MINUTES OF 357TH MEETING OF REGISTRATION BOARD HELD ON 21ST APRIL, 2026

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

357th meeting of Registration Board was held on 21st April, 2026 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.	Malik Muhammad Saleem, Ex Deputy Manager Production. Rhone Poulenc Rorer Pakistan, Rawalpindi.	Member (Virtual)
2.	Dr. Syed Asad Ali Shah, Principal Animal Husbandry In-Service Training Institute, Peshawar.	Member (Virtual)
3.	Dr. Tehseen Fatima, Dow College of Biotechnology, Dow University of Health Sciences, Karachi.	Member (Virtual)
4.	Mr. Ijaz Alvi, Director, Drugs Testing Laboratory, Govt. of Punjab, Rawalpindi.	Member (Virtual)
5.	Dr. Ali Jan, Director, Drugs Testing Laboratory, Govt. of Baluchistan Quetta.	Member (Virtual)
6.	Mr. Imranullah Khan, Director Drugs Testing Laboratory, Govt. of Khyber Pakhtunkhuwa, Peshawar.	Member (Virtual)
7.	Syed Adnan Rizvi, Director Drugs Testing Laboratory, Govt. of Sindh, Karachi.	Member (Virtual)
8.	Ch. Zeeshan Nazir Bajar, Director, Quality Assurance & Lab Testing Division, DRAP.	Member
9.	Dr. Ghazanfar Ali Khan, Director, of Biological Evaluation & Research Division, DRAP.	Member
10.	Hafiz M. Ali Tayyab, Additional Director, Pharmaceutical Evaluation & Registration Division, DRAP.	Member/ Secretary

Mr. Nadeem Alamgir (Pharma Bureau), Dr. Riaz Ahmad & Mr. Maaz (PPMA) and Dr. Shahnawaz (PCDA) attended the meeting as observers.

Item No. I Confirmation of minutes of 356th meeting of registration board.

356th meetings of Registration Board were held on 07th April, 2026. Accordingly, draft minutes of the 356th meeting of Registration Board were prepared and circulated among the members through email for their perusal / approval / comments (if any). All members agreed to the draft minutes. Accordingly, fair minutes of 356th meeting were processed to Chairman, Registration Board for perusal/approval. After approval from Chairman Registration Board, fair minutes of 356th meeting of Registration Board were circulated among concerned divisions/sections for implementation.

Decision: Registration Board confirmed the minutes of 356th meeting.

Item No. II Division of Pharmaceutical Evaluation & Registration

Registration-II

Case No. 1 Withdrawal of Licensed Section of M/s. Nagarsons Pharmaceuticals (Pvt) Ltd., Plot No. 34, Street No. NS-2, National Industrial Zone, Rawat, Under DML No. 000927

Secretary, Central Licensing Board vide letter T. ID: R$V-STM-684Y dated 18-03-2026 has conveyed the decision of 315th meeting of CLB held on 04th March, 2026 wherein External Preparation (Liquid) (General) (New) Section was granted in place of Tablet (Psychotropic) Section in the name of M/s. Nagarsons Pharmaceuticals (Pvt) Ltd., Plot No. 34, Street No. NS-2, National Industrial Zone, Rawat, Under DML No. 000927.

In view of above letter, registration of all the products granted to M/s. Nagarsons Pharmaceuticals (Pvt) Ltd., Plot No. 34, Street No. NS-2, National Industrial Zone, Rawat, in Tablet (Psychotropic) Section Under DML No. 000927 and applications under process for aforesaid section at any level may be cancelled.

Decision: Keeping in view the decision of Central Licensing Board for withdrawal of licensed section the Registration Board deliberated and cancelled the registration of all drug products of Tablet (Psychotropic) Section registered in the name of M/s. Nagarsons Pharmaceuticals (Pvt) Ltd., Plot No. 34, Street No. NS-2, National Industrial Zone, Rawat w.e.f decision of the Licensing Board Lahore alongwith registration applications which are under process at any level.

Case No. 2 Withdrawal of Licensed Section of M/s. Seatle (Pvt) Ltd., 45Km, Multan Road, Lahore.

Secretary, Central Licensing Board has forwarded a letter T. ID: 2HY-X76-3XMH dated 24-03-2026 wherein he has conveyed the decision of 315th meeting of CLB held on 04-03-2026. The Central Licensing Board on the recommendations of FID, decided to accede the request of firm for withdrawal of following sections.

i. Tablet (General) Section
ii. Tablet (Cephalosporin) Section
iii. Capsule (General) Section
iv. Capsule (Cephalosporin) Section
v. Dry Powder Suspension (Cephalosporin) Section.

Decision: Keeping in view the decision of Central Licensing Board for withdrawal of licensed section the Registration Board deliberated and cancelled the registration of all drug products of i. Tablet (General) Section ii. Tablet (Cephalosporin) Section iii. Capsule (General) Section iv. Capsule (Cephalosporin) Section v. Dry Powder Suspension (Cephalosporin) Section registered in the name of M/s. Seatle (Pvt) Ltd., 45Km, Multan Road, Lahore w.e.f decision of the Licensing Board Lahore alongwith registration applications which are under process at any level.

Case No. 3 Invalid of Drug Manufacturing Licenses by Central Licensing Board.

Deputy Director Licensing has forwarded a letter No. F. 1-15/97-Lic. (Vol-I) dated 10-03-2026 wherein he has communicated that Drug Manufacturing License of M/s Seagull Pharma, Tower Point, Gojra Road, Beg Colony, Jhang (000482- by way of Formulation) stands invalid under Drugs Act, 1976 and rules framed thereunder with effect from 18-12-2025.

Decision: Keeping in view the decisions taken by the Central Licensing Board regarding cancellation of DML of above-mentioned firm, Registration Board decided to cancel all the registered drugs w.e.f. date of cancellation of DML of M/s Seagull Pharma, Tower Point, Gojra Road, Beg Colony, Jhang (000482- by way of Formulation) alongwith registration applications which are under process at any level.

Following products of M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore were considered (approved / deferred) by the Registration Board in its 326th meeting held on 14-16 March, 2023 while its Drug Manufacturing License (DML) was valid.

Registration letter of approved products was pending for updated GMP status to be submitted by the firm. Meanwhile, Drug Manufacturing License of the firm was declared Invalid w.e.f. 08-01-2024 vide Licensing Division letter No. 1-62/2011-Lic dated 02-01-2025.

Name and address of manufacturer / Applicant	M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore
Brand Name +Dosage Form + Strength	Zamtrine 20/120mg Tablet
Composition	Each Tablet Contains: Artemether…20mg Lumefantrine…120mg New Details 659-U57-ASA4 PKR 37,030/-: 10-04-2025
Diary No. Date of R& I & fee	Dy No. 16385: 07-03-2019 PKR 20,000/-: 07-03-2019
Pharmacological Group	Antimalarial
Type of Form	Form 5
Finished Product Specification	Ph. Int.
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	RIAMET Tablet WHO PQ formulation
Me-too status	Mefantrin Tablet by Jinnah Pharma
GMP status	Inspection date 13/07/2018, panel recommend grant of DML
Remarks of the Evaluator3.	Latest GMP inspection report conducted within a period of last three years.
Decision: Approved.	
Name and address of manufacturer / Applicant	M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore
Brand Name +Dosage Form + Strength	Zamtrine DS 40/240mg Tablet
Composition	Each Tablet Contains:

	Artemether…40mg Lumefantrine…240mg
Diary No. Date of R& I & fee	Dy No. 16386: 07-03-2019 PKR 20,000/-: 07-03-2019 New Details 85Y-MPL-2M3Q PKR 37,030/-: 10-04-2025
Pharmacological Group	Antimalarial
Type of Form	Form 5
Finished Product Specification	Ph. Int.
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	WHO PQ formulation
Me-too status	Artem DS Plus Tablet by Hilton
GMP status	Inspection date 13/07/2018, panel recommend grant of DML
Remarks of the Evaluator3.	Latest GMP inspection report conducted within a period of last three years.
Decision: Approved.	
Name and address of manufacturer / Applicant	M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore
Brand Name +Dosage Form + Strength	Zamtrine ES 80/480mg Tablet
Composition	Each Tablet Contains: Artemether…80mg Lumefantrine…480mg
Diary No. Date of R& I & fee	Dy No. 16387: 07-03-2019 PKR 20,000/-: 07-03-2019 New Details TTT-VGH-7VZA PKR 37,030/-: 10-04-2025
Pharmacological Group	Antimalarial
Type of Form	Form 5
Finished Product Specification	Ph. Int.
Pack size & Demanded Price	As per SRO

Approval status of product in Reference Regulatory Authorities.	WHO PQ formulation
Me-too status	Artem DS Plus Tablet by Hilton
GMP status	Inspection date 13/07/2018, panel recommend grant of DML
Remarks of the Evaluator3.	Latest GMP inspection report conducted within a period of last three years.
Decision: Approved.	
Name and address of manufacturer / Applicant	M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore
Brand Name +Dosage Form + Strength	Zamtrol 50mg Tablet SR
Composition	Each Tablet Contains: Diclofenac Potassium…50mg
Diary No. Date of R& I & fee	Dy No. 16379: 07-03-2019 PKR 20,000/-: 07-03-2019 New Details 8QW-ES7-RE55 PKR 37,030/-: 10-04-2025
Pharmacological Group	NSAID
Type of Form	Form 5
Finished Product Specification	USP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	MHRA Approved
Me-too status	Maxit Tablet by Hilton
GMP status	Inspection date 13/07/2018, panel recommend grant of DML
Remarks of the Evaluator3.	Latest GMP inspection report conducted within a period of last three years. Revise the label claim to film coated tablet as per the innovator's product as under along with submission of 7500/- fee: Each Film Coated Tablet Contains: Diclofenac Potassium…50mg
Decision: Approved with following label claim:- Each Film Coated Tablet Contains:	

Diclofenac Potassium…50mg	
Name and address of manufacturer / Applicant	M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore
Brand Name +Dosage Form + Strength	E Zole 40mg Tablet
Composition	Each Tablet Contains: Esomeprazole Magnesium…40mg
Diary No. Date of R& I & fee	Dy No. 16378: 07-03-2019 PKR 20,000/-: 07-03-2019 New Details 1PZ-3HV-BMPY PKR 37,030/-: 10-04-2025
Pharmacological Group	PPI
Type of Form	Form 5
Finished Product Specification	Firm has claimed in house specification
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	MHRA Approved
Me-too status	Emzol Tablet by Metro Pharma
GMP status	Inspection date 13/07/2018, panel recommend grant of DML
Remarks of the Evaluator3.	Latest GMP inspection report conducted within a period of last three years. Revise the label claim as per the innovator's product as under along with submission of full fee of registration: Each Delayed Release Tablet Contains: Esomeprazole (as magnesium trihydrate) …40mg
Decision: Approved with following label claim:- Each Delayed Release Tablet Contains: Esomeprazole (as magnesium trihydrate) …40mg	
Name and address of manufacturer / Applicant	M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore
Brand Name +Dosage Form + Strength	Zamadin 40mg Tablet
Composition	Each Film Coated Tablet Contains: Famotidine…40mg

Diary No. Date of R& I & fee	Dy No. 16377: 07-03-2019 PKR 20,000/-: 07-03-2019 New Details Q2S-GSG-W8PY PKR 37,030/-: 10-04-2025
Pharmacological Group	Antiulcer
Type of Form	Form 5
Finished Product Specification	USP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	MHRA Approved
Me-too status	Famikid Tablet by Karsons Pharma
GMP status	Inspection date 13/07/2018, panel recommend grant of DML
Remarks of the Evaluator3.	Latest GMP inspection report conducted within a period of last three years.
Decision: Approved.	
Name and address of manufacturer / Applicant	M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore
Brand Name +Dosage Form + Strength	Fexadin Tablet 120mg
Composition	Each Film coated Tablet Contains: Fexofenadine HCl…120mg
Diary No. Date of R& I & fee	Dy No. 16382: 07-03-2019 PKR 20,000/-: 06-03-2019 New Details NEG-G38-XG7P PKR 37,030/-: 10-04-2025
Pharmacological Group	Antihistamines For Systemic Use
Type of Form	Form 5
Finished Product Specification	USP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	MHRA Approved
Me-too status	Fexet Tablets by Getz

GMP status	Inspection date 13/07/2018, panel recommend grant of DML
Remarks of the Evaluator3.	Latest GMP inspection report conducted within a period of last three years.
Decision: Approved. Registration letter will be issued after submission of updated GMP inspection report by the firm.	
Name and address of manufacturer / Applicant	M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore
Brand Name +Dosage Form + Strength	Fexadin Tablet 180mg
Composition	Each Film Coated Tablet Contains: Fexofenadine HCl…180mg
Diary No. Date of R& I & fee	Dy No. 16381: 07-03-2019 PKR 20,000/-: 07-03-2019 New Details XT6-LUE-X3A6 PKR 37,030/-: 10-04-2025
Pharmacological Group	Antihistamines For Systemic Use
Type of Form	Form 5
Finished Product Specification	USP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	MHRA Approved
Me-too status	Fexet Tablets by Getz
GMP status	Inspection date 13/07/2018, panel recommend grant of DML
Remarks of the Evaluator3.	Latest GMP inspection report conducted within a period of last three years.
Decision: Approved.	
Name and address of manufacturer / Applicant	M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore
Brand Name +Dosage Form + Strength	Corphil Plus 80/80mg
Composition	Each Sugar Coated Tablet Contains: Phloroglucinol Hydrate…80mg Trimethylphloroglucinol…80mg
Diary No. Date of R& I & fee	Dy No. 16395: 07-03-2019

	PKR 20,000/-: 07-03-2019 New Details X68-VY9-TP3B PKR 37,030/-: 10-04-2025
Pharmacological Group	Antispasmodic
Type of Form	Form 5
Finished Product Specification	Firm has claimed in house specifications
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	Spasfon, coated tablet by M/s Teva Sante, ANSM France Approved.
Me-too status	Gluwix Tablet by Wnsfield
GMP status	Inspection date 13/07/2018, panel recommend grant of DML
Remarks of the Evaluator3.	Latest GMP inspection report conducted within a period of last three years.
Decision: Approved.	
Name and address of manufacturer / Applicant	M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore
Brand Name +Dosage Form + Strength	Iro Plus 100mg Capsule
Composition	Each Capsule Contains Iron Hydroxide Polymaltose Complex Eq To Elemental Iron…100mg
Diary No. Date of R& I & fee	Dy No. 16782: 07-03-2019 PKR 20,000/-: 07-03-2019 New Details GDR-AWL-E3PT PKR 37,030/-: 10-04-2025
Pharmacological Group	Hematinic
Type of Form	Form 5
Finished Product Specification	Firm has claimed in house specification
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
Me-too status	Iroplex Capsule by Pharmix
GMP status	Inspection date 13/07/2018, panel recommend grant of DML

Remarks of the Evaluator3.	Latest GMP inspection report conducted within a period of last three years. Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
Decision: Approved.	
Name and address of manufacturer / Applicant	M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore
Brand Name +Dosage Form + Strength	Ezitam 250mg Tablet
Composition	Each Film Coated Tablet Contains: Levetiracetam…250mg
Diary No. Date of R& I & fee	Dy No. 16393: 07-03-2019 PKR 20,000/-: 07-03-2019 New Details 4MQ-TBJ-6684 PKR 37,030/-: 10-04-2025
Pharmacological Group	Other antiepileptics
Type of Form	Form 5
Finished Product Specification	USP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	MHRA Approved
Me-too status	Lumark Tablet by Searle
GMP status	Inspection date 13/07/2018, panel recommend grant of DML
Remarks of the Evaluator3.	Latest GMP inspection report conducted within a period of last three years.
Decision: Approved.	
Name and address of manufacturer / Applicant	M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore
Brand Name +Dosage Form + Strength	Ezitam 500mg Tablet
Composition	Each Film Coated Tablet Contains: Levetiracetam…500mg
Diary No. Date of R& I & fee	Dy No. 16392: 07-03-2019

	PKR 20,000/-: 07-03-2019 New Details 2T4-YM5-W8BW PKR 37,030/-: 10-04-2025
Pharmacological Group	Other antiepileptics
Type of Form	Form 5
Finished Product Specification	USP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	MHRA Approved
Me-too status	Lumark Tablet by Searle
GMP status	Inspection date 13/07/2018, panel recommend grant of DML
Remarks of the Evaluator3.	Latest GMP inspection report conducted within a period of last three years.
Decision: Approved.	
Name and address of manufacturer / Applicant	M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore
Brand Name +Dosage Form + Strength	Ezitam 750mg Tablet
Composition	Each Film Coated Tablet Contains: Levetiracetam…750mg
Diary No. Date of R& I & fee	Dy No. 16391: 07-03-2019 PKR 20,000/-: 07-03-2019 New Details S2H-TAM-Z4DT PKR 37,030/-: 10-04-2025
Pharmacological Group	Other antiepileptics
Type of Form	Form 5
Finished Product Specification	USP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	MHRA Approved
Me-too status	Lumark Tablet by Searle
GMP status	Inspection date 13/07/2018, panel recommend grant of DML

Remarks of the Evaluator3.	Latest GMP inspection report conducted within a period of last three years.
Decision: Approved.	
Name and address of manufacturer / Applicant	M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore
Brand Name +Dosage Form + Strength	All one 5mg Tablet
Composition	Each Film Coated Tablet Contains: Levocetrizine Dihydrochloride…5mg
Diary No. Date of R& I & fee	Dy No. 16380: 07-03-2019 PKR 20,000/-: 07-03-2019 New Details 1EX-REP-Q1AA PKR 37,030/-: 10-04-2025
Pharmacological Group	Antihistaminic
Type of Form	Form 5
Finished Product Specification	USP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	MHRA Approved
Me-too status	BELAIR 5mg Tablet by BAYER
GMP status	Inspection date 13/07/2018, panel recommend grant of DML
Remarks of the Evaluator3.	Latest GMP inspection report conducted within a period of last three years.
Decision: Approved.	
Name and address of manufacturer / Applicant	M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore
Brand Name +Dosage Form + Strength	Mever 200mg SR Capsule
Composition	Each Capsule Contains: Mebeverine HCl (as SR Pellets)..…200mg
Diary No. Date of R& I & fee	Dy No. 16404: 07-03-2019 PKR 20,000/-: 07-03-2019 New Details AQ4-836-6BT3

	PKR 37,030/-: 10-04-2025
Pharmacological Group	Synthetic anticholinergics, esters with tertiary amino group
Type of Form	Form 5
Finished Product Specification	Firm has claimed in-house specifications
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	MHRA Approved
Me-too status	Sameb MR 200mg Capsule by Hilton Pharma
GMP status	Inspection date 13/07/2018, panel recommend grant of DML
Remarks of the Evaluator3.	Source of pellets: M/s Vision Pharmaceuticals, Islamabad. Latest GMP inspection report conducted within a period of last three years.
Decision: Approved with Innovator's specifications.	
Name and address of manufacturer / Applicant	M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore
Brand Name +Dosage Form + Strength	Cormox Capsule 400mg
Composition	Each Capsule Contains Moxifloxacin as HCl eq to Moxifloxacin…400mg
Diary No. Date of R& I & fee	Dy No. 16407: 07-03-2019 PKR 20,000/-: 07-03-2019 New Details 6QY-JUJ-U7QH PKR 37,030/-: 10-04-2025
Pharmacological Group	Antibiotic
Type of Form	Form 5
Finished Product Specification	USP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	MHRA Approved
Me-too status	Avelox Tablet by Bayer
GMP status	Inspection date 13/07/2018, panel recommend grant of DML
Remarks of the Evaluator3.	Latest GMP inspection report conducted within a period of last three years.

	Revise the label claim as per the innovator's product as under along with submission of full fee of registration: Each Film Coated Tablet Contains: Moxifloxacin As HCl…400mg
Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Moxifloxacin as HCl…400mg**	
Name and address of manufacturer / Applicant	M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore
Brand Name +Dosage Form + Strength	Orat 60mg Capsule
Composition	Each Capsule Contains Orlistat (as IR Pellets)…60mg
Diary No. Date of R& I & fee	Dy No. 16408: 07-03-2019 PKR 20,000/-: 07-03-2019 New Details 1Y2-ANP-JEJE PKR 37,030/-: 10-04-2025
Pharmacological Group	Antiobesity
Type of Form	Form 5
Finished Product Specification	USP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	MHRA Approved
Me-too status	Zerolite Capsule by Crystolite
GMP status	Inspection date 13/07/2018, panel recommend grant of DML
Remarks of the Evaluator.	Latest GMP inspection report conducted within a period of last three years. Source of Pellets is M/s. Vision Pharmaceutical, Islamabad.
Decision: Approved.	
Name and address of manufacturer / Applicant	M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore
Brand Name +Dosage Form + Strength	Rabezole 10mg Capsule
Composition	Each Capsule Contains:

	Rabeprazole Sodium Enteric Coated Pellets…10mg
Diary No. Date of R& I & fee	Dy No. 16403: 07-03-2019 PKR 20,000/-: 07-03-2019 New Details EHR-H2S-EWBT PKR 37,030/-: 10-04-2025
Pharmacological Group	Proton Pump Inhibitors
Type of Form	Form 5
Finished Product Specification	Firm has claimed in-house specifications
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
Me-too status	Repit Capsule by Shrooq Pharma
GMP status	The firm is granted GMP certificate based on inspection conducted 02-02-2022.
Remarks of the Evaluator3.	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. Source of Pellets is M/s. Vision Pharmaceutical, Islamabad.
Decision: Deferred for submission of RRA status	
Name and address of manufacturer / Applicant	M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore
Brand Name +Dosage Form + Strength	Rabezole 20mg Capsule
Composition	Each Capsule Contains: Rabeprazole Sodium Enteric Coated Pellets…20mg
Diary No. Date of R& I & fee	Dy No. 16402: 07-03-2019 PKR 20,000/-: 07-03-2019 New Details UMG-L36-ELQU PKR 37,030/-: 10-04-2025
Pharmacological Group	Proton Pump Inhibitors
Type of Form	Form 5
Finished Product Specification	Firm has claimed in-house specifications
Pack size & Demanded Price	As per SRO

Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
Me-too status	Repit Capsule by Shrooq Pharma
GMP status	The firm is granted GMP certificate based on inspection conducted 02-02-2022.
Remarks of the Evaluator3.	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. Source of Pellets is M/s. Vision Pharmaceutical, Islamabad.
Decision: Deferred for submission of RRA status	
Name and address of manufacturer / Applicant	M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore
Brand Name +Dosage Form + Strength	Rivaban 10mg Tablet
Composition	Each Film Coated Tablet Contains: Rivaroxaban…10mg
Diary No. Date of R& I & fee	Dy No. 16390: 07-03-2019 PKR 20,000/-: 07-03-2019 New Details D3U-47W-ZM43 PKR 37,030/-: 10-04-2025
Pharmacological Group	Direct factor Xa inhibitors
Type of Form	Form 5
Finished Product Specification	BP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	MHRA Approved
Me-too status	Taboxa Tablet by Novamed
GMP status	Inspection date 13/07/2018, panel recommend grant of DML
Remarks of the Evaluator3.	Latest GMP inspection report conducted within a period of last three years.
Decision: Approved.	
Name and address of manufacturer / Applicant	M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore
Brand Name +Dosage Form + Strength	Rivaban 15mg Tablet

Composition	Each Film Coated Tablet Contains: Rivaroxaban…15mg
Diary No. Date of R& I & fee	Dy No. 16388: 07-03-2019 PKR 20,000/-: 07-03-2019 New Details RSH-W8B-UUDE PKR 37,030/-: 10-04-2025
Pharmacological Group	Direct factor Xa inhibitors
Type of Form	Form 5
Finished Product Specification	BP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	MHRA Approved
Me-too status	Taboxa Tablet by Novamed
GMP status	Inspection date 13/07/2018, panel recommend grant of DML
Remarks of the Evaluator3.	Latest GMP inspection report conducted within a period of last three years.
Decision: Approved.	
Name and address of manufacturer / Applicant	M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore
Brand Name +Dosage Form + Strength	Rivaban 20mg Tablet
Composition	Each Film Coated Tablet Contains: Rivaroxaban…20mg
Diary No. Date of R& I & fee	Dy No. 16389: 07-03-2019 PKR 20,000/-: 07-03-2019 New Details 3N3-2YD-2W3E PKR 37,030/-: 10-04-2025
Pharmacological Group	Direct factor Xa inhibitors
Type of Form	Form 5
Finished Product Specification	BP
Pack size & Demanded Price	As per SRO

Approval status of product in Reference Regulatory Authorities.	MHRA Approved
Me-too status	Taboxa Tablet by Novamed
GMP status	Inspection date 13/07/2018, panel recommend grant of DML
Remarks of the Evaluator3.	Latest GMP inspection report conducted within a period of last three years.
Decision: Approved.	
Name and address of manufacturer / Applicant	M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore
Brand Name +Dosage Form + Strength	Rosatin 5mg Tablet
Composition	Each Tablet Contains: Rosuvastatin Calcium…5mg
Diary No. Date of R& I & fee	Dy No. 16375: 07-03-2019 PKR 20,000/-: 07-03-2019 New Details UZZ-R9H-2SGH PKR 37,030/-: 10-04-2025
Pharmacological Group	HMG CoA reductase inhibitors
Type of Form	Form 5
Finished Product Specification	USP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	MHRA Approved
Me-too status	Crestat Tablet by CCL
GMP status	Inspection date 13/07/2018, panel recommend grant of DML
Remarks of the Evaluator3.	Latest GMP inspection report conducted within a period of last three years. Revise your label claim as per the innovator's product as under along with submission of full fee of registration: Each Film Coated Tablet Contains: Rosuvastatin (as calcium)…5mg
Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Rosuvastatin (as calcium)…5mg**	

Name and address of manufacturer / Applicant	M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore
Brand Name +Dosage Form + Strength	Rosatin 10mg Tablet
Composition	Each Tablet Contains: Rosuvastatin Calcium…10mg
Diary No. Date of R& I & fee	Dy No. 16374: 07-03-2019 PKR 20,000/-: 07-03-2019 New Details 7MT-Y6W-EX86 PKR 37,030/-: 10-04-2025
Pharmacological Group	HMG CoA reductase inhibitors
Type of Form	Form 5
Finished Product Specification	USP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	MHRA Approved
Me-too status	Crestat Tablet by CCL
GMP status	Inspection date 13/07/2018, panel recommend grant of DML
Remarks of the Evaluator3.	Latest GMP inspection report conducted within a period of last three years. Revise your label claim as per the innovator's product as under along with submission of full fee of registration: Each Film Coated Tablet Contains: Rosuvastatin (as calcium)…10mg
Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Rosuvastatin (as calcium)…10mg**	
Name and address of manufacturer / Applicant	M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore
Brand Name +Dosage Form + Strength	Rosatin 20mg Tablet
Composition	Each Tablet Contains: Rosuvastatin Calcium…20mg
Diary No. Date of R& I & fee	Dy No. 16376: 07-03-2019

	PKR 20,000/-: 07-03-2019 New Details EZU-Y9A-J9SY PKR 37,030/-: 10-04-2025
Pharmacological Group	HMG CoA reductase inhibitors
Type of Form	Form 5
Finished Product Specification	USP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	MHRA Approved
Me-too status	Crestat Tablet by CCL
GMP status	Inspection date 13/07/2018, panel recommend grant of DML
Remarks of the Evaluator3.	Latest GMP inspection report conducted within a period of last three years. Revise your label claim as per the innovator's product as under along with submission of full fee of registration: Each Film Coated Tablet Contains: Rosuvastatin (as calcium)…20mg
Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Rosuvastatin (as calcium)…20mg**	
Name and address of manufacturer / Applicant	M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore
Brand Name +Dosage Form + Strength	Urisin 0.4mg Capsule
Composition	Each Capsule Contains: Tamsulosin HCl…0.4mg
Diary No. Date of R& I & fee	Dy No. 16401: 07-03-2019 PKR 20,000/-: 07-03-2019 New Details BMV-JAX-32PZ PKR 37,030/-: 10-04-2025
Pharmacological Group	Alpha-adrenoreceptor antagonists
Type of Form	Form 5

Finished Product Specification	USP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	MHRA Approved
Me-too status	Maxflow Capsule by CCL
GMP status	Inspection date 13/07/2018, panel recommend grant of DML
Remarks of the Evaluator3.	Source of pellets: M/s Vision Pharmaceuticals, Islamabad. Latest GMP inspection report conducted within a period of last three years. Revise your label claim as per the innovator's product as under along with submission of full fee of registration: Each Capsule Contains: Tamsulosin HCl Modified Release Pellets Eq To Tamsulosin……0.4mg
Decision: Approved with following label claim: **Each Capsule Contains:** **Tamsulosin HCl Modified Release Pellets Eq To Tamsulosin……0.4mg**	
Name and address of manufacturer / Applicant	M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore
Brand Name +Dosage Form + Strength	Ursolic 250mg capsule
Composition	Each Capsule Contains Ursodeoxycholic Acid …250mg
Diary No. Date of R& I & fee	Dy No. 16399: 07-03-2019 PKR 20,000/-: 07-03-2019 New Details 288-823-2V2Y PKR 37,030/-: 10-04-2025
Pharmacological Group	Bile acids and derivatives
Type of Form	Form 5
Finished Product Specification	Firm has claimed in house specifications but available in BP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	MHRA Approved
Me-too status	Ursodol capsule by Aspin Pharma

GMP status	Inspection date 13/07/2018, panel recommend grant of DML
Remarks of the Evaluator3.	Latest GMP inspection report conducted within a period of last three years.
Decision: Approved with BP specifications.	
Name and address of manufacturer / Applicant	M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore
Brand Name +Dosage Form + Strength	Ursolic 500mg capsule
Composition	Each Capsule Contains Ursodeoxycholic Acid …500mg
Diary No. Date of R& I & fee	Dy No. 16398: 07-03-2019 PKR 20,000/-: 07-03-2019 New Details 3PG-H13-JM72 PKR 37,030/-: 10-04-2025
Pharmacological Group	Bile acids and derivatives
Type of Form	Form 5
Finished Product Specification	BP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	Bilheptil 500mg hard capsules MHRA Approved
Me-too status	Ursodol capsule by Aspin Pharma
GMP status	Inspection date 13/07/2018, panel recommend grant of DML
Remarks of the Evaluator3.	Latest GMP inspection report conducted within a period of last three years.
Decision: Approved with BP specifications.	
Name and address of manufacturer / Applicant	M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore
Brand Name +Dosage Form + Strength	Venafax XL 75mg Capsule
Composition	Each Capsule Contains Venlafaxine HCl SR Pellets eq to Venlafaxine…75mg
Diary No. Date of R& I & fee	Dy No. 16400: 07-03-2019 PKR 20,000/-: 07-03-2019 New Details

	3D5-Z81-7Q72 PKR 37,030/-: 10-04-2025
Pharmacological Group	Other antidepressants
Type of Form	Form 5
Finished Product Specification	USP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	USFDA Approved
Me-too status	Venwell Capsule by Fynk
GMP status	Inspection date 13/07/2018, panel recommend grant of DML
Remarks of the Evaluator3.	Source of pellets: M/s Vision Pharmaceuticals, Islamabad. Latest GMP inspection report conducted within a period of last three years.
Decision: Approved.	
Name and address of manufacturer / Applicant	M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore
Brand Name +Dosage Form + Strength	Voricon 50mg Tablet
Composition	Each Film Coated Tablet Contains: Voriconazole…50mg
Diary No. Date of R& I & fee	Dy No. 16384: 07-03-2019 PKR 20,000/-: 07-03-2019 New Details N6W-ATE-D7RD PKR 37,030/-: 10-04-2025
Pharmacological Group	Antimycotics for systemic use
Type of Form	Form 5
Finished Product Specification	Firm has claimed in house specification while monograph is available in JP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	USFDA Approved
Me-too status	Dynazole Tablet by Dyson
GMP status	Inspection date 13/07/2018, panel recommend grant of DML

Remarks of the Evaluator3.	Latest GMP inspection report conducted within a period of last three years.
Decision: Approved with JP specifications.	
Name and address of manufacturer / Applicant	M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore
Brand Name +Dosage Form + Strength	Voricon 200mg Tablet
Composition	Each Film Coated Tablet Contains: Voriconazole…200mg
Diary No. Date of R& I & fee	Dy No. 16383: 07-03-2019 PKR 20,000/-: 07-03-2019 New Details HBJ-DU4-5QPW PKR 37,030/-: 10-04-2025
Pharmacological Group	Antimycotics for systemic use
Type of Form	Form 5
Finished Product Specification	Firm has claimed in house specification while monograph is available in JP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	USFDA Approved
Me-too status	Dynazole Tablet by Dyson
GMP status	Inspection date 13/07/2018, panel recommend grant of DML
Remarks of the Evaluator3.	Latest GMP inspection report conducted within a period of last three years.
Decision: Approved with JP specifications.	

Drug Regulatory Authority of Pakistan

(Pharmaceutical Evaluation & Registration Division)

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Application received on e-app

Sr. No	Title	Description
1	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	**Roryan Pharmaceutical Industries Private Limited** Plot No. 85-B Industrial Estate Hayatabad **(000566)**
	Application Form Dy. No / Tracking ID & date of submission	(1ME-J85-QZGD, 2025-02-11)
	Detail of Fee Submitted	30000.0, 7000.0 2024-04-25, 2024-11-19
	The proposed proprietary name / brand name	**Paracetol Extra**
	Label Claim	Each Tablet Contains Paracetamol 500mg + Caffeine 65mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10s-As per SRO
	Shelf Life (Unit)	2 Yearambient
	For generic drugs (me-too Status)	available
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Pharmagen Pakistan /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	available
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The application fulfils codal formalities and is submitted for consideration of the Board.	
	Decision	
	Approved	
2	Case Category	New License (Abdul Mughees)
	Name, address of Applicant.	**PHARMAQIO RAWALPINDI** 10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. **(000978)**
	Application Form Dy. No / Tracking ID & date of submission	(3TA-UR9-ZNV1, 2026-02-10)
	Detail of Fee Submitted	38700, 2025-12-17,

	The proposed proprietary name / brand name	**Qioval Plus 10/160mg**
	Label Claim	Each Film Coated Tablet contains: Amlodipine Besylate equivalent to Amlodipine ..... 10mg Valsartan..... 160mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x14's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	rand Name: Extor 10/160 Tablet Manufacturer: The Searle Company Limited. Address: F-319,SITE., Karachi-Pakistan.
	Pharmacotherapeutic Group of (API)	provided in modoule I in 1.6.5
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Provided in modoule III in 3.2.P.8.2
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided in modoule III
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided in modoule and III in 3.2.P.2.2.2
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided in modoule III in 3.2.S.7
	The status in reference regulatory authorities	Provided in Modoule I in 1.5.9
	GMP status of the firm	provided in modoule I in 1.6.5
	Evidence of approval of manufacturing facility	Provided in modoule I in 1.3.5
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration of the Board.	
	Decision	
	Approved	
3	Case Category	New License (Abdul Mughees)
	Name, address of Applicant.	**PHARMAQIO RAWALPINDI** 10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. **(000978)**
	Application Form Dy. No / Tracking ID & date of submission	(AX7-8L7-URTZ, 2026-02-12)
	Detail of Fee Submitted	38700, 2025-12-17,
	The proposed proprietary name / brand name	**Qioval A 5/10MG Tablet**
	Label Claim	Each Film Coated Tablet contains: Amlodipine Besylate equivalent to Amlodipine .....5mg Valsartan.....80mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x14's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	rand Name: Extor 5/80 Tablet Manufacturer: The Searle Company Limited. Address: F-319,SITE., Karachi-Pakistan.
	Pharmacotherapeutic Group of (API)	provided in modoule I in 1.6.5
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Provided in modoule III in 3.2.P.8.2

	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided in modoule III
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided in modoule and III in 3.2.P.2.2.2
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided in modoule III in 3.2.S.7
	The status in reference regulatory authorities	Provided in modoule I in 1.5.8
	GMP status of the firm	provided in modoule I in 1.6.5
	Evidence of approval of manufacturing facility	Provided in modoule I in 1.3.5
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration of the Board.	
	Decision	
	Approved	
4	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	(86V-J5A-E25V, 2024-08-19)
	Detail of Fee Submitted	30000.0, 2024-08-16,
	The proposed proprietary name / brand name	**Levlimid 25mg Capsule**
	Label Claim	Each capsule contains: Lenalidomide 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 30 °C.
	For generic drugs (me-too Status)	Relidomide Capsule 25mg, Helix Pharma (Pvt.) Ltd.
	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	REVLIMID, Food & Drug Administration- FDA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration of the Board.	
	Decision	
	Approved	
5	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	(8BM-8JX-B4JW, 2024-08-20)
	Detail of Fee Submitted	30000.0, 2024-08-16,
	The proposed proprietary name / brand name	**Levlimid 10mg Capsule**
	Label Claim	Each capsule contains: Lenalidomide 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 30 °C.
	For generic drugs (me-too Status)	Relidomide Capsule 10mg, Helix Pharma (Pvt.) Ltd.
	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	REVLIMID, Food & Drug Administration- FDA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration of the Board.	
	Decision	
	Approved	
6	Case Category	Import (Abdul Mughees)
	Name, address of Applicant.	**MSA PHARMA** 1st floor, 793-D Block C Faisal Town **(05-352-0066-112591D)**
	Application Form Dy. No / Tracking ID & date of submission	(H3Q-82B-DDV2, 2026-03-17)
	Detail of Fee Submitted	313500, 2026-03-11,
	The proposed proprietary name / brand name	**Ruxotor 10mg Tablet**
	Label Claim	Each film coated tablet contains Ruxolitinib Phosphate equivalent to Ruxolitinib 10 mg.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	60's-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30°C
	For generic drugs (me-too Status)	Jakavi 10 mg tablets
	Pharmacotherapeutic Group of (API)	Antineoplastic agents, protein kinase inhibitors
	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 relevant section of Module 3

	Name, address of Marketing Authorization Holder:	Everest pharmaceuticals limited, Rahman's Regnum Centre (11th floor) 191/1,1 Tejgaon C/A, Dhaka 1208, Bangladesh
	Details of Certificates (CoPP/FSC/cGMP):	Valid
	Details of Authorization Letter :	Not applicable for finished product importer
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached in relevant section of Module 3
	The status in reference regulatory authorities	Jakavi 10 mg tablets
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration of the Board.	
	Decision	
	Approved Registration Board approved the product subjecto to inspection as per import policy.	
7	Case Category	Routine (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	(M7E-U7L-QBLM, 2024-07-08)
	Detail of Fee Submitted	30000.0, 2024-05-29,
	The proposed proprietary name / brand name	**Gabicap 25mg Capsules**
	Label Claim	Each Capsule Contains; Pregabalin.....25mg (BP Spec's)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30ºC
	For generic drugs (me-too Status)	Gabica 25mg capsules, Manufacturer: Getz Pharma (Pvt.) Limited
	Pharmacotherapeutic Group of (API)	ATC N02BF02 Gabapentinoids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	At long-term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	API loan from Seraph Pharma
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	At long-term and accelerated conditions - API from loan premises
	The status in reference regulatory authorities	Lyrica®25mg hard capsules, Manufacturer: Pfizer Service Company BV, Hoge Wei 10, 1930 Zaventem, Belgium(Registered in Europe)
	GMP status of the firm	DML issued 17.01.2024
	Evidence of approval of manufacturing facility	DML issued 17.01.2024
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration of the Board.	
	Decision	
	Approved	

8	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	**AUSPEC PHARMACEUTICALS PVT LTD** 21, Km, Raiwind Road, Lahore. **(000964)**
	Application Form Dy. No / Tracking ID & date of submission	(LDJ-81H-PT9Z, 2024-04-15)
	Detail of Fee Submitted	75000.0, 2024-02-06,
	The proposed proprietary name / brand name	**Sanarte 60mg Injection**
	Label Claim	Each vial contains: Artesunate. 60mg
	Reference to Finished product specifications	The International Pharmacopeia
	Proposed Pack Size	1's / DPC-As per SRO
	Shelf Life (Unit)	2 Year(s)Store Below 25C
	For generic drugs (me-too Status)	Gen-M Injection by M/s Genix Pharma
	Pharmacotherapeutic Group of (API)	Anti-malarial
	Name, address of Manufacturing site:	Aulton Pharmaceuticals-Plot # 84/1, Block A, Phase 5, Industrial Estate, Pakistan-
	Name & address of API manufacturer	MICRO ORGO CHEM, C-1/B-57, LIC Sector, GIDC Vapi-396 195, Gujarat,
	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	Artesunate 60mg Injection By M/s Amivas LLC, 600 Capability Green,Luton,LU1 3LU, USA.
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	Provided
	Evaluation Remarks	
	As per FDA approved label, a 12 mL of sterile 0.3 M pH 8.0 sodium phosphate buffer is provided with Artesunate (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213036s000lbl.pdf).	
	Decision	
	Approved Registration Board approved the product subject to the submission of in-use stability studies of the drug product using the same solvent as recommended by the WHO prequalified reference product. The firm shall also submit batch analysis report in accordance with IP monograph of Artesunate Injection.	
9	Case Category	New License (Abdul Mughees)
	Name, address of Applicant.	**HINUCON (Pvt.) Ltd.** Plot No. IT-03-A3 & IT-04-A3, Korangi Creek Industrial Park (KCIP) **(001001)**
	Application Form Dy. No / Tracking ID & date of submission	(XB5-SXE-A85T, 2026-03-16)
	Detail of Fee Submitted	38700, 2025-12-09,
	The proposed proprietary name / brand name	**Zeegap Capsules 200mg**
	Label Claim	Each capsule contains: Pregabalin, USP.....200mg
	Reference to Finished product specifications	British Pharmacopeia

	Proposed Pack Size	2x 5's, -As per SRO,1x10's, -As per SRO,1x14's, -As per SRO,1x5's,-As per SRO,1X7's, -As per SRO,2x 7's, -As per SRO,2x10's, -As per SRO,2x14's -As per SRO,3x10's, -As per SRO,4x14's-As per SRO,4x7's, -As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30ºC. Protect from sunlight & moisture. Keep out of reach of children.
	For generic drugs (me-too Status)	Gabica 200mg, (Getz Pharma)
	Pharmacotherapeutic Group of (API)	Antiepileptics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches at accelerated and long-term conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	APi loan from Hilton DIL -C-19CF52
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches at accelerated and long-term conditions
	The status in reference regulatory authorities	Lyrica Capsules 200mg ; (Pfizer) https://www.accessdata.fda.gov/drugsatfda_docs/la
	GMP status of the firm	DML no. 001001 issued on 02.12.2024
	Evidence of approval of manufacturing facility	DML no. 001001 issued on 02.12.2024
	Evaluation Remarks	
	The application fulfils codal formalities and is submitted for consideration of the Board.	
	Decision	
	Approved	
10	Case Category	New License (Abdul Mughees)
	Name, address of Applicant.	**HINUCON (Pvt.) Ltd.** Plot No. IT-03-A3 & IT-04-A3, Korangi Creek Industrial Park (KCIP) **(001001)**
	Application Form Dy. No / Tracking ID & date of submission	(XU7-BZU-SHD8, 2026-03-03)
	Detail of Fee Submitted	38700, 2025-12-03,
	The proposed proprietary name / brand name	**Zeegap Capsules 50mg**
	Label Claim	Each capsule contains: Pregabalin, USP.....50mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	3x10's, -As per SRO, 4x7's, -As per SRO,1X 7's, -As per SRO,1x10's, -As per SRO,1x14's, -As per SRO,1x5's, -As per SRO,2x 5's,-As per SRO,2x 7's,-As per SRO,2x10's,-As per SRO,2x14's -As per SRO,4x14's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30ºC. Protect from sunlight & moisture. Keep out of reach of children.
	For generic drugs (me-too Status)	Gabica 25mg, (Getz Pharma)
	Pharmacotherapeutic Group of (API)	Antiepileptics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches at accelerated and long-term conditions

	Documents for the procurement of API with approval from DRAP (in case of Import)	APi import from Hilton, DIL -C-19CF52
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches at accelerated and long-term conditions
	The status in reference regulatory authorities	Lyrica Capsules 50mg ; (Pfizer) https://www.accessdata.fda.gov/drugsatfda_docs/la
	GMP status of the firm	DML no. 001001 issued on 02.12.2024
	Evidence of approval of manufacturing facility	DML no. 001001 issued on 02.12.2024
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration of the Board.	
	Decision	
	Approved	
11	Case Category	New License (Abdul Mughees)
	Name, address of Applicant.	**HINUCON (Pvt.) Ltd.** Plot No. IT-03-A3 & IT-04-A3, Korangi Creek Industrial Park (KCIP) **(001001)**
	Application Form Dy. No / Tracking ID & date of submission	(Y4M-W1S-6T4H, 2026-03-03)
	Detail of Fee Submitted	38700, 2025-12-03,
	The proposed proprietary name / brand name	**Zeegap Capsules 25mg**
	Label Claim	Each capsule contains: Pregabalin, USP.....25mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1x10's,-As per SRO, 1x5's,-As per SRO, 2x 5's, -As per SRO,1x14's, -As per SRO,1X7's, -As per SRO,2x 7's, -As per SRO,2x10's, -As per SRO,2x14's -As per SRO,3x10's,-As per SRO,4x14's-As per SRO,4x7's, -As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30ºC. Protect from sunlight & moisture. Keep out of reach of children.
	For generic drugs (me-too Status)	Gabica 25mg, (Getz Pharma)
	Pharmacotherapeutic Group of (API)	Antiepileptics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches at accelerated and long-term conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	API loan from Hilton DIL -C-19CF52
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches at accelerated and long-term conditions
	The status in reference regulatory authorities	Lyrica Capsules 25mg ; (Pfizer) https://www.accessdata.fda.gov/drugsatfda_docs/la
	GMP status of the firm	DML no. 001001 issued on 02.12.2024
	Evidence of approval of manufacturing facility	DML no. 001001 issued on 02.12.2024
	Evaluation Remarks	

	The applciation fulfills codal formalities and is submitted for consideration of the Board.	
	Decision	
	Approved	
12	Case Category	New License (Abdul Mughees)
	Name, address of Applicant.	**HINUCON (Pvt.) Ltd.** Plot No. IT-03-A3 & IT-04-A3, Korangi Creek Industrial Park (KCIP) **(001001)**
	Application Form Dy. No / Tracking ID & date of submission	(M5U-7RB-GHN5, 2026-03-03)
	Detail of Fee Submitted	38700, 2025-12-09,
	The proposed proprietary name / brand name	**Dulan Capsules 30mg**
	Label Claim	Each delayed release capsule contains: Duloxetine HCI enteric coated pellets equivalent to Duloxetine 30mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x14's, -As per SRO, 3x10's, -As per SRO,1x10's, -As per SRO,1x5's, -As per SRO,2x 5's, -As per SRO,2x 7's, -As per SRO,2x10's,-As per SRO,2x14's, -As per SRO,4x14's-As per SRO,4x7's,-As per SRO,7's, -As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30ºC. Protect from sunlight & moisture. Keep out of reach of children.
	For generic drugs (me-too Status)	Getz Pharma : Lyta 20mg capsule
	Pharmacotherapeutic Group of (API)	anti depressents
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches at accelerated and long-term conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	procured locally (Surge laboratories pvt ltd) pakistan
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches at accelerated and long-term conditions
	The status in reference regulatory authorities	Cymbalta Capsule 30mg Manufacturer: Eli Lilly and Company, Indianapolis, IN 46285, USA accessdata.fda (.gov) https://share.google/W99UGWRdU0G8MNYSe
	GMP status of the firm	DML no. 001001 issued on 02.12.2024
	Evidence of approval of manufacturing facility	DML no. 001001 issued on 02.12.2024
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration of the Board.	
	Decision	
	Approved	
13	Case Category	New License (Abdul Mughees)
	Name, address of Applicant.	**HINUCON (Pvt.) Ltd.** Plot No. IT-03-A3 & IT-04-A3, Korangi Creek Industrial Park (KCIP) **(001001)**
	Application Form Dy. No / Tracking ID & date of submission	(XR3-YBD-HAJX, 2026-03-03)

	Detail of Fee Submitted	38700, 2025-12-09,
	The proposed proprietary name / brand name	**Dulan Capsules 20mg**
	Label Claim	Each delayed release capsule contains: Duloxetine HCI enteric coated pellets equivalent to Duloxetine 20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2x 5's, -As per SRO, 2x 7's, -As per SRO, 2x10's, -As per SRO, 2x14's, -As per SRO,1x10's,-As per SRO,1x14's,-As per SRO,1x5's,-As per SRO,1x7's, -As per SRO,3x10's,-As per SRO,4x14's-As per SRO,4x7's, -As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30ºC. Protect from sunlight & moisture. Keep out of reach of children.
	For generic drugs (me-too Status)	Getz Pharma : Lyta 20mg capsule
	Pharmacotherapeutic Group of (API)	anti depressents
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches at accelerated and long-term conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	procured locally (Surge laboratories pvt ltd) pakistan
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches at accelerated and long-term conditions
	The status in reference regulatory authorities	Cymbalta Capsule 20mg Manufacturer: Eli Lilly and Company, Indianapolis, IN 46285, USA accessdata.fda (.gov) https://share.google/W99UGWRdU0G8MNYSe
	GMP status of the firm	DML no. 001001 issued on 02.12.2024
	Evidence of approval of manufacturing facility	DML no. 001001 issued on 02.12.2024
	Evaluation Remarks	
	The applciation fulfills codal formalities and is submitted for consideration of the Board.	
	Decision	
	Approved	
14	Case Category	Routine (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	(X3V-6VS-NVYR, 2024-08-26)
	Detail of Fee Submitted	30000.0, 2024-08-22,
	The proposed proprietary name / brand name	**Gabicap 100mg Capsules**
	Label Claim	Each capsule contains; Pregabalin.....100mg (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30ºC

	For generic drugs (me-too Status)	Gabica 100mg capsules, Manufacturer: Getz Pharma (Pvt.) Limited
	Pharmacotherapeutic Group of (API)	ATC N02BF02 Gabapentinoids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	At long-term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	API loan from Seraph Pharma
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	At long-term and accelerated conditions - API from loan premises
	The status in reference regulatory authorities	Lyrica 100mg capsules, Company: CP Pharms, (NDA): 021723 (USFDA Approved)
	GMP status of the firm	DML issued 17.01.2024
	Evidence of approval of manufacturing facility	DML issued 17.01.2024
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration of the Board.	
	Decision	
	Approved	
15	Case Category	Routine (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	(U7H-ANT-AQUE, 2024-09-30)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-22, 2024-09-25
	The proposed proprietary name / brand name	**Gabicap 150mg Capsules**
	Label Claim	Each capsule contains; Pregabalin.....150mg (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30ºC
	For generic drugs (me-too Status)	Gabica 150mg capsules, Manufacturer: Getz Pharma (Pvt.) Limited
	Pharmacotherapeutic Group of (API)	ATC N02BF02 Gabapentinoids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	At long-term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	API loan from Seraph Pharma
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	At long-term and accelerated conditions - API from loan premises
	The status in reference regulatory authorities	Brand Name:Lyrica 150mg capsules, Company: CP Pharms (NDA): 021723, USFDA Approved

	GMP status of the firm	DML issued 17.01.2024
	Evidence of approval of manufacturing facility	DML issued 17.01.2024
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration of the Board.	
	Decision	
	Approved	
16	Case Category	Import (Abdul Mughees)
	Name, address of Applicant.	**MSA PHARMA** 1st floor, 793-D Block C Faisal Town **(05-352-0066-112591D)**
	Application Form Dy. No / Tracking ID & date of submission	(P6N-YZM-HXGZ, 2026-03-17)
	Detail of Fee Submitted	313500, 2026-03-10,
	The proposed proprietary name / brand name	**Ruxotor 5mg Tablet**
	Label Claim	Each film coated tablet contains.....Ruxolitinib Phosphate equivalent to Ruxolitinib 5 mg.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	60's-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30°C.
	For generic drugs (me-too Status)	Jakavi 5mg Tablets
	Pharmacotherapeutic Group of (API)	Henan Jin Huaitang Biological Engineering Co.,Ltd, China
	Name, address of Manufacturing site:	Everest Pharmaceuticals Limited.-Rahman's Regnum Centre (11th) Floor) 191/1, Tejgaon C/A, Dhaka-1208,-Bangladesh
	Name & address of API manufacturer	Henan Jin Huaitang Biological Engineering Co.,Ltd,
	Detail of stability batches of drug product	24 Months
	Documents for the procurement of API with approval from DRAP (in case of Import)	Not Applicable for Finished drug Product importer.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in Relavant section of Module 3.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	24 Months
	The status in reference regulatory authorities	Jakavi 5mg Tablets (Novartis, Spain)
	GMP status of the firm	Valid.
	Evidence of approval of manufacturing facility	Attached in Relavant section of Module 1.
	Evaluation Remarks	
	The applciation fulfills codal formalities.	
	Decision	
	Approved Registration Board apporved the product subject to inspection as per import policy.	
17	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	(YGT-E9H-P96V, 2024-07-08)

	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.....15mg
	Reference to Finished product specifications	Manufacturer 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)	ATC N02BF03: analgesics, gabapentinoids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Kehui Pharmaceutical Co, Ltd
	Detail of stability batches of drug product	At long-term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	API loan from HIGH-Q PHARMACEUTICALS
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP with Tarlige, Daiichi sankyo company , PMDA Japan
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	At long-term and accelerated conditions
	The status in reference regulatory authorities	Tarlige tablet by Daiichi sankyo company
	GMP status of the firm	GMP certificate dated 09.01.2024
	Evidence of approval of manufacturing facility	DML 000590
	Evaluation Remarks	
	The applicaiton fulfils codal formalities and is submitted for consideration of the Board.	
	Decision	
	Approved	
18	Case Category	New License (Abdul Mughees)
	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	(4XD-1ZG-3X64, 2025-07-24)
	Detail of Fee Submitted	37000.0, 2025-05-05,
	The proposed proprietary name / brand name	**Muscolax 4mg/2ml Injection**
	Label Claim	Each 2ml ampoule contains: Thiocolchicoside ..... 4mg (As per Innovators specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1,s 5's 10's 30's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store between 15C-30C
	For generic drugs (me-too Status)	Chicowin 4mg/2ml Injection, Wnsfield Pharmaceuticals, Reg. No. 093890. .
	Pharmacotherapeutic Group of (API)	Muscle Relaxant
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Alkaloid Pvt Ltd 834(P), Medchal Shamirpet Road, Medchal Mandal Rangareddy, Telangana, 501401 India
	Detail of stability batches of drug product	Long-term and accelerated conditions

	Documents for the procurement of API with approval from DRAP (in case of Import)	API on loan from Seraph
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed against Muscoril 4mg/2ml Injection by Sonafi Aventis
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Long-term and accelerated conditions
	The status in reference regulatory authorities	ANSM
	GMP status of the firm	GMP 24.02.2025
	Evidence of approval of manufacturing facility	DML dated 18.03.2021
	Evaluation Remarks	
	The European Medicines Agency's Committee on Human Medicinal Products (CHMP) has recommended that the authorised uses for thiocolchicoside-containing medicines for use by mouth or injection should be restricted across the European Union (EU). These medicines are now recommended only as an add-on treatment for painful muscle contractures (permanent tightening of the muscle tissue) resulting from spinal conditions in adults and adolescents 16 years of age or older. In addition, the dose of thiocolchicoside by mouth or injection should be restricted. The review of thiocolchicoside was triggered by the Italian medicines regulatory agency, AIFA, following new experimental evidence which suggested that thiocolchicoside was broken down in the body into a metabolite called M2 or SL59.0955 that could damage dividing cells, resulting in aneuploidy (an abnormal number or arrangement of chromosomes). As a result AIFA asked the CHMP to examine the safety profile of this medicine and consider what regulatory action might be appropriate. The CHMP reviewed the evidence, including the opinions of experts in the field of medicines safety, and concluded that aneuploidy could occur with M2 at levels not much greater than those seen after recommended doses of thiocolchicoside taken by mouth. Aneuploidy is a risk factor for harm to the developing fetus, reduced fertility in men and in theory could increase the risk of developing cancer. The CHMP therefore recommended measures to ensure thiocolchicoside-containing medicines are used as safely as possible. These include restricting the maximum dose and number of days of treatment when given by mouth or injection. Use is also contra-indicated in pregnancy and lactation or in women of childbearing potential not using contraception, as well as in children or for chronic (long-term) conditions.	
	Decision	
	Approved Registration Board approved the product with the following labelling condition: "Thiocolchicoside-containing medicines for use by mouth or injection should be used in adults and adolescents 16 years of age or older."	
19	Case Category	Routine (Abdul Mughees)
	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	(4XJ-43R-WY57, 2024-10-24)
	Detail of Fee Submitted	75000.0, 2024-08-13,
	The proposed proprietary name / brand name	**PREGY XR 82.5mg 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	De-regulated-De-Controlled
	Shelf Life (Unit)	2 Year(s)Don't store over 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Gabapentinoids

	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Long-term and accelerated conditions 03 batches of 2000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate E-4571659932946 dated 28-February 2023
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed against Lyrica CR Tablet 82.5mg by Pfizer Singapore Batch number GT 5816
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Long-term and accelerated conditions
	The status in reference regulatory authorities	LYRICA CR 82.5mg Tablet
	GMP status of the firm	GMP dated 12 August 2024
	Evidence of approval of manufacturing facility	DMl dated 21.08.2020 Renewal letter dated 13-October 2023
	Evaluation Remarks	
	The applciation fulfills codal formalities and is submitted for consideration of the Board.	
	Decision	
	Approved	
20	Case Category	Routine (Abdul Mughees)
	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	(NXX-Q2D-8WUW, 2024-09-10)
	Detail of Fee Submitted	75000.0, 2024-08-13,
	The proposed proprietary name / brand name	**PREGY XR 165mg Tablet**
	Label Claim	Each film coated extended release tablet contains: Pregabalin 165mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	De-regulated-De-Controlled
	Shelf Life (Unit)	2 Year(s)Don't store over 30°C
	For generic drugs (me-too Status)	NCE
	Pharmacotherapeutic Group of (API)	Gabapentinoids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Long-term and accelerated conditions 03 batches of 2000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate E-4571659932946 dated 28-February 2023
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed against Lyrica CR Tablet 165mg by Pfizer Singapore
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Long-term and accelerated conditions
	The status in reference regulatory authorities	LYRICA CR 165mg Tablet
	GMP status of the firm	GMP dated 12 August 2024
	Evidence of approval of manufacturing facility	DMl dated 21.08.2020 Renewal letter dated 13-October 2023
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration of the Board.	

