applicant to furnish following documents/ clarifications. In case the applicant fails to complete the application this time, the application shall be disposed of by the Board in its next meeting.

i. Please submit raw data sheets and chromatograms as evidence of performance of peptide mapping, cell based bio-assay and sodium content of three batches of API for which COAs are submitted?

ii. List of product specific impurities in Drug Substance, their inclusion in API specifications & evidence of performance by API manufacturer & Finished product manufacturer.

iii. Raw data sheets & chromatograms of pH, Specific rotation, Residual Solvents, Sodium Content, Bacterial Endotoxin, TABC, Purity Testing & High Molecular Weight Testing of API performed during stability studies of batches manufactured in 2023 for which stability data is submitted.

iv. Raw data sheets & chromatograms of Identification by RP-LC-UV & peptide mapping, High Molecular Weight Species by SEC, Purity by RP-LC-UV, Osmolality, Syringe Functionality Testing of Finished product of batches manufactured in 2024 for which COAs are submitted.

v. Raw data sheets & chromatograms of purity, HMWS, break loose and glide force, and auto injector testing of Finished product performed during stability studies of batches manufactured in 2022 for which stability data is submitted.

vi. Please clarify that applied product being synthetic peptide is manufactured by manufacturer in which section either Biological or non-biological section.

vii. Following tests are required to be performed by API manufacturer:

a. Enantiomeric purity by GC-MS.

b. Identity of potential counter ion by RP-HPLC

viii. Details of reports of comparative tests of Finished product with Innovator product are still not provided.

ix. In your justification of limits of impurities, following was submitted:

“The proposed limit is supported by impurity levels observed in clinical batches used during Phase 2 and Phase 3 studies. These batches met the proposed specification of NMT 6.0% Total Impurities throughout their shelf life. No safety concerns attributable to impurities were observed in clinical studies. Therefore, the limit is considered clinically qualified.”

You are advised to submit data of Phase 2 and Phase 3 studies in support of justification.

x. Syringe Functionality Test of Finished product is still not submitted; instead general chapter is provided.

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Case Category	Routine (M. Zubair Masood)
Name, address of Applicant.	PUNJAB MEDICAL SERVICES 1st Floor, 6 - Judicial Colony (Extension) Shahrah Nzaria e Pakistan (05-352-0063)
Application Form Dy. No / Tracking ID & date of submission	(EY6-L7V-UYNN, 2025-09-01)
Detail of Fee Submitted	300000.0, 2025-07-30,
The proposed proprietary name / brand name	Tyzepa 5mg Injection
Label Claim	Each 0.5ml contains: Tirzepatide INN.....5 mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1s-As per SRO
Shelf Life (Unit)	2 Year(s)ore between 2-8°C. Do not freeze or shake
For generic drugs (me-too Status)	Not available
Pharmacotherapeutic Group of (API)	GLP-1 & GIP Receptor Agonist
Name, address of Manufacturing site:	Drug International Limited-31/1 Satrong Road, Gopalpur ,Tongoi I/A, Ghazipur Bangladesh-Bangladesh
Pharmaceutical Equivalence and Comparative Dissolution Profile	Not Provided
Name, address of Marketing Authorization Holder:	Drug International Limited, KHWAJA ENAYETPURI (R:) TOWER 17 Bir Uttam K.M Shafiullah Sarak , (Green Road) Dhaka -1205 Bangladesh, Bangladesh

Details of Certificates (CoPP/FSC/cGMP):	Copy of legalized CoPP No. DGDA/6-235/2019/ 2156 dated 25-05-2025
Details of Authorization Letter :	Copy of Letter of Authorization dated 19-05-2025.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: HXTZ620901V, HXTZ620902V, HXTZ820903V Conditions: -20C Realtime, 2-8 C Accelerated.
The status in reference regulatory authorities	mounjaro 5mg solution for injection in Prefilled pen

Evaluation Remarks

The firm has already been granted two opportunities to complete the application. Following are the observations:

Query	Response	Remarks
Please submit revised API specifications including peptide mapping, cell based bio-assay and sodium content along with results of three batches of API indicating these tests?	The firm has submitted revised API specifications including peptide mapping, cell based bio-assay and sodium content along with results of three batches of API indicating these tests.	No raw data sheets and chromatograms submitted in support of performance.
Please provide the list of impurities in API along with their specification limits instead of just mentioning individual unknown, individual known & Total Impurities?	The firm provided the list of non-specific impurities and residual solvents.	No API specific impurities have been tested neither by the Drug Substance nor by Drug Product Manufacturer?
The initially submitted real time stability data of API did not include pH, Specific rotation, Residual Solvents, Sodium Content, Bacterial Endotoxin & TABC tests while now you have revised the stability data of same batches that were manufactured in 2022 and included the results of these tests at each time point?	With reference to the query regarding the initially submitted real-time stability data for the API batches manufactured in 2022, we would like to clarify the following: In the initial submission, the results for pH, Specific Rotation, Residual Solvents, Sodium Content, Bacterial Endotoxin, and Total Aerobic Bacterial Count (TABC) were marked with a dash (“–”) in the stability data tables. This was due to an oversight in documentation and not due to the absence of testing. We confirm that these tests were indeed performed at each stability time point as part of the original real-time stability studies conducted in 2022, in accordance with ICH Q1A(R2) guidelines on Stability Testing of New Drug Substances and Products. The results complied with the predefined specifications at all time points. As per the query raised, we have now revised the stability data to include the actual results of these parameters at each respective time point. No new testing has been conducted retrospectively; the data presented are from the original studies performed in real time in 2022. This update ensures that the stability data set is now complete and compliant with regulatory expectations and ICH guidelines.	No raw data sheets and chromatograms submitted in support of performance of these tests in 2022.
The Innovator has performed Purity Testing & High Molecular Weight Testing during stability	The firm has submitted stability data of three more batches with inclusion of these results.	No raw data sheets and chromatograms submitted in support of

	studies of API while your API manufacturer has not performed these test during stability studies of API. Please explain?		performance of these tests in 2023.
	Please provide Batch analysis data of three batches including Identification of Finished product by RP-LC-UV & peptide mapping, High Molecular Weight Species Testing of Finished product by using SEC, Purity Testing by RP-LC-UV, Osmolality Test and Syringe Functionality Test?	Batch analysis data of three batches including Identification of Finished product by RP-LC-UV & peptide mapping, High Molecular Weight Species Testing of Finished product.	No raw data sheets and chromatograms submitted in support of performance.
	Please provide the method for syringe functionality as you have mention visual inspection?	The firm has submitted SOPs for Syringe Functionality Tests.	
	The initially submitted stability data of Finished product did not include purity, HMWS, break loose and glide force, and auto injector testing while now you have revised the stability data of same batches that were manufactured in Feb-2021 and included the results of these tests at each time point?	With reference to the query regarding the initially submitted stability data of the finished product, we would like to provide the following clarification: In the original stability data submission for the finished product batches manufactured in February 2021, the results for Purity, High Molecular Weight Species (HMWS), Break Loose Force, Glide Force, and Auto injector Testing were not included in the submitted data tables. These parameters were tested at each scheduled stability time point as part of the original real-time stability program conducted in 2021–2023. However, their omission from the initial submission was due to a documentation oversight, potentially influenced by the then-applicable regulatory requirements of the importing country, which did not mandate the inclusion of these specific parameters for product release or stability evaluation. In response to the current query, we have revised the stability data to include the results for the above tests at all relevant time points for the same batches. These results were generated as part of the original stability studies and are not retrospective in nature. These updates ensure that the stability data now comprehensively address both product quality and device functionality over the intended shelf life, in alignment with ICH Q1A(R2) and relevant product- and device specific regulatory expectations	No raw data sheets and chromatograms submitted in support of performance of these tests in 2021.
	Please explain, why all the tests as per COA are not	The purpose of in-use stability studies is to evaluate the stability and integrity of the drug product under conditions that simulate the actual	Justification submitted.