	Decision	
	Approved	
21	Case Category	Routine (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	(82A-5R6-A3N6, 2024-10-21)
	Detail of Fee Submitted	37000.0, 2024-10-01,
	The proposed proprietary name / brand name	**GabaPil CR 330mg Tablets**
	Label Claim	Pregabalin 330mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	20's Tablets-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Gabapentinoids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Progress Life Sciences Pvt. Ltd.
	Detail of stability batches of drug product	Long-term and accelerated conditions of 03 batches 2500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Procurement
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Lyrica CR 82.5mg tablet by Pfizer NY, batch no AW 1036
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Long-term and accelerated conditions
	The status in reference regulatory authorities	LYRICA® CR (Pregabalin) extended-release tablets, for oral use (82.5mg, 165mg & 330mg). Pfizer Inc. 66 Hudson Boulevard East New York, NY 10001-2192 USA
	GMP status of the firm	GNP dated 09-March 2024
	Evidence of approval of manufacturing facility	Application for renewal of DML submitted on 2025-05-09
	Evaluation Remarks	
	The license Form 25-A of the Drug Substance manufacturer (Progress Life Sciences Pvt. Ltd.) is a loan license on the premises of another chemical plant, with unknown impacts on quality, safety and efficacy of the manufactured API. Please justify. Reply: The Pregabalin API manufactured under a Form 25-A loan license by Progress Life Sciences Pvt. Ltd. is produced at a GMP-compliant, licensed facility with established quality systems and validated processes. A formal quality agreement ensures clear delineation of responsibilities. Comprehensive analytical testing, process validation, and stability studies confirm that the loan license arrangement does not impact the quality, safety, or efficacy of the drug substance. Therefore, the manufacturing arrangement is considered fully compliant and acceptable from a regulatory standpoint.	
	Decision	
	Approved Registration Board approved the product subject to undertaking by the applicant to validate API source which is not on loan license in the country of origin.	
22	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	(ADW-B68-LUW1, 2024-08-26)
	Detail of Fee Submitted	75000.0, 2024-07-15,
	The proposed proprietary name / brand name	**Mirogab**
	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	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)	Gabapentinoids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Kehui Pharmaceutical Co, Ltd
	Detail of stability batches of drug product	Long-term and accelrated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	API on loan from High-Q Pharmaceuticals
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed against Tarlige 10mg tablets
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Long-term and accelrated conditions
	The status in reference regulatory authorities	Tarlige tablet by Daiichi sankyo company
	GMP status of the firm	GMP dated 09.01.2024
	Evidence of approval of manufacturing facility	DML dated 08-04-2021
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration of the Board.	
	Decision	
	Approved	
23	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	(D1Y-86M-DSPY, 2024-07-19)
	Detail of Fee Submitted	75000.0, 2024-07-10,
	The proposed proprietary name / brand name	**Mirogab**
	Label Claim	Each film coated tablet contains: Mirogabalin besylate eq to mirogabalin.....2.5mg
	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)	Gabapentinoids
	Name, address of Manufacturing site:	Self Manufacturing
	The status in reference regulatory authorities	Tarlige tablet by Daiichi sankyo company
	Detail of previous approval	

	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration of the Board.	
	Decision	
	Approved	
24	Case Category	Import (Abdul Mughees)
	Name, address of Applicant.	**Sohail Corporation** plot # 7, SR-5, Serai Quarters (Techno City), WH-42, Karachi Pakistan. **(238)**
	Application Form Dy. No / Tracking ID & date of submission	(A3J-SYQ-RMAE, 2026-01-14)
	Detail of Fee Submitted	313500, 2025-09-30,
	The proposed proprietary name / brand name	**Sterile Water for Injection 5ml**
	Label Claim	Each ampoule contains; Sterile water for Injection 5ml
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100 ampoules per box-De-Controlled
	Shelf Life (Unit)	36 MonthStore below 30°C. Use once only and discard any remaining portion.
	For generic drugs (me-too Status)	Sterile Water for Injection 5ml, Manufactured by Pulse Pharmaceutical Pvt Ltd. Lahore-Pakistan.
	Pharmacotherapeutic Group of (API)	API: Water for Injection, Therapeutic classification: Solvents and diluting agents. ATC code: VO7AB
	Name, address of Manufacturing site:	Shandong Hualu Pharmaceutical Co., Ltd.-No.1 Hualu Road, Zhenxing Street, Chiping District, Liaocheng City, Shandong Province.-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Valid Pharmaceutical Equivalence attached in Module 3
	Name, address of Marketing Authorization Holder:	M/s; Sohail Corporation, Address: Plot no 7, (Serai Quarters) SR-5, Techno City, Warehouse No 42, 6th Floor, Karachi. , Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Valid GMP Inspection Report of Manufacturer issued by Shandong Provincial Drug Supervision and Administration Bureau attached herewith
	Details of Authorization Letter :	Not applicable. The product does not contain any active pharmaceutical ingredient. The sole component, Water for Injection, is prepared and sterilized in-house by the drug product manufacturer as per pharmacopeial standards (BP) for Sterile Water for Injection.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Water for Injection is a continuous production material generated and directly utilized within closed pharmaceutical water systems (e.g., purified water systems post-distillation or reverse osmosis). Its production, storage, and transfer occur in a dynamically controlled, in-line process without standalone intermediate storage or long-term distribution steps that would necessitate dedicated stability testing. Given this integrated and continuous nature, stability studies as required by CTD 3.2.S.7 are not applicable to this product.

	The status in reference regulatory authorities	MHRA Approved
	Evaluation Remarks	
	Subject to legalized/Appostile SOle agency agreement and CoPP	
	Decision	
	Approved Registration Board approved the product subject to provison of legalized/Appostile Sole agency agreement & CoPP and inspection as per import policy.	
25	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	**Bryon Pharmaceuticals (Pvt.) Ltd** 48, Hayatabad Industrial Estate **(000388)**
	Application Form Dy. No / Tracking ID & date of submission	(D2J-8U1-B2PA, 2024-08-19)
	Detail of Fee Submitted	30000.0, 9400 2024-07-08, 2026-04-17
	The proposed proprietary name / brand name	**Pregabex 50mg Capsules**
	Label Claim	Pregabalin 50mg / Capsule
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	2x7-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at Room Temperature in Dry Place
	For generic drugs (me-too Status)	Gabalin 50mg Capsules (M/s CCL Pharmaceuticals (Pvt.) Ltd.)
	Pharmacotherapeutic Group of (API)	Gabapentinoids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CTX Life Sciences (Pvt.) Limited
	Detail of stability batches of drug product	long-term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	API loan from Wimits
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Gablin 50 mg capsules
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	long-term and accelerated conditions
	The status in reference regulatory authorities	US-FDA
	GMP status of the firm	GMP report dated 22.10.2021
	Evidence of approval of manufacturing facility	Renewal of DML letter dated 31 December 2021
	Evaluation Remarks	
	Verification of API loan	
	Decision	
	Approved Registration Board approved the product subject to verification of API loan documents.	
26	Case Category	New License (Abdul Mughees)
	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	(JXS-NWJ-8TD6, 2025-04-07)
	Detail of Fee Submitted	37000.0, 2024-12-11,
	The proposed proprietary name / brand name	**Caralid 600mg tablets**

	Label Claim	Each film coated Tablet Contains: Linezolid .....600mg. (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10,s-As per SRO
	Shelf Life (Unit)	2 Year(s)Store between 15C-30C
	For generic drugs (me-too Status)	ZOLDAP 600mg tablets (Getz Pharma)
	Pharmacotherapeutic Group of (API)	ATC J01XX08 systematic antibiotics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Pure and Cure Healthcare Private Limited Village Chachrauli, P.O. Jeoli, TehsilDerabassi, Distt. Sahibzada Ajit Singh Nagar, Punjab - 140501 (INDIA)
	Detail of stability batches of drug product	Long-term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	API loan from Seraph Pharmaceuticals
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Nezkil 600mg S.J &G .Fazul Ellahie Pvt Ltd. Batch number T24020
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Long-term and accelerated conditions
	The status in reference regulatory authorities	FDA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	DML 18.03.2021
	Evaluation Remarks	
	API loan and stability data verification	
	Decision	
	Approved Registration Board approved the product subject to: 1. verification of API loan documents 2. verification of submitted stability data by a panel constituted by Chairman, Registration Board.	
27	Case Category	New License (Abdul Mughees)
	Name, address of Applicant.	**PHARMAQIO RAWALPINDI** 10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. **(000978)**
	Application Form Dy. No / Tracking ID & date of submission	(S8B-RED-YJVB, 2026-03-30)
	Detail of Fee Submitted	38700, 2025-12-17,
	The proposed proprietary name / brand name	**Qiobal 500mcg Tablet**
	Label Claim	Each Sugar coated tablet contains: Mecobalamin.....500mcg (JP Spec's)
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	3x10's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Methycobal 500mcg Tablet by hilton pharma pvt ltd
	Pharmacotherapeutic Group of (API)	Vitamin B12 analog
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	

	Detail of stability batches of drug product	At Long-term and accelerated conditions T033, T034, T035 of 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	API on loan from Danas Pharma
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Methylcobal 500mcg Tablets , manufactured by Hilton pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	At Long-term and accelerated conditions
	The status in reference regulatory authorities	Provided in modoule I in 1.5.9
	GMP status of the firm	DML dated 25-10-2023
	Evidence of approval of manufacturing facility	DML dated 25-10-2023
	Evaluation Remarks	
	Verificaiton of API loan	
	Decision	
	Approved REgistration Board approved the product subject to verifiation of API loan documents.	
28	Case Category	Routine (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	(SRP-6XB-HS7X, 2024-10-08)
	Detail of Fee Submitted	37000.0, 2024-09-24,
	The proposed proprietary name / brand name	**GabaPil CR 165mg Tablets**
	Label Claim	Pregabalin 165mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	20’s Tablets-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Gabapentinoids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Progress Life Sciences Pvt. Ltd.
	Detail of stability batches of drug product	Long-term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Procurement
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Lyrica CR 165mg tablet by Pfizer NY,
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Long-term and accelerated conditions
	The status in reference regulatory authorities	LYRICA® CR (Pregabalin) extended-release tablets, for oral use (82.5mg, 165mg & 330mg). Pfizer Inc. 66 Hudson Boulevard East New York, NY 10001-2192 USA
	GMP status of the firm	GMP dated 09-March 2024
	Evidence of approval of manufacturing facility	Application for renewal of DML submitted on 2025-05-09
	Evaluation Remarks	

	2- The license Form 25-A of the Drug Substance manufacturer (Progress Life Sciences Pvt. Ltd.) is a loan license on the premises of another chemical plant, with unknown impacts on quality, safety and efficacy of the manufactured API. Please justify. Reply: The Pregabalin API manufactured under a Form 25-A loan license by Progress Life Sciences Pvt. Ltd. is produced at a GMP-compliant, licensed facility with established quality systems and validated processes. A formal quality agreement ensures clear delineation of responsibilities. Comprehensive analytical testing, process validation, and stability studies confirm that the loan license arrangement does not impact the quality, safety, or efficacy of the drug substance. Therefore, the manufacturing arrangement is considered fully compliant and acceptable from a regulatory standpoint. 8- Scientific justification for achieving upto 98 per cent dissolution of test and reference CR tablet within 45 minutes in various CDP mediums. Reply: The actual time points are 1st Hour, 4th Hour, 9th 24th Hour & 36th Hour, revised report is attached.	
	Decision	
	Approved Registration Board approved the product subject to undertaking by the applicant to validate API source which is not on loan license in the country of origin.	
29	Case Category	New License (Abdul Mughees)
	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	(STN-QM9-4Y1W, 2025-07-24)
	Detail of Fee Submitted	37000.0, 2025-05-05,
	The proposed proprietary name / brand name	**Muscolax 4mg Capsule**
	Label Claim	Each Capsule contains Thiocolchicoside ..... 4mg As per innovator's Specifications
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's 30's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store between 15C-30C
	For generic drugs (me-too Status)	Thioget 4mg Capsule of M/s. Getz Pharma (Reg.no.086076)
	Pharmacotherapeutic Group of (API)	Muscle Relaxant
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Alkaloid Private Ltd 834(P), Medchal Shamirpet Road, Medchal Mandal Rangareddy, Telangana, 501401 India
	Detail of stability batches of drug product	Long term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	API on loan from Seraph Pharma
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Long term and accelerated conditions
	The status in reference regulatory authorities	ANSM
	GMP status of the firm	-
	Evidence of approval of manufacturing facility	DML 2021
	Evaluation Remarks	
	API loan and stability data verification EMA advisory on use of thiocolchicoside	
	Decision	

Approved

Registration Board approved the product subject to:

1. inclusion of following labelling information "Thiocolchicoside-containing medicines for use by mouth or injection should be used in adults and adolescents 16 years of age or older."
2. verification of API loan documents

30	Case Category	Routine (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	(TVM-2HM-DD9L, 2024-08-29)
	Detail of Fee Submitted	30000.0, 2024-08-19,
	The proposed proprietary name / brand name	**GabaPil CR 82.5mg Tablets**
	Label Claim	Pregabalin 82.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	20’s Tablets-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Gabapentinoids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Progress Life Sciences Pvt. Ltd.
	Detail of stability batches of drug product	Long-term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Procurement
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Lyrica CR 82.5mg tablet by Pfizer NY,
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Long-term and accelerated conditions
	The status in reference regulatory authorities	LYRICA® CR (Pregabalin) extended-release tablets, for oral use (82.5mg, 165mg & 330mg). Pfizer Inc. 66 Hudson Boulevard East New York, NY 10001-2192 USA
	GMP status of the firm	GMP dated 09-March 2024
	Evidence of approval of manufacturing facility	Application for renewal of DML submitted on 2025-05-09
	Evaluation Remarks	
	2- The license Form 25-A of the Drug Substance manufacturer (Progress Life Sciences Pvt. Ltd.) is a loan license on the premises of another chemical plant, with unknown impacts on quality, safety and efficacy of the manufactured API. Please justify. Reply: The Pregabalin API manufactured under a Form 25-A loan license by Progress Life Sciences Pvt. Ltd. is produced at a GMP-compliant, licensed facility with established quality systems and validated processes. A formal quality agreement ensures clear delineation of responsibilities. Comprehensive analytical testing, process validation, and stability studies confirm that the loan license arrangement does not impact the quality, safety, or efficacy of the drug substance. Therefore, the manufacturing arrangement is considered fully compliant and acceptable from a regulatory standpoint. 8- Scientific justification for achieving upto 98 per cent dissolution of test and reference CR tablet within 45 minutes in various CDP mediums. Reply: The actual time points are 1st Hour, 4th Hour, 9th 24th Hour & 36th Hour, revised report is attached.	

	Decision	
	Approved Registration Board approved the product subject to undertaking by the applicant to validate API source which is not on loan license in the country of origin.	
31	Case Category	New License (Abdul Mughees)
	Name, address of Applicant.	**PHARMAQIO RAWALPINDI** 10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. **(000978)**
	Application Form Dy. No / Tracking ID & date of submission	(UYG-XU6-LZ1X, 2026-02-19)
	Detail of Fee Submitted	38700, 2026-01-20,
	The proposed proprietary name / brand name	**Qioval Fort 5/160mg Tablets**
	Label Claim	Amlodipine Besylate equivalent to Amlodipine..... 5mg Valsartan.....160mg
	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 30°C, protect from moisture
	For generic drugs (me-too Status)	Extor 5/160mg Tablet Manufacturer: The Searle Company Limited. Address: F-319,SITE., Karachi-Pakistan.
	Pharmacotherapeutic Group of (API)	Amlodipine Bsylate (Aurore Life Sciences)And Valsartan (Anhui Menovo Pharmaceutical Co.Ltd.)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	NA
	Detail of stability batches of drug product	At long-term and accelrated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	APi on loan from Lawari International
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	At long-term and accelrated conditions
	The status in reference regulatory authorities	HPRA Approved
	GMP status of the firm	DML dated 25.10.2023
	Evidence of approval of manufacturing facility	DML dated 25.10.2023
	Evaluation Remarks	
	API loan verification	
	Decision	
	Approved Registration Board approved the product subject to verification of API loan documents.	
32	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	**Bryon Pharmaceuticals (Pvt.) Ltd** 48, Hayatabad Industrial Estate **(000388)**
	Application Form Dy. No / Tracking ID & date of submission	(ZJ3-X6Y-GMP1, 2024-08-21)

	Detail of Fee Submitted	30000.0, 9400 2024-07-25, 2026-04-17
	The proposed proprietary name / brand name	**Pregabex 150mg Capsules**
	Label Claim	Pregabalin 150mg / Capsules
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	2x7s-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at Room Temperature in Dry Place
	For generic drugs (me-too Status)	Gabalin 150mg Capsules (M/s CCL Pharmaceuticals (Pvt.) Ltd.)
	Pharmacotherapeutic Group of (API)	Gabapentinoids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CTX Life Sciences (Pvt.) Limited
	Detail of stability batches of drug product	long-term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	API loan from Wimits
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Gablin 50 mg capsules
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	long-term and accelerated conditions
	The status in reference regulatory authorities	US-FDA
	GMP status of the firm	GMP report dated 22.10.2021
	Evidence of approval of manufacturing facility	Renewal of DML letter dated 31 December 2021
	Evaluation Remarks	
	API loan verification	
	Decision	
	Approved Registration Board approved the product subject to verification of API loan documents.	
33	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	**AUSPEC PHARMACEUTICALS PVT LTD** 21, Km, Raiwind Road, Lahore. **(000964)**
	Application Form Dy. No / Tracking ID & date of submission	(SX1-WU8-MH6L, 2024-04-15)
	Detail of Fee Submitted	75000.0, 2024-02-06,
	The proposed proprietary name / brand name	**Sanarte 120mg Injection**
	Label Claim	Each vial contains: Artesunate. 120mg
	Reference to Finished product specifications	The International Pharmacopeia
	Proposed Pack Size	1's / DPC-As per SRO
	Shelf Life (Unit)	2 Year(s)Store Below 25C
	For generic drugs (me-too Status)	Gen M Injection By M/s Genix Pharma
	Pharmacotherapeutic Group of (API)	P01BE — Artemisinin and derivatives, Antimalarials
	Name, address of Manufacturing site:	Aulton Pharmaceuticals-Plot # 84/1, Block A, Phase 5, Industrial Estate, Pakistan-
	Name & address of API manufacturer	MICRO ORGO CHEM, C 1/B 57, LIC Sector, GIDC Vapi 396 195, Gujarat,
	Detail of stability batches of drug product	Long-term and accelerated conditions 5000 vials
	Documents for the procurement of API with approval from DRAP	Provided

	(in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Gen-M by Genix pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Long-term and accelerated conditions
	The status in reference regulatory authorities	Artesunate 120mg Injection By M/s Amivas LLC,600 Capability Green,Luton,LU1 3LU, USA.
	GMP status of the firm	Aulton Pharma GMP 2021
	Evidence of approval of manufacturing facility	Aulton Pharma DML Auspec Pharma DML
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration of the Board.	
	Decision	
	Approved Registration Board approved the product subject to the submission of in-use stability studies of the drug product using the same solvent as recommended by the WHO prequalified reference product. The firm shall also submit batch analysis report in accordance with IP monograph of Artesunate Injection.	
34	Case Category	Import (Abdul Mughees)
	Name, address of Applicant.	**MSA PHARMA** 1st floor, 793-D Block C Faisal Town **(05-352-0066-112591D)**
	Application Form Dy. No / Tracking ID & date of submission	(Q27-6D3-3SZ4, 2026-03-10)
	Detail of Fee Submitted	313500, 2026-01-30,
	The proposed proprietary name / brand name	**Abiraxen Tablet 250mg**
	Label Claim	Each film coated tablet contains Abiraterone Acetate USP 250 mg.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4 × 7's tablets per box.Alu-Alu Blisters-As per SRO
	Shelf Life (Unit)	24 Year(s)Do not store above 25°C. Store in the original package in order to protect from moisture.
	For generic drugs (me-too Status)	Abiterone 250mg tablet
	Pharmacotherapeutic Group of (API)	Antineoplatic
	Name, address of Manufacturing site:	Everest Pharmaceuticals Limited. -Plot No.: B-45, 46 & 33, BSCIC I/A, Kanchpur, Narayanganj, Bangladesh -Bangladesh
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Enclosed
	Name, address of Marketing Authorization Holder:	Everest Pharmaceuticals Limited. , BSCIC I/A, Kanchpur, Narayanganj, Bangladesh , Bangladesh
	Details of Certificates (CoPP/FSC/cGMP):	GMP certificate dated 18.01.2023
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Enclosed
	The status in reference regulatory authorities	ZYTIGA 250 mg tablets
	Evaluation Remarks	
	Regsitration Board deferred the case in its 355th meeting for Approval of Bio-equivalence / Bio-availability studies by the Clinical Studies Committees under Bio-Study Rules 2017 is mandatory	

	for locally conducted BE/BA studies as requirement of application of registration of drugs Evidence of approval/ proven conduct of any successful Bio-equivalence / Bio-availability studies by the commissioned center (Clinical Research Organization) in Reference Regulatory Authorities decided in 275th meeting of Registration Board for BE/BA studies performed outside Pakistan The firm has provided list of study centers and approval status of M/s. Taab Biostudy Services, 77/2/1B/1, Bade Raipur Road, Jadavpur, Kolkata-700 032, India on Form CT-09 by CDSCO, New Dehli dated 03-Dec 2020.	
	Decision	
	Approved	
35	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	**Herbion Pakistan (Pvt.) Ltd.** Industrial Triangle, Kahuta road, Humak, Islamabad **(000795)**
	Application Form Dy. No / Tracking ID & date of submission	(H71-GBN-TVGP, 2024-11-14)
	Detail of Fee Submitted	37000.0, 2024-11-04,
	The proposed proprietary name / brand name	**Pega 25 mg Capsule**
	Label Claim	Each capsule contains Pregabalin..... 25mg BP Specifications
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10s-De-Controlled,20s-De-Controlled,2x14s-De-Controlled,2x7s-De-Controlled,30s-De-Controlled
	Shelf Life (Unit)	2 Year(s)15 to 30
	For generic drugs (me-too Status)	Zeegap 25mg Capsule Hilton
	Pharmacotherapeutic Group of (API)	Gabapentinoids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/S Atlas Life Sciences Private Limited
	Detail of stability batches of drug product	Long term and accelerated conditions of 03 batches 2000 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Zeepag 25 mg capsules by manufactured Hilton Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Long term and accelerated conditions
	The status in reference regulatory authorities	https://www.accessdata.fda.gov/scripts/cder/daf/index.event=overview.process&ApplNo=021446
	GMP status of the firm	DML dated 25.03.2024; GMP 16 September 2024
	Evidence of approval of manufacturing facility	DML dated 25.03.2024
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration of the Board.	
	Decision	
	Approved	
36	Case Category	Routine (Adil Saeed)
	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	(1B5-2WQ-9SJM, 2024-09-13)
	Detail of Fee Submitted	75000.0, 2024-09-04,
	The proposed proprietary name / brand name	**Rezam 45mg OD Tablet.**
	Label Claim	Each oral disintegrating tablet contains Mirtazapine ----- 45mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	7s, 10s, 14s, 20s, 2-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)	Not Applicable
	Pharmacotherapeutic Group of (API)	Other antidepressants N06AX11
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Megafine Pharma (P) Ltd
	Detail of stability batches of drug product	3 batches, 1500 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	Auro-mirtazapine 45mg B. No. 83267 Mfg Auro Pharma Canada,
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted.
	The status in reference regulatory authorities	Auro Mirtazapine OD Tablet, Auro Pharma Inc. Canada
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 06.06.2023 is submitted.
	Evidence of approval of manufacturing facility	Section approval letter dated 30.09.2021 is submitted.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
37	Case Category	Routine (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	(JRG-9HH-9M3E, 2024-07-18)
	Detail of Fee Submitted	75000.0, 2024-06-12,
	The proposed proprietary name / brand name	**ACMID 100mg Tablet**
	Label Claim	Each film coated tablet contains: Acotiamide hydrochloride hydrate... 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Donot store over 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	A03FA10 Propulsives
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Emnar Pharma Private Limited. Unit-II, Plot No. 15, Jawaharlal Nehru Pharma City, Tadi (Village),

		Parawada (Mandal), Anakapalli (District), Andhra Pradesh (State), India.
	Detail of stability batches of drug product	3 batches, 2000 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	Acofide 100mg tba B. No. C329 M/s Zeria Pharma Japan.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVb, upto 60 months.
	The status in reference regulatory authorities	Acofide Tablets, PMDA approved
	GMP status of the firm	GMP certificate is submitted.
	Evidence of approval of manufacturing facility	Renewal letter dated 13.10.2023 is submitted wherein Tablet General Section is mentioned.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
38	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	(B73-P6J-T564, 2024-04-30)
	Detail of Fee Submitted	75000.0, 2024-02-03,
	The proposed proprietary name / brand name	**Celefold 200mg Capsule**
	Label Claim	Each Capsule Contains: Celecoxib (USP).....200 mg (Product complies Innovator's 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 25°c
	For generic drugs (me-too Status)	Orthocel 200mg Capsule by Lisko Pharma Karachi
	Pharmacotherapeutic Group of (API)	M01AH01 Coxibs
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No.69/2, Phase II, Industrial Area, Hattar Pakistan-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	CELEFOLD 200mg Capsule approved in 353rd meeting of RB
	Evaluation Remarks	
	Data already approved in 353rd meeting.	
	Decision	
	Approved	
39	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(5PW-BM2-PR45, 2024-12-09)

	Detail of Fee Submitted	37000.0, 2024-10-31,
	The proposed proprietary name / brand name	**Lefluno Tablet 10mg**
	Label Claim	Each film coated tablet contains: Leflunomide..... 20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	7's, 10's, 14's, 20'-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 degree celsius
	For generic drugs (me-too Status)	Lefomide
	Pharmacotherapeutic Group of (API)	L04AK01 Dihydroorotate dehydrogenase (DHODH) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Bo-Chem Private 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 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Lefora Tablets 10mg" (Hilton Pharma (Pvt.) Ltd. Karachi, Pakistan) B. no. 140076
	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 submitted.
	Evidence of approval of manufacturing facility	Section approval mentioned in Renewal letter.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
40	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(7A6-AA8-32JM, 2024-12-09)
	Detail of Fee Submitted	37000.0, 2024-10-31,
	The proposed proprietary name / brand name	**Rupaxin tablet 10mg**
	Label Claim	Each tablet contains: Rupatadine fumarate equivalent to Rupatadine..... 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3's,7's, 10's, 14's,-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 degree celsius
	For generic drugs (me-too Status)	Rupataget 10mg
	Pharmacotherapeutic Group of (API)	R06AX28 Other antihistamines for systemic use
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vasudha Pharma Chem 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 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Rupafin 10mg Tablet J Uriach Y Compania SA B> No. 295983

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVb, upto 24 months.
	The status in reference regulatory authorities	MHRA APPROVED
	GMP status of the firm	GMP certificate is submitted
	Evidence of approval of manufacturing facility	Sectiuon approval mentioned in renewal letter date 27.04.2020
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
41	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(LEE-UP2-PQW8, 2024-12-02)
	Detail of Fee Submitted	37000.0, 2024-11-28,
	The proposed proprietary name / brand name	**Spasnab Tablet 80mg/80mg**
	Label Claim	Each sugar coated tablet contains: Phloroglucinol Dihydrate .....80mg Trimethyl Phloroglucinol.....80mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7’s, 14’s, 10’s, 20’-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Yes
	Pharmacotherapeutic Group of (API)	A03AX12 Other drugs for functional gastrointestinal disorders
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Phloroglucinol Dihydrate (Kaifeng Mingren Pharmaceutical Co., Ltd.),Trimethyl Phloroglucinol (Kaifeng Mingren Pharmaceutical Co., Ltd.)
	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 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Orglu Tablet 80/80mg Tablet B. No. FZK043
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	ANSM, France Approved (SPASFON coated tablet by TEVA HEALTH, France)
	GMP status of the firm	GMP certificate submitted.
	Evidence of approval of manufacturing facility	Section approval submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
42	Case Category	Routine (Adil Saeed)

	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(MHS-QGD-6XAX, 2024-12-09)
	Detail of Fee Submitted	37000.0, 2024-10-31,
	The proposed proprietary name / brand name	**Lefluno Tablet 20mg**
	Label Claim	Each film coated tablet contains: Leflunomide..... 20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	7's, 10's, 14's, 20'-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 degree celsius
	For generic drugs (me-too Status)	Lefomide
	Pharmacotherapeutic Group of (API)	L04AK Dihydroorotate dehydrogenase (DHODH) inhibitors L04AK01
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Bo-Chem Private 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 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Lefora Tablets 20mg (Hilton Pharma Pvt. Ltd. Karachi, Pakistan) B. No. 147280
	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	Renewal letter mentions tablet general section
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
43	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(N6D-N8W-ZPE5, 2024-12-09)
	Detail of Fee Submitted	37000.0, 2024-12-05,
	The proposed proprietary name / brand name	**Mycoderm 1% Cutaneous Solution**
	Label Claim	Each gram contains: Terbinafine Hydrochloride.....10mg (JP Specifications)
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	4g Aluminum Collapsi-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Yes
	Pharmacotherapeutic Group of (API)	D01AE15 Other antifungals for topical use
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Synergene Active Private limited
	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)	Clearance certificate is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Lamisil Once 1% cutaneous solution (GlaxoSmithKline ,Brentford,U.K) B. No. NJ2F
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa, upto 60 months.
	The status in reference regulatory authorities	MHRA, UK Approved (Lamisil Once 1% cutaneous solution by Haleon UK Trading Limited, United Kingdom)
	GMP status of the firm	GMP certificate is sumitted
	Evidence of approval of manufacturing facility	Cream ointment general section is mentioned in Renewal letter dated 27.04.2020
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
44	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(NH6-S7D-7WVU, 2024-12-02)
	Detail of Fee Submitted	75000.0, 2024-11-28,
	The proposed proprietary name / brand name	**Rupaxin Oral Solution 1mg/ml**
	Label Claim	Each ml of Oral Solution contains: Rupatadine Fumarate eq. to Rupatadine.....1mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's (120ml)-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 degree celsius
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	R06AX28 Other antihistamines for systemic use
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vasudha Pharma Chem Limited
	Detail of stability batches of drug product	3 batches, 75 bottles 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	Rupafin 1mg/ml Oral Solution (ERN Laboratories, S.A. Barcelona) WXPDR8CP2W22016
	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 submitted.
	Evidence of approval of manufacturing facility	Section approval mentioned in renewal letter
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	

45	Case Category	Any Other (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	(E7E-28L-SLGN, 2026-03-09)
	Detail of Fee Submitted	75000.0, 2025-05-26,
	The proposed proprietary name / brand name	**Vnosil 50mg Sublingual Tablet**
	Label Claim	Each Sublingual Tablet Contains: Sildenafil as Citrate (USP).....50mg (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)	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	S-04, S-05, S-06
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan Letter along with other documents attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed against Innovator's Brand
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IV-A
	The status in reference regulatory authorities	TGA Australia Approved
	GMP status of the firm	Valid Till 12 Dec, 2027
	Evidence of approval of manufacturing facility	Tablet General Section
	Evaluation Remarks	
	Priority as per decision of 214th meeting. The applicant has requested to withdraw their application.	
	Decision	
	Rejected Application stands withdrawn.	
46	Case Category	Any Other (Adil Saeed)
	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	(9RH-P58-9AYV, 2026-03-09)
	Detail of Fee Submitted	75000.0, 2025-06-20,
	The proposed proprietary name / brand name	**WNAFIL 25MG SUBLINGUAL TABLET**
	Label Claim	Each Sublingual Tablet Contains: Sildenafil as Citrate (USP).....25MG (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)	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	T-10, T-11, T-12
	Documents for the procurement of API with approval from DRAP (in case of Import)	Goods Declaration along with Loan Letter Attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IV-A Attached
	The status in reference regulatory authorities	TGA AUSTRALIA
	GMP status of the firm	Valid till 11th October, 2025
	Evidence of approval of manufacturing facility	Tablet General Section
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Firm has requested to withdraw their application.	
	Decision	
	Rejected The application stands withdrawn	
47	Case Category	Any Other (Adil Saeed)
	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	(Q4L-9PX-TDYE, 2026-03-09)
	Detail of Fee Submitted	75000.0, 2025-06-20,
	The proposed proprietary name / brand name	**Wnafil 50mg Tablet Sublingual**
	Label Claim	Each Sublingual Tablet Contains: Sildenafil as Citrate (USP).....50mg (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)	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	T13, T14, T15
	Documents for the procurement of API with approval from DRAP (in case of Import)	Goods Declaration along with Loan Letter Attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IV-A Attached
	The status in reference regulatory authorities	TGA Australia

	GMP status of the firm	Valid till 11th October, 2025
	Evidence of approval of manufacturing facility	Tablet General Section
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Applicant has requested to withdraw their application.	
	Decision	
	Rejected Application stands withdrawn	
48	Case Category	Any Other (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	(Q5M-9M3-WLG2, 2026-03-09)
	Detail of Fee Submitted	75000.0, 2025-05-26,
	The proposed proprietary name / brand name	**Vnosil 25mg Sublingual Tablet**
	Label Claim	Each Sublingual Tablet Contains: Sildenafil as Citrate (USP).....25MG (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)	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	Batch No. S-01, S-02, S-03
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan Letter along with other documents attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed against Innovator's Brand
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IV-A
	The status in reference regulatory authorities	TGA Australia Approved
	GMP status of the firm	Valid Till 12 Dec, 2027
	Evidence of approval of manufacturing facility	Tablet General Section
	Evaluation Remarks	
	Priority as per decision of 214th authority, Applicant has requested to withdraw their application.	
	Decision	
	Rejected Application stands withdrawn.	
49	Case Category	Any Other (Adil Saeed)
	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	(U5N-LXG-NUL4, 2026-03-03)
	Detail of Fee Submitted	38700, 2025-10-22,
	The proposed proprietary name / brand name	**X-BLU 25mg Tablets**
	Label Claim	Each film-coated tablet contains: Sildenafil Citrate equivalent to 25mg Sildenafil
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4s-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30
	For generic drugs (me-too Status)	Vilagra Tablets Hilton Pharma
	Pharmacotherapeutic Group of (API)	phosphodiesterase (PDE) inhibitors
	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 submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra 25g Tablets (Pfizer USA)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	submitted.
	The status in reference regulatory authorities	Viagra 25mg Tablets (Pfizer USA)
	GMP status of the firm	GMP certificate submitted.
	Evidence of approval of manufacturing facility	Section approval letter submitted
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
50	Case Category	Any Other (Adil Saeed)
	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	(9Q4-1X3-1GSU, 2026-03-03)
	Detail of Fee Submitted	38700, 2025-10-22,
	The proposed proprietary name / brand name	**X-BLU 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	1x4's-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30
	For generic drugs (me-too Status)	Vilagra Tablets Hilton Pharma
	Pharmacotherapeutic Group of (API)	phosphodiesterase (PDE) inhibitors
	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	Clearance certificate is submitted.

	(in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra 50mg Tablets (Pfizer USA)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Viagra 50mg Tablets (Pfizer USA)
	GMP status of the firm	GMP certificate submitted.
	Evidence of approval of manufacturing facility	Section approval submitted.
	Evaluation Remarks	
	Priority as per decision of 214th meeting of authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
51	Case Category	Routine (Adil Saeed)
	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	(QPS-BT2-72NL, 2024-10-09)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-26, 2024-09-13
	The proposed proprietary name / brand name	**Avitam Injection**
	Label Claim	Each vial contains: Ceftazidime pentahydrate equivalent to Ceftazidime.....2.0g. Avibactam Sodium equivalent to Avibactam.....0.5g.
	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 above 30°C.
	For generic drugs (me-too Status)	Zavicefta 2g/0.5g injection (106848)-Pfizer, Pakistan
	Pharmacotherapeutic Group of (API)	J01DD52 ceftazidime and beta-lactamase inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Guangxi Kelun Pharmaceutical Co Ltd.
	Detail of stability batches of drug product	3 batches, 190 vials each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan from M/s Rotex Pharma. Copy of clearance certificate is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Zavicefta B. No. 23K03532 M/s Pfizer Pakistan Ltd
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa upto 24 months.
	The status in reference regulatory authorities	Zavicefta 2 g/0.5 g powder for concentrate for solution for infusion (MHRA Approved)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Dry powder injection ceph section approved vide letter dated 22.12.2017
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board	
	Decision	

	Approved	
52	Case Category	Contract Manufacturing (Adil Saeed)
	Name, address of Applicant.	**Surge Laboratories (Pvt.) Ltd.** 10th KM, Faisalabad Road, Bikhi District, Sheikhupura. **(000484)**
	Application Form Dy. No / Tracking ID & date of submission	(89S-HL2-PZL6, 2026-02-20)
	Detail of Fee Submitted	97200, 2026-01-07,
	The proposed proprietary name / brand name	**Sigra Tablet 25mg**
	Label Claim	Each film-coated tablet contains: Sildenafil Citrate eq. to Sildenafil.....25mg (BP specification)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	2's, 4's, 8's, 10's, 12's, 16's, 20's, 30's, 32's, 50's, & 100's, tabl-De-Controlled
	Shelf Life (Unit)	2 YearStored at 30°C
	For generic drugs (me-too Status)	Getfil 25mg tablet (Getz Pharma)
	Pharmacotherapeutic Group of (API)	Urologicals, Drugs used in Erectile dysfunction
	Name, address of Manufacturing site:	M/s. Nabiqasim Industries (Pvt) Ltd.-17/24, Korangi Industrial Area, Karachi, Pakistan-Pakistan
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Silagro Tablet 25mg (Reg No.128030 approved in 345th DRB Meeting.
	Evaluation Remarks	
	Cross referred product.	
	Decision	
	Approved	
53	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Glitz Pharma** Plot No. 265, Industrial Triangle, Kahuta Road, Islamabad, Pakistan. **(000571)**
	Application Form Dy. No / Tracking ID & date of submission	(8DM-ZNN-43TB, 2026-01-05)
	Detail of Fee Submitted	38700, 2025-09-30,
	The proposed proprietary name / brand name	**Silitz Tablet 25mg**
	Label Claim	Each film-coated Tablet Contains: Sildenafil citrate eq to Sildenafil..... 25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's, 2's, 4's, 10's, 24's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Controlled room temperature
	For generic drugs (me-too Status)	Hilagra Tablet 25mg by Hilton Pharma
	Pharmacotherapeutic Group of (API)	Phosphodiesterase type 5 inhibitors (PDE5)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches, 2000 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	Hilagra 25mg Tablet B. No 159628
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	MHRA reference Attached
	GMP status of the firm	Valid till 18-12-2026
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
54	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Glitz Pharma** Plot No. 265, Industrial Triangle, Kahuta Road, Islamabad, Pakistan. **(000571)**
	Application Form Dy. No / Tracking ID & date of submission	(UYJ-1X6-GPZ9, 2026-01-05)
	Detail of Fee Submitted	38700, 2025-09-30,
	The proposed proprietary name / brand name	**Silitz Tablet 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	1's, 2's, 4's, 10's, 24's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Controlled room temperature
	For generic drugs (me-too Status)	Hilagra Tablet 50mg by Hilton Pharma
	Pharmacotherapeutic Group of (API)	Phosphodiesterase type 5 inhibitors (PDE5)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rakshit
	Detail of stability batches of drug product	3 batches of 2000 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	Hilagra 50mg Tablet of M.s Hilton Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	MHRA reference Attached
	GMP status of the firm	Valid till 18-12-2026
	Evidence of approval of manufacturing facility	Section approval letter is submitted.
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
55	Case Category	Any Other (Adil Saeed)
	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	(4YM-AYV-21LU, 2026-01-05)
	Detail of Fee Submitted	38700, 2025-10-27,
	The proposed proprietary name / brand name	**Sonafil 25mg tab**
	Label Claim	Each film-coated tablet contains: Sildenafil Citrate equivalent to Sildenafil 25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1*10s-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 centigrade
	For generic drugs (me-too Status)	Ripple 25mg tab
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 inhibitor (PDE5-I)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century pharmaceuticals LTD
	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 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Ripple 25mg Tablet M/s Solaris Life Sciences.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted.
	The status in reference regulatory authorities	Viagra 25mg Tab (FDA Approved)
	GMP status of the firm	GMP certificate valid upto 04.05.2026 is submitted.
	Evidence of approval of manufacturing facility	Tablet general section approved.
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
56	Case Category	Any Other (Adil Saeed)
	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	(7D2-EJ4-3XNY, 2026-01-05)
	Detail of Fee Submitted	38700, 2025-10-27,
	The proposed proprietary name / brand name	**Sonafil 50mg tab**
	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*10s-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 centigrade
	For generic drugs (me-too Status)	Ripple 50mg tab
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 inhibitor (PDE5-I)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century pharmaceuticals LTD
	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 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra 50mg tablet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	FDA Approved (Viagra 50mg TAb)
	GMP status of the firm	GMP certificate valid upto 04.05.2026 is submitted.
	Evidence of approval of manufacturing facility	Tablet general section approved.
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
57	Case Category	Any Other (Adil Saeed)
	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	(UJJ-A1T-N9S6, 2026-01-05)
	Detail of Fee Submitted	38700, 2025-10-27,
	The proposed proprietary name / brand name	**Sonafil 100mg tab**
	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*10s-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 centigrade
	For generic drugs (me-too Status)	Ripple 100mg tab
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 inhibitor (PDE5-I)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century pharmaceuticals LTD
	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 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra 100mg
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Viagra 100mg Tab (FDA Approved)
	GMP status of the firm	GMP certificate valid upto 04.05.2026 is submitted.
	Evidence of approval of manufacturing facility	Tablet general section is approved.
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	

	Approved	
58	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Amson Vaccines & Pharma (Pvt.) Ltd.** Plot # 154, Industrial Triangle, Kahuta Road, **(000393)**
	Application Form Dy. No / Tracking ID & date of submission	(DGH-SEM-J6UW, 2026-02-04)
	Detail of Fee Submitted	38700, 2025-10-02,
	The proposed proprietary name / brand name	**Amagra 50mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Sildenafil citrate equivalent to Sildenafil ..... 50 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 x 10's-As per SRO,1 x 6's-As per SRO
	Shelf Life (Unit)	24 Month(s)Below 25°C
	For generic drugs (me-too Status)	Ripple 50mg Tablet, Reg #: 127630, Manufacturer:Solaris Life Sciences Private Limited
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 (PDE5) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. Rakshit Pharmaceuticals Limited, Plot number 68/A, Jawaharlal Nehru, Pharma City, Parawada Mandal, Anakapalli district, Andhra Pradesh, India.
	Detail of stability batches of drug product	3 batches, 5000 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	Comparative dissolution profile study protocol and report with a registered product Hilagra Tablets 50mg B. No. 159751
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	US-FDA approval status of VIAGRA® tablets 50mg, Manufactured by Pfizer Labs Division Inc.NY 10017 USA is provided
	GMP status of the firm	GMP certificate F. 3-4/2018-Addl. Dir. (QA<-FO)-84 is provided
	Evidence of approval of manufacturing facility	Valid DML No. 000393 is provided
	Evaluation Remarks	
	Priority as per decision of 214th meeting of authority. Application fulfills codal formalities. recommended for consideration of board.	
	Decision	
	Approved	
59	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Biogen Life Sciences** 8-KM, Chak Beli Road, Rawat, **(000911)**
	Application Form Dy. No / Tracking ID & date of submission	(R7E-2BZ-DQPG, 2026-03-05)
	Detail of Fee Submitted	38700, 2025-10-03,
	The proposed proprietary name / brand name	**VYTALIX 50mg TABLETS**

	Label Claim	Each Film Coated Tablet contains: Sildenafil Citrate eq to SildenafilL.....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's, 20's, 30's & 10x10's-As per SRO
	Shelf Life (Unit)	3 Year(s)Room Condition`
	For generic drugs (me-too Status)	Company Name: Solaris Life Sciences Private Limited Company Address: Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat Generic Name Sildenafil Citrate Brand Name Product Name:: Ripple 50mg
	Pharmacotherapeutic Group of (API)	Phosphodiesterase type 5 (PDE5) inhibitor
	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 of 1000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	import Doccuments attached in Module 3
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Done with Viagra 50mg TabletTablet by Pfizer inc. Batch No. 19990545AG
	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
	Evidence of approval of manufacturing facility	Section approval letter attached
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
60	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Jinnah Pharmaceuticals Pvt Ltd** 13 Km Lahore Road Multan **(000578)**
	Application Form Dy. No / Tracking ID & date of submission	(3UB-PG5-64MH, 2026-03-09)
	Detail of Fee Submitted	38700, 2025-12-12,
	The proposed proprietary name / brand name	**SILDNEX 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	4`s,8`s,16`s,28,s and 40,s-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30%
	For generic drugs (me-too Status)	Nabi Qasim Industries
	Pharmacotherapeutic Group of (API)	PDE 5 inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rakshit
	Detail of stability batches of drug product	3 batches, 1500 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	Hilagra 50mg Tablets Of m/s hilton pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Viagra 25mg, 50mg & 100mg (sildenafil) tablets, USFDA approved.
	GMP status of the firm	GMP Valid Till 19.11.2028 GMP Certficate NO GM_-C-EAFF51
	Evidence of approval of manufacturing facility	Section approval letter attached.
	Evaluation Remarks	
	priority as per decision of 214th meeting of authority. Application fufills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
61	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Lahore Chemical and Pharmaceutical Works Pvt. Ltd.** 137- Shahrah Maulana Jalaluddin Roomi, Lahore **(000064)**
	Application Form Dy. No / Tracking ID & date of submission	(DZ5-G7G-EU6E, 2026-03-09)
	Detail of Fee Submitted	37000.0, 2025-03-10,
	The proposed proprietary name / brand name	**Erecta 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	2's, 4's, 8's-As per SRO
	Shelf Life (Unit)	2 Year(s)store at room temperature
	For generic drugs (me-too Status)	Viagra
	Pharmacotherapeutic Group of (API)	--
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rakshit Pharmaceuticals Limited 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	FDA USA
	GMP status of the firm	--
	Evidence of approval of manufacturing facility	--
	Evaluation Remarks	
	Priority as per 214th meeting of Authority. The firm has submitted incoherent text generated by AI instead of P part of the Module 3. Firm has been asked 4 times to submit proper CTD dossier as per guidance document, but every time same AI generated text under general headings is being submitted. It is recommended to reject the instant case as firm has failed to submit required data necessary for registration of a drug product.	
	Decision	

	Rejected The board rejected the application for being incomplete and not being as per the requirements laid down in CTD guidance document. The firm has failed to submit original data of CDP and stability studies despite of repeated queries.	
62	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Lahore Chemical and Pharmaceutical Works Pvt. Ltd.** 137- Shahrah Maulana Jalaluddin Roomi, Lahore **(000064)**
	Application Form Dy. No / Tracking ID & date of submission	(L9U-XYD-N6HE, 2026-03-09)
	Detail of Fee Submitted	37000.0, 37030 2025-03-10, 2025-09-16
	The proposed proprietary name / brand name	**Erecta tablet 50mg**
	Label Claim	Each film-coated tablet contains Sildenafil citrate eq. to sildenafil.....100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2's, 4's, 8's-As per SRO
	Shelf Life (Unit)	2 Year(s)room temperature
	For generic drugs (me-too Status)	Viagra
	Pharmacotherapeutic Group of (API)	---
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rakshit Pharmaceuticals Limited 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	FDA USA
	GMP status of the firm	----
	Evidence of approval of manufacturing facility	------
	Evaluation Remarks	
	Priority as per 214th meeting of Authority. The firm has submitted incoherent text generated by AI instead of P part of the Module 3. Firm has been asked 4 times to submit proper CTD dossier as per guidance document, but every time same AI generated text under general headings is being submitted. It is recommended to reject the instant case as firm has failed to submit required data necessary for registration of a drug product.	
	Decision	
	Rejected The board rejected the application for being incomplete and not being as per the requirements laid down in CTD guidance document. The firm has failed to submit original data of CDP and stability studies despite of repeated queries.	
63	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**PHARMEVO (PVT) LTD.** A-29, NORTH WESTERN INDUSTRIAL ZONE, PORT QASSIM KARACHI. **(000504)**

	Application Form Dy. No / Tracking ID & date of submission	(P13-DX5-77ML, 2026-02-04)
	Detail of Fee Submitted	38700, 2025-12-18,
	The proposed proprietary name / brand name	**Erectafil 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, 10's, 20's, 30's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 C
	For generic drugs (me-too Status)	Getfil 100mg Tablet from Getz Pharma
	Pharmacotherapeutic Group of (API)	Phosphodiesterase inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rakshit Pharmaceuticals Ltd.
	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)	Import license issued by DRAP on date 07/Feb/2025 along with the import documents are attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and CDP against the innovator product Viagra 100mg Tablet B. No. B837203 is submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 3 batches is attached
	The status in reference regulatory authorities	Viagra tablet approved by EMA
	GMP status of the firm	GMP issued on basis of inspection report dated 09.01.2024
	Evidence of approval of manufacturing facility	General Tablet (Section approval dated 25.02.2018 is submitted)
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
64	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**PHARMEVO (PVT) LTD.** A-29, NORTH WESTERN INDUSTRIAL ZONE, PORT QASSIM KARACHI. **(000504)**
	Application Form Dy. No / Tracking ID & date of submission	(5PA-NGS-MVQL, 2026-02-03)
	Detail of Fee Submitted	38700, 2025-12-18,
	The proposed proprietary name / brand name	**Erectafil 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	2's, 4's, 10's, 20's, 30's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 C
	For generic drugs (me-too Status)	Getfil 25mg Tablet from Getz Pharma
	Pharmacotherapeutic Group of (API)	Sildenafil is a phosphodiesterase inhibitor used for the treatment of erectile dysfunction.
	Name, address of Manufacturing site:	Self Manufacturing

	Name & address of API manufacturer	Rakshit Pharmaceuticals Ltd.
	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)	Import license issued by DRAP on date 07/Feb/2025 along with the import documents are attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and CDP against the innovator product Hilagra 25mg Tablet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 3 batches is attached
	The status in reference regulatory authorities	Viagra tablet approved by EMA
	GMP status of the firm	GMP issued on basis of inspection report dated 09.01.2024
	Evidence of approval of manufacturing facility	General Tablet (Section approval dated 25.02.2018 is submitted)
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
65	Case Category	Any Other (Adil Saeed)
	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	(488-D4S-PQAS, 2026-01-27)
	Detail of Fee Submitted	38700, 36300 2025-12-31, 2026-03-03
	The proposed proprietary name / brand name	**RIPPLE ODT 50mg Tablets**
	Label Claim	Each Orodispersible Tablet contains: Sildenafil Citrate eq. to Sildenafil 50mg
	Reference to Finished product specifications	British 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)	New Molecule
	Pharmacotherapeutic Group of (API)	Selective inhibitor of cyclic GMP-specificphosphodiesterase (Type V)
	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, 1500 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	Sildenafil 50mg ODT Tablet KRKA Pharma B. NO. 4120639
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa, upto 60 months.
	The status in reference regulatory authorities	MHRA Approved
	GMP status of the firm	GMP certificate valid till 14.01.2028
	Evidence of approval of manufacturing facility	Section approval letter dated 17.01.2024 is submitted.