	performed in your in-use stability studies?	usage by the end user, such as repeated vial puncturing, room temperature exposure, and duration of use after first opening. In-use studies are conducted based on risk based scientific principles as recommended by ICH Q1A(R2) and WHO Technical Report Series No. 992, Annex 2, focusing on parameters that are most likely to be affected during the in-use period. Therefore, not all CoA tests are repeated during in-use stability studies. Instead, a targeted set of stability-indicating tests are selected to assess potential degradation, contamination, or other risks associated with the intended use. This typically includes: Assay / Potency – to confirm drug content over in-use period. Appearance, pH, and Physical Attributes – to identify any visible or measurable changes. Sterility testing—especially for multi-dose formulations, to assess risk of microbial contamination. Tests such as identity, residual solvents, specific rotation, or elemental impurities, which are part of the initial Certificate of Analysis (CoA), are not repeated during inuse studies because they are not expected to change during normal product use and are not stability-indicating under in-use conditions.	
	Tirzepatide is not included in the scope of The provided Drug Manufacturing License of Drug Substance Manufacturer?	The firm submitted that The source of API Tirzepatide is FDA approved	No evidence is yet submit that indicates Tirzepatide API is included in Scope of DML issued by country of origin or document issued by by USFDA.
.	Valid GMP Certificate of Drug Substance Manufacturer issued by regulatory authority of country of origin?	The firm submitted that NMPA no longer issues GMP certificate.	
.	Following tests are required to be performed by API manufacturer: i. Enantiomeric purity by GC-MS ii. Identity of potential counter ion by RP-HPLC	The firm has submitted Purity and Related Substances by HPLC Result Summary and Sodium by HPLC Validation Result Summary	The Purity and Related Substances by HPLC Result Summary provided by the firm has already been submitted in another application Tirzix of same firm imported from another manufacturer at pages-4-6 of their response dated 02-09-2025. The submitted validation of Sodium by HPLC is not performed by APi manufacturer.
.	Details of reports of comparative tests of	Different chromatograms submitted.	The comparative report is still not submitted.

	Finished product with Innovator product are still not provided? Results are provided only for Appearance, pH & Assay?		
.	In your justification of limits of impurities, you submitted that Tirzepatide is a weekly once taken medication the applied 2% limit for total impurities is well acceptable. While as per dossier, you total impurity limit is NMT 6.0%?	The firm submitted the following: “The proposed limit is supported by impurity levels observed in clinical batches used during Phase 2 and Phase 3 studies. These batches met the proposed specification of NMT 6.0% Total Impurities throughout their shelf life. No safety concerns attributable to impurities were observed in clinical studies. Therefore, the limit is considered clinically qualified.”	The firm may be advised to provide the Phase 2 and Phase 3 studies as mentioned by them in their justification.
.	Details of manufacturing section, in which FPP is manufactured?	The firm has submitted copy of GMP Certificate that is indicating Biological Pre-filled/ Cartridge/ pen dosage form.	
.	Syringe Functionality Test of Finished product is still not submitted, instead general chapter is provided.	The firm again submitted General Chapter	Not Submitted.
.	Please provide the justification of Total Impurity limit of 6.0%?	Same as point 13.	