	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
66	Case Category	Any Other (Adil Saeed)
	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	(ET5-9UJ-REX4, 2026-01-27)
	Detail of Fee Submitted	38700, 36300 2025-12-31, 2026-03-03
	The proposed proprietary name / brand name	**RIPPLE ODT 100mg Tablets**
	Label Claim	Each Orodispersible 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)Below 30°C
	For generic drugs (me-too Status)	New Molecule
	Pharmacotherapeutic Group of (API)	Selective inhibitor of cyclic GMP-specificphosphodiesterase (Type V)
	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, 1500 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	Sildenafil 100mg ODT Tablet KRKA Pharma B. NO. 4289763
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa, upto 60 months.
	The status in reference regulatory authorities	MHRA Approved
	GMP status of the firm	GMP certificate valid till 14.01.2028
	Evidence of approval of manufacturing facility	Section approval letter dated 17.01.2024 is submitted.
	Evaluation Remarks	
	Priority as per decision of 214th meeting of authority. Application fufills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
67	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	(BA9-247-PH5H, 2026-01-05)
	Detail of Fee Submitted	38700, 2025-09-26,
	The proposed proprietary name / brand name	**SILESTO 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	1x2's, 1x4's, 1x6's, 1x8's, 1x10's, 2x6's, 2x8's, 2x10's and 3x10's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Donot store over 30ºC
	For generic drugs (me-too Status)	Hilagra
	Pharmacotherapeutic Group of (API)	Phosphodiestrase 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	3 batches, 2500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested invoice is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra 25mg Tablet B. No. B819305U
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	VIAGRA 25mg Tablet (USFDA)
	GMP status of the firm	Valid until 30-06-2027
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
68	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	(VHV-2Q6-BTJ3, 2026-02-17)
	Detail of Fee Submitted	38700, 2025-10-28,
	The proposed proprietary name / brand name	**SILESTO 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	1x2's, 1x4's, 1x6's, 1x8's, 1x10's, 2x6's, 2x8's, 2x10's and 3x10's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Donot store over 30ºC
	For generic drugs (me-too Status)	Hilagra
	Pharmacotherapeutic Group of (API)	Phosphodiestrase inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches, 2000 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. B752509

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	VIAGRA 100mg Tablet (USFDA)
	GMP status of the firm	Valid until 30-06-2027
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
69	Case Category	Contract Manufacturing (Adil Saeed)
	Name, address of Applicant.	**Surge Laboratories (Pvt.) Ltd.** 10th KM, Faisalabad Road, Bikhi District, Sheikhupura. **(000484)**
	Application Form Dy. No / Tracking ID & date of submission	(6GR-7JG-LQ6N, 2026-03-09)
	Detail of Fee Submitted	97200, 2026-01-07,
	The proposed proprietary name / brand name	**Sigra Tablet 100mg**
	Label Claim	Each film-coated tablet contains: Sildenafil Citrate eq. to Sildenafil.....100mg (BP specification)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	2's, 4's, 8's, 10's, 12's, 16's, 20's, 30's, 32's, 50's, & 100's, tablets-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Getfil 100mg tablet (Getz Pharma)
	Pharmacotherapeutic Group of (API)	Urologicals, Drugs used in Erectile dysfunction
	Name, address of Manufacturing site:	Nabiqasim Industries (Pvt.) Ltd.-17/24, Korangi Industrial Area, Korangi, Karachi-Pakistan-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Silgaro 100mg, approved in meeting: 345
	Evaluation Remarks	
	Priority as per decision of 214th meeting of authority. Cross referred case, data already approved.	
	Decision	
	Approved	
70	Case Category	Contract Manufacturing (Adil Saeed)
	Name, address of Applicant.	**Surge Laboratories (Pvt.) Ltd.** 10th KM, Faisalabad Road, Bikhi District, Sheikhupura. **(000484)**
	Application Form Dy. No / Tracking ID & date of submission	(QEB-3MU-H7TY, 2026-03-09)
	Detail of Fee Submitted	97200, 2026-01-07,
	The proposed proprietary name / brand name	**Sigra Tablet 50mg**
	Label Claim	Each film-coated tablet contains: Sildenafil Citrate eq. to Sildenafil.....50mg (BP Specs.)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	4's, 8's, 12's, 16's, tablets-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30°C

	For generic drugs (me-too Status)	Getfil 50mg tablet (Getz Pharma)
	Pharmacotherapeutic Group of (API)	Urologicals, Drugs used in Erectile dysfunction
	Name, address of Manufacturing site:	Nabiqasim Industries (Pvt.) Ltd.-17/24, Korangi Industrial Area, Korangi, Karachi-Pakistan-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Silgaro 50mg, approved in meeting: 345
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Data already approved. cross reference product.	
	Decision	
	Approved	
71	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore **(000576)**
	Application Form Dy. No / Tracking ID & date of submission	(23M-S7N-4DZR, 2026-02-11)
	Detail of Fee Submitted	38700, 2025-09-05,
	The proposed proprietary name / brand name	**Virexo 50mg Tablets**
	Label Claim	Each Film-coated tablet contain: Sildenafil Citrate equivalent to Sildenafil 50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's/As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30oC protect from moisture.
	For generic drugs (me-too Status)	Silagro 50mg Tablets Nabiqasim Industries (Pvt.) Ltd., Karachi
	Pharmacotherapeutic Group of (API)	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	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	Silagro 50mg Tablets (B No. SYH001) Nabiqasim Industries (Pvt.) Ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	11822041-SDC , 11884044-SDC, 11886045-SDC Zone IVa upto 60 momths.
	The status in reference regulatory authorities	Sildenafil 50 mg film-coated tablets Each Film-coated tablet contains: Sildenafil Citrate equivalent to Sildenafil .....….. 50mg PL 20395/0373 Relonchem Limited, Cheshire House Gorsey Lane Widnes Cheshire WA8 0RP United Kingdom
	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	Tablets section approved vide letter dated 14.06.2008
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	

	Decision	
	Approved	
72	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore **(000576)**
	Application Form Dy. No / Tracking ID & date of submission	(RBE-4H8-BUWA, 2026-02-13)
	Detail of Fee Submitted	38700, 2025-09-05,
	The proposed proprietary name / brand name	**Virexo 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	1x10's/As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)As Per Room Temperature
	For generic drugs (me-too Status)	Silagro 25mg Tablets Nabiqasim Industries (Pvt.) Ltd., Karachi
	Pharmacotherapeutic Group of (API)	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	SDAt SB1-25, SDAt SB2-25, SDAt SB3-3 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	Silagro 25mg Tablets (B No. SXH001) Nabiqasim Industries (Pvt.) Ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	11822041-SDC , 11884044-SDC, 11886045-SDC Zone IVa upto 60 momths.
	The status in reference regulatory authorities	Sildenafil 25 mg film-coated tablets Each Film-coated tablet contains: Sildenafil Citrate equivalent to Sildenafil .....….. 25mg PL 48259/0078 Northumbria Pharma Ltd. NETPark Thomas Wright Way Sedgefield Stockton-on-Tees TS21 3FD UK
	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	Tablets section approved vide letter dated 14.06.2008
	Evaluation Remarks	
	Priority as per decision of 214th meeting of authority. Application fulfills codal formalities. Recommended for consideration of board	
	Decision	
	Approved	
73	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**PHARMEVO (PVT) LTD.** A-29, NORTH WESTERN INDUSTRIAL ZONE, PORT QASSIM KARACHI. **(000504)**
	Application Form Dy. No / Tracking ID & date of submission	(G8D-8A1-Z37Y, 2026-03-09)

	Detail of Fee Submitted	38700, 2025-12-18,
	The proposed proprietary name / brand name	**Erectafil 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, 10's, 20's, 30's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 C
	For generic drugs (me-too Status)	Getfil 50mg Tablet from Getz Pharma
	Pharmacotherapeutic Group of (API)	Phosphodiesterase inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rakshit Pharmaceuticals Ltd.
	Detail of stability batches of drug product	Stability data of 3 batches is submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	Import license issued by DRAP on date 07/Feb/2025 along with the import documents are attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and CDP against the innovator product Viagra Tablet is attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Viagra tablet approved by EMA
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	General Tablet (Section approval is attached)
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
74	Case Category	Routine (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	(12P-91Z-2TH4, 2024-10-16)
	Detail of Fee Submitted	37000.0, 2024-09-12,
	The proposed proprietary name / brand name	**VIMLOC 10mg/ml**
	Label Claim	Each ml contains: Lacosamide..... 10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100ml-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 °C
	For generic drugs (me-too Status)	Lalap 10mg/ml Oral Solution
	Pharmacotherapeutic Group of (API)	N03AX18 Other antiepileptics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	VENKATA NARAYANA ACTIVE INGREDIENTS PVT LTD.
	Detail of stability batches of drug product	Zone IVa, upto 6 months. 3 batches, 25 units 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	Vimpat Oral Solution, B No. P1095
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	US-FDA (VIMPAT 10mg/ml oral soultion) (NDA: 022255)
	GMP status of the firm	GMP certificate issued on basis of inspection dated 14.06.2023 is submitted.
	Evidence of approval of manufacturing facility	Renewal letter dated 16.11.2022
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
75	Case Category	Routine (Adil Saeed)
	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	(1EU-QTH-QHWW, 2024-08-19)
	Detail of Fee Submitted	75000.0, 2024-08-16,
	The proposed proprietary name / brand name	**Bistol 2.5mg/ml Oral Solution**
	Label Claim	Each ml contains Bilastine.....2.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30ml, 60ml, 90ml. 12-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store at a temperature above 30°C
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	R06AX29 Other antihistamines for systemic use
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Metrochem API Private Limited
	Detail of stability batches of drug product	Zone IVa, 3 batches.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Ibis 2.5mg/ml Oral solution B. No. 5136782, Mfg Menarini SA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted.
	The status in reference regulatory authorities	Ibis 2.5mg/ml Oral solution (Bilastine) by MenariniInternational Operations Luxembourg, SA1, Avenue de la Gare L-1611 Luxem bourg
	GMP status of the firm	GMP certificate issued on basis of inspection dated 06.06.2023 is submitted.
	Evidence of approval of manufacturing facility	Renewal letter dated 20.09.2021 is submitted wherein oral liquid section is mentioned.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
76	Case Category	Routine (Adil Saeed)

	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	(4SQ-YYQ-7Q8U, 2024-08-12)
	Detail of Fee Submitted	30000.0, 2024-07-12,
	The proposed proprietary name / brand name	**T-Nib 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 Year(s)Store at 20°C to 25°C. Protect from light, heat and moisture.
	For generic drugs (me-too Status)	Tofacnet 5mg Tablet (110051)-Genome Pharmaceutical
	Pharmacotherapeutic Group of (API)	L04AF01 Janus-associated kinase (JAK) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	SICHUAN KELUN PHARMACEUTICAL CO., LTD No. 3 of Yangzong 6th Road, Yang'an Industrial Park, Qionglai, Chengdu, Sichuan 611534, China
	Detail of stability batches of drug product	3 batchs, 3000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Import license is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Tofacenet 5mg B. No. 003 Mfg Genome pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa. upto 24 months.
	The status in reference regulatory authorities	XELJANZ 5 mg film-coated tablets (MHRA Approved)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Copy of section approval letter dated 22.12.2017 is submitted. Tablet General section is mentioned.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
77	Case Category	Routine (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	(RMA-LJS-MMDD, 2024-08-09)
	Detail of Fee Submitted	30000.0, 2024-03-25,
	The proposed proprietary name / brand name	**Fusibet Cream**
	Label Claim	Each gm contains Fusidic acid..... 20mg (2% w/w) Betamethasone valerate eq. to Betamethoasone..... 1mg (0.1% w/w)

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	15g tube-As per SRO,30g tube-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)	Beta-F Cream, Manufacturer: Atco Laboratories
	Pharmacotherapeutic Group of (API)	Corticosteroids, potent, combinations with antibiotic, ATC code: D07CC01
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Halcyon Labs Pvt.Ltd. Address: Halcyon Labs Pvt.Ltd.,Plot No.- 409 ,Phase -IV ,Gidc Industrial Estate,Naroda, City - Ahmed- abad - 382330,Dist.-Ahmedabad Gujarat State,India ,Joyang Laboratories Address: Joyang Laboratories Haidu North Road,Sheyang Economic Development Zone 224300 Jiangsu China
	Detail of stability batches of drug product	3 batches, 60 tubes each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Import licenses of both drug substances are submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Beta-F Cream B. No. PT010J M/s Atco laboratories.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Fusidic Acid: Refrigerated conditions upto 36 months Betamethasone; Zone IVb upto 48 months.
	The status in reference regulatory authorities	Medical and Healthcare Products regulatory Agency (MHRA)
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 03.01.2023 is submitted.
	Evidence of approval of manufacturing facility	Semisolid and toothpaste section approval present in renewal letter dated 03.03.2023
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
78	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**RASCO PHARMA** 5.5KM near Ali Razabad,holiday park,plot #27-28,raiwind road lahore **(000530)**
	Application Form Dy. No / Tracking ID & date of submission	(PGN-2WM-TNNZ, 2024-06-14)
	Detail of Fee Submitted	30000.0, 2023-10-31,
	The proposed proprietary name / brand name	**RE-XIB 60mg TABLET**
	Label Claim	Each film coated tablet contains Etoricoxib 60mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's -As per SRO
	Shelf Life (Unit)	24 Month(s)25 degree
	For generic drugs (me-too Status)	STARCOX TABLET 60mg (075969) by GETZ PHARMA
	Pharmacotherapeutic Group of (API)	M01AH05 Coxibs

	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Assurgen Pharma Pvt.Ltd_ Plot No.23E, Survey No. 24P & 25P, Lalamkoduru Village, Rambilli Mandal, AP SEZ Denotifies area, Atchuthapuram,Visakhapatnam-531 011,Andhra Pradesh, India
	Detail of stability batches of drug product	3 batches, 2000 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	Starcox 60mg Tablet B. No. 241F79 Mfg. Getz pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa upto 60 months.
	The status in reference regulatory authorities	Arcoxia 60mg Tablet by Organon Pharma (UK) Ltd. MHRA APPROVED
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
79	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Variant Pharmaceuticals (Pvt.) Ltd** Plot # 5 M2-Pharmazone, 26KM lahore-sharaqpur road, sheikhupura **(000914)**
	Application Form Dy. No / Tracking ID & date of submission	(6UT-6T4-N75V, 2026-02-03)
	Detail of Fee Submitted	38700, 2025-12-29,
	The proposed proprietary name / brand name	**WIGRA 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	4's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 centigrade. Protect from heat, moisture & sunlight
	For generic drugs (me-too Status)	VIAGRA 100mg Tablet (VIATRIS GLOBAL HEALTHCARE)
	Pharmacotherapeutic Group of (API)	phosphodiesterase-5 (PDE5) inhibitors.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rakshit Pharmaceuticals Limited, India
	Detail of stability batches of drug product	3 batches, 860 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	API documents attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra 100mg Tab B. No. B819405U
	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	Submitted
	Evidence of approval of manufacturing facility	Section Approval letter dated 24.02.2020
	Evaluation Remarks	
	Priority as per decision of 214th meeting. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
80	Case Category	Routine (Adil Saeed)
	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	(5P1-SNN-H11N, 2024-08-22)
	Detail of Fee Submitted	30000.0, 2024-08-21,
	The proposed proprietary name / brand name	**Tofanib 10MG Tablet**
	Label Claim	Each film-coated tablet contains: Tofacitinib citrate eq. to tofacitinib 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 between 20 to 25 degree centigrade, protect from heat, light and moisture
	For generic drugs (me-too Status)	Facib by SAMI Pharmaceuticals (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	L04AF01 Janus-associated kinase (JAK) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Nantong Chanyoo Pharmatech Co., Ltd. Manufacturing Site: No. 2 Tonghai Si Road, Yangkou Chemical Industrial Park, Rudong Coastal Economic Development zone, Nantong, Jiangsu Province, 226407, P.R. 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)	license to import drug substance is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Xeljans mfg Pfizer.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted.
	The status in reference regulatory authorities	Xeljanz by Pfizer Limited (FDA)
	GMP status of the firm	GMP certificate is submitted.
	Evidence of approval of manufacturing facility	tablet general section approval letter is submitted.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
81	Case Category	Routine (Adil Saeed)
	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	(E5X-4G6-EQVE, 2024-08-29)

	Detail of Fee Submitted	75000.0, 2024-08-21,
	The proposed proprietary name / brand name	**Tofanib XR Tablet 11mg**
	Label Claim	Each extended release, film coated tablet contains: Tofacitinib Citrate eq. to Tofacitinib.....11mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7s, 10s, 14s, 20s, 2-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 20°C to 25°C, protect from heat, light and moisture
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	L04AF01 Janus-associated kinase (JAK) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Tofacitinib citrate by Nantong Chanyoo Pharmatech Co., Ltd. No. 2 Tonghai Si Road, Yangkou Chemical Industrial Park, Rudong Coastal Economic Development zone, Nantong, Jiangsu Province
	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)	license to import drug substance is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Xeljans XR mfg Pfizer.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted.
	The status in reference regulatory authorities	Xeljanz XR Tablet 11mg by Pfizer Labs
	GMP status of the firm	GMP certificate is submitted.
	Evidence of approval of manufacturing facility	tablet general section approval letter is submitted.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
82	Case Category	Routine (Adil Saeed)
	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	(MAV-9UP-1QUW, 2024-08-22)
	Detail of Fee Submitted	30000.0, 2024-08-21,
	The proposed proprietary name / brand name	**Tofanib 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	1’s, 7’s, 10’s, 14’s-As per SRO
	Shelf Life (Unit)	24 Year(s)Store between 20 to 25 degree centigrade, protect from heat, light and moisture
	For generic drugs (me-too Status)	Jakjanz by Atco laboratories (114406)
	Pharmacotherapeutic Group of (API)	L04AF01 Janus-associated kinase (JAK) inhibitors

	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Nantong Chanyoo Pharmatech Co., Ltd. Manufacturing Site: No. 2 Tonghai Si Road, Yangkou Chemical Industrial Park, Rudong Coastal Economic Development zone, Nantong, Jiangsu Province, 226407, P.R. China.
	Detail of stability batches of drug product	3 batches data upto 6th month time point submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	License to import drug substance is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Xeljanz by Pfizer Limited
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Xeljanz by Pfizer Limited (FDA)
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
83	Case Category	Routine (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	(32U-TYB-8V9W, 2024-10-16)
	Detail of Fee Submitted	75000.0, 2024-10-08,
	The proposed proprietary name / brand name	**DABI 110 mg capsules**
	Label Claim	Each capsule contains: dabigatran etexilate mesylate eq. to dabigatran etexilate.....110mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3x10-As per SRO
	Shelf Life (Unit)	24 Year(s)Room Temperature
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	B01AE07 Direct thrombin inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zaint Healthcare Labs Pvt, Ltd.
	Detail of stability batches of drug product	3 batches, 3000 capsules 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	Pradaxa 110mg Capsule
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Pradaxa 110mg capsule
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted

	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
84	Case Category	Routine (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	(5BJ-ER7-QLVZ, 2024-10-23)
	Detail of Fee Submitted	37000.0, 2024-10-16,
	The proposed proprietary name / brand name	**Dabi 150mg Capsule**
	Label Claim	Each Capsule contains: Dabigatran Etexilate Mesylate eq. to Dabigatran Etexilate....150mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3x10-As per SRO
	Shelf Life (Unit)	24 Year(s)Room Temperature
	For generic drugs (me-too Status)	Dabiclo 150mg Capsule
	Pharmacotherapeutic Group of (API)	B01AE07 Direct thrombin inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zaint Healthcare Labs Pvt, Ltd.
	Detail of stability batches of drug product	3 batches, 3000 capsules 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	Pradaxa 150mg Capsule
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Pradaxa 150mg capsule
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fufills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
85	Case Category	Routine (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	(6LV-8D6-G537, 2024-09-25)
	Detail of Fee Submitted	37000.0, 2024-09-11,
	The proposed proprietary name / brand name	**THD 100mg CAPSULE**
	Label Claim	Each Capsule Contains: Thalidomide.....100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10-As per SRO

	Shelf Life (Unit)	24 Year(s)Room Temperature
	For generic drugs (me-too Status)	Thalimid 100mg capsule
	Pharmacotherapeutic Group of (API)	L04AX Other immunosuppressants
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Laurus Labs Limited
	Detail of stability batches of drug product	3 batches, 3100 capsules 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	Thalimid 100mg Capsule M/s Pharmasol Pvt Ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Thalomid 100mg Capsule
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
86	Case Category	Routine (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	(Q8J-6YJ-TJAG, 2024-11-05)
	Detail of Fee Submitted	37000.0, 2024-10-29,
	The proposed proprietary name / brand name	**Bastine 20mg Tablet**
	Label Claim	Each tablet contains: Bilastine.....20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2 X 10's-As per SRO
	Shelf Life (Unit)	24 Year(s)Below 30ºC
	For generic drugs (me-too Status)	Bistavo Tablet 20mg
	Pharmacotherapeutic Group of (API)	Antihistamines for systemic use, other antihistamines for systemic use WHO ATC Code: R06AX29.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Virupaksha Organics Limited Unit-I
	Detail of stability batches of drug product	3 batches, 4000 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	Bistavo 20mg tablets M/s Sami
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Ilaxten 20 mg tablets
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	

	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
87	Case Category	Routine (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	(P68-QTG-Q9QU, 2024-08-29)
	Detail of Fee Submitted	30000.0, 2024-08-09,
	The proposed proprietary name / brand name	**Aprilast 30mg Tablet**
	Label Claim	Each Film Coated Tablet Contains Apremilast.....30mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x14-As per SRO
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Kuniz Tablet
	Pharmacotherapeutic Group of (API)	Selective immunosuppressants
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Guangdong Xianqiang Pharmaceutical Co,.Ltd.
	Detail of stability batches of drug product	3 batches, 3400 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	Kuniz 30mg Tablet Mfg Tabros Pharma Pvt Ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Otezla
	GMP status of the firm	Sibmitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
88	Case Category	Routine (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	(Y7H-YBQ-39ZD, 2024-10-18)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-09, 2024-09-13
	The proposed proprietary name / brand name	**APRILAST TABLET STARTER PACK**
	Label Claim	Each Starter Pack Contains Apremilast.....10mg (4 Film Coated Tablets) Apremilast.....20mg (4 Film Coated Tablets) Apremilast.....30mg (47 Film Coated Tablets)
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	1x4, 1x4, 1x5, 3x14-As per SRO
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Kuniz Tablet
	Pharmacotherapeutic Group of (API)	L04AA32 Selective immunosuppressants
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Guangdong Xianqiang Pharmaceutical Co,.Ltd.
	Detail of stability batches of drug product	3400 tablets of each strength (10 20 and 30mg) per batch. 3 batches of each strength. up to 6th month time point stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Kuniz Tablet Starter Pack Mfg M/s Tabros
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Otezla
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board	
	Decision	
	Approved	
89	Case Category	Routine (Adil Saeed)
	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	(B45-997-VS1Q, 2024-08-21)
	Detail of Fee Submitted	30000.0, 2024-08-20,
	The proposed proprietary name / brand name	**Invecaz Injection 2.5g**
	Label Claim	Each vial contains: Ceftazidime pentahydrate equivalent to Ceftazidime: 2.0g. Avibactam Sodium equivalent to Avibactam: 0.5g.
	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)	Zavicefta 2 g/0.5 g powder for concentrate for solution for infusion
	Pharmacotherapeutic Group of (API)	J01DD52 ceftazidime and beta-lactamase inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Chifeng Addison Pharmaceutical co., ltd.
	Detail of stability batches of drug product	3 batches, 100 vials each
	Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested invoice is submitted and drug import license is also submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Zavicefta 2g/0.5g Dry Injection 23K03532
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted

	The status in reference regulatory authorities	Zavicefta 2 g/0.5 g powder for concentrate for solution for infusion https://www.medicines.org.uk/emc/files/pil.2465.p
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board	
	Decision	
	Approved	
90	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(9WV-996-5YXJ, 2024-09-10)
	Detail of Fee Submitted	30000.0, 2024-08-21,
	The proposed proprietary name / brand name	**METAB MR Tablet 35mg**
	Label Claim	Each modified-release tablet contains: Trimetazidine Dihydrochloride 35mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7’s, 10’s, 14’s 20’s-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C.
	For generic drugs (me-too Status)	Trimet MR tablet 35mg (Nova Med Pharmaceuticals Pakistan)
	Pharmacotherapeutic Group of (API)	Other cardiac preparations
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Aragen Life Sciences Limited, Plot No.28A, IDA, Nacharam Village, Uppal Mandal, Medchal - Malkajgiri District, Hyderabad City-500076 Telangana State, India
	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 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Vastarel 35mg MR Tablet Servier Pharma B. No. 7673
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVb, upto 60 minutes.
	The status in reference regulatory authorities	ANSM France approved VASTAREL 35 mg modified-release film-coated tablet
	GMP status of the firm	GMP certificate issued on basis of inspection dated 22.05.2023 is submitted
	Evidence of approval of manufacturing facility	Copy of renewal letter dated 27.04.2020 is submitted.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
91	Case Category	Routine (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	(1HN-RZD-Q13M, 2024-11-19)
	Detail of Fee Submitted	30000.0, 7000.0 2024-09-02, 2024-11-05
	The proposed proprietary name / brand name	**Bacloflex 10mg/5ml**
	Label Claim	Each 5ml of Oral Solution contains: Baclofen.....10mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	150ml-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)	Baclast 10mg/5ml Oral Solution
	Pharmacotherapeutic Group of (API)	M03BX01 Other centrally acting agents
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Reine Lifescience Plot No. 5901, Kanoria Chemical Road, GIDC Estate, Ankleshwar – 393002. Dist. Bharuch (Guj.) India.
	Detail of stability batches of drug product	3 batches, 200 bottles 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	Baclofen 10mg/5ml Oral Solution Thame labs B. No. CRT/58795
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa upto 24months.
	The status in reference regulatory authorities	Medicines and Healthcare Products Regulatory Agency
	GMP status of the firm	GMP certificate issued on basis of inspection dated 03.01.2023 is submitted.
	Evidence of approval of manufacturing facility	Section approval letter dated 03.03.2023 is submitted.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
92	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**OPAL LABORATORIES (PVT) LTD** LC-41, L.I.T.E., Landhi **(000046)**
	Application Form Dy. No / Tracking ID & date of submission	(QMZ-3EA-XVDB, 2026-03-09)
	Detail of Fee Submitted	38700, 2026-01-16,
	The proposed proprietary name / brand name	**Silofil 50mg Tablet**
	Label Claim	Each film coated tablet contains: Sildenafil Citrate Equivalent to Sildenafil .... 50mg (BP Specification)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	4's-De-Controlled
	Shelf Life (Unit)	2 Year(s)store below 30C°

	For generic drugs (me-too Status)	Getfil Tablets 50mg (Getz Pharma)
	Pharmacotherapeutic Group of (API)	Urologicals / (Therapeutic area: Erectile Dysfunction)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rakshit Pharmaceuticals Limited, Plot number 68/A, Jawaharlal Nehru Pharma City, Parawada Mandal, Anakapalli district, Andhra Pradesh
	Detail of stability batches of drug product	Attached in Module-3 P.8 Page No. 321
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached in Module-1 Page No. 161
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in Module-3 P.2 Pharmaceutical Development section P2.6 Page No. 266/267
	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 Inspection Report and GMP Certificate attached
	Evidence of approval of manufacturing facility	Evidence of Manufacturing Facility submitted
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
93	Case Category	Routine (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	(WJJ-P6D-JRWE, 2024-11-19)
	Detail of Fee Submitted	75000.0, 2024-09-11,
	The proposed proprietary name / brand name	**kaylith 15 mEq Extended-Release Tablet**
	Label Claim	Each Extended-Release Tablet Contains: Potassium Citrate..... 15mEq (1620 mg)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10'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)	Nil
	Pharmacotherapeutic Group of (API)	A12BA02
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vasa Pharmachem Pvt. Ltd. Address:Survey No.1354, Bhetawada, Bhetawada-Trasad Road, Dholka-382225, Dist.- Ahmedabad , Gujarat, 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)	License to import drug substance is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Urocit-K 15mEq Extended release tablet.

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	upto 36 months. Zone IVa.
	The status in reference regulatory authorities	Food and Drug Administration - USFDA
	GMP status of the firm	Copy of GMP certificate submitted.
	Evidence of approval of manufacturing facility	Tablet general section mentioned in Renewal letter dated 03.03.2023
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
94	Case Category	Routine (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	(V85-Q5N-3S19, 2024-09-09)
	Detail of Fee Submitted	75000.0, 2024-05-10,
	The proposed proprietary name / brand name	**Renalamer 1.6g sachet**
	Label Claim	Each Sachet contains: Sevelamer Carbonate 1.6g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	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)	None
	Pharmacotherapeutic Group of (API)	V03AE02 Drugs for treatment of hyperkalemia and hyperphosphatemia
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals limited 103-106,GIDC,HALOL -389 350,Dist-PANCHMAHAL
	Detail of stability batches of drug product	3 batches, 50 sachet each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested invoice is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Renvela 1.6g Powder for oral Suspension Mfg Sanofi BV
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	zone IVb, upto 60 months.
	The status in reference regulatory authorities	European Medicines Agency (EMA)
	GMP status of the firm	GMP certificate issued on basis of inspection dated 03.01.2023 is submitted
	Evidence of approval of manufacturing facility	Renewal letter dated 03.03.2023 is submitted wherein Sachet section general is mentioned.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
95	Case Category	Contract Manufacturing (Adil Saeed)

	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	(EXH-ZTT-GM6X, 2024-06-13)
	Detail of Fee Submitted	75000.0, 2024-06-10,
	The proposed proprietary name / brand name	**FETROZOLE 2.5mg Tablet**
	Label Claim	Each film coated tablet contains: Letrozole 2.5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's, 10's & 30's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Lexmara 2.5mg tablet (Letrozole) by The Searle Company Limited Regn. No. 093684
	Pharmacotherapeutic Group of (API)	L02BG04 HORMONE ANTAGONISTS AND RELATED AGENTS
	Name, address of Manufacturing site:	Swiss Pharmaceuticals Pvt. Ltd.-A/159, S.I.T.E. II , Super Highway, Karachi – Pakistan-
	Name & address of API manufacturer	Lianyungang Guike Pharmaceutical Co., Ltd. No.1, Xianfeng Road, Dapu Industry Zone, Economic & Technical Development Area, Lianyungang City, Jiangsu
	Detail of stability batches of drug product	3 batches, 100,000 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	Lezra 2.5mg tablet CL23023A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Femara 2.5 mg Tablets (Letrozole) by M/s. Novartis Pharmaceuticals UK Ltd. Approved by US FDA
	GMP status of the firm	GMP certificate issued on basis of inspection dated 26.10.2023 is submitted.
	Evidence of approval of manufacturing facility	Grudiz 2.5mg Tablet Sami Pharma
	Evaluation Remarks	
	Application has informed that product will be manufactured in Tablet General Section Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
96	Case Category	Routine (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	(J3Z-DUJ-YLQL, 2024-07-15)
	Detail of Fee Submitted	30000.0, 2024-07-11,
	The proposed proprietary name / brand name	**Citinix Tablet 5mg**
	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	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
	Shelf Life (Unit)	2 Year(s)Below 30 °C
	For generic drugs (me-too Status)	Tofacnet Tablet 5mg, Manufactured by: Genome Pharmaceuticals (Pvt) Ltd.
	Pharmacotherapeutic Group of (API)	L04AF01 Janus-associated kinase (JAK) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Source of Drug Substance: Hunan Warrant Chiral Pharmaceutical Co., Ltd. Address: No. 139, Tongguan Avenue, Tongguan Circular Economy Industrial Park, Wangcheng District, Changsha, Hunan, China
	Detail of stability batches of drug product	3 batches, 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate of 350grams drug substance, 100mg WS & 10mg impurity 24 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Tofacnet 5mg Tablet B No. 004 M/s Macter
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa upto 24 months.
	The status in reference regulatory authorities	Xeljanz Tablet, Registered in Food and Drug Administration (FDA)
	GMP status of the firm	GMP certificate is submitted.
	Evidence of approval of manufacturing facility	Tablet general section is approved.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
97	Case Category	Contract Manufacturing (Adil Saeed)
	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	(3SA-PZ1-1JXH, 2024-10-10)
	Detail of Fee Submitted	75000.0, 18000.0 2024-09-04, 2024-10-03
	The proposed proprietary name / brand name	**T-Fab 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	1’s, 7’s, 10’s, 14’s-As per SRO
	Shelf Life (Unit)	24 Year(s)Store between 20 to 25 degree centigrade, protect from heat, light and moisture., light and moisture
	For generic drugs (me-too Status)	Jakjanz by Atco laboratories (114406)
	Pharmacotherapeutic Group of (API)	L04AF01 Janus-associated kinase (JAK) inhibitors
	Name, address of Manufacturing site:	Genix Pharma private Limited -44, 45-B Korangi Creek Road, Karachi-75190, Pakistan -

	Name & address of API manufacturer	Nantong Chanyoo Pharmatech Co., Ltd. Manufacturing Site: No. 2 Tonghai Si Road, Yangkou Chemical Industrial Park, Rudong Coastal Economic Development zone, Nantong, Jiangsu Province, 226407, P.R. China.
	Detail of stability batches of drug product	3 batches data upto 6th month time point submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	License to import drug substance is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Xeljanz by Pfizer Limited
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Xeljanz by Pfizer Limited (FDA)
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
98	Case Category	Contract Manufacturing (Adil Saeed)
	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	(A6S-YVZ-Y7MM, 2024-10-21)
	Detail of Fee Submitted	75000.0, 18000.0 2024-09-04, 2024-10-03
	The proposed proprietary name / brand name	**T-Fab XR Tablet**
	Label Claim	Each extended release, film coated tablet contains: Tofacitinib Citrate eq. to Tofacitinib.....11mg
	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)	2 Year(s)Store below 30°C, protect from heat light and moisture
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	L04AF01 Janus-associated kinase (JAK) inhibitors
	Name, address of Manufacturing site:	Genix Pharma (Pvt) Limited-Plot No.44-45 B, Korangi Creek Road, Karachi -
	Name & address of API manufacturer	Nantong Chanyoo Pharmatech Co., Ltd. No. 2 Tonghai Si Road, Yangkou Chemical Industrial Park, Rudong Coastal Economic Development zone, Nantong, Jiangsu Province
	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)	license to import drug substance is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Xeljans XR mfg Pfizer.

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted.
	The status in reference regulatory authorities	Xeljanz XR Tablet 11mg by Pfizer Labs
	GMP status of the firm	GMP certificate is submitted.
	Evidence of approval of manufacturing facility	tablet general section approval letter is submitted.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
99	Case Category	Contract Manufacturing (Adil Saeed)
	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	(WRT-4VY-REA4, 2024-10-16)
	Detail of Fee Submitted	75000.0, 18000.0 2024-09-04, 2024-10-03
	The proposed proprietary name / brand name	**T-Fab 10mg Tablet**
	Label Claim	Each film-coated tablet contains: Tofacitinib citrate eq. to tofacitinib 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 between 20 to 25 degree centigrade, protect from heat, light and moisture
	For generic drugs (me-too Status)	Facib by SAMI Pharmaceuticals (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	L04AF01 Janus-associated kinase (JAK) inhibitors
	Name, address of Manufacturing site:	Genix Pharma Private Limited-44, 45-B Korangi Creek Road, Karachi-75190, Pakistan -
	Name & address of API manufacturer	
	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)	license to import drug substance is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Xeljans mfg Pfizer.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted.
	The status in reference regulatory authorities	Xeljanz by Pfizer Limited (FDA)
	GMP status of the firm	GMP certificate is submitted.
	Evidence of approval of manufacturing facility	tablet general section approval letter is submitted.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
100	Case Category	Contract Manufacturing (Adil Saeed)
	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	(LYQ-644-LSUV, 2024-10-09)
	Detail of Fee Submitted	75000.0, 18000.0 2024-09-04, 2024-09-23
	The proposed proprietary name / brand name	**Mizpin OD 15mg**
	Label Claim	Each oral disintegrating tablet contains Mirtazapine ----- 30mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	7s, 10s, 14s, 20s, 2-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)	Not Applicable
	Pharmacotherapeutic Group of (API)	N06AX Other antidepressants N06AX11
	Name, address of Manufacturing site:	Genix Pharma Pvt. Ltd.-44, 45-B, Korangi Creek Road, Karachi-
	Name & address of API manufacturer	Megafine Pharma (P) Ltd
	Detail of stability batches of drug product	3 batches 1500 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	Auro-Mirtazapine OD Mfg Auro Canada.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Auro Mirtazapine OD Tablet, Auro Pharma Inc. Canada
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
101	Case Category	Routine (Adil Saeed)
	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	(6MA-REN-U7EL, 2024-09-25)
	Detail of Fee Submitted	75000.0, 2024-09-04,
	The proposed proprietary name / brand name	**Rezam OD 15mg**
	Label Claim	Each oral disintegrating tablet contains Mirtazapine ----- 15mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	7s, 10s, 14s, 20s, 2-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)	Not Applicable
	Pharmacotherapeutic Group of (API)	N06AX Other antidepressants N06AX11
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Megafine Pharma (P) Ltd
	Detail of stability batches of drug product	3 batches 1500 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	Auro-Mirtazapine OD Mfg Auro Canada.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Auro Mirtazapine OD Tablet, Auro Pharma Inc. Canada
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
102	Case Category	Routine (Adil Saeed)
	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	(V1T-9J4-YDUU, 2024-09-18)
	Detail of Fee Submitted	75000.0, 2024-09-04,
	The proposed proprietary name / brand name	**Rezam OD 30mg**
	Label Claim	Each oral disintegrating tablet contains Mirtazapine ----- 30mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	7s, 10s, 14s, 20s, 2-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)	Not Applicable
	Pharmacotherapeutic Group of (API)	N06AX Other antidepressants N06AX11
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Megafine Pharma (P) Ltd
	Detail of stability batches of drug product	3 batches 1500 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	Auro Mirtazapine OD Tablet, Auro Pharma Inc. Canada
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Auro Mirtazapine OD Tablet, Auro Pharma Inc. Canada
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
103	Case Category	Contract Manufacturing (Adil Saeed)

	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	(ZPW-21H-MAHA, 2024-09-25)
	Detail of Fee Submitted	75000.0, 18000.0 2024-09-04, 2024-09-23
	The proposed proprietary name / brand name	**Mizpin OD 45mg**
	Label Claim	Each oral disintegrating tablet contains Mirtazapine ----- 45mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	7s, 10s, 14s, 20s, 2-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)	Not Applicable
	Pharmacotherapeutic Group of (API)	Other antidepressants N06AX11
	Name, address of Manufacturing site:	Genix Pharma Pvt. Ltd.-44, 45-B, Korangi Creek Road, Karachi-
	Name & address of API manufacturer	Megafine Pharma (P) Ltd
	Detail of stability batches of drug product	3 batches, 1500 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	Auro-mirtazapine 45mg B. No. 83267 Mfg Auro Pharma Canada,
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted.
	The status in reference regulatory authorities	Auro Mirtazapine OD Tablet, Auro Pharma Inc. Canada
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 06.06.2023 is submitted.
	Evidence of approval of manufacturing facility	Section approval letter dated 30.09.2021 is submitted.
	Evaluation Remarks	
	Application fulfills codal formalities. recommended for consideration of board.	
	Decision	
	Approved	
104	Case Category	Contract Manufacturing (Adil Saeed)
	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	(PET-ZJQ-TW4N, 2024-08-19)
	Detail of Fee Submitted	75000.0, 2024-08-16,
	The proposed proprietary name / brand name	**Bilaxen 2.5mg/ml Oral Solution**
	Label Claim	Each ml contains Bilastine.....2.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30ml, 60ml, 90ml. 12-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store at a temperature above 30°C

	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	R06AX29 Other antihistamines for systemic use
	Name, address of Manufacturing site:	Genix Pharma (Pvt) Ltd-Plot No. 44-45-B, Korangi Creek Road, Karachi -
	Name & address of API manufacturer	Metrochem API Private Limited
	Detail of stability batches of drug product	Zone IVa, 3 batches.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Ibis 2.5mg/ml Oral solution B. No. 5136782, Mfg Menarini SA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted.
	The status in reference regulatory authorities	Ibis 2.5mg/ml Oral solution (Bilastine) by MenariniInternational Operations Luxembourg, SA1, Avenue de la Gare L-1611 Luxem bourg
	GMP status of the firm	GMP certificate issued on basis of inspection dated 06.06.2023 is submitted.
	Evidence of approval of manufacturing facility	Renewal letter dated 20.09.2021 is submitted wherein oral liquid section is mentioned.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
105	Case Category	Routine (Adil Saeed)
	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	(T2S-JDM-T31Y, 2024-11-15)
	Detail of Fee Submitted	75000.0, 2024-10-29,
	The proposed proprietary name / brand name	**Aznam 2g Powder for solution for infusion**
	Label Claim	Each vial contains: Aztreonam..... 2g. (with approximately 1.56g L-Arginine)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's, 6's, 12's-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30 degrees, protect from heat light and moisture
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	J01DF01 Monobactams
	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	3 batches, 90 vials 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	Azactam 2g Injection B. No. D03140 Mfg Bristol Myers Squib

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Azactam Injection 2gm by Bristol Myers Squibb
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Dry Powder Injection (Penem) Section approval present in renewal letter dated 20.09.2021
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
106	Case Category	Routine (Adil Saeed)
	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	(3TM-U3H-MJW2, 2024-08-31)
	Detail of Fee Submitted	30000.0, 2024-08-26,
	The proposed proprietary name / brand name	**Erbil 20mg Tablet**
	Label Claim	Each tablet contains: Bilastine.....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,50's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30 Degree
	For generic drugs (me-too Status)	Bistavo Tablet 20mg, M/s Sami Pharmaceutical (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	R06AX29 Other antihistamines for systemic use
	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, Visakhapatnam District, Andhra Pradesh, 531021, India
	Detail of stability batches of drug product	3 batches, 1500 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	Bistavo 20mg Tablet B. No. MKK002 M/s Sami Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Ilaxten Tablet, Menarini International Operations Luxembourg S.A, MHRA Approved
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
107	Case Category	Routine (Adil Saeed)

	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	(WQH-3T6-EES2, 2024-09-11)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-29, 2024-09-10
	The proposed proprietary name / brand name	**Erbil 2.5mg/ml Oral Solution**
	Label Claim	Each ml contains: Bilastine.....2.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	120ml-As per SRO,60ml-As per SRO
	Shelf Life (Unit)	2 Year(s)Store Below 30 Degree
	For generic drugs (me-too Status)	Bistin Oral Solution 2.5mg/ml, M/s. Sami Pharmaceutical (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	R06AX29 Other antihistamines for systemic use
	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, Visakhapatnam District, Andhra Pradesh, 531021, India
	Detail of stability batches of drug product	3 batches, 70 bottles 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	Bilaxten oral solution B. No. 3124 Mfg Faes Pharma Spain
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Ilaxten 2.5mg/ml Oral Solution, Menarini International Operations Luxembourg S.A, MHRA Approved.
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
108	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)**
	Application Form Dy. No / Tracking ID & date of submission	(75T-QHJ-89J1, 2024-08-20)
	Detail of Fee Submitted	30000.0, 2024-08-12,
	The proposed proprietary name / brand name	**Zonlac 30mg/ml**
	Label Claim	Each 1mL vial contains: Ketorolac Tromethamine.....30 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	24 Year(s)Store at controlled room temperature 20 °C to 25 °C (68 °F to 77 °F).
	For generic drugs (me-too Status)	TEKAC® 30mg/ml Injection

	Pharmacotherapeutic Group of (API)	Acetic acid derivatives and related substances
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Saurav Chemical Limited Corporate office: Plot no. 370, Industrial area, Phase-II Panchukla-134109 (Haryana) India.
	Detail of stability batches of drug product	2 batches, 2000 vials each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan from M/s Horizon, Loan letter and clearance certificate is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	TEKAC® 30mg/ml ampoule M/s Sami pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Registered drug by US FDA as (Ketorolac Tromethamine injection).
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
109	Case Category	Routine (Adil Saeed)
	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	(D89-9RP-WP6Z, 2024-08-19)
	Detail of Fee Submitted	30000.0, 2024-08-07,
	The proposed proprietary name / brand name	**B-MIDE OPHTHALMIC SUSPENSION 1%/0.2%**
	Label Claim	Each ml of ophthalmic suspension contains: Brinzolamide.....10mg Brimonidine Tartrate.....2mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5ml,10ml,15ml,20ml,3-As per SRO
	Shelf Life (Unit)	2 Year(s)store between 2°C to 25°C
	For generic drugs (me-too Status)	Simbrinza 1%/0.2% Ophthalmic suspension by Novartis Pharma
	Pharmacotherapeutic Group of (API)	Ophthalmologicals, Antiglaucoma preparations and miotics, ATC code: S01EC54
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Brimonidine Tartrate: INDOCO REMEDIES LIMITED,Brinzolamide : Century Pharmaceuticals Limited
	Detail of stability batches of drug product	data of 3 batches is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Simbrinza 1%/0.2% Ophthalmic suspension Alcon Lab, B. No. 8102564
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted

	The status in reference regulatory authorities	Simbrinza® 1%/0.25 by Alcon Laboratories, lnc
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of Board.	
	Decision	
	Approved	
110	Case Category	Contract Manufacturing (Adil Saeed)
	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	(4BR-YLJ-P8LP, 2024-08-20)
	Detail of Fee Submitted	75000.0, 2024-08-07,
	The proposed proprietary name / brand name	**Hedqin 20mg/160mg Tablet**
	Label Claim	Each film coated tablet Contains: Dihydroartemisinin ..... 20mg Piperaquine Phosphate..... 160mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3's & 8's-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)	P01BF07 Artemisinin and derivatives, combinations
	Name, address of Manufacturing site:	Genix Pharma (Pvt.) Ltd.-44, 45-B, Korangi Creek Road, Karachi-75190, Pakistan-
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches, 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificates of both drug substances are submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Eurartesim 20mg/160mg B. No. RA25898
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Eurartesim 160 mg/20 mg ANSM France Approved.
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
111	Case Category	Contract Manufacturing (Adil Saeed)
	Name, address of Applicant.	**Himont Pharmaceuticals (Pvt.) Ltd.** 17-km Ferozpur Road, Lahore **(000231)**
	Application Form Dy. No / Tracking ID & date of submission	(59G-1HT-3UBL, 2024-12-20)

	Detail of Fee Submitted	75000.0, 2024-01-04,
	The proposed proprietary name / brand name	**Hilatin Capsule**
	Label Claim	Each Softgel Capsule contains Choline Alfoscerate.....400mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1 x 30's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25c
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	Other parasympathomimetics
	Name, address of Manufacturing site:	Mass Pharma (Pvt.) Ltd.-17-Km, Ferozpur Road, Lahore-
	Name & address of API manufacturer	Wuhan Recedar Biotechnology Co., Ltd. No. 1, Guanshan Ave, Donghu high-tech Development Zone, Wuhan, Hubei 430205, CN
	Detail of stability batches of drug product	3 batches, 500 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested invoice is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Gliatilin Capsule 400mg B. No 5460120 M/s Italfarmaco
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	AIFA Italy Approved
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Setion approved vide approval letter dated 18.12.2017
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
112	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**S.& G. Fazul Ellahie (pvt) limited.** E-46, S.I.T.E., Karachi **(000083)**
	Application Form Dy. No / Tracking ID & date of submission	(5XH-ES7-GWP9, 2024-11-05)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-23, 2024-10-15
	The proposed proprietary name / brand name	**Rempide**
	Label Claim	Each film coated tablet contains: Rebamipide.....100mg
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)As per zone-IVA
	For generic drugs (me-too Status)	Mucosta Tablet 100mg by Otsuka Pakistan Limited
	Pharmacotherapeutic Group of (API)	Other drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	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)	AD attested invoice of 600grams drug substance is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Mucosta 100mg Tablet B. No. MC215074
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Mucosta by MHLW Japan
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
113	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**S.& G. Fazul Ellahie (pvt) limited.** E-46, S.I.T.E., Karachi **(000083)**
	Application Form Dy. No / Tracking ID & date of submission	(SAS-QQY-MQWV, 2024-08-21)
	Detail of Fee Submitted	75000.0, 2024-02-06,
	The proposed proprietary name / brand name	**Crufer 30mg Capsule**
	Label Claim	Each capsule contains: Ferric Maltol eq. to Iron.....30mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)As per zone IV-A
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Iron Preparation
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. Apicore Pharmaceuticals Pvt. Ltd., Block No. 252-253, Village: Dhobikuva-391 440, Opp: Jainirrigation, Padra Jambusar Highway, Tal-Padra, Dist. Vadodara, Gujarat State, India
	Detail of stability batches of drug product	3 batches, 600 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	Accrufer Capsule B. No. 1030A M/s Shield therapeutics.
	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	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
114	Case Category	Routine (Adil Saeed)

	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	(29X-ATP-N385, 2024-08-19)
	Detail of Fee Submitted	30000.0, 2024-08-16,
	The proposed proprietary name / brand name	**Bistol 20mg Tablet**
	Label Claim	Each tablet contains Bilastine.....20mg
	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)	2 Year(s)Store below 30°C. Protect from heat, light and moisture
	For generic drugs (me-too Status)	Bilafaxin 20 mg tablet by Searle Company Limited
	Pharmacotherapeutic Group of (API)	R06AX29 Other antihistamines for systemic use
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Metrochem API Private Limited
	Detail of stability batches of drug product	3 batches, 1500 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	Drynol 20mg tablet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Drynol 20 mg Tablet (Bilastine) by PCO Manufacturing Unit 10, Ashbourne Business Park Rath Ash bourne Co. Meath Ireland
	GMP status of the firm	GMP certificate issued on basis of inspection dated 06.06.2023 is submitted.
	Evidence of approval of manufacturing facility	Renewal letter dated 20.09.2021 is submitted wherein oral Tablet section is mentioned.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
115	Case Category	Contract Manufacturing (Adil Saeed)
	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	(3E8-HP4-3RHQ, 2024-08-19)
	Detail of Fee Submitted	75000.0, 2024-08-16,
	The proposed proprietary name / brand name	**Bilaxen 20mg Tablet**
	Label Claim	Each tablet contains Bilastine.....20mg
	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)	2 Year(s)Store below 30°C. Protect from heat, light and moisture

	For generic drugs (me-too Status)	Bilafaxin 20 mg tablet by Searle Company Limited
	Pharmacotherapeutic Group of (API)	R06AX29 Other antihistamines for systemic use
	Name, address of Manufacturing site:	Genix Pharma (Pvt) Ltd-Plot No. 44-45-B, Korangi Creek Road, Karachi -
	Name & address of API manufacturer	Metrochem API Private Limited
	Detail of stability batches of drug product	3 batches, 1500 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	Drynol 20mg tablet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Drynol 20 mg Tablet (Bilastine) by PCO Manufacturing Unit 10, Ashbourne Business Park Rath Ash bourne Co. Meath Ireland
	GMP status of the firm	GMP certificate issued on basis of inspection dated 06.06.2023 is submitted.
	Evidence of approval of manufacturing facility	Renewal letter dated 20.09.2021 is submitted wherein oral Tablet section is mentioned.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
116	Case Category	Contract Manufacturing (Adil Saeed)
	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	(4X4-QGZ-AMMG, 2024-08-20)
	Detail of Fee Submitted	75000.0, 2024-08-16,
	The proposed proprietary name / brand name	**Bilaxen 20mg OD Tablet**
	Label Claim	Each orodispersible tablet contains: Bilastine.....20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7’s,10’s,14’s,20’s,2-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	R06AX29 Other antihistamines for systemic use
	Name, address of Manufacturing site:	Genix Pharma Pvt Ltd -44, 45B, KORANGI CREEK ROAD, KARACHI. PAKISTAN-
	Name & address of API manufacturer	Metrochem API Private Limited
	Detail of stability batches of drug product	3 batches, 1500 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	Bilamax Flas OD Tablet 20mg B. No. BT0031 M/s CINFA Laboratories SA

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Bilamax Flas 20mg Orodispersible Tablet by Cinfa Laboratories, SA
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
117	Case Category	Routine (Adil Saeed)
	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	(7MW-Y2P-R2Q2, 2024-09-03)
	Detail of Fee Submitted	75000.0, 2024-08-21,
	The proposed proprietary name / brand name	**Bilaxen 20mg OD Tablet**
	Label Claim	Each orodispersible tablet contains: Bilastine.....20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's,10's,14's,20's,2-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect from heat, light & Moisture
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	R06AX29 Other antihistamines for systemic use
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Metrochem API Private Limited
	Detail of stability batches of drug product	3 batches, 1500 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	Bilamax Flas OD Tablet 20mg B. No. BT0031 M/s CINFA Laboratories SA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Bilamax Flas 20mg Orodispersible Tablet by Cinfa Laboratories, SA
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
118	Case Category	Routine (Adil Saeed)
	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	(3NT-U4A-RVDJ, 2024-10-16)

	Detail of Fee Submitted	75000.0, 2024-10-09,
	The proposed proprietary name / brand name	**Vrontil 20mg/ml drops.**
	Label Claim	Each ml of solution contains: Vortioxetine (D,L)-lactate equivalent to of vortioxetine.....20 mg (Each drop contains: Vortioxetine (D,L)-lactate equivalent to vortioxetine.....1 mg)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	15ml, 30ml, 60ml & 1-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	N06AX26 Other antidepressants
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Lianyungang Jari Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	3 batches, 100 bottles 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	Brintellix 20mg/ml Oral Drops. B No. 5136782
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted.
	The status in reference regulatory authorities	H. Lundbeck A/S, Denmark
	GMP status of the firm	GMP certificate is submitted
	Evidence of approval of manufacturing facility	Section approval is submitted.
	Evaluation Remarks	
	Application fulfills codal formalities recommended for consideration of board.	
	Decision	
	Approved	
119	Case Category	Contract Manufacturing (Adil Saeed)
	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	(AR3-BY7-85B3, 2024-10-10)
	Detail of Fee Submitted	75000.0, 18000.0 2024-09-04, 2024-09-23
	The proposed proprietary name / brand name	**Mizpin OD 15mg**
	Label Claim	Each oral disintegrating tablet contains Mirtazapine ----- 15mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	7s, 10s, 14s, 20s, 2-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)	Not Applicable
	Pharmacotherapeutic Group of (API)	N06AX Other antidepressants N06AX11
	Name, address of Manufacturing site:	Genix Pharma Pvt. Ltd.-44, 45-B, Korangi Creek Road, Karachi-

	Name & address of API manufacturer	Megafine Pharma (P) Ltd
	Detail of stability batches of drug product	3 batches 1500 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	Auro-Mirtazapine OD Mfg Auro Canada.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Auro Mirtazapine OD Tablet, Auro Pharma Inc. Canada
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fufils codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
120	Case Category	Contract Manufacturing (Adil Saeed)
	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	(GLU-JGA-95DG, 2024-08-19)
	Detail of Fee Submitted	75000.0, 2024-08-16,
	The proposed proprietary name / brand name	**Bilaxen 10mg OD Tablet**
	Label Claim	Each orodispersible tablet contains: Bilastine.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7’s,10’s,14’s,20’s,2-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	R06AX29 Other antihistamines for systemic use
	Name, address of Manufacturing site:	Genix Pharma Pvt Ltd -44, 45B, KORANGI CREEK ROAD, KARACHI. PAKISTAN-
	Name & address of API manufacturer	Metrochem API Private Limited Unit-IV, Plot No. 34B, 40B & 60B, J.N. Pharma City, Thanam Village, Parawada Mandal, Visakhapatnam District, Andhra Pradesh, 531021, India (IND).
	Detail of stability batches of drug product	3 batches 1500 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	Bilamax Flas OD Tablet 10mg B. No. BT0021 M/s CINFA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Bilamax Flas 10mg Orodispersible Tablet by Cinfa Laboratories, SA
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted

	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
121	Case Category	Contract Manufacturing (Adil Saeed)
	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	(T5D-H9N-7A8W, 2024-08-29)
	Detail of Fee Submitted	75000.0, 2024-08-21,
	The proposed proprietary name / brand name	**Bistol OD Tablet 10mg**
	Label Claim	Each orodispersible tablet contains: Bilastine.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's,10's,14's,20's,2-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect from heat, light & Moisture
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	R06AX29 Other antihistamines for systemic use
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Metrochem API Private Limited
	Detail of stability batches of drug product	3 batches 1500 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	Bilamax Flas OD Tablet 10mg B. No. BT0021 M/s CINFA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Bilamax Flas 10mg Orodispersible Tablet by Cinfa Laboratories, SA
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
122	Case Category	Contract Manufacturing (Adil Saeed)
	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	(GVZ-TW2-7WS9, 2024-08-19)
	Detail of Fee Submitted	75000.0, 2024-08-07,
	The proposed proprietary name / brand name	**BRIMOZOL OPHTHALMIC SUSPENSION 1%/0.2%**
	Label Claim	Each ml of ophthalmic suspension contains: Brinzolamide.....10mg Brimonidine

		Tartrate.....2mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5ml,10ml,15ml,20ml,3-As per SRO
	Shelf Life (Unit)	2 Year(s)store between 2°C to 25°C
	For generic drugs (me-too Status)	Simbrinza 1%/0.2% Ophthalmic suspension by Novartis Pharma
	Pharmacotherapeutic Group of (API)	Ophthalmologicals, Antiglaucoma preparations and miotics, ATC code: S01EC54
	Name, address of Manufacturing site:	Genix Pharma Pvt Ltd -44, 45B, KORANGI CREEK ROAD, KARACHI. PAKISTAN-
	Name & address of API manufacturer	Brimonidine Tartrate: INDOCO REMEDIES LIMITED,Brinzolamide : Century Pharmaceuticals Limited
	Detail of stability batches of drug product	data of 3 batches is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 of both drug substances is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Simbrinza 1%/0.2% Ophthalmic suspension Alcon Lab, B. No. 8102564
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Simbrinza® 1%/0.25 by Alcon Laboratories, lnc
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
123	Case Category	Routine (Adil Saeed)
	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	(SRH-46M-1T7X, 2024-10-16)
	Detail of Fee Submitted	37000.0, 2024-10-03,
	The proposed proprietary name / brand name	**Ketor (Ketorolac Tromethamine Ophthalmic Solution 0.5%)**
	Label Claim	Each ml of ophthalmic solution contains: Ketorolac Tromethamine.....5mg (0.5%)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3ml,5ml,10ml-As per SRO
	Shelf Life (Unit)	2 Year(s)store between 2°C to 25°C
	For generic drugs (me-too Status)	Ketrosan ophthalmic solution 0.5% by Sante Pvt Ltd
	Pharmacotherapeutic Group of (API)	Antiinflammatory agents, non-steroids S01BC05
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Dr. Reddy's Laboratories Limited
	Detail of stability batches of drug product	data of 3 batches is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Acular 0.5% ophthalmic solution M/s Allergan
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	ACULAR® 0.5mg/ml by Allergan, lnc
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
124	Case Category	Contract Manufacturing (Adil Saeed)
	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	(549-V7V-7QZ4, 2024-11-13)
	Detail of Fee Submitted	93000.0, 2024-10-09,
	The proposed proprietary name / brand name	**Danketo Ophthalmic Solution 0.5%**
	Label Claim	Each ml of ophthalmic solution contains: Ketorolac Tromethamine.....5mg (0.5%)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3ml,5ml,10ml-As per SRO
	Shelf Life (Unit)	2 Year(s)store between 15°C to 25°C
	For generic drugs (me-too Status)	Ketrosan ophthalmic solution 0.5% by Sante Pvt Ltd
	Pharmacotherapeutic Group of (API)	Antiinflammatory agents, non-steroids S01BC05
	Name, address of Manufacturing site:	Genix Pharma Pvt Ltd -44, 45B, KORANGI CREEK ROAD, KARACHI. PAKISTAN-
	Name & address of API manufacturer	Dr. Reddy's Laboratories Limited
	Detail of stability batches of drug product	data of 3 batches is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Acular 0.5% ophthalmic solution M/s Allergan
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	ACULAR® 0.5mg/ml by Allergan, lnc
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fufils codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
125	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Hiranis Pharmaceuticals Pvt. Ltd.** E-145-149, North Western Industrial Zone, Port Qasim, Karachi-75020, Pakistan **(000785)**