Decision

Deferred

Registration Board decided to provide one last opportunity to applicant to furnish following documents/ clarifications. In case the applicant fails to complete the application this time, the application shall be disposed of by the Board in its next meeting.

i. Please submit raw data sheets and chromatograms as evidence of performance of peptide mapping, cell based bio-assay and sodium content of three batches of API for which COAs are submitted?

ii. List of product specific impurities in Drug Substance, their inclusion in API specifications & evidence of performance by API manufacturer & Finished product manufacturer.

iii. Raw data sheets & chromatograms of pH, Specific rotation, Residual Solvents, Sodium Content, Bacterial Endotoxin, TABC, Purity Testing & High Molecular Weight Testing of API performed during stability studies of batches manufactured in 2023 for which stability data is submitted.

iv. Raw data sheets & chromatograms of Identification by RP-LC-UV & peptide mapping, High Molecular Weight Species by SEC, Purity by RP-LC-UV, Osmolality, Syringe Functionality Testing of Finished product of batches manufactured in 2024 for which COAs are submitted.

v. Raw data sheets & chromatograms of purity, HMWS, break loose and glide force, and auto injector testing of Finished product performed during stability studies of batches manufactured in 2022 for which stability data is submitted.

vi. Please clarify that applied product being synthetic peptide is manufactured by manufacturer in which section either Biological or non-biological section.

vii. Following tests are required to be performed by API manufacturer:

a. Enantiomeric purity by GC-MS.

b. Identity of potential counter ion by RP-HPLC

viii. Details of reports of comparative tests of Finished product with Innovator product are still not provided.

ix. In your justification of limits of impurities, following was submitted:

“The proposed limit is supported by impurity levels observed in clinical batches used during Phase 2 and Phase 3 studies. These batches met the proposed specification of NMT 6.0% Total Impurities throughout their shelf life. No safety concerns attributable to impurities were observed in clinical studies. Therefore, the limit is considered clinically qualified.”

You are advised to submit data of Phase 2 and Phase 3 studies in support of justification.

x. Syringe Functionality Test of Finished product is still not submitted; instead general chapter is provided.

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Case Category	Routine (M. Zubair Masood)
Name, address of Applicant.	Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan (01-374-0006)
Application Form Dy. No / Tracking ID & date of submission	(6B1-JH2-AX66, 2025-08-07)
Detail of Fee Submitted	300000.0, 2025-07-18,
The proposed proprietary name / brand name	Brolizum 100 IV Infusion
Label Claim	Each 4ml solution contains: Pembrolizumab.....100mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's-As per SRO
Shelf Life (Unit)	12 Month(s)Store at 2-8°C, protecting from light.
For generic drugs (me-too Status)	New product
Pharmacotherapeutic Group of (API)	L01FF02:Antineoplastic agents
Name, address of Manufacturing site:	Geneway Bio-Technology co., Ltd Incepta Pharma-No.6 Anmin Road, Huangdai Town, Xiangcheng, Suzhou, Jiangsu, Dewan Idris Road, Bara Rangamatia, Zirabo, Savar, Dhaka-China Bangladesh
Pharmaceutical Equivalence and Comparative Dissolution Profile	NA
Name, address of Marketing Authorization Holder:	Incepta Pharmaceuticals Ltd., Dewan Idris Road, Bara Rangamatia, Zirabo,Ashulia, Savar, Dhaka-1341, Bangladesh, Bangladesh
Details of Certificates (CoPP/FSC/cGMP):	Scanned Copy of COPP Certificate No.:DA/6-91/04/15Part-1/21842 Date: 24 Dec 2024 Validity: 2 year
Details of Authorization Letter :	Incepta Pharmaceuticals Ltd., Vaccine Division, a company duly organized under the laws of the Peoples' Republic of Bangladesh, having its main office and principal place of business at 40, Shahid Tajuddin Ahmed Sarani, Tejgaon I/A, Dhaka-1208, Bangladesh hereby certify that: M/s. Lab Diagnostic Systems (SMC) Pvt Ltd Address: 36-A,PSIC,SIE,Taxila Rawalpindi as our

	Exclusive distributor for the territory of Pakistan Validity: December 2026.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	FX01-2015001S FX01-2015002S FX01-2015003S 5C±3C in 0, 3th, 6th month. Below 30C in 0, 6th, 12th month.
The status in reference regulatory authorities	Keytruda Injection Manufacturer name: Merck & Co. Brand name: Keytruda Injection (also referred to as Keytruda®) Strength: 100 mg in 4 ml. This is equivalent to 25 mg/ml. Composition: The ready-to-fill bulk solution, which is similar to Keytruda, contains Pembrolizumab (as the active pharmaceutical ingredient), L- Histidine, Sucrose, Polysorbate 80, and Water for Injections as excipients. USFDA Approved