	Application Form Dy. No / Tracking ID & date of submission	(7E1-4HN-BX93, 2024-07-26)
	Detail of Fee Submitted	75000.0, 2024-06-27,
	The proposed proprietary name / brand name	**Tofajak Oral Solution 1mg/ml**
	Label Claim	Each ml contains:- Tofacitinib citrate eq. to Tofacitinib.....1mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO/DPC-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30C, protect from light and heat
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	L04AF01 Janus-associated kinase (JAK) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Glenmark Life Sciences Ltd.
	Detail of stability batches of drug product	3 batches, 500 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested invoice is required.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	XELJANZ 1 mg/mL oral solution B. NO. 84XL205R2
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	XelJanz Oral Solution, Pfizer, USFDA,
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. recommended for consideration of board.	
	Decision	
	Approved	
126	Case Category	Routine (Adil Saeed)
	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	(DLZ-JLY-JMYT, 2024-10-16)
	Detail of Fee Submitted	37000.0, 2024-10-09,
	The proposed proprietary name / brand name	**Eflort 13.9% Cream**
	Label Claim	Each gm of cream contains: Eflornithine HCl (as monohydrate) 139mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5g, 10g, 15g, 20g, 3-As per SRO
	Shelf Life (Unit)	24 Year(s)Store between 15 to 25 degree centigrade
	For generic drugs (me-too Status)	Trichonil by Maxitech Pharma Pvt Ltd. (083736)
	Pharmacotherapeutic Group of (API)	other dermatological preparations, ATC code: D11AX16 Eflornithine irreversibly inhibits ornithine decarboxylase, an enzyme involved in the production of the hair shaft by the hair

		follicle. Vaniqa has been shown to reduce the rate of hair growth.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	MICRO ORGO CHEM
	Detail of stability batches of drug product	Data of 3 batches is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Vaniqa 13.9% Cream B. No. 154123 M/s VCIpher Pharma Canada
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Health Canada Approved Vaniqa
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
127	Case Category	Contract Manufacturing (Adil Saeed)
	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	(YYJ-AUE-BQHA, 2024-11-13)
	Detail of Fee Submitted	93000.0, 2024-10-16,
	The proposed proprietary name / brand name	**Efloro 13.9% Cream**
	Label Claim	Each gm of cream contains: Eflornithine hydrochloride (as monohydrate) 139mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5g, 10g, 15g, 20g, 3-As per SRO
	Shelf Life (Unit)	24 Year(s)Store between 15 to 25 degree centigrade
	For generic drugs (me-too Status)	Trichonil by Maxitech Pharma Pvt Ltd. (083736)
	Pharmacotherapeutic Group of (API)	other dermatological preparations, ATC code: D11AX16 Eflornithine irreversibly inhibits ornithine decarboxylase, an enzyme involved in the production of the hair shaft by the hair follicle. Vaniqa has been shown to reduce the rate of hair growth.
	Name, address of Manufacturing site:	Genix Pharma Private Limited-44, 45-B Korangi Creek Road, Karachi-75190, Pakistan -
	Name & address of API manufacturer	MICRO ORGO CHEM
	Detail of stability batches of drug product	Data of 3 batches is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Vaniqa 13.9% Cream B. No. 154123 M/s CIpher Pharma Canada
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted

	The status in reference regulatory authorities	Vaniqa by Cipher Pharmaceutical
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
128	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Hiranis Pharmaceuticals Pvt. Ltd.** E-145-149, North Western Industrial Zone, Port Qasim, Karachi-75020, Pakistan **(000785)**
	Application Form Dy. No / Tracking ID & date of submission	(845-D3A-DH51, 2024-11-14)
	Detail of Fee Submitted	75000.0, 2024-11-06,
	The proposed proprietary name / brand name	**PIMS CREAM 1% w/w**
	Label Claim	Each gram of cream contains: Pimecrolimus.....10mg (1%w/w)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5gm, 15gm, 30gm, 60g-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30OC at a dry place, protect from light and heat.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	D11AH02 Agents for dermatitis, excluding corticosteroids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. BrightGene Bio-Medical Technology Co., Ltd.Building C25-C28, No.218 Xinghu Road, Suzhou Industrial Park, Suzhou, Jiangsu, 215123, China.
	Detail of stability batches of drug product	3 batches, 100 tubes 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	ELIDEL 10 MG/G CREAM MK956S Mylan Products Ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	MHRA Approved; Elidel 10 mg/g cream; Mylan Products Ltd., Station Close, Potters Bar, Herts, EN6 1TL, United Kingdom
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
129	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**NovaMed Pharmaceuticals(Pvt.)Ltd** 28-KM Ferozepur Road Lahore **(000590)**

	Application Form Dy. No / Tracking ID & date of submission	(73L-MLS-RGZH, 2024-11-01)
	Detail of Fee Submitted	37000.0, 2024-10-30,
	The proposed proprietary name / brand name	**Facinib 10mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: Tofacitinib citrate eq to tofacitinib.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's , 20's 28's, 30-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store away from direct sunlight, heat and moisture below 30C
	For generic drugs (me-too Status)	Actinib 10mg by Searle
	Pharmacotherapeutic Group of (API)	L04AF01 Janus-associated kinase (JAK) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Kaifeng Pharmaceutical (Group) Company Limited
	Detail of stability batches of drug product	3 batches, 2000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan from M/s High-Q. Loan letter and clearance certificate is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	ACTINIB 10mg B#HCE001 M/s Searle Pakistan
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Xeljanz tablet 10mg by Pfizer labs NY
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
130	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**NovaMed Pharmaceuticals(Pvt.)Ltd** 28-KM Ferozepur Road Lahore **(000590)**
	Application Form Dy. No / Tracking ID & date of submission	(QH2-D4A-PE4T, 2024-10-01)
	Detail of Fee Submitted	37000.0, 2024-09-09,
	The proposed proprietary name / brand name	**Facinib 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	10's , 20's 28's, 30-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30˚C
	For generic drugs (me-too Status)	Jakjanz by Atco
	Pharmacotherapeutic Group of (API)	L04AF01 Janus-associated kinase (JAK) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Kaifeng Pharmaceutical (Group) Company Limited

	Detail of stability batches of drug product	3 batches, 2000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan from M/s High-Q. Loan letter and clearance certificate is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Xeljanz 5mg B#FA3496 M/s Pfizer
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Xeljanz tablet 5mg by Pfizer labs NY
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
131	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**NovaMed Pharmaceuticals(Pvt.)Ltd** 28-KM Ferozepur Road Lahore **(000590)**
	Application Form Dy. No / Tracking ID & date of submission	(XP6-9VT-TZ3N, 2024-08-19)
	Detail of Fee Submitted	, 75000.0 , 2024-04-24
	The proposed proprietary name / brand name	**Feroxyma 1000mg/20ml concentrate for Infusion**
	Label Claim	Each ml contains: Ferric carboxymaltose equivalent to elemental iron.....50 mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1Vial (20ml)-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)	Iron preparation
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Nanjing Hencer Pharmaceutical Co., Ltd china
	Detail of stability batches of drug product	3 batches. 200 vials 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	Ferinject 1000mg/20ml B#3351022EB
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Injectafer 1000mg/20ml (American Reagent,Inc.Shirley)
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	

132	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Remington Pharmaceutical Industries (Pvt) Ltd** 18 Km Multan Road Lahore, 53800, Pakistan **(000061)**
	Application Form Dy. No / Tracking ID & date of submission	(J9G-921-PMHD, 2024-08-20)
	Detail of Fee Submitted	30000.0, 2024-08-06,
	The proposed proprietary name / brand name	**BBG Ophthalmic Suspension**
	Label Claim	Each mL of suspension contains: Brinzolamide .....10 mg Brimonidine Tartrate .....2mg (eq. to 1.3mg Brimonidine)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5ml-As per SRO
	Shelf Life (Unit)	2 Year(s)Store between 2-25°C.
	For generic drugs (me-too Status)	Simbrinza
	Pharmacotherapeutic Group of (API)	Ophthalmologicals, Antiglaucoma preparations and miotics, ATC code: S01EC54
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	SCI PHARMTECH, INC. Taiwan,SYMED LABS LIMITED India
	Detail of stability batches of drug product	3 batches, 1600 bottles 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	Simbrinza SA Alcon-Couvreur NV Rijksweg B# 2ID15AE
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	SIMBRINZA
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of the Board.	
	Decision	
	Approved	
133	Case Category	Routine (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	(NAS-9TL-BWQR, 2024-08-28)
	Detail of Fee Submitted	30000.0, 2024-05-15,
	The proposed proprietary name / brand name	**VOXETO 20mg TABLET**
	Label Claim	Each film coated tablet contains: Vortioxetine Hydrobromide eq. to Vortioxetine.....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)20-25C

	For generic drugs (me-too Status)	Brintellix Tablet 20 Mg Registration Number 087081
	Pharmacotherapeutic Group of (API)	N06AX26 Other antidepressants
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches, 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan from M/s Weatherfold. Clearance certificate and loan letter is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brintellix 20mg Tablket B. No. 2715580
	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	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
134	Case Category	Routine (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	(QN7-5YU-A2JJ, 2024-08-26)
	Detail of Fee Submitted	30000.0, 2024-07-29,
	The proposed proprietary name / brand name	**PAINIL PLUS 5% CREAM**
	Label Claim	Each gram contain Lidocaine.....25mg Prilocaine.....25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	De regulated-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store between 15-30ºC
	For generic drugs (me-too Status)	EPINUM
	Pharmacotherapeutic Group of (API)	anaesthetics, local; amides ATC code: N01B B20
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Alcon Biosciences Private Limited,Gufic Biosciences Ltd
	Detail of stability batches of drug product	3 batches, each batch of 100 tubes
	Documents for the procurement of API with approval from DRAP (in case of Import)	AD Attested invoices are submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Emla 5% Cream B. No TI 7055 AstraZeneca
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	EMLA CREAM 5% MHRA Approved
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	

	Decision	
	Approved	
135	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Amson Vaccines & Pharma (Pvt.) Ltd.** Plot # 154, Industrial Triangle, Kahuta Road, **(000393)**
	Application Form Dy. No / Tracking ID & date of submission	(7YP-9YM-N9Z7, 2026-03-02)
	Detail of Fee Submitted	38700, 2025-10-02,
	The proposed proprietary name / brand name	**Amagra 100mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Sildenafil citrate equivalent to Sildenafil ..... 100 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 x 10's-De-Controlled,1 x 6's-De-Controlled
	Shelf Life (Unit)	24 Month(s)Below 25°C
	For generic drugs (me-too Status)	Me too product available
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 (PDE5) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. Rakshit Pharmaceuticals Limited, Plot number 68/A, Jawaharlal Nehru, Pharma City, Parawada Mandal, Anakapalli district, Andhra Pradesh, India.
	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	Hilagra 100mg tablet of M/s Hilton pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Approved BY US-FDA
	GMP status of the firm	GMP certificate F. 3-4/2018-Addl. Dir. (QA<-FO)-84 is provided
	Evidence of approval of manufacturing facility	Valid DML No. 000393 is provided
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
136	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore **(000576)**
	Application Form Dy. No / Tracking ID & date of submission	(TAX-A4Y-U66Z, 2024-08-16)
	Detail of Fee Submitted	30000.0, 2024-07-04,
	The proposed proprietary name / brand name	**Neusilodoz 8mg Capsule**
	Label Claim	Each capsule contains Silodosin 8mg
	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 at 25C
	For generic drugs (me-too Status)	Silorap by Getz pharma
	Pharmacotherapeutic Group of (API)	DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY G04CA04 Alpha-adrenoreceptor antagonists
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches, 3000 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested invoice submitted in module 2 under heading of commercial invoice.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Rapaflo 8mg Capsule Batch # 1101082M
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Rapaflo by Watson Laboratories, Inc.
	GMP status of the firm	GMP certificate Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. recommended for consideration of board.	
	Decision	
	Approved	
137	Case Category	Routine (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	(A5R-DVZ-JT52, 2024-09-25)
	Detail of Fee Submitted	30000.0, 7000.0 2024-07-22, 2024-09-09
	The proposed proprietary name / brand name	**REBAFOLD 100MG TABLET**
	Label Claim	Each Film Coated Tablet contains: Rebamipide.....100MG (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)Store below 25°c
	For generic drugs (me-too Status)	MUCOSTA TABLET 100MG. Korea Otsuka Pharmaceutical Reg No. 078129
	Pharmacotherapeutic Group of (API)	Other drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	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)	Form 6 is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Mucosta 100mg Tablet B. No.BT493
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted

	The status in reference regulatory authorities	PMDA Japan
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board	
	Decision	
	Approved	
138	Case Category	Any Other (Adil Saeed)
	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	(9D3-4D2-U6TM, 2026-03-09)
	Detail of Fee Submitted	75000.0, 2025-02-03,
	The proposed proprietary name / brand name	**Wnafil 25mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: Sildenafil as Citrate (USP).....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)	Phosphodiesterase-5 inhibitor (PDE5-I)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals
	Detail of stability batches of drug product	T-01, T-02, T-03
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan from M/s WNSFeild. verified in multiple PSIs.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IV-A Attached
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	Valid till 11th October, 2025
	Evidence of approval of manufacturing facility	Tablet General Section
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
139	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Variant Pharmaceuticals (Pvt.) Ltd** Plot # 5 M2-Pharmazone, 26KM lahore-sharaqpur road, sheikhupura **(000914)**
	Application Form Dy. No / Tracking ID & date of submission	(BRL-UBR-8NNT, 2026-03-02)
	Detail of Fee Submitted	38700, 2025-11-26,
	The proposed proprietary name / brand name	**WIGRA 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	4's -As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 centigrade. Protect from heat, moisture & sunlight
	For generic drugs (me-too Status)	VIAGRA 25mg Tablet (VIATRIS GLOBAL HEALTHCARE)
	Pharmacotherapeutic Group of (API)	phosphodiesterase-5 (PDE5) inhibitors.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rakshit Pharmaceuticals Limited, India
	Detail of stability batches of drug product	3 batches, 860 tablets each. Summary sheets are in Module 2, data is in Module 3
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	VIAGRA 25 mg (VIATRIS Pharmaceutical Company) B# B799506U
	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	Valid GMP Attached
	Evidence of approval of manufacturing facility	Section Approval report attached in Module-1
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
140	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Variant Pharmaceuticals (Pvt.) Ltd** Plot # 5 M2-Pharmazone, 26KM lahore-sharaqpur road, sheikhupura **(000914)**
	Application Form Dy. No / Tracking ID & date of submission	(TN8-PL7-SZ4U, 2026-03-09)
	Detail of Fee Submitted	38700, 2025-12-01,
	The proposed proprietary name / brand name	**WIGRA 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	4's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 centigrade. Protect from heat, moisture & sunlight
	For generic drugs (me-too Status)	VIAGRA 50mg Tablet (VIATRIS GLOBAL HEALTHCARE)
	Pharmacotherapeutic Group of (API)	phosphodiesterase-5 (PDE5) inhibitors.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rakshit Pharmaceuticals Limited, India
	Detail of stability batches of drug product	3 batches, 860 tablets each. Summary sheets in Module 2

	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	VIAGRA 50 mg (VIATRIS Pharmaceutical Company) Batch#B819505U
	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	Valid GMP Attached
	Evidence of approval of manufacturing facility	Section Approval report attached in Module-1
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
141	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**BF Biosciences Limited** 5-KM Sundar Raiwind Road, Raiwind, Lahore **(000655)**
	Application Form Dy. No / Tracking ID & date of submission	(XEM-VGE-ALQ7, 2024-10-24)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-30, 2024-10-15
	The proposed proprietary name / brand name	**Brivex 50mg Injection**
	Label Claim	Each 5mL vial contains Brivaracetam..... 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's -As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	N03AX23 Other antiepileptics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shangyu Jingxin Pharmaceutical Co., Ltd
	Detail of stability batches of drug product	3 batches, 1000 vials 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	BRIVIACT 50mg/5mL INJECTION (UCB Pharma S.A) Lot No. 565536
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	BRIVIACT 50MG/5ML INJECTION MHRA approved.
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
142	Case Category	Contract Manufacturing (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	(GA7-RTV-866A, 2024-10-28)
	Detail of Fee Submitted	75000.0, 18000.0 2024-07-03, 2024-09-16
	The proposed proprietary name / brand name	**VECTAZID**
	Label Claim	Each vial contains: Ceftazidime Pentahydrate equivalent to Ceftazidime.....2g Avibactam Sodium equivalent to Avibactam 0.5g
	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, protect from heat, light and moisture
	For generic drugs (me-too Status)	Zavicefta Injection
	Pharmacotherapeutic Group of (API)	J01DD52 ceftazidime and beta-lactamase inhibitor
	Name, address of Manufacturing site:	Healthtek (Pvt.) Ltd.-Plot No.14, Sector 19 , Korangi Industrial Area, Karachi -
	Name & address of API manufacturer	Zhuhai United Laboratories Co., Ltd
	Detail of stability batches of drug product	3 batches, 170 vials 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	Zavicefta 2g/0.5g powder for concentrate for solution for infusion B. No. 2001E0 GlaxoSmithKline Manufacturing S.p.A Via Alessandro Fleming 2 Verona 37135, Italy
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	AVYCAZ Injection
	GMP status of the firm	GMP certificate issued on basis of inspection dated 22.03.2023`
	Evidence of approval of manufacturing facility	Section approval issued with DML in 2007
	Evaluation Remarks	
	Application fufills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
143	Case Category	Routine (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	(X1W-WY3-VNTU, 2024-10-18)
	Detail of Fee Submitted	37000.0, 2024-09-24,
	The proposed proprietary name / brand name	**OVIX 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	De-Controlled-De-Controlled
	Shelf Life (Unit)	2 Year(s)Do not store over 30°C
	For generic drugs (me-too Status)	Egolix
	Pharmacotherapeutic Group of (API)	H01CC03 Anti-gonadotropin-releasing hormones

	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. Nantong Chanyoo Pharmatech Co. Ltd.
	Detail of stability batches of drug product	3 batches, 2000 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	Onlissa 200mg Tablet AbbVie Inc. North Chicago B. No. 1213573
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	ORILISSA Tablets, FDA approved
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Tablet General section approved.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
144	Case Category	Routine (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	(ZWY-ZXH-V3XU, 2024-10-18)
	Detail of Fee Submitted	37000.0, 2024-09-24,
	The proposed proprietary name / brand name	**OVIX 150mg Tablet**
	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	De-Controlled-De-Controlled
	Shelf Life (Unit)	2 Year(s)Do not store over 30°C
	For generic drugs (me-too Status)	Egolix
	Pharmacotherapeutic Group of (API)	H01CC03 Anti-gonadotropin-releasing hormones
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Nanjing Hencer Pharmacetuical Co Ltd
	Detail of stability batches of drug product	3 batches, 2000 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	Onlissa 150mg Tablet AbbVie Inc. North Chicago B. No. 1209436
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	ORILISSA Tablets, FDA approved
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Tablet General section approved.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	

145	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**OPAL LABORATORIES (PVT) LTD** LC-41, L.I.T.E., Landhi **(000046)**
	Application Form Dy. No / Tracking ID & date of submission	(7E5-HXR-A2AM, 2026-02-06)
	Detail of Fee Submitted	38700, 2026-01-16,
	The proposed proprietary name / brand name	**Silofil 100mg**
	Label Claim	Each film coated tablet contains: Sildenafil Citrate Equivalent to Sildenafil 100mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	4's-De-Controlled
	Shelf Life (Unit)	2 Year(s)store below 30C°
	For generic drugs (me-too Status)	Getfil Tablets 100mg (Getz Pharma)
	Pharmacotherapeutic Group of (API)	Urologicals / (Therapeutic area: Erectile Dysfunction)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rakshit Pharmaceuticals Limited, Plot number 68/A, Jawaharlal Nehru Pharma City, Parawada Mandal, Anakapalli district, Andhra Pradesh
	Detail of stability batches of drug product	3 batches, 5000 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	Getfil Tablet B. no. 001FS5
	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	Inspection report dated 23.07.2025 is submitted.
	Evidence of approval of manufacturing facility	Tablet gen section approved vide letter dated 31.05.2021
	Evaluation Remarks	
	Priority as per decision of 214th meeting. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
146	Case Category	Routine (Adil Saeed)
	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	(AMS-8D6-S44R, 2024-10-22)
	Detail of Fee Submitted	30000.0, 2024-06-27,
	The proposed proprietary name / brand name	**DB6 Delayed Release 20/20mg Tablet**
	Label Claim	Each extended-release film coated tablet contains: Doxylamine Succinate.....20mg Pyridoxine HCl.....20mg
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	10's-De-Controlled,20's-De-Controlled,30's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30 Degree
	For generic drugs (me-too Status)	Xyquil XR Forte Tablet 20/20mg, M/s Sami Pharmaceutical (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	R06AA59 ANTIHISTAMINES FOR SYSTEMIC USE
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Huazhong Pharmaceutical Co., Ltd. Address: No 118 Xianshan Road, Xiangyang, Hubei Province, China,R L Fine Chem Pvt. Ltd. Plot No. IP 27-29, KIADB Industrial Area, I Phase, Kudumalakunte Village, Gowribidanoor Taluk, Chikkaballapura, Karnataka, India.
	Detail of stability batches of drug product	3 batches, 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 of both drug substances is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Bonjesta Extended release 20mg/20mg Tablet B. No. A000043574 Mfg Duchesnay USA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Bonjesta, Duchesnay, USFDA Approved.
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
147	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Glitz Pharma** Plot No. 265, Industrial Triangle, Kahuta Road, Islamabad, Pakistan. **(000571)**
	Application Form Dy. No / Tracking ID & date of submission	(B12-6TZ-96E6, 2024-10-28)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-08, 2024-10-09
	The proposed proprietary name / brand name	**Brentil 10mg tablet**
	Label Claim	Each Film coated tablet contains: Vortioxetine Hydrobromide eq. to Vortioxetine.....10 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10’s 14’s 20’s 28’s -As per SRO
	Shelf Life (Unit)	2 Year(s)Store at a cool dry place.
	For generic drugs (me-too Status)	Vorneu 10 mg Tablet by Hilton pharma
	Pharmacotherapeutic Group of (API)	N06AX26 Other antidepressants
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhongshan Wanhan Pharmaceuticals Co., Ltd.
	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)	AD attested invoice is submitted.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brintellix 10mg Tablet B. No. 2715602
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	USFDA
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills coda formalities. Recommended for consideration of board.	
	Decision	
	Approved	
148	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Glitz Pharma** Plot No. 265, Industrial Triangle, Kahuta Road, Islamabad, Pakistan. **(000571)**
	Application Form Dy. No / Tracking ID & date of submission	(RSS-A1J-3BM2, 2024-10-28)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-08, 2024-10-09
	The proposed proprietary name / brand name	**Brentil 5mg tablet**
	Label Claim	Each film coated tablet contains: Vortioxetine HBr eq. to Vortioxetine.....5mg (Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10’s 14’s 20’s 28’s -As per SRO
	Shelf Life (Unit)	2 Year(s)Store at a cool dry place.
	For generic drugs (me-too Status)	Vorneu 5 mg Tablet by Hilton pharma
	Pharmacotherapeutic Group of (API)	N06AX26 Other antidepressants
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhongshan Wanhan Pharmaceuticals Co., Ltd.
	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)	AD attested invoice is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Vorneu 5mg Tablet 147793 M/s Hilton
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	USFDA
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
149	Case Category	Routine (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	(DXA-8UN-12WN, 2024-08-20)

Detail of Fee Submitted	75000.0, 2024-07-08,
The proposed proprietary name / brand name	**Dirutec 25mg Tablet**
Label Claim	Each tablet contains: Chlorthalidone.....25mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	100's-As per SRO,30'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)	Nil
Pharmacotherapeutic Group of (API)	C03BA04 LOW-CEILING DIURETICS, EXCL. THIAZIDES
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	TRICHEM LIFE SCIENCES LIMITED & ADDRESS: 106B 107 KIADB INDUSTRIAL AREA GADWANTHI HUMNABAD BIDAR 585330 KARNATAKA
Detail of stability batches of drug product	3 batches, 700 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	Thalitone 25mg Tablet B. No. _____ Mfg Aurobindo Pharma USA
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa, upto 60 months.
The status in reference regulatory authorities	USFDA Approved
GMP status of the firm	
Evidence of approval of manufacturing facility	Renewal letter dated 03.03.2023 wherein Tablet (General) section is mentioned.

Evaluation Remarks

In dissolution testing (CDP, batch release and stability) the firm has used UV based method to assess the release of drug. It was observed that Abs values are way too low (like 0.083 for 22% drug release) and maximum below 0.2 or 0.3. The firm was asked to justify how such method can be used for assess drug concentration and was asked to submit UV spectrum of drug substance.
Same issue was identified in following applications and same query was forwarded in all of them.
Citrafer 210mg tablet (Ferric Citrate) X9U-NAD-R9ZU
Citrafer 250mg Tablet Ferric Citrate)WBH-1JD-7BP4
Myoprid 3mg Tablet (Pridinol mesylate, New molecule application) Q6A-WU6-T974
Dirutec 50mg Tablet (Chlorthalidone) JVE-BQW-YYUV
Dirutec 25mg Tablet(Chlorthalidone) DXA-8UN-12WN
The firm has submitted same UV spectrum for all above different drug susbtances and have only edited the name of drug over it. The spectra submitted in all application are being presented before the board. Further it indicates firm has not perfomed dissolution in either pharmaceutical equivalence, batch release or in stability and has just submitted made up data.

Decision

Rejected

The board deliberated on the matter of submission of same UV spectrum in applications of 3 different drugs with editing of only drug name and wavelength. It indicates issue of data integrity at end of applicant and due to this reason data of dissolution, either batch analysis or CDP, assessed by UV method cannot be relied upon. Due to this reason the board rejected the application.

150	Case Category	Routine (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	(JVE-BQW-YYUV, 2024-08-20)
	Detail of Fee Submitted	75000.0, 2024-07-08,
	The proposed proprietary name / brand name	**Dirutec 50mg Tablet**
	Label Claim	Each tablet contains: Chlorthalidone 50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	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)	Nil
	Pharmacotherapeutic Group of (API)	C03BA04 LOW-CEILING DIURETICS, EXCL. THIAZIDES
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	TRICHEM LIFE SCIENCES LIMITED & ADDRESS: 106B 107 KIADB INDUSTRIAL AREA GADWANTHI HUMNABAD BIDAR 585330 KARNATAKA
	Detail of stability batches of drug product	3 batches, 700 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	Hygroton 50mg Tablet Mfg Cenexi SAS
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa, upto 60 months.
	The status in reference regulatory authorities	MHRA Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Renewal letter dated 03.03.2023 wherein Tablet (General) section is mentioned.
	Evaluation Remarks	
	In dissolution testing (CDP, batch release and stability) the firm has used UV based method to assess the release of drug. It was observed that Abs values are way too low (like 0.083 for 22% drug release) and maximum below 0.2 or 0.3. The firm was asked to justify how such method can be used for assess drug concentration and was asked to submit UV spectrum of drug substance.	
	Same issue was identified in following applications and same query was forwarded in all of them.	
	Citrafer 210mg tablet (Ferric Citrate) X9U-NAD-R9ZU	
	Citrafer 250mg Tablet Ferric Citrate)WBH-1JD-7BP4	
	Myoprid 3mg Tablet (Pridinol mesylate, New molecule application) Q6A-WU6-T974	
	Dirutec 50mg Tablet (Chlorthalidone) JVE-BQW-YYUV	
	Dirutec 25mg Tablet(Chlorthalidone) DXA-8UN-12WN	
	The firm has submitted same UV spectrum for all above different drug susbtances and have only edited the name of drug over it. The spectra submitted in all application are being presented before the board. Further it indicates firm has not perfomed dissolution in either pharmaceutical equivalence, batch release or in stability and has just submitted made up data.	
	Decision	

Rejected

The board deliberated on the matter of submission of same UV spectrum in applications of 3 different drugs with editing of only drug name and wavelength. It indicates issue of data integrity at end of applicant and due to this reason data of dissolution, either batch analysis or CDP, assessed by UV method cannot be relied upon. Due to this reason the board rejected the application.

151	Case Category	Routine (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	(Q6A-WU6-T974, 2025-02-10)
	Detail of Fee Submitted	75000.0, 2024-10-25,
	The proposed proprietary name / brand name	**Myoprid 3mg Tablet**
	Label Claim	Each tablet contains: Pridinol mesylate eq. to Pridinol.....3.02mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,100s-As per SRO,20s-As per SRO,50s-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 C in cool and dry place
	For generic drugs (me-too Status)	Nil
	Pharmacotherapeutic Group of (API)	M03BX03 Other centrally acting agents Central and peripheral muscle spasms: lumbar pain, torticollis, general muscle pain, in adults.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	PADMAVATI CHEMICALS PVT. LTD Address:Plot No. 5001, 4th Phase, G.I.D.C.,Vapi – 396 195 Gujarat, 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)	Form 6 of 100 g drug substance is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Myditin 4mg tablet B.No. 230621 Mfg Mibe Italy.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa, upto 60 months.
	The status in reference regulatory authorities	MHRA Approved
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 03.01.2023 is submitted.
	Evidence of approval of manufacturing facility	Renewal letter dated 03.03.2023 is submitted.

Evaluation Remarks

Application is of new molecule but is being presented due to similar UV spectrum submitted by the firm in other routine applications and this application,

In dissolution testing (CDP, batch release and stability) the firm has used UV based method to assess the release of drug. It was observed that Abs values are way too low (like 0.083 for 22% drug release) and maximum below 0.2 or 0.3. The firm was asked to justify how such method can be used for assess drug concentration and was asked to submit UV spectrum of drug substance.
Same issue was identified in following applications and same query was forwarded in all of them.
Citrafer 210mg tablet (Ferric Citrate) X9U-NAD-R9ZU
Citrafer 250mg Tablet Ferric Citrate)WBH-1JD-7BP4

Myoprid 3mg Tablet (Pridinol mesylate, New molecule application) Q6A-WU6-T974	
Dirutec 50mg Tablet (Chlorthalidone) JVE-BQW-YYUV	
Dirutec 25mg Tablet(Chlorthalidone) DXA-8UN-12WN	
The firm has submitted same UV spectrum for all above different drug susbtances and have only edited the name of drug over it. The spectra submitted in all application are being presented before the board. Further it indicates firm has not perfomed dissolution in either pharmaceutical equivalence, batch release or in stability and has just submitted made up data.	
Decision	
Rejected The board deliberated on the matter of submission of same UV spectrum in applications of 3 different drugs with editing of only drug name and wavelength. It indicates issue of data integrity at end of applicant and due to this reason data of dissolution, either batch analysis or CDP, assessed by UV method cannot be relied upon. Due to this reason the board rejected the application.	

152	Case Category	Routine (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	(WBH-1JD-7BP4, 2024-08-23)
	Detail of Fee Submitted	75000.0, 2024-06-10,
	The proposed proprietary name / brand name	**Citrafer 250mg Tablet**
	Label Claim	Each film coated tablet contains: Ferric Citrate.....250mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100's-As per SRO,1000's-As per SRO,500'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)	None
	Pharmacotherapeutic Group of (API)	V03AE08 Drugs for treatment of hyperkalemia and hyperphosphatemia
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	West Bengal Chemical Industries Ltd. & Address: 145/1,Jessore Road, Kolkata-700089 West Bengal, India.
	Detail of stability batches of drug product	3 batches, 700 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested invoice, attested on 12.12.2017 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Riona 250mg Tablet B. No. 366Da M/s Japan Tobacco Inc
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone Iva, upto 48 months.
	The status in reference regulatory authorities	Pharmaceuticals and Medical Devices Agency - PMDA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Copy of renewal letter dated 03.03.2023 is submitted.

Evaluation Remarks

In dissolution testing (CDP, batch release and stability) the firm has used UV based method to assess the release of drug. It was observed that Abs values are way too low (like 0.083 for 22% drug release) and maximum below 0.2 or 0.3. The firm was asked to justify how such method can be used for assess drug concentration and was asked to submit UV spectrum of drug substance.
Same issue was identified in following applications and same query was forwarded in all of them.
Citrafer 210mg tablet (Ferric Citrate) X9U-NAD-R9ZU
Citrafer 250mg Tablet Ferric Citrate)WBH-1JD-7BP4
Myoprid 3mg Tablet (Pridinol mesylate, New molecule application) Q6A-WU6-T974
Dirutec 50mg Tablet (Chlorthalidone) JVE-BQW-YYUV
Dirutec 25mg Tablet(Chlorthalidone) DXA-8UN-12WN
The firm has submitted same UV spectrum for all above different drug susbtances and have only edited the name of drug over it. The spectra submitted in all application are being presented before the board. Further it indicates firm has not perfomed dissolution in either pharmaceutical equivalence, batch release or in stability and has just submitted made up data.

Decision

Rejected

The board deliberated on the matter of submission of same UV spectrum in applications of 3 different drugs with editing of only drug name and wavelength. It indicates issue of data integrity at end of applicant and due to this reason data of dissolution, either batch analysis or CDP, assessed by UV method cannot be relied upon. Due to this reason the board rejected the application.

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	Case Category	Routine (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	(X9U-NAD-R9ZU, 2024-07-19)
	Detail of Fee Submitted	75000.0, 2024-06-10,
	The proposed proprietary name / brand name	**Citrafer 210mg tablet**
	Label Claim	Each Film Coated tablet contains: Ferric citrate (1grams) eq. to Iron.....210mg
	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
	Shelf Life (Unit)	2 Year(s)Store in a cool and dry place. Below 30°C
	For generic drugs (me-too Status)	Nil
	Pharmacotherapeutic Group of (API)	V03AE08 Drugs for treatment of hyperkalemia and hyperphosphatemia
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	West Bengal Chemical Industries Ltd. Address: 145/1,Jessore Road, Kolkata-700089 West Bengal, India.
	Detail of stability batches of drug product	3 batches, 700 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested invoice, attested on 12.12.2017 is submitted.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Auryxia 210mg tablet B. No. AH8569 Mfg Keryx Biopharmaceuticals, India
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone Iva, upto 48 months.
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Copy of renewal letter dated 03.03.2023 is submitted.
	Evaluation Remarks	
	In dissolution testing (CDP, batch release and stability) the firm has used UV based method to assess the release of drug. It was observed that Abs values are way too low (like 0.083 for 22% drug release) and maximum below 0.2 or 0.3. The firm was asked to justify how such method can be used for assess drug concentration and was asked to submit UV spectrum of drug substance.	
	Same issue was identified in following applications and same query was forwarded in all of them.	
	Citrafer 210mg tablet (Ferric Citrate) X9U-NAD-R9ZU	
	Citrafer 250mg Tablet Ferric Citrate)WBH-1JD-7BP4	
	Myoprid 3mg Tablet (Pridinol mesylate, New molecule application) Q6A-WU6-T974	
	Dirutec 50mg Tablet (Chlorthalidone) JVE-BQW-YYUV	
	Dirutec 25mg Tablet(Chlorthalidone) DXA-8UN-12WN	
	The firm has submitted same UV spectrum for all above different drug susbtances and have only edited the name of drug over it. The spectra submitted in all application are being presented before the board. Further it indicates firm has not perfomed dissolution in either pharmaceutical equivalence, batch release or in stability and has just submitted made up data.	
	Decision	
	Rejected The board deliberated on the matter of submission of same UV spectrum in applications of 3 different drugs with editing of only drug name and wavelength. It indicates issue of data integrity at end of applicant and due to this reason data of dissolution, either batch analysis or CDP, assessed by UV method cannot be relied upon. Due to this reason the board rejected the application.	
154	Case Category	Routine (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	(HEN-TX8-5MAM, 2024-10-31)
	Detail of Fee Submitted	37000.0, 2024-10-25,
	The proposed proprietary name / brand name	**Citinix Tablet 10mg**
	Label Claim	Each film coated tablet contains: Tofacitinib citrate eq. to Tofacitinib..... 10mg
	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)Below 30 °C
	For generic drugs (me-too Status)	Tofajak Tablet 10mg, Manufactured by: Hiranis Pharmaceuticals (Pvt) Ltd.
	Pharmacotherapeutic Group of (API)	L04AF01 Janus-associated kinase (JAK) inhibitors

	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Source of Drug Substance: Hunan Warrant Chiral Pharmaceutical Co., Ltd. Address: No. 139, Tongguan Avenue, Tongguan Circular Economy Industrial Park, Wangcheng District, Changsha, Hunan, China
	Detail of stability batches of drug product	3 batches, 1500 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	Tofajak 10mg tablet M/s Hiranis Pharma B. No. 001. picture is also submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Xeljanz Tablet, Registered in Food and Drug Administration (FDA)
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
155	Case Category	Routine (Adil Saeed)
	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	(SG2-QGW-DM9M, 2024-07-22)
	Detail of Fee Submitted	30000.0, 2024-05-29,
	The proposed proprietary name / brand name	**Proxet 20mg Film Coated Tablets**
	Label Claim	Each film coated tablet contains: Paroxetine HCl equivalent to Paroxetine.....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 30ºC
	For generic drugs (me-too Status)	Paraxyl 20mg Tablets, Manufacturer: CCL Pharmaceuticals
	Pharmacotherapeutic Group of (API)	N06AB05 Selective serotonin reuptake inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches, 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan from Seraph. Clearance certificate and loan letter is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Paraxyl 20mg Tablets CCL Pharmaceuticals GU376
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Paroxetine 20mg Tablets, Manufacturer: Apotex Pharmaceutical corporation (Registered in USA)

	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fufills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
156	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)**
	Application Form Dy. No / Tracking ID & date of submission	(XR7-EES-M5DD, 2024-08-20)
	Detail of Fee Submitted	75000.0, 2024-08-12,
	The proposed proprietary name / brand name	**Zonlac 15mg/ml injection**
	Label Claim	Each 1mL vial contains: Ketorolac Tromethamine.....15 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	24 Year(s)Store at controlled room temperature 20 °C to 25 °C (68 °F to 77 °F).
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Acetic acid derivatives and related substances
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Saurav Chemical Limited Corporate office: Plot no. 370, Industrial area, Phase-II Panchukla-134109 (Haryana) India.
	Detail of stability batches of drug product	2 batches of 2000 vials each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan from M/s Horizon, Loan letter and clearance certificate is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	15mg/ml injection of M/s Fuson pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	(ANDA): 214456 Company: ALEMBIC USFDA Approved
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
157	Case Category	Routine (Adil Saeed)
	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	(Q93-U64-P7LT, 2024-10-16)
	Detail of Fee Submitted	37000.0, 2024-10-09,
	The proposed proprietary name / brand name	**Eflort 11.5% cream**

	Label Claim	Each gm of cream contains: eflornithine hydrochloride monohydrate eq. eflornithine.....115 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5g, 10g, 15g, 20g, 3-As per SRO
	Shelf Life (Unit)	24 Year(s)Store between 15 to 25 degree centigrade
	For generic drugs (me-too Status)	Trichonil by Maxitech Pharma Pvt Ltd. (095186)
	Pharmacotherapeutic Group of (API)	other dermatological preparations, ATC code: D11AX16 Eflornithine irreversibly inhibits ornithine decarboxylase, an enzyme involved in the production of the hair shaft by the hair follicle. Vaniqa has been shown to reduce the rate of hair growth.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	MICRO ORGO CHEM
	Detail of stability batches of drug product	Data of 3 batches is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Vaniqa 11.5% Cream, B. No. 151263 M/s ALmirall
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted.
	The status in reference regulatory authorities	Vaniqa by Almirall Hermal GmbH Scholtzstrasse 3
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	In application vide tracking ID DLZ-JLY-JMYT, following query was forwarded; The one available in Canada mentions 13.9% strength of Elfornithine HCl wheres MHRA approved product mentions strenght of Elfornithine as 11.5%. Content of Elfornithine on both products is 11.5% and if we consider HCl salt if drug substance then its 13.9% in both products. Its only different way of writing the label claim of applied product. Please select one style, either 11.5% is required or 13.9% is required in label. Other one should be withdrawn. Firm has responded to proceed Eflornithine HCl Cream 13.9% and withdraw this application	
	Decision	
	Rejected Application stands withdrawn	
158	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Seraph Pharmaceutical** Plot No 210, Industrial Triangle Kahuta Road, Islamabad. **(000860)**
	Application Form Dy. No / Tracking ID & date of submission	(2UL-5BY-6R5J, 2024-09-23)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-15, 2024-09-13
	The proposed proprietary name / brand name	**Bilast 10mg Orodispersible tablet**
	Label Claim	Each orodispersible tablet contains: Bilastine 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 30°C
	For generic drugs (me-too Status)	Brand Name: Biltex Orodispersible 10mg Tablet Registration holder: Registered: Wezen Pharmaceuticals Plot # 23 & 24, S-1, RCCI, Industrial Estate, Rawat Approved in 335th drap Meeting
	Pharmacotherapeutic Group of (API)	R06AX29 Other antihistamines for systemic use
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	METROCHEM API LIMITED 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 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Ilaxten Orodispersible 10mg Tablet B. No. 522245 MENARINI INTERNATIONAL UK
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	MHRA Approved drug
	GMP status of the firm	GMP certificate is submitted.
	Evidence of approval of manufacturing facility	Section approval letter is submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
159	Case Category	Contract Manufacturing (Adil Saeed)
	Name, address of Applicant.	**Medwell Pharmaceuticals** 1 km, terbella road, lawrencepur, faqirabad Attock **(000699)**
	Application Form Dy. No / Tracking ID & date of submission	(VY5-7AY-8H5E, 2024-10-24)
	Detail of Fee Submitted	75000.0, 18000.0 2024-05-24, 2024-10-09
	The proposed proprietary name / brand name	**Weldrop Injection**
	Label Claim	Each 1ml ampoule contains: Cholecalciferol.....5mg (Vitamin-D3)
	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 Degree Centigrade
	For generic drugs (me-too Status)	Product Name: Indrop D Injection Strength: 5mg/ml Composition: Each 1ml ampoule contains: Cholecalciferol…..5mg (Vitamin-D3) (Innovator's Specifications) Manufactured By: Neutro Pharma Pvt. Ltd. Reg
	Pharmacotherapeutic Group of (API)	Vitamin D
	Name, address of Manufacturing site:	Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE, Super Highway, Phase II, Karachi-
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Data of 3 batches is submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Indrop D injection B. No. HP 1181
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Cholecalciferol Injection (ANSM France Approved)
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Subnitted
	Evaluation Remarks	
	Application fufills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
160	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Hiranis Pharmaceuticals Pvt. Ltd.** E-145-149, North Western Industrial Zone, Port Qasim, Karachi-75020, Pakistan **(000785)**
	Application Form Dy. No / Tracking ID & date of submission	(EH5-SYS-MHS1, 2024-10-23)
	Detail of Fee Submitted	75000.0, 2024-10-14,
	The proposed proprietary name / brand name	**BRILEP 75MG TABLET**
	Label Claim	Each film coated tablet contains: Brivaracetam.....75mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 14's, 30's/As -As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30OC at a dry place, protect from light and heat.
	For generic drugs (me-too Status)	Cubriva 75mg Tablet; Reg. No. 115903; Genix Pharma
	Pharmacotherapeutic Group of (API)	N03AX23 Other antiepileptics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s JPR Labs Private 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)	AD attested invoice is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	BRIVAMARK 75 MG TABLETS AD5614
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Briviact 75 mg film-coated tablets; UCB Pharma Limited 208 Bath Road Slough Berkshire SL1 3WE United Kingdom; EMA Approved
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
161	Case Category	Contract Manufacturing (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	(1JH-PB4-WZX6, 2025-01-23)
	Detail of Fee Submitted	93000.0, 9400 2024-11-28, 2026-04-14
	The proposed proprietary name / brand name	**DICOZE 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	1x5's, 1 x 10's, 2 x-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 °C
	For generic drugs (me-too Status)	N/A
	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	Sildenafil Tablet, USP 50mg (Advagen Pharma limited, 666 Plainsboro Road Suite 605, Plain boro, NJ, 08536, USA)
	Detail of previous approval	Sildafil 50mg Tablet Reg. No 132211 Approved in 350th meeting,
	Evaluation Remarks	
	cross referred product. Codal formalities are fulfilled	
	Decision	
	Approved	
162	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Hiranis Pharmaceuticals Pvt. Ltd.** E-145-149, North Western Industrial Zone, Port Qasim, Karachi-75020, Pakistan **(000785)**
	Application Form Dy. No / Tracking ID & date of submission	(6X5-WM8-SN8S, 2024-10-23)
	Detail of Fee Submitted	75000.0, 2024-10-14,
	The proposed proprietary name / brand name	**BRILEP 100MG TABLET**
	Label Claim	Each film coated tablet contains: Brivaracetam.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 14's, 30's/As -As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30OC at a dry place, protect from light and heat.
	For generic drugs (me-too Status)	Cubriva 100mg Tablet; Reg. No. 115904; Genix Pharma
	Pharmacotherapeutic Group of (API)	N03AX23 Other antiepileptics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s JPR Labs Private 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)	AD attested invoice is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brivamark 100mg tablet B. No. MZ347

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Briviact 100 mg film-coated tablets; UCB Pharma Limited 208 Bath Road Slough Berkshire SL1 3WE United Kingdom; EMA Approved
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fufills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
163	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Cunningham Pharmaceuticals (Pvt.) Ltd.** Plot No. 81 - Sunder Industrial Estate, Raiwind Road, Lahore- Pakistan **(000840)**
	Application Form Dy. No / Tracking ID & date of submission	(R5L-NVN-W9TS, 2024-09-03)
	Detail of Fee Submitted	30000.0, 45000.0 2024-08-15, 2024-09-02
	The proposed proprietary name / brand name	**Ferol Capsule 30 mg.**
	Label Claim	Each Hard Gelatin capsule contains: Ferric Maltol eq. to Elemental Iron 30 mg.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Short term conditions (Accelerated) 40°C±2°C,75% ±5%RH , Long term conditions (Real time) 30°C ± 2°C,65% ±5 %RH
	For generic drugs (me-too Status)	Not applicable since it's a new product.
	Pharmacotherapeutic Group of (API)	Iron preparation
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Global Calcium Pvt. Ltd.
	Detail of stability batches of drug product	3 batches, 2000 capsules 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	Accrufer® Capsule Shield Therapeutics (UK) Ltd B. No. 1NYCKYD48N
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	ACCRUFER® capsule is Approved in USFDA
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommend for consideration of board.	
	Decision	
	Approved	
164	Case Category	Contract Manufacturing (Adil Saeed)
	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	(QAN-7HD-ZMS5, 2024-10-16)
	Detail of Fee Submitted	75000.0, 18000.0 2023-11-28, 2024-10-17
	The proposed proprietary name / brand name	**Qferol 5mg/1ml IM Injection**
	Label Claim	Each 1ml ampoule contains: Cholecalciferol.....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)Store below 25 Degree Centigrade
	For generic drugs (me-too Status)	Product Name: Indrop D Injection Strength: 5mg/ml Composition: Each 1ml ampoule contains: Cholecalciferol…..5mg (Vitamin-D3) (Innovator's Specifications) Manufactured By: Neutro Pharma Pvt. Ltd. Reg
	Pharmacotherapeutic Group of (API)	Vitamin D3
	Name, address of Manufacturing site:	Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE, Super Highway, Phase II, Karachi-
	Name & address of API manufacturer	Sichuan Province Yuxin Pharmaceutical Co Ltd
	Detail of stability batches of drug product	3 batches, 80 units each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate of 10kg drug substance is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Indrop D Injection B. No. 023170 M/s Neutro pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Cholecalciferol Injection (ANSM France Approved)
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 10.06.2024 is submitted
	Evidence of approval of manufacturing facility	Renewal letter dated 08.06.2021 is submitted.
	Evaluation Remarks	
	Application fufils codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
165	Case Category	Contract Manufacturing (Adil Saeed)
	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	(HHY-J4D-H9XD, 2024-10-16)
	Detail of Fee Submitted	75000.0, 2023-11-28,
	The proposed proprietary name / brand name	**Qetotrom Injection**
	Label Claim	Each ml ampoule 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 Year(s)Store below 25 Degree Centigrade
	For generic drugs (me-too Status)	Product Name: Toradol Injection Strength: 30mg/ml Composition: Each ml ampoule

		contains: Ketorolac Tromethamine…..30mg (USP Specifications) Manufactured By: Martin Dow Pvt. Ltd. Reg. No.: 108584
	Pharmacotherapeutic Group of (API)	NSAID
	Name, address of Manufacturing site:	Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE, Super Highway, Phase II, Karachi-
	Name & address of API manufacturer	
	Detail of stability batches of drug product	data of 3 batches is submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested invoice submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Toradol 30mg/ml B. No. 108584 M/s Martin Dow Marker
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Ketorolac Injection Manufactured by Pfizer (FDA Approved)
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. recommended for consideration of board.	
	Decision	
	Approved	
166	Case Category	Contract Manufacturing (Adil Saeed)
	Name, address of Applicant.	**Radiant Pharma (Pvt.) Ltd.,** 43-E Sundar Industrial Estate, Sundar Raiwind Road, Lahore **(000776)**
	Application Form Dy. No / Tracking ID & date of submission	(74P-U4T-NWBR, 2024-08-31)
	Detail of Fee Submitted	75000.0, 2024-08-27,
	The proposed proprietary name / brand name	**Vitamin D3 glass ampoule 200000IU**
	Label Claim	Each 1mL ampoule contains cholecalciferol (Vitamin D3) ..... 5mg (200,000 IU)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	4 Year(s)store at 25C
	For generic drugs (me-too Status)	D-Tres injection by SAMI pharmaceutical pvt ltd
	Pharmacotherapeutic Group of (API)	Vitamin D
	Name, address of Manufacturing site:	Neutro Pharma Pvt Ltd-9.5-km Sheikhupura Road Lahore-Pakistan-
	Name & address of API manufacturer	ZHEJIANG NHU COMPANY LTD Xinchang Dadao West Road, Qixing Street, Xinchang Country, Zhejiang Province, China
	Detail of stability batches of drug product	3 batches, 7300 ampoules approx 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	D-Tres Injection of M/s Sami pharma Batch# 006K

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Vitamin D3 Good 200,000 IU / 1 ml IM solution for injection by Bouchara-Recordati (ANSM, France)
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
167	Case Category	Import (Adil Saeed)
	Name, address of Applicant.	**Otsuka Pakistan Limited** F/4-9 Hub industrial Estate, Distt, Lasbella, Balocistan Pakistan **(HB/291/19-R/LASBELA)**
	Application Form Dy. No / Tracking ID & date of submission	(4DY-AQQ-N151, 2026-02-16)
	Detail of Fee Submitted	313500, 2025-11-07,
	The proposed proprietary name / brand name	**UBIT 100mg Tablet**
	Label Claim	Each film coated tablet contains: Urea 13C.....100mg
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	10-As per SRO
	Shelf Life (Unit)	24 Month(s)Store at in a cool and dry place. Highly sensitive towards moisture.
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	Diagnostic Agent
	Name, address of Manufacturing site:	Otsuka Pharmaceutical Co., Ltd-Otsuka Pharmaceutical Co.,Ltd.2-9 Kanda Tsukasacho, Chiyoda-ku, Tokyo-Japan
	Pharmaceutical Equivalence and Comparative Dissolution Profile	---
	Name, address of Marketing Authorization Holder:	Otsuka Pharmaceutical Co., Ltd, Otsuka Pharmaceutical Co.,Ltd.2-9 Kanda Tsukasacho, Chiyoda-ku, Tokyo, Japan
	Details of Certificates (CoPP/FSC/cGMP):	GMP certificate is submitted
	Details of Authorization Letter :	COPP and letter of authorization are submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone II, upto 36 months.
	The status in reference regulatory authorities	PMDA Japan
	Evaluation Remarks	
	Its an innovator product. Clinical studies are submitted in module 5	
	Observation: 3.2.P.8 Long term stability studies of finished drug product are conducted as per Zone II conditions. Data of stability studies performed as per conditions of zone IVa are required.	
	Response: The stability studies for UBIT Tablet 100 mg have been submitted under long-term conditions of 25°C/60% RH for 36 months and accelerated conditions of 40°C/75% RH for 6 months. In addition, extensive stress stability studies have also been performed, including exposure to elevated temperature and high humidity conditions. Considering the above, the existing stability	

	data sufficiently establishes the stability profile of the product under the proposed storage conditions.	
	Stress studies are conducted at 60C, product is stable upto 6 months.	
	Product is very sensitive towards moisture. In labeling it needs to be highlighted with instructions to store away from moisture in dry place.	
	Decision	
	Approved Subjection to policy for inspection abroad and submission of an undertaking that drug product manufacturer will perform stability studies of drug product as per Zone IVa conditions and will submit them timely to the secretary registration board.	
168	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	(2J8-LWP-PWJ7, 2026-02-10)
	Detail of Fee Submitted	75000, 2025-08-07,
	The proposed proprietary name / brand name	**Lovaz 1g Soft Gelatin Capsule**
	Label Claim	Each Capsule Contains: omega-3-acid ethyl ester liquid concentrate 1 gram eq. to 900mg omega-3-acid ethyl esters. Eicosatetraenoic acid (EPA) ethyl ester: 465 mg and Docosahexaenoic acid (DHA) ethyl ester: 375 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	120's-As per SRO,30'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)	NIL
	Pharmacotherapeutic Group of (API)	C10AX06 Antilipemic or lipid-regulating agents
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	KinOmega Biopharm Inc. & No. 161, South Yinghuashan Road Shifang, Deyang City Sichuan, China 618400
	Detail of stability batches of drug product	3 batches, 900 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	Lovaza 1g softgel capsule B. No. B-LB1084 Mfg Waylis Therapeutics USA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa, upto 36 months.
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection report dated 03.01.2023 is submitted.
	Evidence of approval of manufacturing facility	Softgel section approved vide letter dated 18.05.2021. Renewal letter dated 03.03.2023 also mentions it.
	Evaluation Remarks	

	The firm is not submitting CDP and is saying that they are unable to do it because the oily product inside the capsule will float on dissolution media. The firm has submitted USP dissolution chapter as reference.	
	Their claim is not justifiable as per USP guidance chapter. The USP dissolution chapter states "Surfactants, dispersing agents, or solubility enhancers may be used in the dissolution medium when the capsule «ll and/or the active ingredient are hydrophobic or water-insoluble. They may also be used if the media described in ⟨1092⟩ and in the FDA guidances are ineffective in dispersing the capsule «ll or in achieving proper sink conditions for the active ingredient."	
	Further another application of similar product (import) vide tracking ID VM5-5UX-DGSB was evaluated and approved in a previous meeting and in that application CDP was attached. They had performed CDP by using surfactant in dissolution media of each pH.	
	Decision	
	Deferred Deferred for submission of comparative dissolution profile (CDP).	
169	Case Category	Routine (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	(18D-TED-RP2M, 2024-09-09)
	Detail of Fee Submitted	75000.0, 2024-08-07,
	The proposed proprietary name / brand name	**Calcidiol 3mg Oral Solution**
	Label Claim	Each 1.5ml of solution contains Calcifediol Monohydrate..... 3mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1.5mL (1 bottle per -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)	Nil
	Pharmacotherapeutic Group of (API)	A11CC06 Vitamin D and analogues
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CARBOGEN AMCIS B.V & Address: Nieuweweg 2A, Veenendaal, 3901BE, Netherlands
	Detail of stability batches of drug product	3 batches, 100 bottles 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	Hideroferol Choque 3mg Oral solution B. No. 23001
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa, upto 60 months.
	The status in reference regulatory authorities	Spanish Agency for Medicines and Health Products (AEMPS)
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 03.01.2023 is submitted.
	Evidence of approval of manufacturing facility	Liquid section approved vide letter dated 03.03.2023
	Evaluation Remarks	
	Firm is using 15% overage. Firm was asked to justify it.	