Evaluation Remarks

The case was evaluated and following are the observations:

Sr. No.	Query	Response
1.	Please submit written details of the detector used in the peptide mapping of drug substance as picture is not downloading.	
2.	Quality comparison with Innovator product as required under WHO guidelines is not performed by finished product manufacturer of Bangladesh?	We would also like to highlight that DRAP has previously approved similar products in alignment with the Guidelines for Registration of Biosimilar Products (2018), issued by the Directorate General of Drug Administration (Bangladesh). As per these guidelines, submission of finished product biosimilarity data is not mandatory where bulk product data has been adequately demonstrated. In this context, DRAP has already approved products such as: · Nivolunix 100 mg Injection (Nivolumab) · Pembroxim 100 mg Injection (Pembrolizumab) These approvals were granted in the 334th Registration Board meeting held on 25th January, 2024, based on the above principles.
3.	Process validation of commercial batches by Finished product manufacturer?	A commitment letter provided that data will be submitted till 15-10-2025.

Decision

Deferred

The Registration Board has deferred the application pending submission of the following documents/clarifications:

- Comprehensive biosimilarity data (covering Quality, Safety, and Efficacy) from the finished product manufacturer, in accordance with WHO Biosimilarity Guidelines, and in comparison to the innovator product.
- Process validation data for commercial-scale batches from the finished product manufacturer.
- Clarification of un-registered status of finished product of bulk manufacturer in country of origin i.e. China.

Additionally, the Board observed that a product using the same API source was previously approved during 334th meeting under the name of M/s Himmel Pharmaceuticals (Pvt.) Ltd., Lahore. The Board has advised BE&R Division to ask M/s Himmel Pharmaceuticals (Pvt.) Ltd., Lahore regarding the submission of biosimilarity data (Quality, Safety, and Efficacy) by the finished product manufacturer in line with WHO guidelines.

Case Category	Routine (Muneeb Ahmed Cheema)

Name, address of Applicant.	Nextar Pharma (pvt) Ltd Plot No. E-58, North Western Industrial Zone, Port Qasim, Karachi (000777)
Application Form Dy. No / Tracking ID & date of submission	(HM7-ZQY-AB1T, 2024-04-25)
Detail of Fee Submitted	30000.0, 270000.0 2024-03-13, 2025-01-30
The proposed proprietary name / brand name	Nexmab Solution for injection 40mg/0.8ml (Pre-filled Syringe)
Label Claim	Each 0.8ml Pre-filled Syringe contains: Adalimumab.....40mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	as per SRO/ DPC-As per SRO
Shelf Life (Unit)	2 YearsStore at 5°C±3°C
For generic drugs (me-too Status)	Adalimab Solution for Injection 40mg/0.8ml in Vial (Approved in 323rd DRB Meeting) Getz Pharma (Pvt.) Ltd.
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Self Manufacturing
The status in reference regulatory authorities	Humira Solution for Injection 40mg/0.8mL USFDA Approved
Detail of previous approval	
Evaluation Remarks	
The product was approved in 329th meeting of Registration Board in name of M/s The Searle Company Limited, Karachi contract manufactured by M/s Nextar Pharma Karachi. The bulk concentrate shall be imported form M/s Hisun Biopharmaceutical Co., Limited China and will be formulated, filled and packed at M/s Nextar Pharma Karachi. Registration letter was issued on 06.12.2023 vide No. F.3-135/2016-ADC (BD) (Vol-II)(M-329).	
Decision	
Approved	
Registration Board approved application on the basis of already approved data in 329th meeting for self manufacturing.	

Meeting ended with a vote of thanks to and from the Chair.

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