Firm has stated that its a vitamin D preparation so during manufacturing processes it losses 15% of its potency, thats why they have used 15% overage.
Firm was further asked to give reference of international guidance allowing it.
Firm has quoted ICH Q8 (R2) guidelines section "2.2.2 Overages," The quoted section states as under;
2.2.2 OveragesIn general, use of an overage of a drug substance to compensate for degradation during manufacture or a product's shelf life, or to extend shelf life, is discouraged. Any overages in the manufacture of the drug product, whether they appear in the final formulated product or not, should be justified considering the safety and efficacy of the product. Information should be provided on the 1) amount of overage, 2) reason for the overage (e.g., to compensate for expected and documented manufacturing losses), and 3) justification for the amount of overage. The overage should be included in the amount of drug substance listed in the batch formula (3.2.P.3.2).
Even if international guidelines permit overage in especial circumstances, international guidelines also instruct to perform impurity profiling of finished drug product, which local manufacturers don't perform. Due to this reason if 15% drug substance has degraded during formulation then it must have degraded into some degradation products, which are neither identified nor quantified.
Observation 2: in section 3.2.S.7 stability data was submitted in generic tables, it was neither on letter head of drug substance manufacturer nor was signed or stamped. Firm was asked to submit Signed and stamped stability data sheets from drug substance manufacturer.
In response firm submitted changes submitted by the drug substance manufacturer to EDQM. As per this document DS manufacturer had performed stability of DS as per Zone II conditions and in 2011 & 2018, and in initial submission data was as per Zone IVa and was of 2016.
Firm was asked about these differences.
Firm stated that DS manufacturer has performed stability on both conditions.
Firm has not submitted stability summary sheets of DS signed and stamped by the DS manufacturer

Decision

Deferred

Deferred for following;

- **Submission of detailed analysis and quantification of degradation products in the finished drug product.**
- **Submission of signed stability datasheets of drug substance from drug substance manufacturer.**
- **Submission of clarification from drug substance manufacturer regarding performance of stability studies according to different climatic conditions.**

170	Case Category	Routine (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	(HEH-38E-TX97, 2024-09-23)
	Detail of Fee Submitted	75000.0, 2024-08-07,
	The proposed proprietary name / brand name	**calcidiol 0.1mg/mL Oral drops in Solution**
	Label Claim	Each ml of solution contains Calcifediol monohydrate..... 0.1mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10mL-As per SRO,20mL-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)	Nil

Pharmacotherapeutic Group of (API)	A11CC06 Vitamin D and analogues
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Nieuweweg 2A , Veenendaal ,3901 BE , Netherlands
Detail of stability batches of drug product	3 batches, 100 bottles 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	Hideroferol Choque 0.1mg Oral solution
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa, upto 60 months.
The status in reference regulatory authorities	Spanish Agency for Medicines and Health Products (AEMPS)
GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 03.01.2023 is submitted.
Evidence of approval of manufacturing facility	Liquid section approved vide letter dated 03.03.2023

Evaluation Remarks

Firm is using 15% overage. Firm was asked to justify it.
Firm has stated that its a vitamin D preparation so during manufacturing processes it losses 15% of its potency, thats why they have used 15% overage.
Firm was further asked to give reference of international guidance allowing it.
Firm has quoted ICH Q8 (R2) guidelines section “2.2.2 Overages,” The quoted section states as under;
2.2.2 OveragesIn general, use of an overage of a drug substance to compensate for degradation during manufacture or a product’s shelf life, or to extend shelf life, is discouraged. Any overages in the manufacture of the drug product, whether they appear in the final formulated product or not, should be justified considering the safety and efficacy of the product. Information should be provided on the 1) amount of overage, 2) reason for the overage (e.g., to compensate for expected and documented manufacturing losses), and 3) justification for the amount of overage. The overage should be included in the amount of drug substance listed in the batch formula (3.2.P.3.2).
Even if international guidelines permit overage in especial circumstances, international guidelines also instruct to perform impurity profiling of finished drug product, which local manufacturers don't perform. Due to this reason if 15% drug substance has degraded during formulation then it must have degraded into some degradation products, which are neither identified nor quantified.
Observation 2: in section 3.2.S.7 stability data was submitted in generic tables, it was neither on letter head of drug substance manufacturer nor was signed or stamped. Firm was asked to submit Signed and stamped stability data sheets from drug substance manufacturer.
In response firm submitted changes submitted by the drug substance manufacturer to EDQM. As per this document DS manufacturer had performed stability of DS as per Zone II conditions and in 2011 & 2018, and in initial submission data was as per Zone IVa and was of 2016.
Firm was asked about these differences.
Firm stated that DS manufacturer has performed stability on both conditions.
Firm has not submitted stability summary sheets of DS signed and stamped by the DS manufacturer

Decision

Deferred

Deferred for following;

Submission of detailed analysis and quantification of degradation products in the finished drug product.

	Submission of signed stability datasheets of drug substance from drug substance manufacturer. Submission of clarification from drug substance manufacturer regarding performance of stability studies according to different climatic conditions.	
171	Case Category	Routine (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	(JQE-Y8Z-G52W, 2024-08-28)
	Detail of Fee Submitted	75000.0, 2024-08-07,
	The proposed proprietary name / brand name	**Calcidiol 0.266mg oral solution**
	Label Claim	Each 1.5ml of solution contains: Calcifediol monohydrate..... 0.266mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1.5mL (10 bottles pe-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)	Nil
	Pharmacotherapeutic Group of (API)	A11CC06 Vitamin D and analogues
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CARBOGEN AMCIS B.V & Address: Nieuweweg 2A, Veenendaal, 3901BE, Netherlands
	Detail of stability batches of drug product	3 batches, 100 bottles 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	Hideroferol 0.266mg Oral solution B. No. 23023
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa, upto 60 months.
	The status in reference regulatory authorities	Spanish Agency for Medicines and Health Products (AEMPS)
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 03.01.2023 is submitted.
	Evidence of approval of manufacturing facility	Liquid section approved vide letter dated 03.03.2023
	Evaluation Remarks	

Firm is using 15% overage. Firm was asked to justify it.
Firm has stated that its a vitamin D preparation so during manufacturing processes it losses 15% of its potency, thats why they have used 15% overage.
Firm was further asked to give reference of international guidance allowing it.
Firm has quoted ICH Q8 (R2) guidelines section “2.2.2 Overages,” The quoted section states as under;
2.2.2 OveragesIn general, use of an overage of a drug substance to compensate for degradation during manufacture or a product’s shelf life, or to extend shelf life, is discouraged. Any overages in the manufacture of the drug product, whether they appear in the final formulated product or not, should be justified considering the safety and efficacy of the product. Information should be provided on the 1) amount of overage, 2) reason for the overage (e.g., to compensate for expected and documented manufacturing losses), and 3) justification for the amount of overage. The overage should be included in the amount of drug substance listed in the batch formula (3.2.P.3.2).

Even if international guidelines permit overage in especial circumstances, international guidelines also instruct to perform impurity profiling of finished drug product, which local manufacturers don't perform. Due to this reason if 15% drug substance has degraded during formulation then it must have degraded into some degradation products, which are neither identified nor quantified.	
Observation 2: in section 3.2.S.7 stability data was submitted in generic tables, it was neither on letter head of drug substance manufacturer nor was signed or stamped. Firm was asked to submit Signed and stamped stability data sheets from drug substance manufacturer.	
In response firm submitted changes submitted by the drug substance manufacturer to EDQM. As per this document DS manufacturer had performed stability of DS as per Zone II conditions and in 2011 & 2018, and in initial submission data was as per Zone IVa and was of 2016.	
Firm was asked about these differences.	
Firm stated that DS manufacturer has performed stability on both conditions.	
Firm has not submitted stability summary sheets of DS signed and stamped by the DS manufacturer	
Decision	
Deferred **Deferred for following;** • **Submission of detailed analysis and quantification of degradation products in the finished drug product.** • **Submission of signed stability datasheets of drug substance from drug substance manufacturer.** • **Submission of clarification from drug substance manufacturer regarding performance of stability studies according to different climatic conditions.**	

172	Case Category	Routine (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	(STB-PEW-TEZL, 2024-09-11)
	Detail of Fee Submitted	75000.0, 2024-07-12,
	The proposed proprietary name / brand name	**Calcidiol 15mg/100mL oral solution in drops**
	Label Claim	Each 100ml of solution contains: Calcifediol (as monohydrate)..... 15mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10mL-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)	Nil
	Pharmacotherapeutic Group of (API)	A11CC06 Vitamin D and analogues
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CARBOGEN AMCIS B.V & Address: Nieuweweg 2A, Veenendaal, 3901BE, Netherlands
	Detail of stability batches of drug product	3 batches, 100 bottles 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	Dedrogyl 0.15mg/ml oral solution for drops.

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa, upto 60 months.
	The status in reference regulatory authorities	National Agency for the, Safety of Medicine and Health Products (ANSM)
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 03.01.2023 is submitted.
	Evidence of approval of manufacturing facility	Liquid section approved vide letter dated 03.03.2023
	Evaluation Remarks	
	Firm is using 15% overage. Firm was asked to justify it.	
	Firm has stated that its a vitamin D preparation so during manufacturing processes it losses 15% of its potency, thats why they have used 15% overage.	
	Firm was further asked to give reference of international guidance allowing it.	
	Firm has quoted ICH Q8 (R2) guidelines section “2.2.2 Overages,” The quoted section states as under;	
	2.2.2 OveragesIn general, use of an overage of a drug substance to compensate for degradation during manufacture or a product’s shelf life, or to extend shelf life, is discouraged. Any overages in the manufacture of the drug product, whether they appear in the final formulated product or not, should be justified considering the safety and efficacy of the product. Information should be provided on the 1) amount of overage, 2) reason for the overage (e.g., to compensate for expected and documented manufacturing losses), and 3) justification for the amount of overage. The overage should be included in the amount of drug substance listed in the batch formula (3.2.P.3.2).	
	Even if international guidelines permit overage in especial circumstances, international guidelines also instruct to perform impurity profiling of finished drug product, which local manufacturers don't perform. Due to this reason if 15% drug substance has degraded during formulation then it must have degraded into some degradation products, which are neither identified nor quantified.	
	Observation 2: in section 3.2.S.7 stability data was submitted in generic tables, it was neither on letter head of drug substance manufacturer nor was signed or stamped. Firm was asked to submit Signed and stamped stability data sheets from drug substance manufacturer.	
	In response firm submitted changes submitted by the drug substance manufacturer to EDQM. As per this document DS manufacturer had performed stability of DS as per Zone II conditions and in 2011 & 2018, and in initial submission data was as per Zone IVa and was of 2016.	
	Firm was asked about these differences.	
	Firm stated that DS manufacturer has performed stability on both conditions.	
	Firm has not submitted stability summary sheets of DS signed and stamped by the DS manufacturer	
	Decision	
	Deferred **Deferred for following;** • **Submission of detailed analysis and quantification of degradation products in the finished drug product.** • **Submission of signed stability datasheets of drug substance from drug substance manufacturer.** • **Submission of clarification from drug substance manufacturer regarding performance of stability studies according to different climatic conditions.**	
173	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Biogen Life Sciences** 8-KM, Chak Beli Road, Rawat, **(000911)**
	Application Form Dy. No / Tracking ID & date of submission	(ZM8-7EP-LV47, 2024-08-23)

	Detail of Fee Submitted	30000.0, 2024-04-02,
	The proposed proprietary name / brand name	**IROGEN 50MG/ML INJECTION**
	Label Claim	Each 10ml ampoule contains: Ferric carboxymaltose equivalent to elemental iron 500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1ml x5's-As per SRO
	Shelf Life (Unit)	2 Year(s)Room Condition
	For generic drugs (me-too Status)	Fercari Dispersion for Injection/Infusion 50 mg Iron/ml by Hilton Pharma
	Pharmacotherapeutic Group of (API)	Iron Preparation
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	BRIGHT GENE BIO-MEDICAL TECHNOLOGY CO., LTD China
	Detail of stability batches of drug product	3 batches, 500 ampoules 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	Ferinject Injection 50 mg/ml; 10 ml
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Ferinject ® Dispersion for Injection/Infusion is approved in USFDA
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
174	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Arsons Pharmaceutical Industries (Pvt) Ltd** 22 KM, Multan Road, Off 2.5 KM Defence Road, Lahore **(000514)**
	Application Form Dy. No / Tracking ID & date of submission	(5X8-4RJ-E66V, 2025-12-10)
	Detail of Fee Submitted	38700, 2025-09-01,
	The proposed proprietary name / brand name	**SILDAFIL 50MG TABLET**
	Label Claim	Each Tablet contains Sildenafil Citrate eq to Sildenafil....50mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Ambient
	For generic drugs (me-too Status)	Hilgra 50mg Tablet
	Pharmacotherapeutic Group of (API)	PDE-5 Inhibitor
	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 Phone: +91 40 2381 0385

	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)	Submitted
	The status in reference regulatory authorities	USFDA approved
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority.	
	Initially firm had submitted CDP data of 6 units at each pH. then firm was asked to submit CDP studies performed by using 12 units at each pH value (as per ICH guidelines) In response the firm as submitted same CDP data for both 100mg and 50mg Strength. After Scanning of CDP report only strength is edit to the applied one. Batch Number of reference product and all abs values are same.	
	Decision	
	Rejected The board deliberated that batch numbers and release values at each time point of reference product and test product used in CDP are same for both 50mg and 100mg strength and only label is edit to change the strength in submitted data. This raises serious concerns regarding integrity of submitted data. Due to this reason board rejected the case.	
175	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Arsons Pharmaceutical Industries (Pvt) Ltd** 22 KM, Multan Road, Off 2.5 KM Defence Road, Lahore **(000514)**
	Application Form Dy. No / Tracking ID & date of submission	(JLS-16P-G9EG, 2026-03-09)
	Detail of Fee Submitted	38700, 2025-09-01,
	The proposed proprietary name / brand name	**SILDAFIL 100MG TABLET**
	Label Claim	Each Tablet Contains Sildenafil Citrate..... 100mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearAmbient
	For generic drugs (me-too Status)	Attached
	Pharmacotherapeutic Group of (API)	Attached
	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 Phone: +91 40 2381 0385
	Detail of stability batches of drug product	Attached
	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	Attached
	GMP status of the firm	Attached
	Evidence of approval of manufacturing facility	Attached
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority.	
	Initially firm had submitted CDP data of 6 units at each pH. then firm was asked to submit CDP studies performed by using 12 units at each pH value (as per ICH guidelines) In response the firm as submitted same CDP data for both 100mg and 50mg Strength. After Scanning of CDP report only strength is edit to the applied one. Batch Number of reference product and all abs values are same.	
	Decision	
	Rejected The board deliberated that batch numbers and release values at each time point of reference product and test product used in CDP are same for both 50mg and 100mg strength and only label is edit to change the strength in submitted data. This raises serious concerns regarding integrity of submitted data. Due to this reason board rejected the case.	
176	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore **(000576)**
	Application Form Dy. No / Tracking ID & date of submission	(AP2-Z69-D65N, 2024-07-18)
	Detail of Fee Submitted	30000.0, 2024-04-29,
	The proposed proprietary name / brand name	**SERTRALIN TAB 50MG**
	Label Claim	Each film coated tablet contains: Sertraline HCl equivalent to Sertraline 50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1×10's, 1×14's -As per SRO
	Shelf Life (Unit)	2 Year(s)store at 25C
	For generic drugs (me-too Status)	SERT 50mg Tablet by Barrett Hodgson
	Pharmacotherapeutic Group of (API)	N06AB06 Selective serotonin reuptake inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches, 2000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested invoice is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Sert 50mg tablet M/s Barrett B. No. D7883
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	ZOLOFT 50mg Tablet by Pfizer (USFDA Approved)
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	

	Approved	
177	Case Category	Contract Manufacturing (Adil Saeed)
	Name, address of Applicant.	**Inner 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	(DT8-9M7-QX8L, 2024-09-11)
	Detail of Fee Submitted	75000.0, 2024-07-11,
	The proposed proprietary name / brand name	**Zetose Injection 500mg**
	Label Claim	Each 10ml contains: Ferric Carboxymaltose eq. to iron..... 500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1*10ml-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30oC
	For generic drugs (me-too Status)	Feservoir 500mg Injection by Martin Dow
	Pharmacotherapeutic Group of (API)	Iron preparation
	Name, address of Manufacturing site:	GT Pharma (Pvt.) Ltd.-Plot # 713 Sundar Industrial Estate, Lahore-
	Name & address of API manufacturer	Nanjing Hencer Pharmacetuical Co Ltd
	Detail of stability batches of drug product	3 batches, 100 vials 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	Feservoir Injection B. No. L22028 Mfg Martin Dow Quetta
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	MHRA
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. recommended for consideration of board.	
	Decision	
	Approved	
178	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Seraph Pharmaceutical** Plot No 210, Industrial Triangle Kahuta Road, Islamabad. **(000860)**
	Application Form Dy. No / Tracking ID & date of submission	(V37-LR5-S5AB, 2024-08-28)
	Detail of Fee Submitted	30000.0, 2024-08-15,
	The proposed proprietary name / brand name	**Bilast 20mg tablet**
	Label Claim	Each tablet contains: Bilastine 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 30°C
	For generic drugs (me-too Status)	Brand Name: Biltex 20mg Tablet Registration holder: Registered: Wezen Pharmaceuticals Plot #

		23 & 24, S-1, RCCI, Industrial Estate, Rawat Approved in 335th drap Meeting
	Pharmacotherapeutic Group of (API)	R06AX29 Other antihistamines for systemic use
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	METROCHEM API LIMITED 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 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Ilaxten 20mg Tablet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	MHRA Approved drug
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
179	Case Category	Routine (Adil Saeed)
	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	(E6B-94Z-J6PL, 2024-10-09)
	Detail of Fee Submitted	75000.0, 2024-09-06,
	The proposed proprietary name / brand name	**Damcin Powder for solution for Injection/Infusion 500mg**
	Label Claim	Each vial contains: Daptomycin.....500mg After reconstitution with 10ml of sodium chloride 9mg/ml (0.9%) solution for Injection, each ml provides: Daptomycin.....50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's, 5's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a refrigerator (2-8°C)
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	J01XX09 Other antibacterials
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	SUMAR BIOTECH LLP, Plot-No.:112, 113,114 GIDC Estate Gozariya, Tal. & Dist.: Mehsana 382825, Gujarat, India.
	Detail of stability batches of drug product	3 batches, 300 vials each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate of 700 gm lyophilized Daptomycin is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Daptomycin 500mg Powder for Soluton for injection/ Infusion B No. 0851783 Mfg Reddy Holding GmbH
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Real time at -20C

	The status in reference regulatory authorities	Daptomycin Powder for solution for Injection/Infusion 500mg by Reddy Holding GmbH, Germany
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Renewal letter dated 20.09.2021 is submitted.
	Evaluation Remarks	
	Applicant is importing Lyophilized ready to fill powder of Daptomycin. Innovator product and other products approved by RRA are manufactured by lyophilization of product in final vial. (instead of bulk lyophilization and then filling as general powder) The firm was asked 2 times to submit evidence of such manufacturing process approved by any RRA, but they couldn't provide any. They have only submitted that "the final product complies with all required quality attributes, including sterility, as demonstrated by batch release and stability data. This approach ensures that product quality and sterility assurance are maintained throughout the manufacturing process."	
	Decision	
	Deferred The board deliberated on the matter that innovator product is lyophilized in final vials while applicant is filling bulk lyophilized powder in final vials. After thorough deliberation board deferred the case for submission of pharmaceutical equivalence of the applicant's products' trial batches with reference products performed by any government drug testing lab. The reference product will be arranged and provided to the lab by the applicant and all the cost of testing shall also be borne by the applicant. The testing must include comparison of moisture content along with other necessary parameters.	
180	Case Category	Contract Manufacturing (Adil Saeed)
	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	(VVJ-8YX-WGRV, 2024-11-13)
	Detail of Fee Submitted	93000.0, 2024-10-24,
	The proposed proprietary name / brand name	**Vtrin**
	Label Claim	Each soluble tablet contains: Vigabatrin 500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7s, 10s, 14s, 20s, 2-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)	Not Applicable
	Pharmacotherapeutic Group of (API)	Antiepileptic, Fatty acid derivatives N03AG04
	Name, address of Manufacturing site:	Genix Pharma Pvt. Ltd.-44, 45-B, Korangi Creek Road, Karachi-
	Name & address of API manufacturer	Metrochem API Private Limited
	Detail of stability batches of drug product	3 batches, 1500 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	Kigabeq 500mg soluble tablet, ORPHELIA Pharma SAS, France B. No. 051248
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted

	The status in reference regulatory authorities	Kigabeq 500mg soluble tablet, ORPHELIA Pharma SAS, France
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
181	Case Category	Contract Manufacturing (Adil Saeed)
	Name, address of Applicant.	**Akhai Pharmaceuticals Private Limited** A-248, A256 to A-259, HITE Lasbella Baluchistan **(000640)**
	Application Form Dy. No / Tracking ID & date of submission	(8XH-EAB-T9S8, 2024-08-28)
	Detail of Fee Submitted	75000.0, 2023-10-06,
	The proposed proprietary name / brand name	**Aclova 500mg Injection**
	Label Claim	Each lyophilized vial contains: Acyclovir sodium equivalent to Acyclovir 500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 25°c
	For generic drugs (me-too Status)	Arpes 500mg lyophilized injection (Reg No. 084917)
	Pharmacotherapeutic Group of (API)	J05AB01 Nucleosides and nucleotides excl. reverse transcriptase inhibitors
	Name, address of Manufacturing site:	MTI Medical Pvt. Ltd.-586-587 Sundar Industrial State Lahore-
	Name & address of API manufacturer	Hubei yitai Pharmaceutical Co. Ltd. Fengchengyuan, Suburban district of Tianmen city, Hubei province, China
	Detail of stability batches of drug product	3 batches, one batch is of 4700 vials, 1 is of 3800 vials, and 3rd is of 3700 vials Firm was asked why batch size is variable. The firm submitted stability data of 2 other batches having batch size of 4700 vials each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested invoice is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Aclovir Daneen Pharma B# 00901032
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	USFDA
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Section approval letter dated 11.04.2017 is submitted.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	

182	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Akhai Pharmaceuticals Private Limited** A-248, A256 to A-259, HITE Lasbella Baluchistan **(000640)**
	Application Form Dy. No / Tracking ID & date of submission	(HZB-1YR-MRQ3, 2024-08-28)
	Detail of Fee Submitted	75000.0, 2023-10-06,
	The proposed proprietary name / brand name	**Aclova 250mg Injection**
	Label Claim	Each lyophilized vial contains: Acyclovir sodium equivalent to Acyclovir 250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 25°c
	For generic drugs (me-too Status)	Arpes 250mg lyophilized injection (Reg No. 084916)
	Pharmacotherapeutic Group of (API)	J05AB01 Nucleosides and nucleotides excl. reverse transcriptase inhibitors
	Name, address of Manufacturing site:	MTI Medical Pvt. Ltd.-Plot# 586-587, Sundar Industrial Estate, Raiwind Road, Lahore. -
	Name & address of API manufacturer	Hubei yitai Pharmaceutical Co. Ltd. Fengchengyuan, Suburban district of Tianmen city, Hubei province, China
	Detail of stability batches of drug product	5 batches, 5000 vials each
	Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested invoice is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Aclovir Daneen Pharma B# 00431033
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	MHRA
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Section approval letter dated 11.04.2017 is submitted.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
183	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)**
	Application Form Dy. No / Tracking ID & date of submission	(M8J-7XS-NZMU, 2024-08-20)
	Detail of Fee Submitted	75000.0, 2024-08-12,
	The proposed proprietary name / brand name	**Zonlac 60mg/2ml**
	Label Claim	Each 2mL vial contains: Ketorolac Tromethamine.....60 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO

	Shelf Life (Unit)	24 Year(s)Store at controlled room temperature 20 °C to 25 °C (68 °F to 77 °F).
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Acetic acid derivatives and related substances
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Saurav Chemical Limited Corporate office: Plot no. 370, Industrial area, Phase-II Panchukla-134109 (Haryana) India.
	Detail of stability batches of drug product	2 batchesm 2000 vials each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan from M/s Horizon, Loan letter and clearance certificate is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Ketorolac 60mg/2ml Injection Mfg Fuson Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	USFDA Approved ANDA: 075772 HIKMA
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
184	Case Category	Routine (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	(BEN-ATG-PWDJ, 2024-10-24)
	Detail of Fee Submitted	75000.0, 2024-09-20,
	The proposed proprietary name / brand name	**Hexal 1% Cream**
	Label Claim	Each gram of cream Contains: Chlorhexidine gluconate.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30's-As per SRO,60'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)	Nil
	Pharmacotherapeutic Group of (API)	D08AC02 ANTISEPTICS AND DISINFECTANTS
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Bajaj Healthcare Limited 6th Floor, Bhoomi Velocity In- fotech Park Above ICICI Bank, Road No. 23 Wagle Industrial Estate Thane (W) -400 604
	Detail of stability batches of drug product	3 batches, 33 tubes each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Import license is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	--

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa upto 48 months.
	The status in reference regulatory authorities	EMA Approved.
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 03.01.2023
	Evidence of approval of manufacturing facility	Semisolid and toothpaste section approved vide letter dated 03.03.2023
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
185	Case Category	Contract Manufacturing (Adil Saeed)
	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	(WGR-RA5-E71Y, 2024-10-09)
	Detail of Fee Submitted	93000.0, 2024-09-24,
	The proposed proprietary name / brand name	**Daptocin Powder for solution for Injection/Infusion**
	Label Claim	Each vial contains: Daptomycin.....500mg After reconstitution with 10ml of sodium chloride 9mg/ml (0.9%) solution for Injection, each ml provides: Daptomycin.....50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's, 5's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a refrigerator (2-8°C)
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	J01XX09 Other antibacterials
	Name, address of Manufacturing site:	Genix Pharma (Pvt) Limited-Plot No.44-45 B, Korangi Creek Road, Karachi -
	Name & address of API manufacturer	SUMAR BIOTECH LLP, Plot-No.:112, 113,114 GIDC Estate Gozariya, Tal. & Dist.: Mehsana 382825, Gujarat, India.
	Detail of stability batches of drug product	3 batches, 300 vials each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate of 700 gm lyophilized Daptomycin is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Daptomycin 500mg Powder for Soluton for injection/ Infusion B No. 0851783 Mfg Reddy Holding GmbH
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Real time at -20C
	The status in reference regulatory authorities	Daptomycin Powder for solution for Injection/Infusion 500mg by Reddy Holding GmbH, Germany
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Renewal letter dated 20.09.2021 is submitted.
	Evaluation Remarks	
	Applicant is importing Lyophilized ready to fill powder of Daptomycin.	

Innovator product and other products approved by RRA are manufactured by lyophilization of product in final vial. (instead of bulk lyophilization and then filling as general powder)	
The firm was asked 2 times to submit evidence of such manufacturing process approved by any RRA, but they couldn't provide any. They have only submitted that "the final product complies with all required quality attributes, including sterility, as demonstrated by batch release and stability data. This approach ensures that product quality and sterility assurance are maintained throughout the manufacturing process."	
Decision	
Deferred The board deliberated on the matter that innovator product is lyophilized in final vials while applicant is filling bulk lyophilized powder in final vials. After thorough deliberation board deferred the case for submission of pharmaceutical equivalence of the applicant's products' trial batches with reference products performed by any government drug testing lab. The reference product will be arranged and provided to the lab by the applicant and all the cost of testing shall also be borne by the applicant. The testing must include comparison of moisture content along with other necessary parameters.	

186	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	(BWV-DV6-3YL6, 2024-08-22)
	Detail of Fee Submitted	30000.0, 2024-07-15,
	The proposed proprietary name / brand name	**BUPRIO IR**
	Label Claim	Each film coated tablet contains: Bupropion Hydrochloride (USP)..... 100mg (USP specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10`s, 20`s a-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 degree celsius
	For generic drugs (me-too Status)	Smokik tablet 100mg Hilton Pharma (Pvt.) Ltd. Reg. No.: 048505
	Pharmacotherapeutic Group of (API)	Aminoketone (Antidepressent)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Glenmark Life Sciences
	Detail of stability batches of drug product	3 batches having batch size of 600 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 25-06-2023 specifying 1.6kg Bupropion Hydrochloride. Firm has also submitted copy of form 6 issued dated 10-04-2023 specifying 1.6kg Bupropion Hydrochloride.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Bupropion Hydrochloride Tablets 100mg by M/s Apotex Corporation
	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
	The status in reference regulatory authorities	WELLBUTRIN 75mg, 100mg film coated tablets USFDA Approved Discontinued **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
	GMP status of the firm	

	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 27-04-2020 specifying Tablet (General) section.
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved	
187	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	(TDD-9S3-3LLL, 2024-08-22)
	Detail of Fee Submitted	30000.0, 2024-05-06,
	The proposed proprietary name / brand name	**BUPRIO IR**
	Label Claim	Each film coated tablet contains: Bupropion Hydrochloride (USP).....75mg (USP specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10`s, 20`s a-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 degree celsius
	For generic drugs (me-too Status)	Smokik tablet 75mg Hilton Pharma (Pvt.) Ltd. Reg. No.: 035774
	Pharmacotherapeutic Group of (API)	Aminoketone (Antidepressent)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Glenmark Life Sciences
	Detail of stability batches of drug product	3 batches having batch size of 650 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 25-06-2023 specifying 1.6kg Bupropion Hydrochloride. Firm has also submitted copy of form 6 issued dated 10-04-2023 specifying 1.6kg Bupropion Hydrochloride.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Butrin Tablets 75mg manufactured by Genetics 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-B
	The status in reference regulatory authorities	WELLBUTRIN 75mg, 100mg film coated tablets USFDA Approved Discontinued **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 27-04-2020 specifying Tablet (General) section.
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	

Approved

188	Case Category	Routine (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	(DNQ-XU6-VX63, 2024-06-03)
	Detail of Fee Submitted	75000.0, 9400 2024-05-06, 2026-02-04
	The proposed proprietary name / brand name	**Lefahil Tablets 600mg**
	Label Claim	Each film-coated tablet contains: Lefamulin acetate eq. to Lefamulin.....600mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,5's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Xenlamo 600mg tablet by CCL Pharma
	Pharmacotherapeutic Group of (API)	Antibacterial for Community Acquired Bacterial Pneumonia (CABP) ATC Code: J01XX12
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Yibin Hongguang 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 (in case of Import)	Firm has submitted copy of form 6 dated 21-11-2022 specifying 2.5kg Lefamulin acetate oral grade. Firm has also submitted copy of invoice dated 14-09-2022 specifying 2.5kg Lefamulin acetate oral grade. Firm has also submitted copy of goods declaration
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Xenleta 600mg tablets by M/s Nabriva Therapeutics Ireland DAC.
	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	XENLETA 600mg film coated tablets USFDA Approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 23-01-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 30-06-2020 specifying Tablet (General) section.
	Evaluation Remarks	

Sr. No	Shortcomings	Firm's Response
1	Clarification is required for not including the water content test in finished product specifications as per innovator's product	The specification has been updated to include water content test. The updated specification corresponding batch analysis along with registration variation fee Rs. 9400/- for variation specifications is submitted

	Decision
	Approved

189	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	(25Q-U6L-89UP, 2024-08-21)
	Detail of Fee Submitted	30000.0, 2024-08-12,
	The proposed proprietary name / brand name	**Luras Tablet 20mg**
	Label Claim	Each film-coated tablet contains: Lurasidone Hydrochloride.....20mg (Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 20's, 30's tab-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Rasidon 20mg Tablet by Hilton Pharma (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Antipsychotics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Metrochem API Private limited
	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 clearance certificate issued dated 25-06-2023 specifying 3.6kg Lurasidone Hydrochloride. Firm has also submitted copy of form 6 issued dated 05-05-2023 specifying 3.6kg Lurasidone Hydrochloride.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Lurasidone HCl 20mg tablet
	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
	The status in reference regulatory authorities	Latuda tablet 20mg by Sunovion Pharmaceuticals Inc., USA, US FDA 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 of renewal of DML dated 27-04-2020 specifying Tablet (General) section.
	Evaluation Remarks	

Sr. No	Shortcomings	Firm's Response
1.	Please submit details of the comparator product used in the PE and CDP studies, including the name of the manufacturer/marketing authorization holder.	Firm has submitted details of comparator's pro Lurasidone Hydrochloride Tablets 2 manufactured by M/s Alkem Laborites Ltd., India Distributed by M/s Ascend Laboratories, L parsippany, NJ USA

The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
Decision	
Approved	
190	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	(5T5-M8Q-PYGM, 2024-10-18)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-12, 2024-09-18
	The proposed proprietary name / brand name	**Luras Tablet 60mg**
	Label Claim	Each film-coated tablet contains: Lurasidone Hydrochloride.....60mg (Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 20's, 30's tab-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Rasidon 60mg Tablet by Hilton Pharma (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Antipsychotics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Metrochem API Private Limited
	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 clearance certificate issued dated 25-06-2023 specifying 3.6kg Lurasidone Hydrochloride. Firm has also submitted copy of form 6 issued dated 05-05-2023 specifying 3.6kg Lurasidone Hydrochloride.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Lurasidone HCl 60mg tablet
	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
	The status in reference regulatory authorities	Latuda tablet 60mg by Sunovion Pharmaceuticals Inc., USA, USA FDA 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 of renewal of DML dated 27-04-2020 specifying Tablet (General) section.
	Evaluation Remarks	

Sr. No	Shortcomings	Firm's Response
1.	Please submit details of the comparator product used in the PE and CDP studies, including the name of the manufacturer/marketing authorization holder.	Firm has submitted details of comparator's pro Lurasidone Hydrochloride Tablets 6 manufactured by M/s Alkem Laborites Ltd., I approved in USFDA and Distributed by M/s Asc Laboratories, LLC, parsippany, NJ USA

	The application fulfills codal formalities and is submitted for consideration by the Registration Board.
	Decision
	Approved
191	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	(MU2-PZX-DYQP, 2024-08-22)
	Detail of Fee Submitted	75000.0, 2024-08-12,
	The proposed proprietary name / brand name	**Luras Tablet 120mg**
	Label Claim	Each film-coated tablet contains: Lurasidone Hydrochloride.....120mg (Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 20's, 30's -De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Sidura Tablet 120mg by M/s. Genix Pharma (Pvt) Ltd.
	Pharmacotherapeutic Group of (API)	Antipsychotics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Metrochem API Private Limited
	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 clearance certificate issued dated 25-06-2023 specifying 3.6kg Lurasidone Hydrochloride. Firm has also submitted copy of form 6 issued dated 05-05-2023 specifying 3.6kg Lurasidone Hydrochloride.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Lurasidone HCl 120mg tablet
	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
	The status in reference regulatory authorities	Latuda tablet 120mg by Sunovion Pharmaceuticals Inc., USA., USFDA 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 of renewal of DML dated 27-04-2020 specifying Tablet (General) section.
	Evaluation Remarks	
	Sr. No / Shortcomings / Firm's Response	
	1. Please submit details of the comparator product used in the PE and CDP studies, including the name of the manufacturer/marketing authorization holder.	Firm has submitted details of comparator's pro Lurasidone Hydrochloride Tablets 12 manufactured by M/s Alkem Laborites Ltd., I approved in USFDA and Distributed by M/s Asc Laboratories, LLC, parsippany, NJ USA
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved	
192	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**Hiranis Pharmaceuticals Pvt. Ltd.** E-145-149, North Western Industrial Zone, Port Qasim, Karachi-75020, Pakistan **(000785)**
	Application Form Dy. No / Tracking ID & date of submission	(Y9M-UAJ-TDZ2, 2024-10-22)

	Detail of Fee Submitted	75000.0, 2024-10-03,
	The proposed proprietary name / brand name	**Veguat 2.5mg tablet**
	Label Claim	Each film coated tablet contains: Vericiguat 2.5mg (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 14's, 28's, As-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect from light, heat and moisture. Keep out of the reach of children.
	For generic drugs (me-too Status)	Reciquat Tablets 2.5mg by M/s Nabiqasim Industries
	Pharmacotherapeutic Group of (API)	Soluble guanylate cyclase (sGC) stimulators
	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 2000 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 24-01-2023 specifying 185gm Vericiguat IH. Firm has also submitted copy of commercial invoice, DHL receipt and goods declaration for procurement of API.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Verquvo 2.5mg Tablet (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
	The status in reference regulatory authorities	Verquvo 2.5mg film coated Tablet USFDA Approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 14-12-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 07-02-2014 specifying Tablet (General) section.
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved	
193	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**Hiranis Pharmaceuticals Pvt. Ltd.** E-145-149, North Western Industrial Zone, Port Qasim, Karachi-75020, Pakistan **(000785)**
	Application Form Dy. No / Tracking ID & date of submission	(3MY-BR7-T2RU, 2024-10-23)
	Detail of Fee Submitted	75000.0, 2024-10-03,
	The proposed proprietary name / brand name	**Veguat 5mg Tablet**
	Label Claim	Each film coated Tablet contains Vericiguat 5mg As per Innovator's Specification
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	10s, 14s, 28s -As per SRO
	Shelf Life (Unit)	2 Year(s)Store Below 30 degree Celsius. Protect from light, heat and moisture. Keep out of the reach of children
	For generic drugs (me-too Status)	Reciquat Tablets 5mg by M/s Nabiqasim Industries
	Pharmacotherapeutic Group of (API)	Soluble guanylate cyclase (sGC) stimulators
	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 2000 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 24-01-2023 specifying 185gm Vericiguat IH. Firm has also submitted copy of commercial invoice, DHL receipt and goods declaration for procurement of API.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Verquvo 5mg Tablet (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
	The status in reference regulatory authorities	Verquvo 5mg film coated Tablet USFDA Approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 14-12-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 07-02-2014 specifying Tablet (General) section.
	Evaluation Remarks	
	Firm has also submitted copy of commercial invoice, DHL receipt and goods declaration for procurement of API.	
	Decision	
	Approved	
194	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**Hiranis Pharmaceuticals Pvt. Ltd.** E-145-149, North Western Industrial Zone, Port Qasim, Karachi-75020, Pakistan **(000785)**
	Application Form Dy. No / Tracking ID & date of submission	(6RW-8ZH-5AW5, 2024-10-28)
	Detail of Fee Submitted	75000.0, 2024-10-03,
	The proposed proprietary name / brand name	**Veguat 10mg tablet**
	Label Claim	Each film coated tablet contains; Vericiguat ..... 10mg (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,14's-As per SRO,28's-As per SRO,As per SRO/PRC-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect from light, heat and moisture. Keep out of the reach of children.

	For generic drugs (me-too Status)	Reciquat Tablets 10mg by M/s Nabiqasim Industries
	Pharmacotherapeutic Group of (API)	Soluble guanylate cyclase (sGC) stimulators
	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 2000 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 24-01-2023 specifying 185gm Vericiguat IH. Firm has also submitted copy of commercial invoice, DHL receipt and goods declaration for procurement of API.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Verquvo 10mg Tablet (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
	The status in reference regulatory authorities	Verquvo 10mg film coated Tablet USFDA Approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 14-12-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 07-02-2014 specifying Tablet (General) section.
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved	
195	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	(GBJ-E2R-T813, 2024-08-22)
	Detail of Fee Submitted	30000.0, 2024-07-15,
	The proposed proprietary name / brand name	**BUPRIO SR**
	Label Claim	Each extended Release film coated tablet contains: Bupropion Hydrochloride (USP)..... 150mg (USP Specification)
	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 degree celsius
	For generic drugs (me-too Status)	Zylexx SR 150mg Tablet A'raf (Pvt) Ltd Reg. No.: 077154
	Pharmacotherapeutic Group of (API)	Aminoketone (Antidepressent)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Glenmark Life Sciences
	Detail of stability batches of drug product	3 batches having batch size of 600 tablets each
	Documents for the procurement of API with approval from DRAP	Firm has submitted copy of clearance certificate issued dated 25-06-2023 specifying 1.6kg

	(in case of Import)	Bupropion Hydrochloride. Firm has also submitted copy of form 6 issued dated 10-04-2023 specifying 1.6kg Bupropion Hydrochloride.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Zylexx SR Tablets 150mg by A'raf 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-B
	The status in reference regulatory authorities	WELLBUTRIN SR 100mg, 150mg, 200mg, sustained-release tablets USFDA Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 27-04-2020 specifying Tablet (General) section.

Evaluation Remarks

Sr. No	Shortcomings	Firm's Response
1.	You have performed system suitability test in analytical method verification without using Bupropion Related Compound C and Bupropion Related Compound F, clarify	Bupropion Related Compound C and Bupro Related Compound F are requested for exclusively in the system suitability test demonstrate adequate chromatographic resolut The relative retention times (RRTs) for these rel compounds are defined in the USP Buprop Hydrochloride Extended-Release Tablets monogr and are applied only for Identification purposes. use of these related compounds does not impact analytical results or the quality of the finis product. Upon approval of the product, and du technology transfer to the Quality Control laborat the system suitability solution will be executed c commercial scale batch in accordance with approved analytical procedure. -
2.	Clarify the reported CDP time points (15, 20, 30, 45, and 60 minutes) for 0.1 N HCl, considering the product is an extended-release formulation. CDP data for 100 mg (reference and test) in pH 4.5 buffer and water is provided, whereas the applied strength is 150mg; submit clarification and CDP data for 150mg.	The firm submitted that it was typographical mis and submitted revised corrected documents.

Decision

Deferred

Deferred for submission of system suitability test in analytical method verification study of drug product using Bupropion Related Compound C and Bupropion Related Compound F as per USP monograph

196	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	(MEB-5VQ-842E, 2024-08-22)
	Detail of Fee Submitted	75000.0, 2024-07-15,
	The proposed proprietary name / brand name	**BUPRIO SR**

Label Claim	Each extended release film coated tablet contains: bupropion hydrochloride (USP).....100mg (USP Specification)
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 degree celsius
For generic drugs (me-too Status)	NA
Pharmacotherapeutic Group of (API)	Aminoketone (Antidepressent)
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Glenmark Life Sciences
Detail of stability batches of drug product	3 batches having batch size of 600 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 25-06-2023 specifying 1.6kg Bupropion Hydrochloride. Firm has also submitted copy of form 6 issued dated 10-04-2023 specifying 1.6kg Bupropion Hydrochloride.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Zylexx SR Tablets 150mg by A'raf 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-B
The status in reference regulatory authorities	WELLBUTRIN SR 100mg, 150mg, 200mg, sustained-release tablets USFDA Approved
GMP status of the firm	
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 27-04-2020 specifying Tablet (General) section.

Evaluation Remarks

Sr. No	Shortcomings	Firm's Response
1.	CDP and PE studies of 150mg strength is submitted while applied product is 100mg strength	PE and CDP studies performed against Bupropion HCl SR Tablets 100mg by M/s Sciengen Pharmaceuticals
2.	Justify submission of data in Sections 3.2.P.1–3.2.P.3.5 for 150 mg and provide corresponding data for the applied 100 mg strength.	Firm has submitted revised document for 100mg tablets
3	You have performed system suitability test in analytical method verification without using Bupropion Related Compound C and Bupropion Related Compound F, clarify	Bupropion Related Compound C and Bupropion Related Compound F are requested for use exclusively in the system suitability test to demonstrate adequate chromatographic resolution. The relative retention times (RRTs) for these related compounds are defined in the USP Bupropion Hydrochloride Extended-Release Tablets monograph and are applied only for Identification purposes. The use of these related compounds does not impact the analytical results or the quality of the finished product. Upon approval of the product, and during technology transfer to the Quality Control laboratory, the system suitability solution will be executed on a

		commercial scale batch in accordance with the approved analytical procedure.
	Decision	
	Deferred Deferred for submission of system suitability test in analytical method verification study of drug product using Bupropion Related Compound C and Bupropion Related Compound F as per USP monograph	
197	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**AGP Limited** B-23-C, S.I.T.E., Karachi **(000348)**
	Application Form Dy. No / Tracking ID & date of submission	(JP2-EB2-Z7GH, 2024-07-18)
	Detail of Fee Submitted	75000.0, 2024-05-23,
	The proposed proprietary name / brand name	**Verivo 2.5mg Tablet**
	Label Claim	Each Film coated Tablet Contains Vericiguat----------2.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10s, 14s,20s, 28s,30-De-Controlled
	Shelf Life (Unit)	2 Year(s)Do not store over 30ºC. Protect from direct sunlight, heat & moisture
	For generic drugs (me-too Status)	Reciquat Tablets 2.5mg by M/s Nabiqasim Industries
	Pharmacotherapeutic Group of (API)	Soluble guanylate cyclase (sGC) stimulators
	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 4500 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 18-08-2023 specifying 0.7kg Vericiguat. Firm has also submitted copy of form 3, form 7, commercial invoice, packing list, DHL receipt and goods declaration.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Verquvo 2.5mg Tablet by Bayer, 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
	The status in reference regulatory authorities	Verquvo 2.5mg film coated Tablet USFDA Approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 15-06-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 30-06-2020 specifying Tablet (General) section.
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	

	Approved	
198	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**AGP Limited** B-23-C, S.I.T.E., Karachi **(000348)**
	Application Form Dy. No / Tracking ID & date of submission	(GNQ-721-DVHH, 2024-07-18)
	Detail of Fee Submitted	, ,
	The proposed proprietary name / brand name	**Verivo 5mg tablet**
	Label Claim	Each Film coated Tablet Contains Vericiguat----------5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10s, 14s,20s, 28s,30-De-Controlled
	Shelf Life (Unit)	2 Year(s)Do not store over 30ºC. Protect from direct sunlight, heat & moisture.
	For generic drugs (me-too Status)	Reciquat Tablets 5mg by M/s Nabiqasim Industries
	Pharmacotherapeutic Group of (API)	Soluble guanylate cyclase (sGC) stimulators
	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 3000 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 18-08-2023 specifying 0.7kg Vericiguat. Firm has also submitted copy of form 3, form 7, commercial invoice, packing list, DHL receipt and goods declaration.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Verquvo 5mg Tablet by Bayer, 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
	The status in reference regulatory authorities	Verquvo 5mg film coated Tablet USFDA Approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 15-06-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 30-06-2020 specifying Tablet (General) section.
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved	
199	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**AGP Limited** B-23-C, S.I.T.E., Karachi **(000348)**
	Application Form Dy. No / Tracking ID & date of submission	(9B9-BUW-21M4, 2024-07-18)
	Detail of Fee Submitted	75000.0, 2024-05-23,

	The proposed proprietary name / brand name	**Verivo 10mg tablet**
	Label Claim	Each Film coated Tablet Contains Vericiguat----------10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10s, 14s,20s, 28s,30-De-Controlled
	Shelf Life (Unit)	2 Year(s)Do not store over 30ºC. Protect from direct sunlight, heat. & moisture
	For generic drugs (me-too Status)	Reciquat Tablets 10mg by M/s Nabiqasim Industries
	Pharmacotherapeutic Group of (API)	Soluble guanylate cyclase (sGC) stimulators
	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 3000 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 18-08-2023 specifying 0.7kg Vericiguat. Firm has also submitted copy of form 3, form 7, commercial invoice, packing list, DHL receipt and goods declaration.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Verquvo 10mg Tablet by Bayer, 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
	The status in reference regulatory authorities	Verquvo 10mg film coated Tablet USFDA Approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 15-06-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 30-06-2020 specifying Tablet (General) section.
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved	
200	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**Scotmann Pharmaceuticals** Plot #5D , Industrial Area, I-10/3 Islamabad **(000498)**
	Application Form Dy. No / Tracking ID & date of submission	(BZR-J91-9GU4, 2024-08-05)
	Detail of Fee Submitted	30000.0, 2024-01-16,
	The proposed proprietary name / brand name	**Prucalax Tablet 2mg**
	Label Claim	Each film coated tablet contains: Prucalopride succinate eq. to Prucalopride ..... 2mg (Innovator’s Specifications)
	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
	Shelf Life (Unit)	2 Year(s)Between 15°C-30°C

For generic drugs (me-too Status)	Pruvix Tablet 2mg, Manufactured by: Horizon Healthcare (Pvt) Ltd.
Pharmacotherapeutic Group of (API)	Serotonin receptor agonist
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Source of Drug Substance: SYMED LABS LIMITED Address: Unit –VI, Survey No. 744, 745, 750, 751, 752 & 753, Mandollagudem (Village), Choutuppal (Mandal), Yadadri Bhuvangiri (Dist) – 508 204,Telangana, I
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 clearance certificate issued dated 23-08-2023 specifying 0.1kg Prucalopride Succinate.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Pruvix 2mg tablet manufactured by M/s Horizon Healthcare
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	Motegrity Tablet, USFDA Approved
GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 22-02-2024.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of approval of revised layout plan/ Regularization/Additional section dated 15-02-2019 specifying Tablet section general (reallocated)

Evaluation Remarks

Sr. No	Shortcomings	Firm's Response
1	Justification shall be submitted for using six unit for dissolution test in CDP studies instead of 12 units as recommended by WHO guideline for conducting comparative dissolution profiles	The firm submitted that the comparative dissolu data generated using 12 units/tablets, in accorda with WHO recommendations, had already b submitted at the time of dossier submission. For submitted CDP studies, the total 12 tablets for t test and innovator products were evaluated in phases, as detailed below: Phase 1: Compara dissolution performed using 6 tablets each of test innovator products, and the similarity factor (f2) calculated separately for this set. Phase Comparative dissolution performed using remaining 6 tablets each of test and innov products, and the similarity factor (f2) was a calculated separately for this set. Thus, the ove CDP assessment comprised 12 units/tablets product, with f2 similarity evaluation perfor independently for each set of 6 tablets, ensu compliance with WHO guideline requirements. results from both phases collectively demonst comparable dissolution behavior between the test innovator products.

Decision

Approved

The firm shall submit revised CDP data generated using 12 units in a single study, along with combined calculations (% release, mean, and similarity factor), instead of presenting results from

	two separate phases of 6 units each.	
201	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	(NS8-ZUP-2E1M, 2024-07-09)
	Detail of Fee Submitted	30000.0, 9400 2024-05-09, 2026-02-17
	The proposed proprietary name / brand name	**Iromax 20mg/ml (100mg/5ml) IV INJECTION**
	Label Claim	Each ml contains: Iron (as Sucrose).....20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5mlx5's Ampoules -As per SRO
	Shelf Life (Unit)	2 Year(s)store in cool & dry place below 30 degree Celsius
	For generic drugs (me-too Status)	Rubiject Injection by AGP Limited Reg# 036270
	Pharmacotherapeutic Group of (API)	Iron replacement
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	SNJ Labs Pvt. Ltd.
	Detail of stability batches of drug product	3 batches having batch size of 9615 ampoules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate issued dated 28-12-2023 specifying 150kg Iron Sucrose.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Ferosoft Injection 100mg/5ml by M/s Hilton 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	Venofer 20mg/ml Injection by Vifor Pharma UK Limited MHRA 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 of additional section dated 03-12-2018 specifying Liquid Vial/Infusion (General) SVP section.
	Evaluation Remarks	
	Sr. No / Shortcomings / Firm's Response	
	1 / Standardize the label claim in section 1.5.2 as per reference formulation along with submission of applicable fee	Firm has standardized label claim as per refere formulation along with submission of Rs. 9400/- deposit slip#936866835843. One millilitre of solu contains 20 mg of iron as iron sucrose (iron(hydroxide sucrose complex).
	Decision	
	Approved Approved with following label claim; One millilitre of solution contains 20 mg of iron as iron sucrose (iron(III)-hydroxide sucrose complex).	
202	Case Category	Routine (Dr. Farhad Ullah)

	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	(7S6-DXA-29TZ, 2024-11-07)
	Detail of Fee Submitted	75000.0, 2024-09-26,
	The proposed proprietary name / brand name	**Sotaglif Tablets 200mg**
	Label Claim	Each film-coated tablet contains: Sotagliflozin.....200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store above 30°C.
	For generic drugs (me-too Status)	Sotazin 200mg by M/s Horizon Healthcare (pvt.) ltd.
	Pharmacotherapeutic Group of (API)	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 having batch size of 2000 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 30-10-2023 specifying 5kg Sotagliflozin. Firm has also submitted copy of commercial invoice, airway bill, form 7 and goods declaration.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Inpefa Tablet 200mg by M/s Lexicon Pharmaceutical, Inc. USA
	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	INPEFA Tablets 200mg by M/s Lexicon Pharmaceuticals, Inc. USFDA Approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 10-11-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 30-10-2019 specifying Tablet (General) section.
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved	
203	Case Category	Routine (Dr. Farhad Ullah)
	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	(MET-NMV-GEYT, 2024-11-07)
	Detail of Fee Submitted	75000.0, 2024-09-26,
	The proposed proprietary name / brand name	**Sotaglif Tablets 400mg**
	Label Claim	Each film-coated tablet contains: Sotagliflozin.....400mg

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store above 30°C.
	For generic drugs (me-too Status)	Sotazin 400mg by M/s Horizon Healthcare (pvt.) ltd.
	Pharmacotherapeutic Group of (API)	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 having batch size of 2000 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 30-10-2023 specifying 5kg Sotagliflozin. Firm has also submitted copy of commercial invoice, airway bill, form 7 and goods declaration.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Inpefa Tablet 400mg by M/s Lexicon Pharmaceutical, Inc. USA
	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	INPEFA Tablets 400mg by M/s Lexicon Pharmaceuticals, Inc. USFDA Approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 10-11-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 30-10-2019 specifying Tablet (General) section.
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved	
204	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**Bryon Pharmaceuticals (Pvt.) Ltd** 48, Hayatabad Industrial Estate **(000388)**
	Application Form Dy. No / Tracking ID & date of submission	(632-V48-4S4D, 2024-11-11)
	Detail of Fee Submitted	37000.0, 9400 2024-10-08, 2026-04-15
	The proposed proprietary name / brand name	**Senri 20mg Capsules**
	Label Claim	Each capsule contains: Duloxetine..... 20mg as enteric coated pellets of Duloxetine HCl
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2x7s-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at Room Temperature in Dry Place
	For generic drugs (me-too Status)	Duzalta 20mg Capsules (M/s PharmEvo Pharmaceuticals (Pvt.) Ltd.)
	Pharmacotherapeutic Group of (API)	Antidepressant, Anxiolytic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vision Pharmaceuticals (Pvt.) Limited
	Detail of stability batches of drug product	3 batches having batch size of 765 capsule each

	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of Sales Tax Invoice and Delivery Challan dated 20-02-2024 specifying 2kg Duloxetine (HCl) EC Pellets (USP) 17% from M/s Vision Pharma in the name of Bryon Pharmaceuticals.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Duzalta capsule 20mg by M/s PharmEvo
	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	Cymbalta 20mg Capsules USFDA Approved
	GMP status of the firm	The firm has submitted DML inspection report dated 26-06-2025, concluding that the facility is operating at good level of GMP compliance and unanimously recommended grant of renewal of DML
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 31-12-2021 specifying Capsule (General) section.
	Evaluation Remarks	

Sr. No	Shortcomings	Firm's Response
1.	Standardize the label claim in section 1.5.2 as per reference formulation considering the salt factor along with submission of applicable fee	Each Capsule contain: Duloxetine HCl equivaler Duloxetine …… 20mg 22.4mg of duloxetine equal to 20mg duloxetine (as enteric coated pell Firm has submitted fee Rs. 9400/- on deposit s 7561411759 for revision of label claim
2	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is required	As product was analyzed with HPLC Shima system Model LC 10 AT (old model) so 21 C software and audit trial is not available.

Decision

Rejected

Rejected, as the firm has submitted that compliance record of HPLC software with 21 CFR and audit trail reports for product testing are not available.

205	Case Category	Routine (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	(MRU-S8Y-X6HG, 2024-07-10)
	Detail of Fee Submitted	30000.0, 19350 2024-07-08, 2026-04-15
	The proposed proprietary name / brand name	**Prulax 2mg tablet**
	Label Claim	Each film coated tablet contains Prucalopride (as Succinate)-2mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 x 10-As per SRO
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Pru-cic 2mg Tablet by The Searle Company Limited
	Pharmacotherapeutic Group of (API)	Other drugs for constipation
	Name, address of Manufacturing site:	Self Manufacturing

Name & address of API manufacturer	Nuray chemicals private limited
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 05-07-2023 specifying 200gm Prucalopride Succinate.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Pru-cic 2mg tablet manufactured by M/s The Searle Company 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
The status in reference regulatory authorities	Resolor 2mg film coated Tablet Aifa Italy Approved
GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 24 & 25-05-2023.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 07-07-2021 specifying Tablet (General) section

Evaluation Remarks

Sr. No	Shortcomings	Firm's Response
1.	Submit the analytical record of the Comparative Dissolution Profile (CDP) studies conducted in three physiological media (pH 1.2, pH 4.5, and pH 6.8), including individual and mean dissolution data and standard deviations comparing test and reference products. Furthermore, the submitted Comparative Dissolution Profile (CDP) data presents comparison of Prulax 2mg tablets with Resolor 2mg tablets in the tabulated results, whereas the graphical representation compares Prulax 2 mg with Pru-cic 2 mg. Clarification is required to justify and confirm which comparator product has been used for the CDP study.	With reference to the query regarding submission of mean dissolution data and standard deviations, it is submitted that the Comparative Dissolution Profile (CDP) study has been conducted in three physiological media (pH 1.2, 4.5, and 6.8) using 12 units for both test and reference products. The updated CDP now includes: Individual dissolution data for each unit at all specified time points Calculated mean (% drug release) values for both test and reference products Standard deviation (SD) values to demonstrate variability and consistency With reference to the query regarding the discrepancy between tabulated and graphical representations in the Comparative Dissolution Profile (CDP) study, it is respectfully submitted that the comparator product actually used in the study is Pru-cic 2 mg Tablets. Therefore, it is requested to consider the typographical error in CDP data to become the part of this dossier.

	2.	Clarification shall be submitted for the dissolution medium used for dissolution test, as three different media are provided in analytical method. Additionally, clarify the dissolution time, as multiple sampling time points are provided.	With reference to the query regarding the dissolution medium and sampling time points, it is respectfully submitted that the analytical method includes multiple dissolution media (pH 1.2, 4.5, and 6.8) as part of method development and comparative dissolution profile (CDP) studies, in line with regulatory recommendations to evaluate product performance under different physiological conditions. However, for routine quality control (QC) testing, a single optimized dissolution medium has been selected. The finalized dissolution conditions are as follows: Apparatus: Apparatus II RPM: 50 rpm Medium: 0.1 N HCL Volume 900 ml Time 20 Minutes Updated analytical procedure of Finished product is submitted. Firm has also submitted fee Rs. 19350/- on deposit slip# 3586894136
	Decision		
	Approved		

206	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**Bryon Pharmaceuticals (Pvt.) Ltd** 48, Hayatabad Industrial Estate **(000388)**
	Application Form Dy. No / Tracking ID & date of submission	(GR6-Z9Z-BSP7, 2024-11-11)
	Detail of Fee Submitted	37000.0, 9400 2024-10-08, 2026-04-15
	The proposed proprietary name / brand name	**Senri 60mg Capsules**
	Label Claim	Each capsule contains: Duloxetine..... 60mg as enteric coated pellets of Duloxetine HCl
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2x7s-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at Room Temperature in Dry Place
	For generic drugs (me-too Status)	Duzalta 60mg Capsules (M/s PharmEvo Pharmaceuticals (Pvt.) Ltd.)
	Pharmacotherapeutic Group of (API)	Antidepressant, Anxiolytic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vision Pharmaceuticals (Pvt.) 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 Sales Tax Invoice and Delivery Challan dated 20-02-2024 specifying 2kg Duloxetine (HCl) EC Pellets (USP) 17% from M/s Vision Pharma in the name of Bryon Pharmaceuticals.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Duzalta capsule 60mg by M/s PharmEvo
	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	Cymbalta 60mg Capsules USFDA Approved
	GMP status of the firm	The firm has submitted DML inspection report dated 26-06-2025, concluding that the facility is operating at good level of GMP compliance and unanimously recommended grant of renewal of DML
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 31-12-2021 specifying Capsule (General) section.
	Evaluation Remarks	

Sr. No	Shortcomings	Firm's Response
1.	Standardize the label claim in section 1.5.2 as per reference formulation considering the salt factor along with submission of applicable fee	Each Capsule contain: Duloxetine HCl equivalen Duloxetine …… 60mg 67.2mg of duloxetine equal to 60mg duloxetine (as enteric coated pell Firm has submitted fee Rs. 9400/- on dep slip#676284191049 for revision of label claim
2.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is required	As product analyzed with HPLC Shimadzu sys Model LC 10 AT (old model) so 21 CFR software audit trial is not available.

	Decision
	Rejected Rejected, as the firm has submitted that compliance record of HPLC software with 21 CFR and audit trail reports for product testing are not available.
207	Case Category: Routine (Dr. Farhad Ullah)
	Name, address of Applicant.: **Bryon Pharmaceuticals (Pvt.) Ltd** 48, Hayatabad Industrial Estate **(000388)**
	Application Form Dy. No / Tracking ID & date of submission: (GXX-5SW-AQVP, 2024-10-11)
	Detail of Fee Submitted: 37000.0, 9400 2024-10-04, 2026-04-15
	The proposed proprietary name / brand name: **Senri 30mg Capsules**
	Label Claim: Each Capsule Contains : Duloxetine 30mg as enteric coated pellets of Duloxetine HCl
	Reference to Finished product specifications: United States Pharmacopeia
	Proposed Pack Size: 2x7s-As per SRO
	Shelf Life (Unit): 2 Year(s)Store at Room Temperature in Dry Place
	For generic drugs (me-too Status): Duzalta 30mg Capsules (M/s PharmEvo Pharmaceuticals (Pvt.) Ltd.)
	Pharmacotherapeutic Group of (API): Antidepressant, Anxiolytic
	Name, address of Manufacturing site: Self Manufacturing
	Name & address of API manufacturer: Vision Pharmaceuticals (Pvt.) 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 Sales Tax Invoice and Delivery Challan dated 20-02-2024 specifying 2kg Duloxetine (HCl) EC Pellets (USP) 17%

		from M/s Vision Pharma in the name of Bryon Pharmaceuticals.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Duzalta capsule 30mg by M/s PharmEvo
	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	Cymbalta 30mg Capsules USFDA Approved
	GMP status of the firm	The firm has submitted DML inspection report dated 26-06-2025, concluding that the facility is operating at good level of GMP compliance and unanimously recommended grant of renewal of DML
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 31-12-2021 specifying Capsule (General) section.
	Evaluation Remarks	

Sr. No	Shortcomings	Firm's Response
1.	Standardize the label claim in section 1.5.2 as per reference formulation considering the salt factor along with submission of applicable fee	Each Capsule contain: Duloxetine HCl equivalent Duloxetine …… 30mg 33.6mg of duloxetine H equal to 30mg duloxetine (as enteric coated pellets Firm has submitted fee Rs. 9400/- on deposit slip# 0877124482 for revision of label claim
2.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is required	As product analyzed with HPLC Shimadzu sys Model LC 10 AT (old model) so 21 CFR software audit trial is not available.

Decision

Rejected

Rejected, as the firm has submitted that compliance record of HPLC software with 21 CFR and audit trail reports for product testing are not available.

208	Case Category	Routine (Dr. Farhad Ullah)
	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	(PW1-Y7J-3V4P, 2024-09-13)
	Detail of Fee Submitted	37000.0, 9400 2024-09-06, 2026-04-15
	The proposed proprietary name / brand name	**Prucal 1mg Tablets**
	Label Claim	Each film-coated tablet contains: Prucalopride Succinate eq. to Prucalopride 1mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 Tablets-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Kaloprid 1mg Tablet by M/s Solaris Lifesciences Pvt. Ltd
	Pharmacotherapeutic Group of (API)	Serotonin receptor agonist (Drugs used for constipation)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Loncom 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 clearance certificate issued dated 24-01-2024 specifying 0.1kg Prucalopride succinate.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Prutide 1mg tablet manufactured by M/s CCL 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
	The status in reference regulatory authorities	MOTEGRITY (prucalopride) 1mg & 2mg tablets, Takeda Pharmaceuticals, USA, Inc. Lexington, MA 02421, USFDA Approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 11-01-2024.
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Shortcomings	Firm's Response
	Justification shall be submitted for using six unit for dissolution test in CDP studies instead of 12 units as recommended by WHO guideline for conducting comparative dissolution profiles	Revised CDP studies performed against Prokal 1mg tablets by CCL Pharma with 12 units is submitted.
	Justification shall be submitted for selecting a different dissolution medium volume and dissolution time (500ml; 30minutes) in the finished product specifications compared to those recommended for the innovator product (900ml; 20minutes).	The selection of a 500 mL dissolution medium volume with a 30-minute time point instead of the innovator conditions (900 mL; 20 minutes) is justified based on demonstrated maintenance of sink conditions across physiological pH ranges, ensuring no impact on dissolution kinetics or drug release mechanism. Comparative dissolution studies confirm that profile shape, release rate, and similarity factor ($f2 \geq 50$) remain unaffected under the proposed conditions. The method retains adequate discriminatory capability and robustness, as confirmed through method variability and stress testing. The extended time point compensates for reduced hydrodynamic volume while ensuring complete drug release within specification limits. Therefore, the modified conditions remain scientifically valid and compliant with FDA dissolution guidance principles for immediate-release solid oral dosage forms. Meanwhile, after receiving your query, we have tested the same on the innovator specs (900 mL; 20 minutes) as advised by yourself also in the query and it had observed that the results from both methods found satisfactory results. However as recommended by yourself also we had revised the dissolution test method as per innovator specifications (900 mL; 20 minutes). Results of the revised specs as per innovator and Revised SAP is submitted. Firm has also submitted fee Rs 9400/- on deposit slip# 764443798483 for revision of specifications
	Decision	
	Approved	
209	Case Category	Routine (Dr. Farhad Ullah)
	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	(5D2-5TV-RDUR, 2024-10-31)
Detail of Fee Submitted	37000.0, 9400 2024-09-06, 2026-04-15
The proposed proprietary name / brand name	**Prucal 2mg Tablets**
Label Claim	Each film-coated tablet contains: Prucalopride Succinate eq. to Prucalopride 2mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	10 Tablets-As per SRO
Shelf Life (Unit)	2 Year(s)Below 30°C
For generic drugs (me-too Status)	Kaloprid 2mg Tablet by M/s Solaris Lifesciences Pvt. Ltd
Pharmacotherapeutic Group of (API)	Serotonin receptor agonist (Drugs used for constipation)
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Shandong Loncom 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 clearance certificate issued dated 24-01-2024 specifying 0.1kg Prucalopride succinate.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Prutide 2mg tablet manufactured by M/s CCL Pharmaceuticals
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 2 batches of drug substance as per zone IV
The status in reference regulatory authorities	MOTEGRITY (prucalopride) 1mg & 2mg tablets, Takeda Pharmaceuticals, USA, Inc. Lexington, MA 02421, USFDA Approved
GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 11-01-2024.
Evidence of approval of manufacturing facility	Submitted

Evaluation Remarks

Shortcomings	Firm's Response
Justification shall be submitted for using six unit for dissolution test in CDP studies instead of 12 units as recommended by WHO guideline for conducting comparative dissolution profiles	Revised CDP studies performed against Prucalp 2mg tablets by Seraph Pharma with 12 units is submitted.
Justification shall be submitted for selecting a different dissolution medium volume and dissolution time (500ml; 30minutes) in the finished product specifications compared to those recommended for the innovator product (900ml; 20minutes).	The selection of a 500 mL dissolution medium volume with a 30-minute time point instead of the innovator conditions (900 mL; 20 minutes) is justified based on demonstrated maintenance of sink conditions across physiological pH ranges, ensuring no impact on dissolution kinetics or drug release mechanism. Comparative dissolution studies confirm that profile shape, release rate, and similarity factor ($f2 \geq 50$) remain unaffected under the proposed conditions. The method retains adequate discriminatory capability and robustness, as confirmed through method variability and stress testing. The extended time point compensates for reduced hydrodynamic volume while ensuring complete drug release within specification limits. Therefore, the modified conditions remain scientifically valid and compliant with FDA dissolution guidance principles for immediate-release solid oral dosage forms. Meanwhile, after

		receiving your query, we have tested the same on the innovator specs (900 mL; 20 minutes) as advised by yourself also in the query and it had observed that the results from both methods found satisfactory results. However as recommended by yourself also we had revised the dissolution test method as per innovator specifications (900 mL; 20 minutes). Results of the revised specs as per innovator and Revised SAP is submitted Firm has also submitted fee Rs 9400/- on deposit slip# 97060539207 for revision of specifications
	Decision	
	Approved	
210	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	(YVT-B89-E2UQ, 2024-03-12)
	Detail of Fee Submitted	30000.0, 2023-12-04,
	The proposed proprietary name / brand name	**Pharbion injection**
	Label Claim	Each 3 ml of ampoule contains: Vitamin B1 (Thiamine hydrochloride) .....100 mg Vitamin B6 (Pyridoxine hydrochloride)..... 100 mg Vitamin B12 (Cyanocobalamin) ..... 1000 mcg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3ml-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30C
	For generic drugs (me-too Status)	Neurobion Injection by Martin Dow Marker Ltd
	Pharmacotherapeutic Group of (API)	Vitamin B1 in combination with vitamin B6 and/or vitamin B12
	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 1000 ampoules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate dated 30-04-2022 specifying 100kg Pyridoxin HCl and 100kg Thiamine HCl. Firm has also submitted copy of clearance certificate dated 30-04-2022 specifying 01kg Cyanocobalamin.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Neurobion Injection by M Martin Dow Marker 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
	The status in reference regulatory authorities	Neurobion solution for injection Germany 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	Not submitted
	Evaluation Remarks	

Deferred in 353rd meeting of RB;

Deferment Reason	Firm's Response
Registration Board decided to defer the case for submission of assay results of cyanocobalamin on HPLC method	Firm has submitted assay results of cyanocobalamin by HPLC method

Decision

Approved

211	Case Category	New Section (Dr. Farhad Ullah)
	Name, address of Applicant.	**Bio-Labs(Pvt) Ltd** Plot 145, Industrial Triangle, Kahuta Road **(000296)**
	Application Form Dy. No / Tracking ID & date of submission	(BZU-WPZ-JLYR, 2024-12-20)
	Detail of Fee Submitted	30000.0, 2024-03-01,
	The proposed proprietary name / brand name	**Miniox 5% topical solution**
	Label Claim	Each ml contain: Minoxidil.....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	60ml-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30C
	For generic drugs (me-too Status)	Regro Solution 5% by M/s Seatle Private Ltd.,
	Pharmacotherapeutic Group of (API)	Vasodilator
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Kumar Organic Products Limited
	Detail of stability batches of drug product	3 batches having batch size of 150 Bottles each (60ml)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate issued dated 09-06-2023 specifying 100kg Minoxidil in name of M/s Maxitech Pharma,
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Minoxin 5% Topical Solution by M/s Brookes 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	Rogaine Extra Strength (for Men) 5% Topical Solution USFDA Approved
	GMP status of the firm	Not submitted
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of additional Section dated 27-09-2021 specifying Lotion (General) (in place of licensed Vaccine Veterinary Section).

Evaluation Remarks

Deferred in 348th meeting of RB;

Deferment Reason	Firm's Response
Deferred as decided in application of Miniox Topical Solution 2% (w/v) tracking ID; SH4-3W7-XGSP of M/s Bio-Labs (Pvt.) Ltd., presented in instant meeting.	The Board accepted M/s Bio-Labs (Pvt.) Ltd.'s apology for the administrative oversight and decided to issue Warning to M/s Bio-Labs (Pvt.) Ltd., for strict adherence to DRAP procedures. Miniox Topical Solution 2% (w/v) tracking ID; SH4-3W7-XGSP has been approved in 353rd meeting of RB.

Decision

	Approved	
212	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**Hicon Pharmaceuticals** 131- Industrial estate Hayatabad **(000583)**
	Application Form Dy. No / Tracking ID & date of submission	(4VJ-JEV-SPMJ, 2024-09-27)
	Detail of Fee Submitted	37000.0, 2024-09-16,
	The proposed proprietary name / brand name	**sp con forte 80mg tablet**
	Label Claim	Each tablet contains: Drotaverine HCL.....80mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 degree
	For generic drugs (me-too Status)	No-Spa Forte Tablet by Hoechst Pakistan Limited (029431)
	Pharmacotherapeutic Group of (API)	Antispasmodics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	cohance life sciences limited
	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 clearance certificate issued dated 12-07-2023 specifying 100kg Drotaverine Hydrochloride.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Relispa Forte 80mg Tablet
	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	Approved in 3 European countries (Poland, Hungary, Latvia).
	GMP status of the firm	The firm has submitted renewal of DML inspection report dated 17-03-2026, concluding that the facility is operating at good level of GMP compliance and unanimously recommended grant of renewal of DML
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved	
213	Case Category	Routine (Dr. Farhad Ullah)
	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	(TZ5-36H-L57P, 2024-08-21)

Detail of Fee Submitted	30000.0, 2024-02-13, 0000-00-00
The proposed proprietary name / brand name	**Motig 02mg Tablet**
Label Claim	Prucalopride Succinate Eq to Prucalopride--------2mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1x10`s-As per SRO,1x20`s-As per SRO,1x30`s-As per SRO,1x40`s-As per SRO,1x50`s-As per SRO
Shelf Life (Unit)	2 Year(s)15-30C
For generic drugs (me-too Status)	Pruvix 2mg tablet (prucalopride)by Horizons healthcare (Pvt)Ltd.
Pharmacotherapeutic Group of (API)	Other drugs for constipation
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	MS Metrochem API Private Limited
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 clearance certificate issued dated 06-04-2023 specifying 50gm Prucalopride Succinate.
Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and PE studies performed against Pruvix 2mg Table manufactured by M/s Horizon Healthcare
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	MOTEGRITY (prucalopride) 1mg & 2mg tablets, USFDA Approved
GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 05-05-2023.
Evidence of approval of manufacturing facility	Firm has submitted approval of layout plan and regularization letter dated 27-06-2022specifying tablet general section

Evaluation Remarks

Shortcomings	Firm's Response
Section approval letter from licensing division is required	Firm has submitted approval of layout plan and regularization letter dated 27-06-2022specifying tablet general section
Standardize the label claim and mention the salt form of applied product as per reference formulation along with submission of applicable fee	Firm has revised the label claim along with submission of Rs. 9400/- on deposit slip#5982479508. The revised label claim is; Each film coated tablet contains; Prucalopride Succinate equivalent to prucalopride……2mg
Valid copy of cGMP certificate or DML of API manufacturer issued by relevant regulatory authority of country of origin is required	Firm has submitted copy of cGMP certificate of API manufacturer valid upto 28-10-2022
Justification shall be submitted for selecting a different dissolution time (30minutes) in the finished product specifications compared to those recommended for the innovator product (20minutes).	Firm has submitted revised finished product dissolution method in which time for dissolution test has been revised. Firm has also fee Rs. 9400/- for revision of dissolution time on deposit slip#98837473394. The firm submitted that it was typographical mistake submitted revised dissolution method. The dissolution profile is also mentioned in 6th month, 9th month, 12th month, 18th month, 24th month and currently

		also performed with comparative dissolution with Pruvix 2mg tab.
	Decision	
	Approved Approved with following label claim; Each film coated tablet contains; Prucalopride Succinate equivalent to prucalopride……2mg	
214	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**shrooq pharmaceuticals pvt ltd** 21km feorzpur road lahore **(000577)**
	Application Form Dy. No / Tracking ID & date of submission	(UGH-4SX-JXZ5, 2024-07-30)
	Detail of Fee Submitted	30000.0, 2024-04-18,
	The proposed proprietary name / brand name	**Draz Ophthalmic Solution 2%**
	Label Claim	Each ml contains Dorzolamide HCl 2%
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5ml-As per SRO
	Shelf Life (Unit)	2 Year(s)2-25°C
	For generic drugs (me-too Status)	Glacu Ophthalmic Solution 2% by Ophth pharma Karachi
	Pharmacotherapeutic Group of (API)	Carbonic anhydrase inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Flax laboratories
	Detail of stability batches of drug product	3 batches having batch size of 01 Liter (192 bottles) each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate issued dated 17-09-2022 specifying 01kg Dorzolamide. Firm has also submitted copy of form 6 issued dated 12-05-2022 specifying 01kg Dorzolamide HCl.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Glacu Ophthalmic solution 2% by M/s Ophth 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	TRUSOPT 20mg/ml eye drops, solution MHRA Approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 01-12-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 20-01-2022 specifying Eye/Ear/Nose Drop section (New section).
	Evaluation Remarks	
	Shortcomings	Firm's Response
	Standardize the applied label claim as per the reference formulation along with submission of applicable fee	Firm has submitted the standardized label claim without submission of fee. Firm has submitted that it is already aligned with RRA product. Each ml contains: Dorzolamide as Hydrochloride…… 20 mg

	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved Approved with following label claim; Each ml contains: Dorzolamide as Hydrochloride……20 mg 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.	
215	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**Saffron Pharmaceuticals** 19-Km Sheikhupura Road **(000616)**
	Application Form Dy. No / Tracking ID & date of submission	(Z1R-LJA-EQ69, 2024-03-14)
	Detail of Fee Submitted	30000.0, 9400 2023-08-28, 2026-04-16
	The proposed proprietary name / brand name	**ERTU-MET 2.5mg/500mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid Eq. to Ertugliflozin ..... 2.5 mg Metformin HCl ..... 500mg (Manufacturer's Specifications)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	14's-As per SRO,20's-As per SRO,28's-As per SRO,7's-As per SRO
	Shelf Life (Unit)	24 Month(s)Do not store above 30°C.
	For generic drugs (me-too Status)	Ertuvia-M Tablet by Ferozsons Laboratories
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Ipca Laboratories Limited,H-4, M.I.D.C., Waluj Aurangabad (Maharashtra) Pin : 431136, India,Zhejiang Hongyuan Pharmaceutical Co. LTD. Chem & API's Industrial Zone, Linhai, Zhejiang, P.R. China.
	Detail of stability batches of drug product	3 batches having batch size of 800 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate dated 14-05-2022 specifying 0.25kg Ertugliflozin L-pyroglutamic acid. Firm has submitted copy of clearance certificate dated 26-06-2022 specifying 1000kg Metformin HCl.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies and CDP performed against Ertuvia-M 2.5mg/500mg Tablet by M/s Ferozsons Laboratories.
	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	Segluroet 2.5/500mg Tablet USFDA Approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 14-02-2024.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 16-05-2024 specifying Tablet I

		Section (General) (Regularization) and Tablet II Section (General) (Regularization)
	Evaluation Remarks	
	Deferred in 349th meeting of RB;	
	Deferment Reason	Firm's Response
	Deferred for submission of product development & batch release data wherein dissolution test shall have been performed as per recommendations of innovator drug product. Moreover, firm shall submit applicable fee for revision of data.	Firm has submitted revised finished product specifications, analytical method, CDP studies, product development and stability study data upto 3 months wherein dissolution test has been performed as per recommendations of innovator's product along with submission of Rs 9400/- on deposit slip#45470881851
	Decision	
	Approved Registration Board further decided that the registration letter shall be issued after submission of the remaining Pre-Registration Variation fee of Rs. 9950/-, as per S.R.O. 1399(I)/2025 dated 01-08-2025 for submission of afresh stability data of drug product.	
216	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**Saffron Pharmaceuticals** 19-Km Sheikhupura Road **(000616)**
	Application Form Dy. No / Tracking ID & date of submission	(Z6M-6AD-TQ94, 2024-03-15)
	Detail of Fee Submitted	30000.0, 9400 2023-09-13, 2026-04-16
	The proposed proprietary name / brand name	**ERTU-MET 7.5mg/500mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid Eq. to Ertugliflozin ..... 7.5 mg Metformin HCl ..... 500mg (Manufacturer's Specifications)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	14's-As per SRO,20's-As per SRO,28's-As per SRO,7's-As per SRO
	Shelf Life (Unit)	24 Month(s)Do not store above 30°C.
	For generic drugs (me-too Status)	Ertuvia-M Tablet by Ferozsons Laboratories
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Ipca Laboratories Limited,H-4, M.I.D.C., Waluj Aurangabad (Maharashtra) Pin : 431136, India,Zhejiang Hongyuan Pharmaceutical Co. LTD. Chem & API's Industrial Zone, Linhai, Zhejiang, P.R. China.
	Detail of stability batches of drug product	3 batches having batch size of 800 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate dated 14-05-2022 specifying 0.25kg Ertugliflozin L-pyroglutamic acid. Firm has submitted copy of clearance certificate dated 26-06-2022 specifying 1000kg Metformin HCl.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies and CDP performed against Ertuvia-M 7.5mg/500mg Tablet by M/s Ferozsons Laboratories.

	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	Segluroet 7.5/500mg Tablet USFDA Approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 14-02-2024.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 16-05-2024 specifying Tablet I Section (General) (Regularization) and Tablet II Section (General) (Regularization)
	Evaluation Remarks	
	Deferred in 349th meeting of RB;	
	Deferment Reason	Firm's Response
	Deferred for submission of product development & batch release data wherein dissolution test shall have been performed as per recommendations of innovator drug product. Moreover, firm shall submit applicable fee for revision of data.	Firm has submitted revised finished product specifications, analytical method, CDP studies, product development and stability study data upto 3 months wherein dissolution test has been performed as per recommendations of innovator's product along with submission of Rs 9400/- on deposit slip# 98180774
	Decision	
	Approved Registration Board further decided that the registration letter shall be issued after submission of the remaining Pre-Registration Variation fee of Rs. 9950/-, as per S.R.O. 1399(I)/2025 dated 01-08-2025 for submission of afresh stability data of drug product.	
217	Case Category	Routine (Dr. Farhad Ullah)
	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	(PWM-ME8-GL9X, 2024-06-28)
	Detail of Fee Submitted	30000.0, 2024-04-29,
	The proposed proprietary name / brand name	**Baclosol 10mg Tablets**
	Label Claim	Each Uncoated Tablet Contains; Baclofen .....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 Year(s)Below 30ºC
	For generic drugs (me-too Status)	Baclin 10mg Tablets, Manufacturer: Genome Pharmaceuticals (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	gamma-aminobutyric acid (GABA) agonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Panchsheel organic Ltd.
	Detail of stability batches of drug product	3 batches having batch size of 1500 capsule each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted a request letter for borrowing of API (indicating Baclofen 0.2kg) and loan agreement between M/s Solaris life sciences and M/s Seraph pharmaceuticals for API loan. Firm has submitted copy of clearance certificate dated 26-10-2023 specifying 25kg Baclefen in name of M/s Seraph Pharmaceuticals

	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Baclin10mg Tablets by M/s Genome Pharmaceuticals(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
	The status in reference regulatory authorities	Lioresal 10mg Tablets, Manufacturer: Novartis Ireland Limited (Registered in Ireland)
	GMP status of the firm	New DML issued dated 17-01-2024
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 17-01-2024 specifying Tablet Section-I (General).
	Evaluation Remarks	
	Deferred in 353rd meeting of RB;	
	Deferment Reason	Firm's Response
	Deferred for submission of valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	Firm has submitted copy of cGMP certificate of API manufacturer valid upto 5 years from date of issue (date of issue; 02-03-2022.) Firm has also submitted copy license retention certificate of API manufacturer valid upto 31-12-2026
	Decision	
	Approved	
218	Case Category	Routine (Dr. Farhad Ullah)
	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	(WRD-AZ2-E4TG, 2024-06-03)
	Detail of Fee Submitted	30000.0, 9400 2024-04-29, 2025-12-23
	The proposed proprietary name / brand name	**Baclosol 20mg Tablets**
	Label Claim	Each un-coated Tablet Contains; Baclofen .....20mg (USP Spec's)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30ºC
	For generic drugs (me-too Status)	Baclin 20mg Tablets, Manufacturer: Genome Pharmaceuticals (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	gamma-aminobutyric acid (GABA) agonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Panchsheel organic Ltd.
	Detail of stability batches of drug product	3 batches having batch size of 1500 capsule each
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Baclin 20mg Tablets by M/s Genome Pharmaceuticals(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

	The status in reference regulatory authorities	Baclofen 20mg Tablets Manufacturer: Sanis Health INC. (Registered in Canada)
	GMP status of the firm	New DML issued dated 17-01-2024
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 17-01-2024 specifying Tablet Section-I (General).
	Evaluation Remarks	
	Deferred in 353rd meeting of RB;	
	Deferment Reason	Firm's Response
	Deferred for submission of valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	Firm has submitted copy of cGMP certificate of API manufacturer valid upto 5 years from date of issue (date of issue; 02-03-2022.) Firm has also submitted copy license retention certificate of API manufacturer valid upto 31-12-2026
	Decision	
	Approved	
219	Case Category	Routine (Dr. Farhad Ullah)
	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	(LPL-HNR-LEM2, 2024-05-09)
	Detail of Fee Submitted	75000.0, 2024-05-08,
	The proposed proprietary name / brand name	**BEGENT OINTMENT**
	Label Claim	EACH GRAM CONTAINS: BETAMETHASONE DIPROPIONATE 0.64MG EQUIVALENT TO BETAMETHASON.....0.5MG GENTAMICIN SULPHATE 1.7MG EQUIVALENT TO GENTAMICIN.....
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	15gm-As per SRO,30gm-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a cool dry place, below 30oC.
	For generic drugs (me-too Status)	RELIGENT-B OINTMENT BY RELIANCE PHARMA
	Pharmacotherapeutic Group of (API)	Betamethasone Dipropionate(Corticosteroids) ATC code: D07XC01 Gentamicin Sulfate (Aminoglycoside Antibiotics) ATC code: J01GB03
	Name, address of Manufacturing site:	Global Pharmaceuticals Pakistan-Plot 8, Street No. S-8, R.C.C.I, Industrial Estate Rawat, Islamabad-Pakistan-
	Name & address of API manufacturer	ENVEE DRUGS PVT LTD ADDRESS: N . H . No. 8, DUMRAL-387 355, TA. NADIAD, DIST KHEDA GUJRAT, INDIA.,Fuan Pharmaceutical group Yantai justaware Pharmaceutical Co. Ltd. ADDRESS: No. 1 Yanfu Road, Zhifu District, Yantai, Shandong Province
	Detail of stability batches of drug product	2 batches having batch size of 500 tubes each

	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy loan letter from M/s Reliance pharma to M/s Global pharmaceuticals for procurement of API. Firm has submitted copy of clearance certificate dated 13-06-2023 and 14-07-2023 specifying 05kg Betamethasone Dipropionate and 30gm Gentamicin Sulphate respectively in name of M/s Global Pharmaceuticals
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Effigenta Ointment manufactured by M/s Mass 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	Diprogenta ointment Germany Approved
	GMP status of the firm	Applicant; Firm has submitted copy of cGMP certificate of the firm based on inspection dated 03-01-2022. Manufacturer; Firm has submitted copy of cGMP certificate of the firm based on inspection dated 19-01-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of renewal of DML dated 04-07-2022 specifying Ointment/Cream Section (General)
	Evaluation Remarks	
	Deferred in 353rd meeting of RB;	
	Deferment Reason	Firm's Response
	Deferred for submission of following; Copy of cGMP certificate / GMP inspection report of contract manufacturer conducted within last three years Valid copy of cGMP certificate / DML of the Drug Substance manufacturer for betamethasone and gentamycin issued by relevant regulatory authority of country of origin	Firm has submitted copy of panel inspection report of contract manufacturer for issuance of cGMP certificate dated 11-12-2025 and copy of application and submitted fee challan for issuance of cGMP certificate Firm has submitted copy of cGMP certificate of API manufacturer for betamethasone valid upto 17-08-2027. Firm has also submitted copy of retention of license of API manufacturer for betamethasone valid upto 25-02-2028 Firm has submitted copy of pharmaceutical production license of API manufacturer for gentamycin valid upto 15-10-2023.
	Decision	
	Approved	
220	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore **(000789)**
	Application Form Dy. No / Tracking ID & date of submission	(7VW-ZD7-Q325, 2024-09-13)
	Detail of Fee Submitted	75000.0, 7500 2024-08-27, 2026-04-15
	The proposed proprietary name / brand name	**Veriget 2.5mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Vericiguat.....2.5mg
	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(s)Store in a cool & Dry place below 30
	For generic drugs (me-too Status)	Reciquat Tablets 2.5mg by M/s Nabiqasim Industries
	Pharmacotherapeutic Group of (API)	Soluble guanylate cyclase (sGC) stimulators
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Nantong Chanyoo Pharmatech Co., Ltd Add: No.2 Tonghai Si Road, Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province 226407, China
	Detail of stability batches of drug product	3 batches having batch size of 1050 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 27-04-2024 specifying 0.0700kg Vericiguat. Firm has also submitted copy of goods declaration for procurement of API.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Verquvo 2.5mg Tablet by M/s Bayer AG, 51368 Leverkusen, Deutschland, 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	VERQUVO (vericiguat) tablet 2.5mg of M/s Bayer AG, Leverkusen, Germany (USFDA Approved)
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 03-04-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 07-02-2014 specifying Tablet (General Human) section.
	Evaluation Remarks	
	Shortcomings	Firm's Response
	Justification shall be submitted for selecting a dissolution time of 30 minutes in the finished product specifications, instead of 15 minutes as recommended for the innovator product.	Our product achieves required dissolution profile within 15 minutes as evident from submitted CDP. We are hereby submitting revised drug product analytical procedure with dissolution limits of 15 minutes, as per innovator. Firm has also submitted fee on deposit slip# 90542909563 for revision of specification.
	Pirfenidone 267 mg tablet is mentioned at the top of the table for CDP studies under acetate buffer conditions, while Vericiguat is mentioned below. Please clarify since applied product is vericiguat tablets.	We confirm that all Comparative Dissolution Profile (CDP) studies provided in the dossier correspond to Vericiguat tablets only. The document has been revised accordingly to correct this error. It was mistakenly written. As correct file is attached while its only in 4.5 buffer protocol.(see Attachment)
	Compliance record of HPLC 21 CFR compliance and audit trial are required	Audit trial report is submitted
	Decision	
	Approved	
221	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore **(000789)**
	Application Form Dy. No / Tracking ID & date of submission	(81Y-4ZJ-QXSP, 2024-09-23)

	Detail of Fee Submitted	75000.0, 2024-08-27,
	The proposed proprietary name / brand name	**Veriget 5mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Vericiguat.....5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 X 10's, 2 X 10's, -As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a cool & Dry place below 30
	For generic drugs (me-too Status)	Reciquat Tablets 5mg by M/s Nabiqasim Industries
	Pharmacotherapeutic Group of (API)	Soluble guanylate cyclase (sGC) stimulators
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Nantong Chanyoo Pharmatech Co., Ltd Add: No.2 Tonghai Si Road, Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province 226407, China
	Detail of stability batches of drug product	3 batches having batch size of 1050 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 27-04-2024 specifying 0.0700kg Vericiguat. Firm has also submitted copy of goods declaration for procurement of API.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Verquvo 5mg Tablet by M/s Bayer AG, 51368 Leverkusen, Deutschland, 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	VERQUVO (vericiguat) tablet 5mg of M/s Bayer AG, Leverkusen, Germany (USFDA Approved)
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 03-04-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 07-02-2014 specifying Tablet (General Human) section.
	Evaluation Remarks	
	Shortcomings	Firm's Response
	Justification shall be submitted for selecting a dissolution time of 30 minutes in the finished product specifications, instead of 15 minutes as recommended for the innovator product.	Our product achieves required dissolution profile within 15 minutes as evident from submitted CDP. We are hereby submitting revised drug product analytical procedure with dissolution limits of 15 minutes, as per innovator. Firm has also submitted fee on deposit slip# 10480521508 for revision of specification.
	Compliance record of HPLC 21 CFR compliance and audit trial are required	Audit trial report is submitted
	Decision	
	Approved	
222	Case Category	Routine (Dr. Farhad Ullah)
	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	(9U9-RVZ-89YD, 2024-07-11)
Detail of Fee Submitted	30000.0, 2024-06-27,
The proposed proprietary name / brand name	**Olan-7.5 Tablets**
Label Claim	Each film-coated tablet contains: Olanzapine.....7.5mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	10 Tablets-As per SRO
Shelf Life (Unit)	2 Year(s)Below 30°C
For generic drugs (me-too Status)	Nilcosyn 7.5mg Tablet, Indus Pharma (Pvt.) Ltd.
Pharmacotherapeutic Group of (API)	Psycholeptics, diazepines, oxazepines, thiazepines and oxepines
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Smilax Laboratories Limited.
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 clearance certificate issued dated 29-08-2023 specifying 15kg olanzapine.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Zyprexa 7.5mg tablets by Eli Lilly
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	Zyprexa 7.5mg Coated Tablets, Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands
GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 11-01-2024.
Evidence of approval of manufacturing facility	Submitted

Evaluation Remarks

Shortcomings	Firm's Response
Revise the label claim as film coated tablet in section 1.5.2 as per reference formulation along with submission of applicable fee	Firm has revised the label claim as per reference formulation along with submission of fee Rs. 9400/- on deposit slip#900295871333. Each film coated tablet contains: Olanzapine……7.5mg
Mention the USP dissolution test number used for the dissolution test of the applied product. Furthermore, clarification shall be submitted for providing UV method for dissolution test in analytical method instead of HPLC as per USP monograph	Firm submitted that USP Test 1, as per USP was initially followed for the applied product. However, the use of the UV method for dissolution testing was inadvertently overlooked by the analyst. Subsequently, upon review, it was realized that the USP monograph specifies the HPLC method for dissolution testing. Therefore, the analytical method was revised accordingly in compliance with the USP requirements, and the updated method has been submitted for reference. Furthermore, As supporting evidence, Last time point stability data as per USP Compliance HPLC Assay and HPLC dissolution has also been submitted.
Dissolution test results in the stability study have been performed using UV method instead of HPLC. Clarification is required	Firm has submitted that USP Test 1, as per USP was initially followed for the applied product. However, the use of the UV method for dissolution testing was inadvertently overlooked by the analyst. Subsequently, upon review, it was realized that the USP monograph specifies the HPLC method for dissolution testing. Therefore,

		the analytical method was revised accordingly in compliance with the USP requirements, and the updated method has been attached for reference. Furthermore, As supporting evidence, Last time point stability data as per USP Compliance HPLC Assay and HPLC dissolution has also been submitted.
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is required	Audit trial report is submitted
	Decision	
	Deferred Deferred for verification of the authenticity of the submitted stability data by the panel constituted by the Chairman, Registration Board, with specific focus on the dissolution testing at initially submitted 6th month and final (24th month) data.	
223	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore **(000789)**
	Application Form Dy. No / Tracking ID & date of submission	(XJW-GDV-VZ5A, 2024-09-18)
	Detail of Fee Submitted	75000.0, 2024-08-27,
	The proposed proprietary name / brand name	**Veriget 10mg Tablet**
	Label Claim	Each Film coated tablet contains Vericiguat 10mg
	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 in a cool & Dry place below 30
	For generic drugs (me-too Status)	Reciquat Tablets 10mg by M/s Nabiqasim Industries
	Pharmacotherapeutic Group of (API)	Soluble guanylate cyclase (sGC) stimulators
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Nantong Chanyoo Pharmatech Co., Ltd Add: No.2 Tonghai Si Road, Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province 226407, China
	Detail of stability batches of drug product	3 batches having batch size of 1050 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 27-04-2024 specifying 0.0700kg Vericiguat. Firm has also submitted copy of goods declaration for procurement of API.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Verquvo 10mg Tablet by M/s Bayer AG, 51368 Leverkusen, Deutschland, 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	VERQUVO (vericiguat) tablet 10mg of M/s Bayer AG, Leverkusen, Germany (USFDA Approved)
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 03-04-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 07-02-2014 specifying Tablet

		(General Human) section.
	Evaluation Remarks	
	Shortcomings	Firm's Response
	Justification shall be submitted for selecting a dissolution time of 30 minutes in the finished product specifications, instead of 15 minutes as recommended for the innovator product.	Our product achieves required dissolution profile within 15 minutes as evident from submitted CDP. We are hereby submitting revised drug product analytical procedure with dissolution limits of 15 minutes, as per innovator. Firm has also submitted fee on deposit slip# 6797933827 for revision of specification.
	Compliance record of HPLC 21 CFR compliance and audit trial are required	Audit trial report is submitted
	Decision	
	Approved	
224	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**Saffron Pharmaceuticals** 19-Km Sheikhupura Road **(000616)**
	Application Form Dy. No / Tracking ID & date of submission	(37N-PY6-4VJD, 2024-03-12)
	Detail of Fee Submitted	30000.0, 9400 2023-08-28, 2026-04-16
	The proposed proprietary name / brand name	**ERTU-MET 2.5mg/1000mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid Eq. to Ertugliflozin ..... 2.5 mg Metformin HCl ..... 1000mg (Manufacturer's Specifications)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	7's-As per SRO
	Shelf Life (Unit)	24 Month(s)Do not store above 30°C.
	For generic drugs (me-too Status)	Ertuvia-M Tablet by Ferozsons Laboratories
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhejiang Hongyuan Pharmaceutical Co. LTD. Chem & API's Industrial Zone, Linhai, Zhejiang, P.R. China.
	Detail of stability batches of drug product	3 batches having batch size of 750 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate dated 14-05-2022 specifying 0.25kg Ertugliflozin L-pyroglutamic acid. Firm has submitted copy of clearance certificate dated 26-06-2022 specifying 1000kg Metformin HCl.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies and CDP performed against Ertuvia-M 2.5mg/1000mg Tablet by M/s Ferozsons Laboratories.
	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	(Segluroet 2.5/1000mg Tablet) USFDA approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 14-02-2024.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 16-05-2024 specifying Tablet I Section (General) (Regularization) and Tablet II Section (General) (Regularization)
	Evaluation Remarks	
	Deferred in 349th meeting of RB;	
	Deferment Reason	Firm's Response
	Deferred for submission of product development & batch release data wherein dissolution test shall have been performed as per recommendations of innovator drug product. Moreover, firm shall submit applicable fee for revision of data.	Firm has submitted revised finished product specifications, analytical method, CDP studies, product development and stability study data upto 3 months wherein dissolution test has been performed as per recommendations of innovator's product along with submission of Rs 9400/- on deposit slip# 369668468
	Decision	
	Approved Registration Board further decided that the registration letter shall be issued after submission of the remaining Pre-Registration Variation fee of Rs. 9950/-, as per S.R.O. 1399(I)/2025 dated 01-08-2025 for submission of afresh stability data of drug product.	
225	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**Scotmann Pharmaceuticals** Plot #5D , Industrial Area, I-10/3 Islamabad **(000498)**
	Application Form Dy. No / Tracking ID & date of submission	(V74-41B-8G8X, 2024-10-31)
	Detail of Fee Submitted	37000.0, 2024-10-11,
	The proposed proprietary name / brand name	**Advance-O Capsule 12mg/25mg**
	Label Claim	Each capsule contains: Olanzapine..... 12mg Fluoxetine as HCl..... 25mg (USP Specifications)
	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,7's-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30 °C
	For generic drugs (me-too Status)	CO-Olan 12mg/25mg Capsule, Manufactured by: Medizan Laboratories (Pvt) Ltd.
	Pharmacotherapeutic Group of (API)	Olanzapine: Atypical antipsychotics Fluoxetine HCl: Selective Serotonin Reuptake Inhibitors (SSRIs)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Source of Drug Substance: Satyadivis Pharmaceuticals Pvt. Ltd. Address: Survey No.

	733, Chinna Kondur Village, Choutuppal Mandal, Yadari Bhuvanagiri, District-508252, Telangana State, Indi Survey No. 10 Gaddapotaram (V), Khazipally I.D.A., Jinnaram (M), S,Source of Drug Substance: Vision Drugs Private Limited. Address: Survey No. 733, Chinna Kondur Village, Choutuppal Mandal, Yadari Bhuvanagiri, District-508252, Telangana State, India.
Detail of stability batches of drug product	3 batches having batch size of 1500 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 28-12-2022 specifying 300gm Olanzapine. Firm has submitted copy of clearance certificate issued dated 13-12-2022 specifying 25kg Fluoxetine HCl.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against CO-OLAN Capsule 12mg/25mg manufactured by M/s Medizan Laboratories
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	Olanzapine and Fluoxetine Hydrochloride 12mg;25mg USFDA Approved
GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 22-02-2024.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 26-04-2024 specifying Capsule Section (General)

Evaluation Remarks

Shortcomings	Firm's Response
Justification shall be submitted for using six unit for dissolution test in CDP studies instead of 12 units as recommended by WHO guideline for conducting comparative dissolution profiles	The firm submitted that the comparative dissolution data generated using 12 units/tablets, in accordance with WHO recommendations, had already been submitted at the time of dossier submission. For the submitted CDP studies, the total 12 tablets for both test and innovator products were evaluated in two phases, as detailed below: Phase 1: Comparative dissolution performed using 6 tablets each of test and innovator products, and the similarity factor (f2) was calculated separately for this set. Phase 2: Comparative dissolution performed using the remaining 6 tablets each of test and innovator products, and the similarity factor (f2) was again calculated separately for this set. Thus, the overall CDP assessment comprised 12 units/tablets per product, with f2 similarity evaluation performed independently for each set of 6 tablets, ensuring compliance with WHO guideline requirements. The results from both phases collectively demonstrate comparable dissolution behavior between the test and innovator products.
Justification shall be submitted for not including the test for uniformity of dosage units in finished product specifications as per USP monograph	The firm submitted that Content Uniformity testing was being performed routinely at the finished product stage as part of our quality control process. However, it was inadvertently not included in the approved product specifications. We have now revised the Method of Analysis (MOA) and product specifications to

		explicitly include the Content Uniformity test, ensuring full compliance with regulatory requirements. Firm has also submitted fee Rs. 9400/- on deposit slip#9892597048 for revision of specifications.

Decision

Approved

The firm shall submit revised CDP data generated using 12 units in a single study, along with combined calculations (% release, mean, and similarity factor), instead of presenting results from two separate phases of 6 units each.

226	Case Category	Routine (Dr. Farhad Ullah)
	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	(YQN-6XL-1LQS, 2024-10-17)
	Detail of Fee Submitted	37000.0, 38000 2024-10-01, 2026-04-20
	The proposed proprietary name / brand name	**Olan-20 Tablets**
	Label Claim	Olanzapine 20mg Tablets
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10 Tablets-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Psycholeptics, diazepines, oxazepines, thiazepines and oxepines
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Smilax Laboratories Limited.
	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 clearance certificate issued dated 29-08-2023 specifying 15kg olanzapine.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Malanxin 20mg Tablet by M/s Maddox Pharma Netherland
	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	Zyprexa 20mg Coated Tablets Netherlands Approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 11-01-2024.
	Evidence of approval of manufacturing facility	Submitted

Evaluation Remarks

Shortcomings	Firm's Response
Submit evidence of me-too product or submit differential fee as applied product is a new strength	Firm has submitted fee Rs. 38000/- on deposit slip#24857769 as applied strength is new strength

	Mention the USP dissolution test number used for the dissolution test of the applied product. Furthermore, clarification shall be submitted for providing UV method for dissolution test in analytical method instead of HPLC as per USP monograph	Firm submitted that USP Test 1, as per USP was initially followed for the applied product. However, the use of the UV method for dissolution testing was inadvertently overlooked by the analyst. Subsequently, upon review, it was realized that the USP monograph specifies the HPLC method for dissolution testing. Therefore, the analytical method was revised accordingly in compliance with the USP requirements, and the updated method has been submitted for reference. Furthermore, As supporting evidence, Last time point stability data as per USP Compliance HPLC Assay and HPLC dissolution has also been submitted. Firm has also submitted fee Rs. 9400/- on deposit slip#2644134593 for revision of dissolution method
	Dissolution test results in the stability study have been performed using UV method instead of HPLC. Clarification is required	Firm has submitted that USP Test 1, as per USP was initially followed for the applied product. However, the use of the UV method for dissolution testing was inadvertently overlooked by the analyst. Subsequently, upon review, it was realized that the USP monograph specifies the HPLC method for dissolution testing. Therefore, the analytical method was revised accordingly in compliance with the USP requirements, and the updated method has been attached for reference. Furthermore, As supporting evidence, Last time point stability data as per USP Compliance HPLC Assay and HPLC dissolution has also been submitted.
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is required	Audit trial report is submitted
	Decision	
	Deferred Deferred for verification of the authenticity of the submitted stability data by the panel constituted by the Chairman, Registration Board, with specific focus on the dissolution testing at initially submitted 6th month and final (24th month) data.	
227	Case Category	Routine (Farooq Aslam)
	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	(RJ9-LXU-DT87, 2024-09-02)

	Detail of Fee Submitted	75000.0, 2024-07-12,
	The proposed proprietary name / brand name	**Eslicarb**
	Label Claim	Each tablet contains: Eslicarbazepine Acetate.....600mg
	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,60'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)	could not be confirmed
	Pharmacotherapeutic Group of (API)	Anti-epileptic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CTX LIFE SCIENCES PVT. LTD, Block no 251/P 252/P 253/P to 255, 256/P, 276/ P, 277,278/P 279 to 282 283/P, and 284/P, GIDC, SACHIN, DISTT SURAT, and GUJRAT STATE, INDIA.
	Detail of stability batches of drug product	03 bathes (Batch size: 700 tablets) 06 months real time and 06 months accelerated as per zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 for 6kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e.Eslicarbazepine acetate 600mg tablet by M/s Aristo Pharma GmbH.
	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 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 03-01-2023 is submitted.
	Evidence of approval of manufacturing facility	Tablet General section is approved.
	Evaluation Remarks	
	The firm shall submit valid GMP certificate of drug substance manufacturer.	
	Decision	
	Approved The firm shall submit valid GMP certificate of drug substance manufacturer before issuance of registration letter.	
228	Case Category	Routine (Farooq Aslam)
	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	(JS1-8BA-H5SY, 2024-08-29)
	Detail of Fee Submitted	75000.0, 2024-07-12,
	The proposed proprietary name / brand name	**Eslicarb 400mg Tablet**
	Label Claim	Each tablet contains: Eslicarbazepine Acetate..... 400mg
	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,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)	could not be confirmed
	Pharmacotherapeutic Group of (API)	Anti-epileptic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CTX LIFE SCIENCES PVT. LTD. Address : Block no 251/P 252/P 253/P to 255, 256/P, 276/ P, 277,278/P 279 to 282 283/P, and 284/P, GIDC, SACHIN, DISTT SURAT, and GUJRAT STATE, INDIA.
	Detail of stability batches of drug product	03 bathes (Batch size: 1000 tablets) 06 months real time and 06 months accelerated as per zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 for 6kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Zebinix tablet by M/s Bial Portela & C, EMA.
	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 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 03-01-2023 is submitted.
	Evidence of approval of manufacturing facility	Tablet General section is approved.
	Evaluation Remarks	
	The firm shall submit valid GMP certificate of drug substance manufacturer.	
	Decision	
	Approved The firm shall submit valid GMP certificate of drug substance manufacturer before issuance of registration letter.	
229	Case Category	Routine (Farooq Aslam)
	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	(USG-HX6-41WB, 2024-08-26)
	Detail of Fee Submitted	75000.0, 2024-07-12,
	The proposed proprietary name / brand name	**Eslicarb**
	Label Claim	Each Tablet Contains: Eslicarbazepine Acetate.....200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	20's-As per SRO,60'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)	could not be confirmed
	Pharmacotherapeutic Group of (API)	Anti-epileptic
	Name, address of Manufacturing site:	Self Manufacturing

	Name & address of API manufacturer	CTX LIFE SCIENCES PVT. LTD, Block no 251/P 252/P 253/P to 255, 256/P, 276/ P, 277,278/P 279 to 282 283/P, and 284/P, GIDC, SACHIN, DISTT SURAT, and GUJRAT STATE, INDIA.
	Detail of stability batches of drug product	03 bathes (Batch size: 1000 tablets) 06 months real time and 06 months accelerated as per zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 for 6kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Zebinix tablet by M/s Bial Portela & C, EMA.
	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 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 03-01-2023 is submitted.
	Evidence of approval of manufacturing facility	Tablet General section is approved.
	Evaluation Remarks	
	The firm shall submit valid GMP certificate of drug substance manufacturer.	
	Decision	
	Approved The firm shall submit valid GMP certificate of drug substance manufacturer before issuance of registration letter.	
230	Case Category	Routine (Farooq Aslam)
	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	(N6V-HVX-WNDY, 2024-09-02)
	Detail of Fee Submitted	75000.0, 2024-07-12,
	The proposed proprietary name / brand name	**Eslicarb**
	Label Claim	Each tablet contains: Eslicarbazepine Acetate.....800mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	20's-As per SRO,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)	could not be confirmed
	Pharmacotherapeutic Group of (API)	Anti-epileptic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CTX LIFE SCIENCES PVT. LTD, Block no 251/P 252/P 253/P to 255, 256/P, 276/ P, 277,278/P 279 to 282 283/P, and 284/P, GIDC, SACHIN, DISTT SURAT, and GUJRAT STATE, INDIA.
	Detail of stability batches of drug product	03 bathes (Batch size: 700 tablets) 06 months real time and 06 months accelerated as per zone IV-A.

	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 for 6kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Zebinix tablet by M/s Bial Portela & C, EMA.
	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 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 03-01-2023 is submitted.
	Evidence of approval of manufacturing facility	Tablet General section is approved.
	Evaluation Remarks	
	The firm shall submit valid GMP certificate of drug substance manufacturer.	
	Decision	
	Approved The firm shall submit valid GMP certificate of drug substance manufacturer before issuance of registration letter.	
231	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**QADIR PHARMACEUTICALS** FATEH GHAR SAHUWALA ROAD SIALKOT **(000944)**
	Application Form Dy. No / Tracking ID & date of submission	(85U-H5U-AX58, 2024-11-05)
	Detail of Fee Submitted	37000.0, 2024-10-18,
	The proposed proprietary name / brand name	**ANGIQAD 10mg/160mg Tablets**
	Label Claim	Each film-coated tablet contains: Amlodipine as amlodipine besylate.....10mg Valsartan.....160mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2x7's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C and protect from light
	For generic drugs (me-too Status)	Exforge 10mg/160mg Tablets
	Pharmacotherapeutic Group of (API)	Antihypertensive
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Prudence Pharma chem. & Zhuhai Rundu Pharmaceutical Co., 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	Approved in EMA, HPRA, EMC, FDA regulatory authorities.
	GMP status of the firm	..
	Evidence of approval of manufacturing facility	Table General Section is approved

	Evaluation Remarks	
	The firm was asked to provide stability data of Amlodipine according to zone IV-A, the firm has submitted the data of zone II by changing the storage conditions of already submitted data.	
	Decision	
	Rejected The Board, upon deliberation, emphasized that the integrity and authenticity of submitted information is a basic requirement for the fair proceeding. In light of the submission of falsified and edited stability data pertaining to the drug substance by the applicant, the Board decided to reject the case.	
232	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**QADIR PHARMACEUTICALS** FATEH GHAR SAHUWALA ROAD SIALKOT **(000944)**
	Application Form Dy. No / Tracking ID & date of submission	(ZBQ-21G-RR68, 2024-11-05)
	Detail of Fee Submitted	37000.0, 2024-10-18,
	The proposed proprietary name / brand name	**ANGIQAD 5mg/80mg Tablets**
	Label Claim	Each film-coated tablet contains: 5mg of Amlodipine (as amlodipine besylate) and 80mg of Valsartan
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2x7's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C and protect from light
	For generic drugs (me-too Status)	Exforge 5mg/80mg Tablets
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Prudence Pharma chem. & Zhuhai Rundu Pharmaceutical Co., 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	Approved in EMA, HPRA, EMC, FDA regulatory authorities.
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm was asked to provide stability data of Amlodipine according to zone IV-A, the firm has submitted the data of zone II by changing the storage conditions of already submitted data.	
	Decision	
	Rejected The Board, upon deliberation, emphasized that the integrity and authenticity of submitted information is a basic requirement for the fair proceeding. In light of the submission of falsified and	

	edited stability data pertaining to the drug substance by the applicant, the Board decided to reject the case.	
233	Case Category	Any Other (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	(Q7W-RTZ-8QVR, 2026-02-03)
	Detail of Fee Submitted	38700, 2025-11-24,
	The proposed proprietary name / brand name	**TADAFLO 20mg Tablet**
	Label Claim	Each film coated tablet contains: Tadalafil.....20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x2's, 1x4's, 1x5's, 1x6's, 2x4's, 1x10's, 1x14's, 2x10's and 3x10's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Donot store over 30ºC
	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	Century Pharmaceuticals Limited
	Detail of stability batches of drug product	03 batches (Batch size: 2500 tablets) 06 months acc and 06 months real time
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 06-01-2025 for 0.5kg material is submitted,
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against 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 zone IV-A is submitted.
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	Valid until 30-06-2027
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been processed on priority in compliance to the decision of DRAP Authority.	
	Decision	
	Approved	
234	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	**Jawa Pharmaceuticals (Pvt) Ltd** 112/10 Quaid-e-Azam Industrial Area, Kot Lakhpat, Lahore **(000150)**
	Application Form Dy. No / Tracking ID & date of submission	(6QH-BTP-41Y4, 2025-11-10)
	Detail of Fee Submitted	37000, 1700 2025-07-24, 2025-10-06
	The proposed proprietary name / brand name	**Viralon Tablet 20mg**
	Label Claim	Each film coated Tablet Contains: Tadalafil ..... 20mg (As per USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1×6's-As per SRO

	Shelf Life (Unit)	2 Year(s)Store at 30 Degree Protect From light & Moisture
	For generic drugs (me-too Status)	FILDIL 20MG TABLETS BY HIGHNOON LABORTORIES LTD
	Pharmacotherapeutic Group of (API)	Phosphodiesterase 5 (PDE5) inhibitors.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited
	Detail of stability batches of drug product	03 batches: (Batch size: 2000 tablets) 06 months accelerated and 06 months real time stability data according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 22-03-2025 for 0.3kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Cialis 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 zone IV-A is submitted.
	The status in reference regulatory authorities	TADALAFIL 20MG TABLETS BY TEVA PHARMA S.L.U., C/C,n.4, Poligono Industrial Malpica, Zaragoza, 50016, Spain
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 13-10-2023 & 07-11-2023 is submitted.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been processed in compliance to the decision of DRAP Authority.	
	Decision	
	Approved	
235	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	**dwa Pharmaceuticals (Pvt) Ltd** 112/10 Quaid-e-Azam Industrial Area, Kot Lakhpat, Lahore **(000150)**
	Application Form Dy. No / Tracking ID & date of submission	(VQM-GZ9-XJVD, 2026-01-07)
	Detail of Fee Submitted	38700, 2025-11-26,
	The proposed proprietary name / brand name	**Viralon Tablet 10mg**
	Label Claim	Each film coated tablet contains: Tadalafil 10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10 ?s-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 30 Degree Protect From light & Moisture
	For generic drugs (me-too Status)	FILDIL 10MG TABLETS BY HIGHNOON LABORTORIES LTD
	Pharmacotherapeutic Group of (API)	Phosphodiesterase 5 (PDE5) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	03 batches: (Batch size: 2000 tablets) 06 months accelerated and 06 months real time stability data according to zone IV-A.

	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 22-03-2025 for 0.3kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Cialis 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 zone IV-A is submitted.
	The status in reference regulatory authorities	TADALAFIL 10MG TABLETS BY TEVA PHARMA S.L.U., C/C,n.4, Poligono Industrial Malpica, Zaragoza, 50016, Spain
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 13-10-2023 & 07-11-2023 is submitted.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been processed in compliance to the decision of DRAP Authority.	
	Decision	
	Approved	
236	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	**Herbion Pakistan (Pvt.) Ltd.** Industrial Triangle, Kahuta road, Humak, Islamabad **(000795)**
	Application Form Dy. No / Tracking ID & date of submission	(26Y-VLV-442E, 2025-11-10)
	Detail of Fee Submitted	75000, 2025-11-06,
	The proposed proprietary name / brand name	**TDF 2.5 mg Tablet**
	Label Claim	Each film coated tablet contains: Tadalafil..... 2.5 mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10s-De-Controlled,12s-De-Controlled,14s-De-Controlled,28s-De-Controlled,2s-De-Controlled,4s-De-Controlled,6s-De-Controlled,84s-De-Controlled,8s-De-Controlled
	Shelf Life (Unit)	2 Year(s)15 to 30
	For generic drugs (me-too Status)	Fildil (Highnoon laboratories ltd)
	Pharmacotherapeutic Group of (API)	phosphodiesterase 5 (PDE5) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Synergene Active Ingredients Pvt Ltd, Unit II, Plot No: 59 - D, Jawaharlal Nehru Pharma city, Parawada Mandal, Vishakapatnam, Dist 531021. AP. India
	Detail of stability batches of drug product	B# ST25D007, B# ST25D008, B#ST25D009 (Batch size: 1500 tablet) 06 months accelerated and 06 months real time
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 29-11-2024 for 350 grams of material along with unattested inovice is submitted, Clearance certificate is not submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and Pe studies have been performed against Cialis Tablet

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 36 months real time stability data of 03 batches according to zone IV-B is submitted.
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	GMP Valid till 01-07-2027
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been processed in compliance to the decision of DRAP Authority.	
	Decision	
	Approved	
237	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	**Herbion Pakistan (Pvt.) Ltd.** Industrial Triangle, Kahuta road, Humak, Islamabad **(000795)**
	Application Form Dy. No / Tracking ID & date of submission	(JT4-W7P-82RR, 2025-11-10)
	Detail of Fee Submitted	75000, 2025-11-06,
	The proposed proprietary name / brand name	**TDF 5 mg Tablet**
	Label Claim	Each film coated tablet contains:- Tadalafil..... 5 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10s-De-Controlled,14s-De-Controlled,28s-De-Controlled,2s-De-Controlled,4s-De-Controlled,6s-De-Controlled,84s-De-Controlled,8s-De-Controlled
	Shelf Life (Unit)	2 Year(s)15 to 30
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	phosphodiesterase 5 (PDE5) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Synergene Active Ingredients Pvt Ltd, Unit II, Plot No: 59 - D, Jawaharlal Nehru Pharma city, Parawada Mandal, Vishakapatnam, Dist 531021. AP. India
	Detail of stability batches of drug product	B# ST25D004, B# ST25D005, B#ST25D006 (Batch size: 1500 tablet) 06 months acc and 06 months real time
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 29-11-2024 for 350 grams of material along with unattested inovice is submitted, Clearance certificate is not submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and Pe studies have been performed against Cialis Tablet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Studies attached as per Zone IV
	The status in reference regulatory authorities	https://www.accessdata.fda.gov/scripts/cder/daf/index.event=BasicSearch.process
	GMP status of the firm	GMP Valid till 01-07-2027
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been processed in compliance to the decision of DRAP Authority.	
	Decision	

	Approved	
238	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	**Herbion Pakistan (Pvt.) Ltd.** Industrial Triangle, Kahuta road, Humak, Islamabad **(000795)**
	Application Form Dy. No / Tracking ID & date of submission	(PY8-334-3B99, 2025-11-24)
	Detail of Fee Submitted	38700, 2025-11-20,
	The proposed proprietary name / brand name	**TDF 10 mg Tablet**
	Label Claim	Each film coated tablet contains: Tadalafil..... 10 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10s-De-Controlled,12s-De-Controlled,14s-De-Controlled,28s-De-Controlled,2s-De-Controlled,4s-De-Controlled,6s-De-Controlled,84s-De-Controlled,8s-De-Controlled
	Shelf Life (Unit)	2 Year(s)15 to 30
	For generic drugs (me-too Status)	Fildil 10 mg Tablet , Highnoon Laboratories Ltd.
	Pharmacotherapeutic Group of (API)	phosphodiesterase 5 (PDE5) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Synergene Active Ingredients Pvt Ltd. Unit II, Plot No: 59 - D, Jawaharlal Nehru Pharma city, Parawada Mandal, Vishakapatnam, Dist 531021. AP. India
	Detail of stability batches of drug product	B# ST25D017, B# ST25D018, B#ST25D019 (Batch size: 1500 tablet) 06 months acc and 06 months real time
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 29-11-2024 for 350 grams of material along with unattested inovice is submitted, Clearance certificate is not submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	conducted against Fildil 10 mg Tablet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 36 months real time stability data of 03 batches according to zone IV-B is submitted.
	The status in reference regulatory authorities	https://www.accessdata.fda.gov/scripts/cder/daf/index.event=BasicSearch.process
	GMP status of the firm	GMP Valid till 01-07-2027
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been processed in compliance to the decision of DRAP Authority.	
	Decision	
	Approved	
239	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	**Herbion Pakistan (Pvt.) Ltd.** Industrial Triangle, Kahuta road, Humak, Islamabad **(000795)**
	Application Form Dy. No / Tracking ID & date of submission	(R77-W1Q-X2YV, 2025-11-24)

	Detail of Fee Submitted	38700, 2025-11-20,
	The proposed proprietary name / brand name	**TDF 20 mg Tablet**
	Label Claim	Each film coated tablet contains: Tadalafil..... 20 mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10s-De-Controlled,12s-De-Controlled,14s-De-Controlled,28s-De-Controlled,2s-De-Controlled,4s-De-Controlled,6s-De-Controlled,84s-De-Controlled,8s-De-Controlled
	Shelf Life (Unit)	2 Year(s)15 to 30
	For generic drugs (me-too Status)	Fildil 20 mg Tablet , Highnoon Laboratories Ltd.
	Pharmacotherapeutic Group of (API)	phosphodiesterase 5 (PDE5) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Synergene Active Ingredients Pvt Ltd. Unit II, Plot No: 59 - D, Jawaharlal Nehru Pharma city, Parawada Mandal, Vishakapatnam, Dist 531021. AP. India
	Detail of stability batches of drug product	B# ST25D005, B# ST25D006, B#ST25D007 (Batch size: 1500 tablet) 06 months acc and 06 months real time
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 29-11-2024 for 350 grams of material along with unattested inovice is submitted, Clearance certificate is not submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	conducted against Fildil 20 mg Tablet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 36 months real time stability data of 03 batches according to zone IV-B is submitted.
	The status in reference regulatory authorities	https://www.accessdata.fda.gov/scripts/cder/daf/index.event=BasicSearch.process
	GMP status of the firm	GMP Valid till 01-07-2027
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been processed in compliance to the decision of DRAP Authority.	
	Decision	
	Approved	
240	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	**AGP Limited** B-23-C, S.I.T.E., Karachi **(000348)**
	Application Form Dy. No / Tracking ID & date of submission	(XLR-DWW-93UD, 2026-01-05)
	Detail of Fee Submitted	38700, 2025-10-21,
	The proposed proprietary name / brand name	**Ciafil Tablet 10mg**
	Label Claim	Each film coated tablet contains: Tadalafil.....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's (2x2's),10's (1x10's), 20's(2x10's) & 40's (4x10's), -De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30° C
	For generic drugs (me-too Status)	Tadalis by Hilton Pharma, Pakistan

	Pharmacotherapeutic Group of (API)	Phosphodiesterase type 5 (PDE5) inhibitors.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CENTURY PHARMACEUTICALS LIMITED
	Detail of stability batches of drug product	3 months accelerated & 3 months long term stability studies and ongoing (at zone IV-A)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 30-08-2023 for 2kg material along with GD No.KPAF-8770-2023 dated 24-09-2023 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Tadalafil 10mg Tablet by Torrent Pharmaceutical Ltd. India USFDA Approved NDC 13668-567-30
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	6 months accelerated & 60 months long term stability studies at zone IV-A for 03 batches.
	The status in reference regulatory authorities	Cialis tablet by Eli Lilly Nederland B.V
	GMP status of the firm	GMP certificate valid till 14.10. 2028,
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been processed in compliance to the decision of DRAP Authority.	
	Decision	
	Approved	
241	Case Category	Any Other (Farooq Aslam)
	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	(SNA-31S-HPUQ, 2026-01-07)
	Detail of Fee Submitted	38700, 2025-11-05,
	The proposed proprietary name / brand name	**Akdala 2.5mg Tab**
	Label Claim	Each film coated tablet contains: Tadalafil.....2.5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10s, As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 centigrade
	For generic drugs (me-too Status)	Fildil 2.5mg Tab
	Pharmacotherapeutic Group of (API)	Phosphodiesterase 5 (PDE5) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century pharmaceuticals LTD
	Detail of stability batches of drug product	03 batches: Batch size: 1000 tablets 06 months acc and 06 months real time
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 26-03-2025 for 0.2kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and Pe studies have been performed against Fildil 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 zone IV-A is submitted,
	The status in reference regulatory authorities	FDA Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 05-05-2023

	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been processed in compliance to the decision of DRAP Authority.	
	Decision	
	Approved	
242	Case Category	Any Other (Farooq Aslam)
	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	(S1A-R28-LV4Z, 2026-02-03)
	Detail of Fee Submitted	38700, 2025-11-05,
	The proposed proprietary name / brand name	**Akdala 5mg Tab**
	Label Claim	Each film coated tablet contains: Tadalafil.....5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10s, As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 centigrade
	For generic drugs (me-too Status)	Fildil 5mg Tab
	Pharmacotherapeutic Group of (API)	Phosphodiesterase 5 (PDE5) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century pharmaceuticals LTD
	Detail of stability batches of drug product	03 batches: Batch size: 1000 tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 26-03-2025 for 0.2kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and Pe studies have been performed against Fildil 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 zone IV-A is submitted,
	The status in reference regulatory authorities	FDA Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 05-05-2023
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been processed in compliance to the decision of DRAP Authority.	
	Decision	
	Approved	
243	Case Category	Any Other (Farooq Aslam)
	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	(78Q-7X3-Q69S, 2026-02-03)
	Detail of Fee Submitted	38700, 2025-11-05,
	The proposed proprietary name / brand name	**Akdala 10mg Tab**

	Label Claim	Each film coated tablet contains: Tadalafil.....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10s, As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 centigrade
	For generic drugs (me-too Status)	Fildil 10mg Tab
	Pharmacotherapeutic Group of (API)	Phosphodiesterase 5 (PDE5) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century pharmaceuticals LTD
	Detail of stability batches of drug product	03 batches: Batch size: 1000 tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 26-03-2025 for 0.2kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and Pe studies have been performed against Fildil 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 zone IV-A is submitted,
	The status in reference regulatory authorities	FDA Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 05-05-2023
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been processed in compliance to the decision of DRAP Authority.	
	Decision	
	Approved	
244	Case Category	Any Other (Farooq Aslam)
	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	(6Q4-Q51-1LVQ, 2026-02-03)
	Detail of Fee Submitted	38700, 2025-11-05,
	The proposed proprietary name / brand name	**Akdala 20mg Tab**
	Label Claim	Each film coated tablet contains: Tadalafil.....20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10s, As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 centigrade
	For generic drugs (me-too Status)	Fildil 20mg Tab
	Pharmacotherapeutic Group of (API)	Phosphodiesterase 5 (PDE5) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century pharmaceuticals LTD
	Detail of stability batches of drug product	03 batches: Batch size: 1000 tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 26-03-2025 for 0.2kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and Pe studies have been performed against Fildil 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 zone IV-A is submitted,
	The status in reference regulatory authorities	FDA Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 05-05-2023
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been processed in compliance to the decision of DRAP Authority.	
	Decision	
	Approved	
245	Case Category	Routine (Farooq Aslam)
	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	(L6B-JT2-TYGT, 2024-10-23)
	Detail of Fee Submitted	37000.0, 2024-10-10,
	The proposed proprietary name / brand name	**Carvedol**
	Label Claim	Each film-coated tablet contains; Carvedilol.....3.125mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,28's-De-Controlled,30's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Carveda 3.125mg Tablet
	Pharmacotherapeutic Group of (API)	Nonselective adrenergic blocker
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	N/A
	Detail of stability batches of drug product	03 batches (Batch size: 7142 tablet) 06 months accelerated and 06 months real time stability data according to zone Iv-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 25-01-2024 for 2kg of material is submitted. Copy of GD No. KPAF-2401-2024 Date: 06-03-2024.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. Carveda tablet by M/s Ferozsons Laboratories Limited.
	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-B.
	The status in reference regulatory authorities	Coreg Tablets -USFDA
	GMP status of the firm	GMP certificate issues on the basis of inspection conducted on 17-05-2023 is submitted.
	Evidence of approval of manufacturing facility	Tablet General Section I and II are approved.
	Evaluation Remarks	
	Form 6 dated 25-01-2024 for 2kg of material is submitted.Copy of GD No. KPAF-2401-2024 Date: 06-03-2024.	
	Decision	

	Approved	
246	Case Category	Routine (Farooq Aslam)
	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	(NVJ-T9X-3VA3, 2024-10-23)
	Detail of Fee Submitted	37000.0, 2024-10-10,
	The proposed proprietary name / brand name	**Carvedol**
	Label Claim	Each film-coated tablet contains; Carvedilol.....6.25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,28's-De-Controlled,30's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Carveda 6.25mg Tablet
	Pharmacotherapeutic Group of (API)	Nonselective adrenergic blocker
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shodhana Laboratories Private Limited
	Detail of stability batches of drug product	03 batches (Batch size: 6896 tablet) 06 months accelerated and 06 months real time stability data according to zone Iv-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 25-01-2024 for 2kg of material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. Carveda tablet by M/s Ferozsons Laboratories Limited.
	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-B.
	The status in reference regulatory authorities	Coreg Tablets -USFDA
	GMP status of the firm	GMP certificate issues on the basis of inspection conducted on 17-05-2023 is submitted.
	Evidence of approval of manufacturing facility	Tablet General Section I and II are approved.
	Evaluation Remarks	
	Form 6 dated 25-01-2024 for 2kg of material is submitted.Copy of GD No. KPAF-2401-2024 Date: 06-03-2024.	
	Decision	
	Approved	
247	Case Category	Routine (Farooq Aslam)
	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	(Q3S-PEL-2778, 2024-10-23)
	Detail of Fee Submitted	37000.0, 2024-10-10,
	The proposed proprietary name / brand name	**Carvedol**

	Label Claim	Each Film-coated Tablet Contains: Carvedilol.....25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,28's-De-Controlled,30's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Carveda 25mg Tablet by Ferozsons Labs
	Pharmacotherapeutic Group of (API)	Nonselective adrenergic blocker
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shodhana Laboratories Pvt Limited
	Detail of stability batches of drug product	03 batches (Batch size: 4545 tablet) 06 months accelerated and 06 months real time stability data according to zone Iv-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 25-01-2024 for 2kg of material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. Carveda tablet by M/s Ferozsons Laboratories Limited.
	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-B.
	The status in reference regulatory authorities	Coreg 25mg Tablet (USFDA Approved)
	GMP status of the firm	GMP certificate issues on the basis of inspection conducted on 17-05-2023 is submitted.
	Evidence of approval of manufacturing facility	Tablet General Section I and II are approved.
	Evaluation Remarks	
	Form 6 dated 25-01-2024 for 2kg of material is submitted.Copy of GD No. KPAF-2401-2024 Date: 06-03-2024.	
	Decision	
	Approved	
248	Case Category	Routine (Farooq Aslam)
	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	(WPS-NXB-SRJN, 2024-10-23)
	Detail of Fee Submitted	37000.0, 2024-10-10,
	The proposed proprietary name / brand name	**Carvedol**
	Label Claim	Each Film-Coated Tablet Contains: Carvedilol.....12.5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,28's-De-Controlled,30's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Carveda 12.5mg Tablet by Ferozsons Labs
	Pharmacotherapeutic Group of (API)	Nonselective adrenergic blocker
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shodhana Laboratories Pvt Limited

	Detail of stability batches of drug product	03 batches (Batch size: 4761 tablet) 06 months accelerated and 06 months real time stability data according to zone Iv-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 25-01-2024 for 2kg of material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. Carveda tablet by M/s Ferozsons Laboratories Limited.
	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-B.
	The status in reference regulatory authorities	Coreg 12.5mg Tablet (USFDA Approved)
	GMP status of the firm	GMP certificate issues on the basis of inspection conducted on 17-05-2023 is submitted.
	Evidence of approval of manufacturing facility	Tablet General Section I and II are approved.
	Evaluation Remarks	
	Form 6 dated 25-01-2024 for 2kg of material is submitted.Copy of GD No. KPAF-2401-2024 Date: 06-03-2024.	
	Decision	
	Approved	
249	Case Category	Routine (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	(E8S-TR8-BLEY, 2024-10-08)
	Detail of Fee Submitted	30000.0, 9400 2024-09-02, 2026-02-24
	The proposed proprietary name / brand name	**IGN Tablets 500mg**
	Label Claim	Each film-coated tablet contains: Imeglimin HCl 500mg
	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 below 30°C. Protect from Sunlight & Moisture
	For generic drugs (me-too Status)	Ameeg Tablets by AGP Limited
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Metrochem API Private Limited
	Detail of stability batches of drug product	Batches: IMG-1052-08/24, IMG-1052-09/24, IMG-1052-10/24 (Batch Size: 1600 tablets) 06 months real time and 06 months accelerated stability data according t zone IV-A is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 05-09-2023 for 3kg material is submitted. Unattested invoice and copy of airway bill are submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the innovator's product i.e. Twymeeg 500mg tablet by M/s Sumitomo Pharma, Japan.

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 12 months real time stability data of 03 batches according to the conditions of zone IV-B.
	The status in reference regulatory authorities	PMDA Approved - Twymeeg Tablets 500 mg by Sumitomo Dainippon Pharma Co., Ltd
	GMP status of the firm	GMP certificate issued on the basis of inspection condutced on 23-10-2023.
	Evidence of approval of manufacturing facility	Tablet General Section is approved. GMP certificate issued on the basis of inspection conducted on 23-01-2023.
	Evaluation Remarks	
	Form 6 dated 05-09-2023 for 3kg material is submitted.Unattested invoice and copy of airway bill are submitted.	
	Decision	
	Approved	
250	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(3U1-837-WW7M, 2024-07-10)
	Detail of Fee Submitted	30000.0, 2024-07-04,
	The proposed proprietary name / brand name	**ASAP**
	Label Claim	Each enteric coated tablet contains: Acetylsalicylic acid.....81mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's, 20's, 30's-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 degree
	For generic drugs (me-too Status)	Aslow 81mg tablet, Helix pharma
	Pharmacotherapeutic Group of (API)	NSAID
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Hebei Jingye Medical Technology Corp., LTD.
	Detail of stability batches of drug product	03 bathces (Batch size: 1000 tablets) 06 months real time and 06 months accelerated according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 06-06-2022 for 1kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Aspirin 81mg enteric coated tablet by M/s Bayer Spain.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 48 months real time stability data of 03 batches according to zone IV-A.
	The status in reference regulatory authorities	Health Canada approved - ASPIRIN-81mg Tablet; Bayer Inc. (https://health-products.canada.ca/dpd-bdpp/info?lang=eng&code=91745)
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 22-05-2023.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	

	The firm shall submit valid DML/GMP of drug substance manufacturer.	
	Decision	
	Approved Subject to submission of valid DML/GMP of drug substance manufacturer.	
251	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(PW4-78Q-TBEA, 2024-08-12)
	Detail of Fee Submitted	30000.0, 2024-07-15,
	The proposed proprietary name / brand name	**Bisolol Tablet 10mg**
	Label Claim	Each film-coated tablet contains: Bisoprolol Fumarate USP.....10mg
	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 below 30°C
	For generic drugs (me-too Status)	concor 10mg tablet by MartinDow.
	Pharmacotherapeutic Group of (API)	Antihypertensive
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Supriya Lifescience Ltd.
	Detail of stability batches of drug product	03 batches, Batch size: 5000 tablets 06 months real time and 06 months accelerated stability data according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 13-10-2023 for 0.4kg material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. Concor tablet by M/s MartinDow.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 24 months real time stability data of 03 batches according to zone IV-B
	The status in reference regulatory authorities	MHRA Approved (Bisoprolol 10 mg Film-coated Tablet by Accord Healthcare Limited, United Kingdom)
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 22-05-2023.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	Decision	
	Approved	
252	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(H53-7BD-29P1, 2024-08-23)
	Detail of Fee Submitted	30000.0, 2024-07-15,
	The proposed proprietary name / brand name	**Bisolol Tablet 2.5mg**

	Label Claim	Each film-coated tablet contains: Bisoprolol Fumarate USP.....2.5mg
	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 below 30°C
	For generic drugs (me-too Status)	concor 2.5mg tablet by MartinDow.
	Pharmacotherapeutic Group of (API)	Antihypertensive
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Supriya Lifescience Ltd.
	Detail of stability batches of drug product	03 batches, Batch size: 2000 tablets 06 months real time and 06 months accelerated stability data according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 13-10-2023 for 0.4kg material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. Concor tablet by M/s MartinDow.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 24 months real time stability data of 03 batches according to zone IV-B
	The status in reference regulatory authorities	MHRA Approved (Bisoprolol 2.5 mg Film-coated Tablet by Accord Healthcare Limited, United Kingdom)
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 22-05-2023.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	Decision	
	Approved	
253	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(GE1-V57-HMNB, 2024-08-22)
	Detail of Fee Submitted	30000.0, 2024-07-15,
	The proposed proprietary name / brand name	**Bisolol Tablet 5mg**
	Label Claim	Each film-coated tablet contains: Bisoprolol Fumarate USP.....5mg
	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 below 30°C
	For generic drugs (me-too Status)	concor 5mg tablet by MartinDow.
	Pharmacotherapeutic Group of (API)	Antihypertensive
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Supriya Lifescience Ltd.
	Detail of stability batches of drug product	03 batches, Batch size: 2000 tablets 06 months real time and 06 months accelerated stability data according to zone IV-A.

	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 13-10-2023 for 0.4kg material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. Concor tablet by M/s MartinDow.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 24 months real time stability data of 03 batches according to zone IV-B
	The status in reference regulatory authorities	MHRA Approve (Bisoprolol 5 mg Film-coated Tablet by Accord Healthcare Limited, United Kingdom)
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 22-05-2023.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	Decision	
	Approved	
254	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Dyson Research Laboratories (Pvt.) Ltd** 28-Km Ferozpur Road Lahore **(000559)**
	Application Form Dy. No / Tracking ID & date of submission	(DL8-JZL-2TVZ, 2024-10-29)
	Detail of Fee Submitted	75000.0, 2024-08-26,
	The proposed proprietary name / brand name	**Deflazacort**
	Label Claim	Each tablet contains: Deflazacort.....18mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3 x 10's Alu/Alu Bli-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Not Available.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Swati Spentose Private Limited (Unit-II) situated at Plot No: A-1/2111, III Phase, G.I.D.C. VAPI – 396 195 Valsad, Gujrat State 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	Deflazacort Tablet 18mg, USFDA Approved.
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm was asked to provide Section Approval letter for Tablet (Steroidal) Section since you have submitted section approval letter for Tablet (Steroidal Hormone) Section while the applied product	

	is Steroidal Tablet.	
	Reply: The firm has stated that the active metabolite of Deflazacort binds to glucocorticoid receptor and mimics the action of cortisol which is a natural hormone. Moreover, the firm has stated that the export registration (EX-011959) has already been granted.	
	Decision	
	Rejected The Board discussed that Deflazacort is classified as corticosteroid, and therefore the Tablet Steroidal Section is required. However, the applicant does not have the approved section of Steroidal Tablet. The applicant has provided the evidence of approval of Tablet Steroidal Hormone Section therefore, the Board decided to reject the case. The Board further directed PE&R division for issuance of show cause for cancellation of export only registration.	
255	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Dyson Research Laboratories (Pvt.) Ltd** 28-Km Ferozpur Road Lahore **(000559)**
	Application Form Dy. No / Tracking ID & date of submission	(Z6X-3UE-TUYH, 2024-10-02)
	Detail of Fee Submitted	75000.0, 2024-08-26,
	The proposed proprietary name / brand name	**Deflazacort**
	Label Claim	Each tablet contains: Deflazacort.....6mg
	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 YearStore below 30C
	For generic drugs (me-too Status)	Not Available.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Swati spentose (Pvt.) Ltd (Unit-II). situated at Plot No: A-1/2111, III Phase, G.I.D.C. VAPI – 396 195 Valsad, Gujrat State 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	Defal Tablet 6mg. Applied formulation is registered in Spanish Agency for Medicines and Health Products
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm was asked to provide Section Approval letter for Tablet (Steroidal) Section since you have submitted section approval letter for Tablet (Steroidal Hormone) Section while the applied product is Steroidal Tablet.	
	Reply: The firm has stated that the active metabolite of Deflazacort binds to glucocorticoid receptor and mimics the action of cortisol which is a natural hormone. Moreover, the firm has stated that the export registration (EX-011959) has already been granted.	
	Decision	

	Rejected The Board discussed that Deflazacort is classified as corticosteroid, and therefore the Tablet Steroidal Section is required. However, the applicant does not have the approved section of Steroidal Tablet. The applicant has provided the evidence of approval of Tablet Steroidal Hormone Section therefore, the Board decided to reject the case. The Board further directed PE&R division for issuance of show cause for cancellation of export only registration.	
256	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Dyson Research Laboratories (Pvt.) Ltd** 28-Km Ferozpur Road Lahore **(000559)**
	Application Form Dy. No / Tracking ID & date of submission	(HHP-95M-3N9L, 2024-11-13)
	Detail of Fee Submitted	75000.0, 2024-10-17,
	The proposed proprietary name / brand name	**Deflazacort**
	Label Claim	Each tablet contains: Deflazacort.....36mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Alu x Alu blister (3-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Not Applicable.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Swati spentose (Pvt.) Ltd (Unit-II). situated at Plot No: A-1/2111, III Phase, G.I.D.C. VAPI – 396 195 Valsad, Gujrat State 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	Deflazacort Tablet 36mg, USFDA Approved.
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm was asked to provide Section Approval letter for Tablet (Steroidal) Section since you have submitted section approval letter for Tablet (Steroidal Hormone) Section while the applied product is Steroidal Tablet.	
	Reply: The firm has stated that the active metabolite of Deflazacort binds to glucocorticoid receptor and mimics the action of cortisol which is a natural hormone. Moreover, the firm has stated that the export registration (EX-011959) has already been granted.	
	Decision	
	Rejected The Board discussed that Deflazacort is classified as corticosteroid, and therefore the Tablet Steroidal Section is required. However, the applicant does not have the approved section of Steroidal Tablet. The applicant has provided the evidence of approval of Tablet Steroidal Hormone Section therefore, the Board decided to reject the case. The Board further directed PE&R division for issuance of show cause for cancellation of export only registration.	

257	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Hiranis Pharmaceuticals Pvt. Ltd.** E-145-149, North Western Industrial Zone, Port Qasim, Karachi-75020, Pakistan **(000785)**
	Application Form Dy. No / Tracking ID & date of submission	(XEP-EZW-AQSH, 2024-08-27)
	Detail of Fee Submitted	75000.0, 2024-07-11,
	The proposed proprietary name / brand name	**Safcort Oral Suspension**
	Label Claim	Each ml contains:- Deflazacort.....22.75mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO/DPC-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30C, protect from light and heat
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s ANUH PHARMA LIMITED
	Detail of stability batches of drug product	Batches: (Batch size: 250 bottles:13mL) 06 months real time and 06 months accelerated stability data is submitted according to the conditions of zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 15-04-2022 for 1.5kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the reference product i.e. Emflaza 22.75/mL suspension by M/s PTC Therap, USA.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 48 months real time stability data of 03 batches according to the conditions of zone IV-A.
	The status in reference regulatory authorities	EMFLAZA Oral Suspension ; PTC Therapeutics, Inc. South Plainfield, NJ 07080 U.S.A.
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 14-12-2023 is submitted.
	Evidence of approval of manufacturing facility	Liquid (Steroid) Section is approved as per Letter No. F.1-33/2009-Lic dated 07-02-2014. GMP certificate issued on the basis of inspection conducted on 14-12-2023 is submitted.
	Evaluation Remarks	
	The firm shall submit applicable fee for correction of specifications for LOD from 0.1% to 1% for DS.	
	Decision	
	Deferred Deferred for submission of system log/audit trail report of HPLC system and applicable fee for revision of specifications.	
258	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Hiranis Pharmaceuticals Pvt. Ltd.** E-145-149, North Western Industrial Zone, Port Qasim, Karachi-75020, Pakistan **(000785)**

	Application Form Dy. No / Tracking ID & date of submission	(494-TL5-XDNL, 2024-08-27)
	Detail of Fee Submitted	75000.0, 2024-07-10,
	The proposed proprietary name / brand name	**Safcort 36mg Tablet**
	Label Claim	Each tablet contains:- Deflazacort.....36mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO/DPC-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30C, protect from light and heat
	For generic drugs (me-too Status)	could not be confirmed
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s ANUH PHARMA LIMITED
	Detail of stability batches of drug product	Batches: T0010, T0011, T0012 (Batch size: 1000 tablets) 06 months real time and 06 months accelerated stability data is submitted according to the conditions of zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 15-04-2022 for 1.5kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Emflaza 36mg tablet by M/s PTC Therap, USA.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 48 months real time stability data of 03 batches according to the conditions of zone IV-A.
	The status in reference regulatory authorities	EMFLAZA 36MG TABLET
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 14-12-2023 is submitted.
	Evidence of approval of manufacturing facility	Tablet (Steroid) Section is approved as per Letter No. F.1-33/2009-Lic dated 07-02-2014. GMP certificate issued on the basis of inspection conducted on 14-12-2023 is submitted.
	Evaluation Remarks	
	The firm shall submit applicable fee for correction of specifications for LOD from 0.1% to 1% for DS.	
	Decision	
	Deferred Deferred for submission of system log/audit trail report of HPLC system and applicable fee for revision of specifications.	
259	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Hiranis Pharmaceuticals Pvt. Ltd.** E-145-149, North Western Industrial Zone, Port Qasim, Karachi-75020, Pakistan **(000785)**
	Application Form Dy. No / Tracking ID & date of submission	(3G1-WDD-J8QZ, 2024-08-27)
	Detail of Fee Submitted	30000.0, 2024-07-10,
	The proposed proprietary name / brand name	**Safcort 6mg Tablet**
	Label Claim	Each tablet contains:- Deflazacort.....6mg

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO/DPC-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30C, protect from light and heat
	For generic drugs (me-too Status)	could not be confirmed
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s ANUH PHARMA LIMITED
	Detail of stability batches of drug product	06 months real time and 06 months accelerated stability data is submitted according to the conditions of zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	.Clearance certificate dated 15-04-2022 for 1.5kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 48 months real time stability data of 03 batches according to the conditions of zone IV-A.
	The status in reference regulatory authorities	EMFLAZA 6MG TABLET USFDA Approved
	GMP status of the firm	The firm shall submit applicable fee for correction of specifications for LOD from 0.1% to 1% for DS.
	Evidence of approval of manufacturing facility	Tablet (Steroid) Section is approved as per Letter No. F.1-33/2009-Lic dated 07-02-2014. GMP certificate issued on the basis of inspection conducted on 14-12-2023 is submitted.
	Evaluation Remarks	
	The firm shall submit applicable fee for correction of specifications for LOD from 0.1% to 1% for DS.	
	Decision	
	Deferred Deferred for submission of system log/audit trail report of HPLC system and applicable fee for revision of specifications.	
260	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Hiranis Pharmaceuticals Pvt. Ltd.** E-145-149, North Western Industrial Zone, Port Qasim, Karachi-75020, Pakistan **(000785)**
	Application Form Dy. No / Tracking ID & date of submission	(MU4-61V-4ZYQ, 2024-07-26)
	Detail of Fee Submitted	75000.0, 2024-07-11,
	The proposed proprietary name / brand name	**Safcort 18mg Tablet**
	Label Claim	Each tablet contains:- Deflazacort.....18mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO/DPC-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30C, protect from light and heat
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s ANUH PHARMA LIMITED

	Detail of stability batches of drug product	Batches: T004, T005, T006 (Batch size: 1000 tablets) 06 months real time and 06 months accelerated stability data is submitted according to the conditions of zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 15-04-2022 for 1.5kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Emflaza 18mg tablet by M/s PTC Therap, USA.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 48 months real time stability data of 03 batches according to the conditions of zone IV-A.
	The status in reference regulatory authorities	EMFLAZA 18MG TABLET;Marathon Pharmaceuticals, LLC Northbrook, IL, 60062 U.S.A.
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 14-12-2023 is submitted.
	Evidence of approval of manufacturing facility	Tablet (Steroid) Section is approved as per Letter No. F.1-33/2009-Lic dated 07-02-2014. GMP certificate issued on the basis of inspection conducted on 14-12-2023 is submitted.
	Evaluation Remarks	
	The firm shall submit applicable fee for correction of specifications for LOD from 0.1% to 1% for DS.	
	Decision	
	Deferred Deferred for submission of system log/audit trail report of HPLC system and applicable fee for revision of specifications.	
261	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Hiranis Pharmaceuticals Pvt. Ltd.** E-145-149, North Western Industrial Zone, Port Qasim, Karachi-75020, Pakistan **(000785)**
	Application Form Dy. No / Tracking ID & date of submission	(TBU-ABX-5TDH, 2024-07-26)
	Detail of Fee Submitted	30000.0, 2024-07-10,
	The proposed proprietary name / brand name	**Safcort 30mg Tablet**
	Label Claim	Each tablet contains:- Deflazacort.....30mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO/DPC-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30C, protect from light and heat
	For generic drugs (me-too Status)	Calcort Tablet (Hoechst Marion Roussel)
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s ANUH PHARMA LIMITED
	Detail of stability batches of drug product	Batches: T007, T008, T009 (Batch size: 1000 tablets) 06 months real time and 06 months accelerated stability data is submitted according to the conditions of zone IV-A.

	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 15-04-2022 for 1.5kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Emflaza 30mg tablet by M/s PTC Therap, USA.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 48 months real time stability data of 03 batches according to the conditions of zone IV-A.
	The status in reference regulatory authorities	EMFLAZA 30MG TABLET; Marathon Pharmaceuticals, LLC Northbrook, IL, 60062 U.S.A.
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 14-12-2023 is submitted.
	Evidence of approval of manufacturing facility	Tablet (Steroid) Section is approved as per Letter No. F.1-33/2009-Lic dated 07-02-2014. GMP certificate issued on the basis of inspection conducted on 14-12-2023 is submitted.
	Evaluation Remarks	
	The firm shall submit applicable fee for correction of specifications for LOD from 0.1% to 1% for DS.	
	Decision	
	Deferred Deferred for submission of system log/audit trail report of HPLC system and applicable fee for revision of specifications.	
262	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Naeem Pharmaceuticals (SMC-Pvt) Ltd.** Plot No.95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan **(000986)**
	Application Form Dy. No / Tracking ID & date of submission	(R4W-2BW-VTSE, 2024-10-21)
	Detail of Fee Submitted	37000.0, 2024-09-24,
	The proposed proprietary name / brand name	**Meroval 200mg Tablet**
	Label Claim	Each film coated tablet contains: Sacubitril...97mg Valsartan....103mg (as sacubitril-Valsartan sodium salt complex)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14 s-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30 Degree C
	For generic drugs (me-too Status)	Savesto 200 Tablets Getz Pharma (Pvt) Limited. 093112
	Pharmacotherapeutic Group of (API)	Antihypertensive
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Nantong Chanyoo Pharmatech Co,LTD
	Detail of stability batches of drug product	03 batches: 1500 tablets 06 months real time and 06 months accelerated stability data acc to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan letter 20-01-2024 for 10kg material is submitted.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	....
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	According to zone II
	The status in reference regulatory authorities	Entresto 200mg Tablet Approved by MHRA/USFDA Approved
	GMP status of the firm	New License issued w.e.f 26-10-2023
	Evidence of approval of manufacturing facility	Tablet General Section is approved
	Evaluation Remarks	
	The firm has submitted same data of CDP and PE in all the 03 strength by changing the strength of the applied tablet in header.	
	Same chromatograms have been submitted in the 03 strengths. Name of sample name is changed while other parameters are exactly same e.g value of area, height, time & date etc.	
	Stability summary sheets have exactly the same values for all the parameters including assay and dissolution results for all the 03 strengths.	
	Decision	
	Rejected The Board was apprised that the applicant has submitted same data of pharmaceutical equivalence, comparative dissolution profile in all the applied 03 strengths of Sacubitril/Valsartan tablets by changing the strength tablet in the header only. The submitted chromatograms for all the 03 strengths have exactly the same values for different parameters for corresponding time points which is not possible practically. Furthermore, the submitted stability summary sheets have exactly same results for all the parameters including assay and dissolution for all the strengths. The Board showed concerns over the data integrity issue and decided to reject the case.	
263	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Naeem Pharmaceuticals (SMC-Pvt) Ltd.** Plot No.95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan **(000986)**
	Application Form Dy. No / Tracking ID & date of submission	(M17-VUV-BUB1, 2024-10-21)
	Detail of Fee Submitted	37000.0, 2024-09-24,
	The proposed proprietary name / brand name	**Meroval Plus 50mg Tablet**
	Label Claim	Each film coated tablet contains: Sacubitril...24mg Valsartan....26mg (as sacubitril-Valsartan sodium salt complex)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14 s-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30 Degree
	For generic drugs (me-too Status)	Savesto 50 Tablets Getz Pharma 093110(Pvt) Limited.
	Pharmacotherapeutic Group of (API)	Antihypertensive
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Nantong Chanyoo Pharmatech Co Ltd
	Detail of stability batches of drug product	03 batches: 1500 tablets 06 months real time and 06 months accelerated stability data acc to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan letter 20-01-2024 for 10kg material is submitted.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Entresto tablet by M/s Novartis.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	..
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	New License issued w.e.f 26-10-2023
	Evidence of approval of manufacturing facility	Tablet General Section is approved
	Evaluation Remarks	
	The firm has submitted same data of CDP and PE in all the 03 strength by changing the strength of the applied tablet in header.	
	Same chromatograms have been submitted in the 03 strengths. Name of sample name is changed while other parameters are exactly same e.g value of area, height, time & date etc.	
	Stability summary sheets have exactly the same values for all the parameters including assay and dissolution results for all the 03 strengths.	
	Decision	
	Rejected The Board was apprised that the applicant has submitted same data of pharmaceutical equivalence, comparative dissolution profile in all the applied 03 strengths of Sacubitril/Valsartan tablets by changing the strength tablet in the header only. The submitted chromatograms for all the 03 strengths have exactly the same values for different parameters for corresponding time points which is not possible practically. Furthermore, the submitted stability summary sheets have exactly same results for all the parameters including assay and dissolution for all the strengths. The Board showed concerns over the data integrity issue and decided to reject the case.	
264	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Naeem Pharmaceuticals (SMC-Pvt) Ltd.** Plot No.95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan **(000986)**
	Application Form Dy. No / Tracking ID & date of submission	(ERG-ZZE-YVPW, 2024-10-09)
	Detail of Fee Submitted	37000.0, 2024-09-24,
	The proposed proprietary name / brand name	**Meroval 100mg Tablet**
	Label Claim	Each film coated tablet contains: Sacubitril...49mg Valsartan....51mg (as sacubitril-Valsartan sodium salt complex)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	28 s,56 s-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30 degree C
	For generic drugs (me-too Status)	Savesto 100 Tablets Getz Pharma (Pvt) Limited Reg .NO 093111
	Pharmacotherapeutic Group of (API)	Antihypertensive
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Nantong Chanyoo Pharmatech Co Ltd,China
	Detail of stability batches of drug product	03 batches: 1500 tablets 06 months real time and 06 months accelerated stability data acc to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan letter 20-01-2024 for 10kg material is submitted.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	.....
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	According to zone II
	The status in reference regulatory authorities	Entresto 100 tablet MHRA Approved
	GMP status of the firm	New License issued w.e.f 26-10-2023
	Evidence of approval of manufacturing facility	Tablet General Section is approved
	Evaluation Remarks	
	The firm has submitted same data of CDP and PE in all the 03 strength by changing the strength of the applied tablet in header.	
	Same chromatograms have been submitted in the 03 strengths. Name of sample name is changed while other parameters are exactly same e.g value of area, height, time & date etc.	
	Stability summary sheets have exactly the same values for all the parameters including assay and dissolution results for all the 03 strengths.	
	Decision	
	Rejected The Board was apprised that the applicant has submitted same data of pharmaceutical equivalence, comparative dissolution profile in all the applied 03 strengths of Sacubitril/Valsartan tablets by changing the strength tablet in the header only. The submitted chromatograms for all the 03 strengths have exactly the same values for different parameters for corresponding time points which is not possible practically. Furthermore, the submitted stability summary sheets have exactly same results for all the parameters including assay and dissolution for all the strengths. The Board showed concerns over the data integrity issue and decided to reject the case.	
265	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	**Highnoon Laboratories Pvt Ltd** 13 Km Lahore Road Multan **(000578)**
	Application Form Dy. No / Tracking ID & date of submission	(8R6-4DQ-L37T, 2026-01-08)
	Detail of Fee Submitted	38700, 2025-12-12,
	The proposed proprietary name / brand name	**TALDEX 10mg Tablet**
	Label Claim	Each film coated tablet contains: Tadalafil 10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4`s and 10`s-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30%
	For generic drugs (me-too Status)	Fildil 10mg Tablet Highnoon Laboratories Ltd 127634
	Pharmacotherapeutic Group of (API)	Phosphodiesterase type 5 (PDE5) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	03 batches (Batch Size; 1500 tablets) 06 months real time and 06 months accelerated stability data according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 24-02-2025 for 0.03Kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. Tadalis by Hilton Pharma.

	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 zone IV-B.
	The status in reference regulatory authorities	CIALIS 10 mg Tablet Lilly USA, LLC Indianapolis, IN 46285, USA FDA Approved.
	GMP status of the firm	GMP Valid Till 19.11.2028 GMP Certificate NO GM_-C-EAFF51
	Evidence of approval of manufacturing facility	Phosphodiesterase type 5 (PDE5) inhibitors
	Evaluation Remarks	
	The application has been processed on priority in compliance to the decision of DRAP Authority for ED drugs.	
	Decision	
	Approved	
266	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	**Don Valley** don valley pharmaceuticals (Pvt.) Ltd, 31 kilometer main Ferozepur Road Lahore **(000395)**
	Application Form Dy. No / Tracking ID & date of submission	(4SV-93P-UDWL, 2026-02-03)
	Detail of Fee Submitted	38700, 2025-12-17,
	The proposed proprietary name / brand name	**Peformix**
	Label Claim	Each film-coated tablet contains Tadalafil 20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5's, 10's, 14's, 30's-De-Controlled
	Shelf Life (Unit)	2 Year(s)store below 30 degree
	For generic drugs (me-too Status)	Fildil Tablet by Highnoon Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Urologicals, Drugs used in erectile dysfunction
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	03 batches (Batch size: 1500 tablets) 06 months accelerated and 06 months real time stability data according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 20-01-2025 for 0.25kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Cialis 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 zone IV-A.
	The status in reference regulatory authorities	USA (FDA Approved)
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 22-03-2024.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been processed on priority in compliance to the decision of DRAP Authority regarding ED drugs.	
	Decision	

	Approved	
267	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	**Bio-Labs(Pvt) Ltd** Plot 145, Industrial Triangle, Kahuta Road **(000296)**
	Application Form Dy. No / Tracking ID & date of submission	(714-5LT-8L17, 2026-01-05)
	Detail of Fee Submitted	38700, 2025-10-09,
	The proposed proprietary name / brand name	**Dalafil**
	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 10's 12's 14's 28's 84's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30C
	For generic drugs (me-too Status)	Edifil 5mg Tablet Highnoon
	Pharmacotherapeutic Group of (API)	Urologicals; 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	03btahces (batch size: 1000 tablet) 06 months accelerated and 06 months real time stability data according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 20-04-2025 for 0.2Kg material is submited.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Cialis tablet.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 60 moths real time stability data of 03 batches according to zone IV-A is submitted,
	The status in reference regulatory authorities	Cialis Tablets 5mg Lilly Spain
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 17-10-2025.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been processed on priority in compliance to the decision of DRAP Authority regarding ED drugs.	
	Decision	
	Approved	
268	Case Category	Any Other (Farooq Aslam)
	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	(XSP-P23-549P, 2026-02-04)
	Detail of Fee Submitted	38700, 2025-11-12,
	The proposed proprietary name / brand name	**Ax-Celis 10mg Tablet**
	Label Claim	Each tablet contains: Tidalafil----10mg
	Reference to Finished product specifications	United States Pharmacopeia

	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,20's-De-Controlled,5's-De-Controlled,7's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Fildil 10mg Tablet by Highnoon Labs. lTD.
	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	03 batches (Batch size 2500 tablets)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clerance certificate dated 13-06-2025 for 0.5kgmaterial is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Fildil Tablet by Highnoon.
	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 zone IV-A.
	The status in reference regulatory authorities	Cialis Tablet 10mg FDA Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 03-07-2024.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been processed on priority in compliance to the decision of DRAP Authority regarding ED drugs.	
	Decision	
	Approved	
269	Case Category	Any Other (Farooq Aslam)
	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	(URW-5MN-S8L1, 2026-02-23)
	Detail of Fee Submitted	38700, 2025-11-12,
	The proposed proprietary name / brand name	**Ax-Celis 20mg Tablet**
	Label Claim	Each film coated tablet contains: Tadalafil---- -20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,20's-De-Controlled,5's-De-Controlled,7's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Fildil 20mg Tablet by Hignoon Labs. Ltd.
	Pharmacotherapeutic Group of (API)	phosphodiesterase-5 (PDE5) inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhejiang Huahai Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	03 batches (Batch size 2500 tablets)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clerance certificate dated 13-06-2025 for 0.5kgmaterial is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Fildil Tablet by Highnoon.

	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 zone IV-A.
	The status in reference regulatory authorities	Cialis Tablet 20mg FDA Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 03-07-2024.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been processed on priority in compliance to the decision of DRAP Authority regarding ED drugs.	
	Decision	
	Approved	
270	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	**Bio-Labs(Pvt) Ltd** Plot 145, Industrial Triangle, Kahuta Road **(000296)**
	Application Form Dy. No / Tracking ID & date of submission	(467-7LM-A65R, 2026-01-05)
	Detail of Fee Submitted	38700, 2025-10-09,
	The proposed proprietary name / brand name	**Dalafil**
	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 10's 12's 14's 28's 84's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30C
	For generic drugs (me-too Status)	Fildil 20mg Tablet Highnoon
	Pharmacotherapeutic Group of (API)	Urologicals; 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	03btahces (batch size: 1000 tablet) 06 months accelerated and 06 months real time stability data according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 20-04-2025 for 0.2Kg material is submited.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Cialis tablet.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 60 moths real time stability data of 03 batches according to zone IV-A is submitted,
	The status in reference regulatory authorities	Cialis Tablets 20mg Lilly Spain
	GMP status of the firm	valid till 08-10-2025 Renewal been applied on PSW.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been processed on priority in compliance to the decision of DRAP Authority regarding ED drugs.	
	Decision	
	Approved	
271	Case Category	Routine (Farooq Aslam)

	Name, address of Applicant.	**Ferozsons Laboratories Limited** PO Ferozsons, Amangarh **(000038)**
	Application Form Dy. No / Tracking ID & date of submission	(9XB-B95-GMTE, 2024-08-02)
	Detail of Fee Submitted	75000.0, 2024-07-05,
	The proposed proprietary name / brand name	**Imeglin Tablets 500mg**
	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,14's-As per SRO,15's-As per SRO,20's-As per SRO,21's-As per SRO,25's-As per SRO,28's-As per SRO,30's-As per SRO,5'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)	Imeglu 500mg tablet by M/s AGP Limited.
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Ami Lifesciences Private Limited
	Detail of stability batches of drug product	Batches: 082NS04, 082NS05, 082NS06 (Batch Size: 700 tablets) 06 months accelerated and 06 months real time stability data according to the conditions of zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 18-07-2023 for 1.5KG material is submitted. Intimation letter regarding the receiving of raw material dated 12-08-2023 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the innovator's product i.e. Twymeeg tablet 500mg by M/s Sumitomo Pharma, Japan.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 24 months real time stability data of 03 batches according to the conditions of zone IV-A.
	The status in reference regulatory authorities	Brand Name: Twymeeg Tablets 500 mg Manufacturer: Sumitomo Pharma Co., Ltd - PMDA
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 16-05-2023.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	Form 6 dated 18-07-2023 for 1.5KG material is submitted.Intimation letter regarding the receiving of raw material dated 12-08-2023 is submitted.	
	Decision	
	Approved	
272	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Herbion Pakistan (Pvt.) Ltd.** Industrial Triangle, Kahuta road, Humak, Islamabad **(000795)**
	Application Form Dy. No / Tracking ID & date of submission	(4V7-JBH-URTG, 2024-08-27)
	Detail of Fee Submitted	30000.0, 2024-07-10,

The proposed proprietary name / brand name	**Volvo-H 10-160-12.5 mg Tablets**
Label Claim	Each Film coated Tablet contains: Amlodipine as Besylate .....10 mg Valsartan.....160 mg Hydrochlorothiazide.....12.5 mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	2x14s-De-Controlled,2x7s-De-Controlled
Shelf Life (Unit)	2 Year(s)25-30
For generic drugs (me-too Status)	Co-Extor 10-160-12.5 mg Tablets Manufactured by Searle Pharmaceuticals
Pharmacotherapeutic Group of (API)	Anti-hypertensive
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Cadila Pharmaceuticals Limited. 1389, Trasad Road Dholka-382225 Dist – Ahmedabad Gujarat - INDIA ,Changzhou Pharmaceutical Factory (Shortened as "Changzhou Pharma") Address: No.518 Laodong East Road, Changzhou, Jiangsu Province, P.R. China,Zhejiang Tianyu Pharmaceutical Co., Ltd. Address: No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China.
Detail of stability batches of drug product	03 batches (Batch size 3000 tablets) 03 month acc and 03 months real time
Documents for the procurement of API with approval from DRAP (in case of Import)	Amlodipine: Clearance certificate 21-09-2021 for 0.7kg material is submitted. Valsartan: Clearance certificate date 21-06-201 for 12kg material. HCT: Clearance certificate dated 08-07-2021 for 0.7kg material.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Exforge HCT tablet
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Amlodipine: 06 months accelerated Valsartan: 06 months accelerated and 36 months real time acc to zone IV-A. HCT: 06 months accelerated and 36 months real time.
The status in reference regulatory authorities	https://www.accessdata.fda.gov/drugsatfda_docs/l USFDA Approved
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 01-02-2024.
Evidence of approval of manufacturing facility	Tablet General Section is approved
Evaluation Remarks	
The firm was asked to provide real time stability data of Amlodipine according to zone IV-A. The firm has submitted the data of zone II by changing the storage conditions in stability summary sheets. Moreover, as per the details mentioned in 3.2.S.7 of HCT, the real time stability data is according to zone II whereas the summary sheets mention the storage conditions as per zone IV-A.	
Decision	
Rejected The Board, upon deliberation, emphasized that the integrity and authenticity of submitted information is a basic requirement for the fair proceeding. In light of the submission of falsified and edited stability data pertaining to the drug substances by the applicant, the Board decided to reject the case.	

273	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Herbion Pakistan (Pvt.) Ltd.** Industrial Triangle, Kahuta road, Humak, Islamabad **(000795)**
	Application Form Dy. No / Tracking ID & date of submission	(BNX-N2Q-ER6S, 2024-07-16)
	Detail of Fee Submitted	30000.0, 2024-07-10,
	The proposed proprietary name / brand name	**volvo-H 10-160-25 mg tablets**
	Label Claim	Each film coated tablet contains: Amlodipine as Besylate.....10mg Valsartan.....160mg Hydrochlorothiazide..... 25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14s and 2x14s-De-Controlled
	Shelf Life (Unit)	2 Year(s)25 to 30
	For generic drugs (me-too Status)	exforge HCT 10-160-25
	Pharmacotherapeutic Group of (API)	Anti-hypertensive
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Cadila Pharmaceuticals Limited. 1389, Trasad Road Dholka-382225 Dist – Ahmedabad Gujarat - INDIA,Changzhou Pharmaceutical Factory Shortened as Changzhou Pharma No.518 Laodong East Road, Changzhou, Jiangsu Province, P.R. China,Zhejiang Tianyu Pharmaceutical Co., Ltd. No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City
	Detail of stability batches of drug product	03 batches (Batch size 3000 tablets) 03 month acc and 03 months real time
	Documents for the procurement of API with approval from DRAP (in case of Import)	Amlodipine: Clearance certificate 21-09-2021 for 0.7kg material is submitted. Valsartan: Clearance certificate date 21-06-201 for 12kg material. HCT: Clearance certificate dated 08-07-2021 for 0.7kg material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Exforge HCT tablet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Amlodipine: 06 months accelerated Valsartan: 06 months accelerated and 36 months real time acc to zone IV-A. HCT: 06 months accelerated and 36 months real time.
	The status in reference regulatory authorities	https://www.accessdata.fda.gov/scripts/cder/daf/in event=overview.process&ApplN, USFDA APrrovedo=0 22314
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 01-02-2024.
	Evidence of approval of manufacturing facility	Tablet General Section is approved
	Evaluation Remarks	
	The firm was asked to provide real time stability data of Amlodipine according to zone IV-A. The firm has submitted the data of zone II by changing the storage conditions in stability summary sheets. Moreover, as per the details mentioned in 3.2.S.7 of HCT, the real time stability data is according to zone II whereas the summary sheets mention the storage conditions as per zone IV-A.	
	Decision	

	Rejected The Board, upon deliberation, emphasized that the integrity and authenticity of submitted information is a basic requirement for the fair proceeding. In light of the submission of falsified and edited stability data pertaining to the drug substance by the applicant, the Board decided to reject the case.	
274	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Herbion Pakistan (Pvt.) Ltd.** Industrial Triangle, Kahuta road, Humak, Islamabad **(000795)**
	Application Form Dy. No / Tracking ID & date of submission	(JXU-VWB-DZM8, 2024-08-27)
	Detail of Fee Submitted	30000.0, 2024-07-10,
	The proposed proprietary name / brand name	**Volvo-H 5-160-12.5 mg Tablets**
	Label Claim	Each film coated tablet contains: Amlodipine as besylate.....5mg Valsartan.....160 mg Hydrochlorothiazide.....12.5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2x14s-De-Controlled,2x7s-De-Controlled
	Shelf Life (Unit)	2 Year(s)25°C-30°C
	For generic drugs (me-too Status)	Co-Extor 5-160-12.5mg Tablet
	Pharmacotherapeutic Group of (API)	Anti-hypertensive
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Cadila Pharmaceuticals Limited Address:294, G.I.D.C. Industrial Estate Ankleshwar - 393 002 .Gujarat, INDIA ,Changzhou Pharmaceutical Factory (Shortened as “Changzhou Pharma”) Address: No.518 Laodong East Road, Changzhou, Jiangsu Province, P.R. China,Zhejiang Tianyu Pharmaceutical Co., Ltd. Address: No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City,Zhejiang Province, China
	Detail of stability batches of drug product	03 batches (Batch size 3000 tablets) 03 month acc and 03 months real time
	Documents for the procurement of API with approval from DRAP (in case of Import)	Amlodipine: Clearance certificate 21-09-2021 for 0.7kg material is submitted. Valsartan: Clearance certificate date 21-06-201 for 12kg material. HCT: Clearance certificate dated 08-07-2021 for 0.7kg material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Exforge HCT tablet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Amlodipine: 06 months accelerated Valsartan: 06 months accelerated and 36 months real time acc to zone IV-A. HCT: 06 months accelerated and 36 months real time.
	The status in reference regulatory authorities	https://www.accessdata.fda.gov/drugsatfda_docs/l
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 01-02-2024.
	Evidence of approval of manufacturing facility	Tablet General Section is approved
	Evaluation Remarks	

	The firm was asked to provide real time stability data of Amlodipine according to zone IV-A. The firm has submitted the data of zone II by changing the storage conditions in stability summary sheets. Moreover, as per the details mentioned in 3.2.S.7 of HCT, the real time stability data is according to zone II whereas the summary sheets mention the storage conditions as per zone IV-A.	
	Decision	
	Rejected The Board, upon deliberation, emphasized that the integrity and authenticity of submitted information is a basic requirement for the fair proceeding. In light of the submission of falsified and edited stability data pertaining to the drug substance by the applicant, the Board decided to reject the case.	
275	Case Category	Routine (Farooq Aslam)
	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	(A9Z-5JJ-R2L5, 2024-08-07)
	Detail of Fee Submitted	75000.0, 2024-05-06,
	The proposed proprietary name / brand name	**Ozenox**
	Label Claim	Each gram of cream contains: Ozenoxacin..... 20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10g x 10-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)	could not be confirmed (1% cream is approved)
	Pharmacotherapeutic Group of (API)	Quinolone antibiotic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	METROCHEM API PVT LTD and Address: PlotNo.34B,40B,&60B,J.N. Pharma City Thanam (V),Parawada (M) , Visakhapatnam Dist - 531021,Andhra Pradesh,India.
	Detail of stability batches of drug product	03 batches (batch size: 320gram (10g tubes) 06 months acc and 24 moths real time stability data acc to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested invoice dated 27-01-2021 for 50grams of material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the reference product i.e. Zebiax Oily cream 2% by M/s Marutho, Japan.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months acc and 36 months real time stability data of 03 batches according to zone IV-A.
	The status in reference regulatory authorities	Pharmaceuticals and Medical Devices Agency (PMDA-Japan)
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 03-01-2023.
	Evidence of approval of manufacturing facility	Topical Section (Cream/Ointment/Gel/Paste) (General /Steroidal) along with steroidal dispensing) (Revision/Regularization)
	Evaluation Remarks	
	Decision	

	Approved	
276	Case Category	Routine (Farooq Aslam)
	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	(WY1-U9E-7APN, 2024-08-12)
	Detail of Fee Submitted	75000.0, 2024-05-06,
	The proposed proprietary name / brand name	**Ozenox 1% Topical Cream**
	Label Claim	Each gram of cream contains: Ozenoxacin 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30g, 45g-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)	1% cream by M/s Hamaz
	Pharmacotherapeutic Group of (API)	Quinolone antibiotic
	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, Visakhapatnam District, Andhra Pradesh, 531021, India (IND).
	Detail of stability batches of drug product	03 batches (batch size: 320gram (10g tubes) 06 months acc and 24 moths real time stability data acc to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested invoice dated 27-01-2021 for 50grams of material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the reference product i.e. Xepi cream 1% by M/s Biofronta Inc. USA.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months acc and 36 months real time stability data of 03 batches according to zone IV-A.
	The status in reference regulatory authorities	CIMA Spain Approved (https://cima.aemps.es/cima/publico/detalle.html?nregistro=82357)
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 03-01-2023.
	Evidence of approval of manufacturing facility	Topical Section (Cream/Ointment/Gel/Paste) (General /Steroidal) along with steroidal dispensing) (Revision/Regularization)
	Evaluation Remarks	
	Decision	
	Approved	
277	Case Category	Routine (Farooq Aslam)
	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	(MMB-RJ7-54NG, 2024-08-20)

	Detail of Fee Submitted	75000.0, 2024-07-12,
	The proposed proprietary name / brand name	**Eslicarb**
	Label Claim	Each ml of oral suspension contains: Eslicarbazepine acetate.....50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	200ml-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)	Eslipin 50mg/ml Suspension M/s Daneen
	Pharmacotherapeutic Group of (API)	Anti-epileptic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CTX LIFE SCIENCES PVT. LTD. Address: Block no 251/P 252/P 253/P to 255, 256/P, 276/ P, 277,278/P 279 to 282 283/P, and 284/P, GIDC, SACHIN, DISTT SURAT, and GUJRAT STATE, INDIA.
	Detail of stability batches of drug product	03 bathces (Batch size: 1000L, 60mL bottle) 06 months accelerated and 06 month real time according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 for 6kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the reference product i.e. Zebinix 50mg/mL by M/s Bial Pharma, EMA.
	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 zone IV-A.
	The status in reference regulatory authorities	EMA Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 03-01-2023 is submitted.
	Evidence of approval of manufacturing facility	Liquid section is approved
	Evaluation Remarks	
	Decision	
	Approved The firm shall submit valid GMP certificate of drug substance manufacturer before issuance of registration letter.	
278	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	(AQN-YTW-DP12, 2024-10-29)
	Detail of Fee Submitted	37000.0, 2024-10-02,
	The proposed proprietary name / brand name	**Zilsart 80mg Tablet**
	Label Claim	Each Tablet contains: Azilsartan Medoxomil as Potassium 80mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	11x10's, 2x7's, 2x10-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a cool & Dry place below 30
	For generic drugs (me-too Status)	Available

	Pharmacotherapeutic Group of (API)	Antihypertensive
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CTX Lifesciences Pvt. Ltd., Add: Block No: 251-252, Sachin- Magdalla Road GIDC Sachin, Surat – 394 230 GUJARAT, INDIA
	Detail of stability batches of drug product	03 batches : 1000 tablets 06 months accelerated and 06 months real time stability data according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Memorandum of understanding for 600grams of material from M/s Novamed is submitted. Loan letter dated 01-12-2022. AD attested invoice dated 24-09-2021 is submitted (NOVAMED)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Edarbi tablet.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated (25oC/60%RH) and 24 months real time (2-8oC)
	The status in reference regulatory authorities	Edarbi(Azilsartan Kamedoxomil) 80mg Tablet of M/s Takeda Ireland (USFDA 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	
	Memorandum of understanding for 600grams of material from M/s Novamed is submitted.Loan letter dated 01-12-2022.AD attested invoice dated 24-09-2021 is submitted (NOVAMED)	
	Decision	
	Approved Subject to verification of loan letter.	
279	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	(REN-NPR-2SLE, 2024-10-29)
	Detail of Fee Submitted	37000.0, 2024-10-02,
	The proposed proprietary name / brand name	**Zilsart 40mg Tablet**
	Label Claim	Each Tablet contains: Azilsartan Medoxomil Potassium as Azilsartan Medoxomil 40mg
	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 in a cool & Dry place below 30
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	Antihypertensive
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CTX Lifesciences Pvt. Ltd., Add: Block No: 251-252, Sachin- Magdalla Road GIDC Sachin, Surat – 394 230 GUJARAT, INDIA
	Detail of stability batches of drug product	03 batches : 1000 tablets 06 months accelerated and 06 months real time stability data according to zone IV-A.
	Documents for the procurement of API with approval from DRAP	Memorandum of understanding for 600grams of material from M/s Novamed is submitted. Loan

	(in case of Import)	letter dated 01-12-2022. AD attested invoice dated 24-09-2021 is submitted (NOVAMED)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Edarbi tablet.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated (25oC/60%RH) and 24 months real time (2-8oC)
	The status in reference regulatory authorities	Edarbi(Azilsartan Kamedoxomil) 40mg Tablet of M/s Takeda Ireland (USFDA 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	
	Memorandum of understanding for 600grams of material from M/s Novamed is submitted.Loan letter dated 01-12-2022.AD attested invoice dated 24-09-2021 is submitted (NOVAMED)	
	Decision	
	Approved Subject to verification of loan letter.	
280	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(AEN-8M4-Q45P, 2024-10-22)
	Detail of Fee Submitted	75000.0, 2024-07-24,
	The proposed proprietary name / brand name	**Nabiloc HCT Tablet 5mg/25mg**
	Label Claim	Each film-coated tablet contains: Nebivolol Hydrochloride BP.....5mg Hydrochlorothiazide USP.....25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7’s, 10’s, 14’s, 28’-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Gneb-H Tablet 5/25mg by Genix Pharma
	Pharmacotherapeutic Group of (API)	Antihypertensive
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Hydrochlorothiazide (By CTX Lifesciences Pvt. Ltd.),Nebivolol Hydrochloride (By Abhilasha Pharma Pvt. Ltd.)
	Detail of stability batches of drug product	02 batches (Batch size; 5000 tablets) 06 months real time and 06 months accelerated stability data according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Nebivolol: AD Attested invoice issued vide Dy. no. 14805/2021 dated 20-12-2021 for 5kg material is submitted. HCT: AD Attested invoice issued vide Dy. no. 11503/2020 dated 15-10-2020 for 100kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Nomexor Plus Tablet 5/25 by M/s Menarini Pharma GmbH.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Nebivolol: 06 months accelerated and 12 months real time stability data of 03 batches according to zone IV-B. HCT: 06 months accelerated and 72

		months real time stability data of 03 batches according to zone IV-A.
	The status in reference regulatory authorities	EMA Approved (Nebilet Plus Tablet 5mg/25mg by Menarini International Operations Luxembourg, manufactured by Berlin-Chemie AG, Germany)
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 22-05-2023.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	Decision	
	Approved	
281	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(JQP-193-BH4Z, 2024-10-22)
	Detail of Fee Submitted	37000.0, 2024-10-04,
	The proposed proprietary name / brand name	**Ratimod**
	Label Claim	Each film coated tablet contains: Iguratimod 25mg
	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)	2 Year(s)Store below 30 degree celsius
	For generic drugs (me-too Status)	Iguramod 25mg by Kaizen
	Pharmacotherapeutic Group of (API)	anti-rheumatic drug
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Lewens Lab Private Limited
	Detail of stability batches of drug product	03 bathes (Batch size: 3000 tablets)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 30-01-2024 for 300 grams of material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDp studies have been performed against the innovator's product i.e. Careram 25mg tablet PMDA Japan.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated (25°C/ 60 % RH) and 60 months real time (2°c to 8°C) of 03 batches is submitted.
	The status in reference regulatory authorities	PMDA Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 22-05-2023.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	Decision	
	Approved	
282	Case Category	Routine (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	(AWT-85Y-T2EE, 2024-10-29)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-28, 2024-09-24
	The proposed proprietary name / brand name	**ROSERA EZ 20mg/10mg Tablet**
	Label Claim	Each bilayer film coated tablet contains: Rosuvastatin as calcium.....20mg Ezetimibe.....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)	Rovista EZ
	Pharmacotherapeutic Group of (API)	Lipid modifying agents
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shangyu Jingxin Pharmaceutical Co., Ltd.,,Zhejiang Tianyu Pharmaceutical Co., Lt.,
	Detail of stability batches of drug product	Batches: Lab 01, Lab 02, Lab 03 (Batch size: 2500 tablets) 06 months accelerate and 06 months real time according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Rosuvastatin: AD attested invoice vide Dy. NO. 14303/2021 dated 08-12-2021 for 50kg material. Ezetimibe: AD attested invoice dy.no. 3436/2021 dated 18-03-2021 issued to M/s Hilton Pharma Pvt. Limited. (Intimation to DRAP dated 27-04-2023 is submitted). Loan letter is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. Rovista EZ 20/10 by M/s Getz Pharma.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Rosuvastatin: 06 months accelerated and 24months real time stability data of 03 batches according to zone IV-B is submitted. Ezetimibe: 06 months accelerated and 36months real time stability data of 03 batches according to zone IV-B is submitted.
	The status in reference regulatory authorities	The Netherlands approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 01-07-2024 is submitted.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	Decision	
	Approved Subject to verification of loan letter from M/s Hilton Pharma Pvt. Limited for Ezetimibe.	
283	Case Category	Routine (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	(N3P-GE9-9ZY8, 2024-09-18)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-28, 2024-09-16
	The proposed proprietary name / brand name	**ROSERA EZ 10mg/10mg Tablet**

	Label Claim	Each bilayer film coated tablet contains: Rosuvastatin as Calcium.....10mg Ezetimibe.....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)	Rovista EZ
	Pharmacotherapeutic Group of (API)	Lipid modifying agents
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shangyu Jingxin Pharmaceutical Co., Ltd.,,Zhejiang Tianyu Pharmaceutical Co., Lt.,
	Detail of stability batches of drug product	Batches: Lab 01, Lab 02, Lab 03 (Batch size: 2500 tablets) 06 months accelerate and 06 months real time according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Rosuvastatin: AD attested invoice vide Dy. NO. 14303/2021 dated 08-12-2021 for 50kg material. Ezetimibe: AD attested invoice dy.no. 3436/2021 dated 18-03-2021 issued to M/s Hilton Pharma Pvt. Limited. (Intimation to DRAP dated 27-04-2023 is submitted). loan lette ris submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. Rovista EZ 10/10 by M/s Getz Pharma.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Rosuvastatin: 06 months accelerated and 24months real time stability data of 03 batches according to zone IV-B is submitted. Ezetimibe: 06 months accelerated and 36months real time stability data of 03 batches according to zone IV-B is submitted.
	The status in reference regulatory authorities	The Netherlands approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 01-07-2024 is submitted.
	Evidence of approval of manufacturing facility	GMP certificate issued on the basis of inspection conducted on 01-07-2024 is submitted.
	Evaluation Remarks	
	Decision	
	Approved Subject to verification of loan letter from M/s Hilton Pharma Pvt. Limited for Ezetimibe.	
284	Case Category	Routine (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	(T5V-LA9-VV8L, 2024-10-09)
	Detail of Fee Submitted	37000.0, 2024-09-12,
	The proposed proprietary name / brand name	**ROSERA EZ 5mg/10mg Tablet**
	Label Claim	Each bilayer film coated tablet contains: Rosuvastatin as Calcium.....5mg Ezetimibe.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	De-Controlled-De-Controlled

	Shelf Life (Unit)	2 Year(s)Do not store over 30°C
	For generic drugs (me-too Status)	Rovista EZ
	Pharmacotherapeutic Group of (API)	Lipid modifying agents
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shangyu Jingxin Pharmaceutical Co., Ltd.,,Zhejiang Tianyu Pharmaceutical Co., Lt.,
	Detail of stability batches of drug product	Batches: Lab 01, Lab 02, Lab 03 (Batch size: 2500 tablets) 06 months accelerate and 06 months real time according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Rosuvastatin: AD attested invoice vide Dy. NO. 14303/2021 dated 08-12-2021 for 50kg material. Ezetimibe: AD attested invoice dy.no. 3436/2021 dated 18-03-2021 issued to M/s Hilton Pharma Pvt. Limited. (Intimation to DRAP dated 27-04-2023 is submitted). loan letter is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. Rovista EZ 05/10 by M/s Getz Pharma.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Rosuvastatin: 06 months accelerated and 24months real time stability data of 03 batches according to zone IV-B is submitted. Ezetimibe: 06 months accelerated and 36months real time stability data of 03 batches according to zone IV-B is submitted.
	The status in reference regulatory authorities	CIMA Spain Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 01-07-2024 is submitted.
	Evidence of approval of manufacturing facility	GMP certificate issued on the basis of inspection conducted on 01-07-2024 is submitted.
	Evaluation Remarks	
	Decision	
	Approved Subject to verification of loan letter from M/s Hilton Pharma Pvt. Limited for Ezetimibe.	
285	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Pinnacle Biotech (Pvt.) Ltd.** FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi. **(000939)**
	Application Form Dy. No / Tracking ID & date of submission	(DVB-SDG-5G1V, 2024-07-22)
	Detail of Fee Submitted	30000.0, 2024-05-31,
	The proposed proprietary name / brand name	**Nebiflow 2.5mg Tablets**
	Label Claim	Each tablet contains: Nebivolol as Hydrochloride.....2.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14s Tablets -As per SRO
	Shelf Life (Unit)	2 Year(s)Shelf life only applies under appropriate conditions of storage specified on package.
	For generic drugs (me-too Status)	Nebil by Getz Pharma.
	Pharmacotherapeutic Group of (API)	Selective B1 blocker
	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: T-242, T-243, T-244 (Batch size: 1500 tablets) 06 months real time and 06 months accelerated stability studies according to the conditions of zone IV-a.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 28-12-2021 for 0.26kg material is submitted. AD attested invoice issued on 28-12-2021 (0.26kg).
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Bystolic 2.5mg tablet by M/s Jenssen Belgium.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months real time and 60 months accelerated stability data according to 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 21-10-2022.
	Evidence of approval of manufacturing facility	Tablet General Section is approved. .
	Evaluation Remarks	
	The import documents confirm that the material was imported in the month of June, 2024 while the application is submitted in July, 2024.	
	Decision	
	Approved	
286	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Pinnacle Biotech (Pvt.) Ltd.** FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi. **(000939)**
	Application Form Dy. No / Tracking ID & date of submission	(YZM-4WH-8ADE, 2024-07-30)
	Detail of Fee Submitted	30000.0, 2024-05-31,
	The proposed proprietary name / brand name	**Nebiflow 10mg Tablets**
	Label Claim	Each tablet contains: Nebivolol as Hydrochloride 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14s Tablets -As per SRO
	Shelf Life (Unit)	2 Year(s)Shelf life only applies under appropriate conditions of storage specified on package.
	For generic drugs (me-too Status)	Nebil by Getz Pharma.
	Pharmacotherapeutic Group of (API)	Selective B1 blocker
	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: T-201, T-235, T-240 (Batch size: 1500 tablets) 06 months real time and 06 months accelerated stability studies according to the conditions of zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 28-12-2021 for 0.26kg material is submitted. AD attested invoice No. ZHP72/2021 dated 16-12-2021 issued on 28-12-2021 (0.26kg).
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. BByvas 10mg tablet by M/s Pharmevo.

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months real time and 60 months accelerated stability data according to 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 21-10-2022.
	Evidence of approval of manufacturing facility	Tablet General Section is approved. .GMP certificate issued on the basis of inspection conducted on 21-10-2022.
	Evaluation Remarks	
	Form 6 dated 28-12-2021 for 0.26kg material is submitted.AD attested invoice No. ZHP72/2021 dated 16-12-2021 issued on 28-12-2021 (0.26kg).	
	Decision	
	Approved	
287	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Pinnacle Biotech (Pvt.) Ltd.** FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi. **(000939)**
	Application Form Dy. No / Tracking ID & date of submission	(PYE-HN6-J6W5, 2024-07-18)
	Detail of Fee Submitted	30000.0, 2024-05-31,
	The proposed proprietary name / brand name	**Nebiflow 5mg Tablets**
	Label Claim	Each tablet contains: Nebivolol as Hydrochloride.....5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14s Tablets -As per SRO
	Shelf Life (Unit)	2 Year(s)Shelf life only applies under appropriate conditions of storage specified on package.
	For generic drugs (me-too Status)	Nebil by Getz Pharma.
	Pharmacotherapeutic Group of (API)	Selective B1 blocker
	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: T-189, T-195, T-196 (Batch size: 1500 tablets) 06 months real time and 06 months accelerated stability studies according to the conditions of zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 28-12-2021 for 0.26kg material is submitted. AD attested invoice No. ZHP72/2021 dated 16-12-2021 issued on 28-12-2021 (0.26kg).
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Bystolic 5mg tablet by M/s Jenssen Belgium.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months real time and 60 months accelerated stability data according to zone IV-A.
	The status in reference regulatory authorities	Food and Drug Regulatory Authority USA
	GMP status of the firm	.GMP certificate issued on the basis of inspection conducted on 21-10-2022.
	Evidence of approval of manufacturing facility	Tablet General Section is approved
	Evaluation Remarks	
	Form 6 dated 28-12-2021 for 0.26kg material is submitted.AD attested invoice No. ZHP72/2021 dated 16-12-2021 issued on 28-12-2021 (0.26kg).	
	Decision	

	Approved	
288	Case Category	New Molecule/Formulation (Farooq Aslam)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(ZLP-H72-Z4BQ, 2026-04-20)
	Detail of Fee Submitted	75000, 2026-04-07,
	The proposed proprietary name / brand name	**Coprex Tablet 12.5mg**
	Label Claim	Each tablet contains: Cenobamate.....12.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Packed in Alu pvc blister pack of 7's, 10's, 14's, 20's, 28's & 30's tablets.-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30ºC
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Anti-epileptics, other antiepileptics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Metrochem API Private Limited.
	Detail of stability batches of drug product	Submitted stability study data of 3 batches at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months and the real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 06 months.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 26-02-2025 for 4kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted pharmaceutical equivalence of our product against the product Ontozry by (AngeliniPharma, Italy Rome.) Submitted CDP results of our product against the product Ontozry by (AngeliniPharma, Italy Rome.)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted stability study data of 3 batches of Cenobamate at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C + 75%RH ± 5% for 12 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.
	Evidence of approval of manufacturing facility	Tablet (General) section is approved.
	Evaluation Remarks	
	Background: The firm initially had submitted a single application for 12.5mg and 25mg tablet vide application ID NO. PLA-7WL-E4EV. The case was approved in 354th meeting as combo pack containing 12.5mg tablet and 25mg tablet which was according to the innovator product's approval in reference authority. The firm was granted approval in the same meeting for all the other strengths since the dose is titrated to higher doses starting from 12.5mg, 25mg, 50mg, 100mg, 150mg to 200mg of maximum dose.	
	Request by the firm: The firm has requested for registration of separate products of 12.5mg and 25mg.	
	Submitted for consideration by the Board.	

	Decision	
	Approved The Board acceded the request of the firm and decided to approve the instant case. The Board further decided that the application ID No. PLA-7WL-E4EV submitted earlier for combo pack of 12.5mg and 25mg tablets shall be considered as rejected.	
289	Case Category	New Molecule/Formulation (Farooq Aslam)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(LLN-T8H-HMM4, 2026-04-20)
	Detail of Fee Submitted	75000, 2026-04-07,
	The proposed proprietary name / brand name	**Coprex Tablet 25mg**
	Label Claim	Each film-coated tablet contains: Cenobamate.....25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Packed in Alu pvc blister pack of 7's, 10's, 14's, 20's 28's & 30's tablets.-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30ºC
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Anti-epileptics, other antiepileptics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Metrochem API Private Limited.
	Detail of stability batches of drug product	Submitted stability study data of 3 batches at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months and the real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 06 months.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 26-02-2025 for 4kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted pharmaceutical equivalence of our product against the product Ontozry by (AngeliniPharma, Italy Rome.) Submitted CDP results of our product against the product Ontozry by (AngeliniPharma, Italy Rome.)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted stability study data of 3 batches of Cenobamate at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C + 75%RH ± 5% for 12 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.
	Evidence of approval of manufacturing facility	Tablet (General) section is approved.
	Evaluation Remarks	
	Background: The firm initially had submitted a single application for 12.5mg and 25mg tablet vide application ID NO. PLA-7WL-E4EV. The case was approved in 354th meeting as combo pack containing 12.5mg tablet and 25mg tablet which was according to the innovator product's approval in reference authority. The firm was granted approval in the same meeting for all the other strengths	

	since the dose is titrated to higher doses starting from 12.5mg, 25mg, 50mg, 100mg, 150mg to 200mg of maximum dose.	
	Request by the firm: The firm has requested for registration of separate products of 12.5mg and 25mg. This has been requested to improve economic affordability for patients, as separate registration of each strength will allow procurement of only the required strength and thereby help make the therapy more economical. Furthermore, separate registration of both strengths will facilitate accurate prescribing and dispensing, improve market availability of individual strengths, support efficient inventory management, and remove confusion among healthcare professionals.	
	Submitted for consideration by the Board.	
	Decision	
	Approved The Board acceded the request of the firm and decided to approve the instant case. The Board further decided that the application ID No. PLA-7WL-E4EV submitted earlier for combo pack of 12.5mg and 25mg tablets shall be considered as rejected.	
290	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	**Bristol Mayer Biotech Pakistan** 73 B Guldasht Town Zarrar Shaheed Lahore **(05-352-0068-109282D)**
	Application Form Dy. No / Tracking ID & date of submission	(49N-4RZ-JXDN, 2026-03-19)
	Detail of Fee Submitted	300000.0, 2025-05-02,
	The proposed proprietary name / brand name	**GLUTHIO 600**
	Label Claim	Each vial contains: L- Glutathione as Sodium.....600 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 at a temperature not exceeding 30°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Antidotes, ATC code: V03AB32
	Name, address of Manufacturing site:	Celon Laboratories Private Limited-Plot No.2, ALEAP Industrial Estate, Gajularamaram, Medchal Malkajagiri District, Quthbullapur (M) -500090, Telangana State, INDIA-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence is provided with reference drug TAD-600 by M/s Bimedica.
	Name, address of Marketing Authorization Holder:	Bristol Mayer Biotech Pakistan, 73 B Guldasht Town Zarrar Shaheed Lahore, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	L.Dis.No:137960/TS/2024 Dated:10/05/2024 Valid until:09/05/2025 License retention certificate dated 06-08-2025 is submitted.
	Details of Authorization Letter :	FSC: Copy of free sale certificate valid till 19-11-2026 is submitted. The product is avaialable for domestic sale. LOA: LOA dated 04-03-226 is

		submitted. DSL: Valid copy of DSL is submitted (validity 18-10-2028)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies are conducted on Glutathione batches (B161228, B161232 and B161233) manufactured at Shandong Jincheng Bio pharmaceutical Co., Ltd (India) Pvt. Ltd, at accelerated (40°C ± 2°C / 75% RH ± 5% RH) and long term (25°C ± 2°C / 60% RH ± 5% RH) conditions for 36 months.
	The status in reference regulatory authorities	AIFA Italy approved, TAD-600 (Biomedica Foscama Industria Chimico-Farmaceutica S.P.A.)
	Evaluation Remarks	
	The application has been processed on priority in compliance to the decision of 220th meeting DRAP Authority. The firm shall submit applicable fee for correction of specifications and legalized/apostille CoPP.	
	Decision	
	Approved As per policy of inspection of manufacturer abroad. The firm shall submit applicable fee for correction of specifications and legalized/apostille CoPP before issuance of registration letter.	
291	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	**Bristol Mayer Biotech Pakistan** 73 B Guldasht Town Zarrar Shaheed Lahore **(05-352-0068-109282D)**
	Application Form Dy. No / Tracking ID & date of submission	(4NH-934-PT27, 2026-03-26)
	Detail of Fee Submitted	313500, 2026-03-19,
	The proposed proprietary name / brand name	**CARBOFER**
	Label Claim	Each ml contains: Ferric Carboxymaltose equivalent to elemental Iron.....50 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 x 10 ml Vial-As per SRO
	Shelf Life (Unit)	24 Month(s)Store below 30°C. Do not freeze. Keep out of reach of children
	For generic drugs (me-too Status)	Elinjec by Sami Pharma
	Pharmacotherapeutic Group of (API)	Anti-anaemic preparation
	Name, address of Manufacturing site:	Precise Biopharma Pvt. Ltd.-Plot No. C-384, T.T.C. Ind. Area, MIDC, Pawane Village, Navi Mumbai-400 703, Dist. -Thane - Zone 7-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the comparator's product i.e. Orofer FCM.
	Name, address of Marketing Authorization Holder:	Precise Biopharma Pvt. Ltd., Plot No. C-384, T.T.C. Ind. Area, MIDC, Pawane Village, Navi Mumbai-400 703, Dist. -Thane - Zone 7, India
	Details of Certificates (CoPP/FSC/cGMP):	Certificate No. 17P/1/54/2019/5505 Date of Issue : 26/07/2024
	Details of Authorization Letter :	FSC: Copy of free sale certificate dated 16-03-2026 is submitted, DSL: DSL valid till 18-10-2028 is submitted. LOA: Copy of letter of authorization is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies of three batches FCM/01012022,FCM/02012022 &

		FCM/03012022 at 40 ± 2° / 75 ± 5% RH (in accelerated condition for 6 months), 30±2°C, RH 65±5% and 30±2°C, RH 75±5% (in real time condition) for 24 months.
	The status in reference regulatory authorities	MHRA approved (Ferinject 50mg/ml)
	Evaluation Remarks	
	The application has been processed in compliance to the decision of 220th meeting of DRAP Authority. The firm has submitted Form 28-A which is a loan license. The firm shall submit legalized/apostille LOA and free sale certificate.	
	Decision	
	Deferred For the policy decision for loan license.	
292	Case Category	Routine (Farooq Aslam)
	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	(53W-MHT-DT2H, 2024-08-26)
	Detail of Fee Submitted	30000.0, 2024-08-13,
	The proposed proprietary name / brand name	**Nebiol 5mg Tablets**
	Label Claim	Each Tablet contains: Nebivolol (as HCl).....5mg (IP Spec's.)
	Reference to Finished product specifications	The International Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30ºC
	For generic drugs (me-too Status)	Bynevol 5mg Tablets, Manufacturer: Atco Laboratories
	Pharmacotherapeutic Group of (API)	Selective B1 blocker
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Maithili Life Sciences Private Limited
	Detail of stability batches of drug product	Batches: 24DT34, 24DT35, 24DT36 (Batch size: 1000 tablets) 06 month accelerated and 06 months real time
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan agreement from M/s Medizan Laboratories pvt. ltd. Clarance certificate dated 13-03-2024 for 5kg material is submitted (Medizan)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. Bynevol 5mg tablet by M/s Atco Laboratories.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 18 months real time according to zone IV-a.
	The status in reference regulatory authorities	Bystolic 5mg Tablet, Manufacturer: ALLERGAN USA, INC. (NDA): 021742 (USFDA Approved)
	GMP status of the firm	New License approved w.e.f. 17-01-2024.
	Evidence of approval of manufacturing facility	Tablet General Section (I&II) are approved. New License approved w.e.f. 17-01-2024.
	Evaluation Remarks	
	Decision	
	Approved	

	subject to verification of loan letter.	
293	Case Category	Routine (Farooq Aslam)
	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	(HA9-68S-NG54, 2024-08-26)
	Detail of Fee Submitted	30000.0, 2024-08-13,
	The proposed proprietary name / brand name	**Nebiol 2.5mg Tablets**
	Label Claim	Each Tablet contains: Nebivolol (as HCl).....2.5mg
	Reference to Finished product specifications	The International Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30ºC
	For generic drugs (me-too Status)	Bynevol 2.5mg Tablets, Manufacturer: Atco Laboratories
	Pharmacotherapeutic Group of (API)	Selective B1 blocker
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Batches: 24DT43, 24DT45, 24DT46 (Batch size: 1000 tablets) 06 months real time and 06 months accelerated.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan agreement from M/s Medizan Laboratories pvt. ltd. Clarance certificate dated 13-03-2024 for 5kg material is submitted (Medizan)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. Bynevol 5mg tablet by M/s Atco Laboratories.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	.06 months accelerated and 18 months real time according to zone IV-a.
	The status in reference regulatory authorities	Bystolic 2.5mg Tablet, Manufacturer: ALLERGAN USA, INC. (NDA): 021742, USFDA Approved
	GMP status of the firm	New License approved w.e.f. 17-01-2024.
	Evidence of approval of manufacturing facility	Tablet General Section (I&II) are approved. New License approved w.e.f. 17-01-2024.
	Evaluation Remarks	
	Decision	
	Approved subject to verification of loan letter.	
294	Case Category	Routine (Farooq Aslam)
	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	(M9R-TVT-J9N8, 2024-08-26)
	Detail of Fee Submitted	30000.0, 2024-08-13,
	The proposed proprietary name / brand name	**Nebiol 10mg Tablets**

	Label Claim	Each Tablet contains: Nebivolol (as HCl).....10mg (IP Spec's.)
	Reference to Finished product specifications	The International Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30ºC
	For generic drugs (me-too Status)	Bynevol 10mg Tablets, Manufacturer: Atco Laboratories
	Pharmacotherapeutic Group of (API)	Selective B1 blocker
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Batches: 24DT37, 24DT39, 24DT38 (Batch size: 1000 tablets) 06 months accelerated and 06 months real time
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan agreement from M/s Medizan Laboratories pvt. ltd. Clarance certificate dated 13-03-2024 for 5kg material is submitted (Medizan)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. Bynevol 10mg tablet by M/s Atco Laboratories.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 18 months real time stability data according to zone IV-A.
	The status in reference regulatory authorities	Bystolic 10mg Tablet, Manufacturer: ALLERGAN USA, INC. (NDA): 021742 (USFDA Approved)
	GMP status of the firm	New License approved w.e.f. 17-01-2024.
	Evidence of approval of manufacturing facility	Tablet General Section (I&II) are approved. New License approved w.e.f. 17-01-2024.
	Evaluation Remarks	
	Decision	
	Approved subject to verification of loan letter.	
295	Case Category	Routine (Farooq Aslam)
	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	(NV8-U15-56ZD, 2024-08-26)
	Detail of Fee Submitted	30000.0, 2024-08-13,
	The proposed proprietary name / brand name	**Nebiol 20mg Tablets**
	Label Claim	Each Tablet contains: Nebivolol (as HCl).....20mg
	Reference to Finished product specifications	The International Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30ºC
	For generic drugs (me-too Status)	NOBU 20mg Tablets, Manufacturer: Scotmann Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Selective B1 blocker
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	

	Detail of stability batches of drug product	Batches: 24DT29, 24DT28, 24DT30 (Batch size: 1000 tablets) 06 months real time and 06 months accelerated.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan agreement from M/s Medizan Laboratories pvt. ltd. Clarance certificate dated 13-03-2024 for 5kg material is submitted (Medizan)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. Bynevol 20mg tablet by M/s Atco Laboratories.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 18 months real time stability data according to zone IV-A.
	The status in reference regulatory authorities	Bystolic 20mg Tablet, Company: ALLERGAN USA, INC. (NDA): 02174, (USFDA Approved)
	GMP status of the firm	New License approved w.e.f. 17-01-2024.
	Evidence of approval of manufacturing facility	Tablet General Section (I&II) are approved. New License approved w.e.f. 17-01-2024.
	Evaluation Remarks	
	Decision	
	Approved subject to verification of loan letter.	
296	Case Category	Routine (Farooq Aslam)
	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	(T8J-R6X-8UJ4, 2024-06-21)
	Detail of Fee Submitted	30000.0, 2024-05-29,
	The proposed proprietary name / brand name	**Vetram 250mg Tablets**
	Label Claim	Each Film Coated Tablet Contains: Levetiracetam.....250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30ºC
	For generic drugs (me-too Status)	Xeticam 250mgTablets, Manufacturer: Getz Phrama (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Antiepileptic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Batches: LVT250T-01, LVT250T-02, LVT250T-03 (Batch size: 500 tablets) 06 months real time and 06 months acc.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan agreement dated 08-01-2024 from Seraph Pharmaceuticals is submitted. Clearance certificate dated 28-04-2023 from Seraph pharma is submitted for 250kg material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Xeticam 250mg tablet by M/s Getz Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 60 months real time stability data is submitted for 03 batches according to the conditions of zone IV-A.

	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	NEW DML was approved w.e.f 17-01-2024.
	Evidence of approval of manufacturing facility	Tablet section is approved.
	Evaluation Remarks	
	Decision	
	Approved subject to verification of loan letter.	
297	Case Category	Routine (Farooq Aslam)
	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	(TZJ-HW2-N62T, 2024-06-21)
	Detail of Fee Submitted	30000.0, 2024-05-29,
	The proposed proprietary name / brand name	**Vetram 500mg Tablets**
	Label Claim	Each Film Coated Tablet Contains: Levetiracetam.....500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30ºC
	For generic drugs (me-too Status)	Xeticam 500mg Tablets, Manufacturer: Getz Phrama (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Antiepileptic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Batches: LVT500T-01, LVT500T-02, LVT500T-03 (Batch size: 500 tablets) 06 months accelerated and 06 months real time.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan agreement dated 08-01-2024 from Seraph Pharmaceuticals is submitted. Clearance certificate dated 28-04-2023 from Seraph pharma is submitted for 250kg material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Xeticam 500mg tablet by M/s Getz Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 60 months real time stability data is submitted for 03 batches according to the conditions of zone IV-A.
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	NEW DML was approved w.e.f 17-01-2024.
	Evidence of approval of manufacturing facility	Tablet section is approved.
	Evaluation Remarks	
	Decision	
	Approved subject to verification of loan letter.	
298	Case Category	Routine (Farooq Aslam)

	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	(QHY-39A-QVDP, 2024-07-02)
	Detail of Fee Submitted	75000.0, 2024-05-03,
	The proposed proprietary name / brand name	**SPASMOL INJECTION**
	Label Claim	Each 4ml ampoule contains: Hydrated Phloroglucinol.....40mg + TrimethylPhloroglucinol.....0.04mg
	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)	ANAFORTAN PLUS By AGP Pakistan
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Seraph Pharmaceuticals-Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad-PAKISTAN.-
	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	Amaforex plus By Hungary Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has cross referred the approval of stability data through PRV letter no. No.F119/PRVC/2024(Part II) dated 16-05-2024. The approval has been granted to M/s Seraph Pharmaceuticals for change of manufacturing facility from M/s Swiss Pharmaceuticals to self manufacturing. The firm shall submit applicable fee for change of status of already approved data from Yes to No in online application.	
	Decision	
	Approved subject to submission of fee of Rs. 9,400/- for preregistration variation i.e. change of status for already approved data.	
299	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	**Bio-Labs(Pvt) Ltd** Plot 145, Industrial Triangle, Kahuta Road **(000296)**
	Application Form Dy. No / Tracking ID & date of submission	(DLR-D5G-D7ST, 2026-01-05)
	Detail of Fee Submitted	38700, 2025-10-09,
	The proposed proprietary name / brand name	**Dalafil**
	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 10's 12's 14's 28's 84's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30C
	For generic drugs (me-too Status)	Fildil 10mg Tablet Highnoon
	Pharmacotherapeutic Group of (API)	Urologicals; 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	03btahces (batch size: 1000 tablet) 06 months accelerated and 06 months real time stability data according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 20-04-2025 for 0.2Kg material is submited.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Cialis tablet.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 60 moths real time stability data of 03 batches according to zone IV-A is submitted,
	The status in reference regulatory authorities	Tadalafil 10mg Tablets USFDA
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 17-10-2025.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been processed in compliance to the decision of DRAP Authority regarding ED drugs.	
	Decision	
	Approved	
300	Case Category	Priority As Per 257-M of RB (Farooq Aslam)
	Name, address of Applicant.	**Pharma Lord (Pvt) Ltd** 12-km Lahore Road Layyah **(000774)**
	Application Form Dy. No / Tracking ID & date of submission	(6EB-BAG-914R, 2025-08-01)
	Detail of Fee Submitted	37000.0, 2025-06-12,
	The proposed proprietary name / brand name	**Palib**
	Label Claim	Each Capsule contains: Palbociclib 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	21-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30
	For generic drugs (me-too Status)	Ibrance capsule 100mg By Pfizer Pakistan Limited
	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	Stability study conditions: Real time: 30°C±2°C/75±5%RH for 6 months Accelerated: 40°C±2°C/75±5%RH for 6 months Batches: T001 , T002, T003 (Batch size: 500 tablets)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 19-02-2024 is submitted for 450grams material along with unattested invoice.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	The firm has performed pharmaceutical equivalence and CDP studies against Palboxen capsule by M/s Everest Pharmaceuticals Ltd., Bangladesh.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C±2°C/75±5%RH for 18 months Accelerated: 40°C±2°C/75±5%RH for 6 months Batches: PLB2301, PLB2302 , PLB2303
	The status in reference regulatory authorities	Ibrance capsule 100mg By US FDA
	GMP status of the firm	Submitted for renewal and Last GMP Inspection dated 24-03-2022 concludes as 'GOOD' based on designed and established at an acceptable level of compliance of GMP requirements.
	Evidence of approval of manufacturing facility	Capsule (Anti-cancer) sections is approved approved
	Evaluation Remarks	
	anticancer	
	Decision	
	Approved	
301	Case Category	Priority As Per 257-M of RB (Farooq Aslam)
	Name, address of Applicant.	**Pharma Lord (Pvt) Ltd** 12-km Lahore Road Layyah **(000774)**
	Application Form Dy. No / Tracking ID & date of submission	(PY3-M87-BXMH, 2025-08-04)
	Detail of Fee Submitted	37000.0, 2025-07-24,
	The proposed proprietary name / brand name	**Palib**
	Label Claim	Each Capsule contains: Palbociclib 125mg
	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
	For generic drugs (me-too Status)	Ibrance capsule 125mg By Pfizer Pakistan Limited
	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	Stability study conditions: Real time: 30°C±2°C/75±5%RH for 6 months Accelerated: 40°C±2°C/75±5%RH for 6 months Batches: T001 , T002, T003 (Batch size: 500 tablets)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 19-02-2024 is submitted for 450grams material along with unattested invoice.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The firm has performed pharmaceutical equivalence and CDP studies against Palboxen capsule by M/s Everest Pharmaceuticals Ltd., Bangladesh.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C±2°C/75±5%RH for 18 motnhs Accelerated: 40°C±2°C/75±5%RH for 6 months Batches: PLB2301, PLB2302 , PLB2303

	The status in reference regulatory authorities	Ibrance capsule 125mg By US FDA
	GMP status of the firm	Submitted for renewal and Last GMP Inspection dated 24-03-2022 concludes as 'GOOD' based on designed and established at an acceptable level of compliance of GMP requirements.
	Evidence of approval of manufacturing facility	Capsule (Anti-cancer) sections was approved
	Evaluation Remarks	
	Anticancer	
	Decision	
	Approved	
302	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	(G8U-15J-9E8A, 2024-10-31)
	Detail of Fee Submitted	37000.0, 2024-10-21,
	The proposed proprietary name / brand name	**Imeg 500mg Tablet**
	Label Claim	Each film-coated tablet contains: Imeglimin Hydrochloride.....500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10s-As per SRO,14s-As per SRO,15s-As per SRO,20s-As per SRO,28s-As per SRO,30s -As per SRO,56s-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)	GLYMEG 500MG TABLET by NABIQASIM PHARMA
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Ami Lifesciences Pvt. ltd, Block 82/B, ECP road, AT & Post, Karakhadi, Tal-Padra, Dist Baroda, Gujrat
	Detail of stability batches of drug product	Batches: 347B23, 348B23, 346B23 (Batch size: 1500 tablets)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 09-10-2023 for 3kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the innovator's product i.e. Twymeeg 500mg tablet by M/s Sumitomo Pharma, Japan.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 24 months real time stability data is submitted for 03 batches according to the conditions of zone IV-A.
	The status in reference regulatory authorities	TWYMEEG TABLET 500MG BY M/S Sumitomo Dainippon Pharma Co., Ltd.) PMDA APPROVED
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 22-02-2023 is submitted.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	Decision	

	Approved	
303	Case Category	Routine (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	(PV3-3NM-5UDU, 2024-08-21)
	Detail of Fee Submitted	75000.0, 2024-07-11,
	The proposed proprietary name / brand name	**Twygen Tablet 500mg**
	Label Claim	Each film coated tablet contains: Imeglimin HCl..... 500mg
	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
	Shelf Life (Unit)	2 Year(s)Below 30 °C
	For generic drugs (me-too Status)	Imeglu 500mg tablet by M/s AGP Limited.
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Source of Drug Substance: Ami Lifesciences Private Limited. Address: Block No.82/B, ECP Road, AT & Post: Karakhadi-391450, Taluka: Padra, District Vadodara, Gujarat, India.
	Detail of stability batches of drug product	Batches: Trial#1, Trial#2, Trial#3 (Batch size: 1500 tablets) 06 months accelerated and 06 months real time stability data according to the conditions of zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 27-10-2023 for 11.5KG of material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the innovator's product i.e. Twymeeg 500mg tablet by M/s Sumitomo Pharma, Japan.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 24 months real time stability data of 03 batches according to the conditions of zone IV-A is submitted.
	The status in reference regulatory authorities	Twymeeg Tablet 500mg, Registered in Pharmaceuticals and Medical Devices Agency (PMDA)
	GMP status of the firm	Last inspection report dated 22-02-2024 for renewal of DML is submitted.
	Evidence of approval of manufacturing facility	Tablet General Section is approved. Last inspection report dated 22-02-2024 for renewal of DML is submitted.
	Evaluation Remarks	
	CDP studies have been performed in two phases. 06 units for test and comparator's product are included for each phase with separate calculations for f2 values.	
	Decision	
	Approved The firm shall submit revised CDP data generated using 12 units in a single study, along with combined calculations (% release, mean, and similarity factor), instead of presenting results from two separate phases of 6 units each.	

304	Case Category	New Molecule/Formulation (Farooq Aslam)
	Name, address of Applicant.	**Hiranis Pharmaceuticals Pvt. Ltd.** E-145-149, North Western Industrial Zone, Port Qasim, Karachi-75020, Pakistan **(000785)**
	Application Form Dy. No / Tracking ID & date of submission	(MB4-GG9-GNTR, 2025-05-05)
	Detail of Fee Submitted	75000.0, 2025-03-20,
	The proposed proprietary name / brand name	**MACTEN 10MG TABLET**
	Label Claim	Each film coated tablet contains: Macitentan.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 20's, 30's/ As-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30OC at a dry place, protect from light and heat.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Anti-hypertensive
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. GANSU HAOTIAN PHARMACEUTICAL CO., LTD,Address: NO. 11, CHONGQING ROAD, SMALL AND MEDIUM-SIZED ENTERPRISE BUSINESS BASE BAIYIN GANSU P. R. CHINA,
	Detail of stability batches of drug product	The applicant has manufactured 03 stability batches comprising of 1000 tablets. 06 months real time and 06 month accelerated stability data is submitted according to zone IV-A is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 22-03-2024 for 0.075kg material along with copy of GD No. KPAF-3086-2024 Date: 25-03-2024. Clearance certificate has not been submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The applicant has established pharmaceutical equivalency and performed CDP studies against the reference product i.e. Opsumit tablet by Actelion Pharmaceuticals Ltd., Switzerland.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 24 months of 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 (NDA 204410); Opsumit 10mg Tablets; Actelion Pharmaceuticals, LTD
	GMP status of the firm	GMP certificate issued on the basis of inspection on 14-12-2023.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	Query: Since you have adopted DS manufacturer's method of analysis and the manufacturer has used intermediate, starting material, impurity A and B for system suitability testing. Therefore, for confirming the validity of assay test for DS, system suitability is required to be performed by spiking the dilution with impurity A and B,	
	Reply: Although the drug substance manufacturer utilized starting material and impurity A and impurity B for system suitability in their internal procedure, the validated analytical method used for AMV does not mandate the inclusion of these impurities specifically for system suitability testing. The capability of the method to detect and separate impurity A and impurity B was already established during method validation through specificity and resolution studies.	

	Moreover, the DS exists in two polymorphic forms I and II. The innovator's literature describes the polymorphism but the specific form used in the product has not been disclosed. The applicant has stated has the form II is used in the product development.	
	Decision	
	Deferred 1. For further deliberation regarding the active polymorphic form produced by the drug substance manufacturer and the form used for manufacturing of innovator's product. 2. For submission system suitability testing by spiking the dilution with impurity A and B as done by the drug substance manufacturer.	
305	Case Category	Priority As Per 257-M of RB (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	(XQ8-2AQ-PT97, 2025-10-02)
	Detail of Fee Submitted	75000.0, 2025-04-24,
	The proposed proprietary name / brand name	**Maceta 10mg Tablets**
	Label Claim	Each film coated tablet contains: Macitentan.....10mg
	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: It belongs to the pharmacotherapeutic group of endothelin receptor antagonists (ERAs), specifically a dual ERA, used for the treatment of pulmonary arterial hypertension (PAH).
	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	The applicant has manufactured 03 stability batches comprising of 1200 tablets. 06 months real time and 06 month accelerated stability data is submitted according to zone IV-A is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	...
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The applicant has established pharmaceutical equivalency and performed CDP studies against the reference product i.e. Opsumit tablet by Actelion Pharmaceuticals Ltd., Switzerland.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 24 months of real time stability data of 03 batches according to the conditions of zone IV-A is submitted.
	The status in reference regulatory authorities	OPSUMIT® (Macitentan) tablets, for oral use Initial U.S. Approval: 2013 Actelion Pharmaceuticals US, Inc. 5000 Shoreline Court,

		Ste. 200 South San Francisco, CA 94080, USA ACT20181023
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 11-01-202.
	Evidence of approval of manufacturing facility	Tablet General Section is approved
	Evaluation Remarks	
	Query: Since you have adopted DS manufacturer's method of analysis and the manufacturer has used intermediate, starting material, impurity A and B for system suitability testing. Therefore, for confirming the validity of assay test for DS, system suitability is required to be performed by spiking the dilution with impurity A and B,	
	Reply: We have not procured and used impurity A and B in AMV system suitability as per manufacturer method. DRAP gave relaxation for impurities testing, But for future, if essential, we will procure for commercial batches as per manufacturer after getting approval.	
	Decision	
	Deferred 1. For further deliberation regarding the active polymorphic form produced by the drug substance manufacturer and the form used for manufacturing of innovator's product. 2. For submission system suitability testing by spiking the dilution with impurity A and B as done by the drug substance manufacturer.	
306	Case Category	Routine (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	(5W4-ZXR-R8MM, 2024-08-19)
	Detail of Fee Submitted	30000.0, 2024-07-25,
	The proposed proprietary name / brand name	**CAFEXO 20mg/ml Solution for Infusion and Oral Solution**
	Label Claim	Each 1 ml ampoule contains: Caffeine Citrate.....20 mg (Equivalent to 10mg Caffeine Base)
	Reference to Finished product specifications	British 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)	Peyona 20mg/ml Solution for Infusion and Oral Solution M/s Chiesi Pharma
	Pharmacotherapeutic Group of (API)	Drug for primary apnoea of premature newborns
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	AARTI PHARMA LABS LIMITED, Unit – III, Plot no. K – 17/18/19, M.I.D.C.,Tarapur, Taluka & District Palghar, Maharashtra, India Pin 401 506
	Detail of stability batches of drug product	03 batches : 1000mL 06 months real time and 06 months acc.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Unattested invoice dated 16-06-2023 for 1kg material Fedex receipt for airway bill No. 77269446998 along with copy of airway bill dated 18-06-2023.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the innovator's product i.e. Peyona 20mg/mL by M/s Chiesi Pharmaceuticals Pvt. Ltd., Pakistan.

	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 zone IV-A.
	The status in reference regulatory authorities	Peyona 20 mg/ml solution for infusion and oral solution, MHRA approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted in May, 2022.
	Evidence of approval of manufacturing facility	Liquid Injection SVP General
	Evaluation Remarks	
	Decision	
	Approved	
307	Case Category	New Molecule/Formulation (Farooq Aslam)
	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	(S58-5JL-8895, 2026-02-04)
	Detail of Fee Submitted	75000, 2025-11-05,
	The proposed proprietary name / brand name	**Enadustat**
	Label Claim	Each Film Coated Tablet Contains: Enarodustat 2mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	140'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)	could not be confirmed
	Pharmacotherapeutic Group of (API)	HIF-PH (Hypoxia-Inducible Factor Prolyl Hydroxylase)inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Loncom Pharmaceutical Co., Ltd and No 127, Qizhong Avenue, Yanbei Sub-district, Qihe County, Dezhou City, Shandong Province, 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) months (completed)} for 03 batches (Batch size: 1000 tablets)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 31-12-2024 for 0.05kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence and CDP studies have been performed against the reference product i.e Enaroy tablet.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	The applicant has submitted 06 months accelerated and 36 months real time stability data of 03 batches according to the conditions of zone IV-A.
	The status in reference regulatory authorities	Pharmaceuticals and Medical Devices Agency (PMDA)
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 20-11-2024.

	Evidence of approval of manufacturing facility	Tablet (General) section is approved.
	Evaluation Remarks	
	Decision	
	Approved	
308	Case Category	New Molecule/Formulation (Farooq Aslam)
	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	(S8V-TTW-VV6J, 2026-02-04)
	Detail of Fee Submitted	75000, 2025-11-05,
	The proposed proprietary name / brand name	**Enadustat**
	Label Claim	Each Film Coated Tablet Contains: Enarodustat 4mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	140'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)	Not applicable since this is a new product.
	Pharmacotherapeutic Group of (API)	HIF-PH (Hypoxia-Inducible Factor Prolyl Hydroxylase)inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Loncom Pharmaceutical Co., Ltd and No 127, Qizhong Avenue, Yanbei Sub-district, Qihe County, Dezhou City, Shandong Province, 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) months (completed)} for 03 batches (Batch size: 1000 tablets)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 31-12-2024 for 0.05kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence and CDP studies have been performed against the reference product i.e Enaroy tablet.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	The applicant has submitted 06 months accelerated and 36 months real time stability data of 03 batches according to the conditions of zone IV-A.
	The status in reference regulatory authorities	Pharmaceuticals and Medical Devices Agency (PMDA)
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 20-11-2024.
	Evidence of approval of manufacturing facility	Tablet (General) section is approved.
	Evaluation Remarks	
	Decision	
	Approved	
309	Case Category	Any Other (Farooq Aslam)

	Name, address of Applicant.	**Bristol Mayer Biotech Pakistan** 73 B Guldasht Town Zarrar Shaheed Lahore **(05-352-0068-109282D)**
	Application Form Dy. No / Tracking ID & date of submission	(G5G-GJN-5JXJ, 2026-03-26)
	Detail of Fee Submitted	313500, 2026-03-19,
	The proposed proprietary name / brand name	**Carbeto**
	Label Claim	Each ml contains: Carbetocin.....100mcg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5 vials (1's)-As per SRO
	Shelf Life (Unit)	24 Month(s)Store at upto 30°C.Dont freeze
	For generic drugs (me-too Status)	Carbella Injection by RG Pharmaceutica Pvt. Ltd
	Pharmacotherapeutic Group of (API)	Oxytocin and analogue
	Name, address of Manufacturing site:	Precise Biopharma PVT LTD-Survey No. 46/1-4, Village Kadaiya, Nani Daman- 396 210-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted.
	Name, address of Marketing Authorization Holder:	Precise Biopharma PVT LTD, Survey No. 46/1-4, Village Kadaiya, Nani Daman- 396 210, India
	Details of Certificates (CoPP/FSC/cGMP):	GMP certificate valid till 13-12-2027 with scope of manufacturing of small volume parenteral issued to M/s Precise Biopharma Pvt. Ltd. C/o Sovereign Pharma Pvt. Ltd.,.
	Details of Authorization Letter :	COPP: Copy of CoPP valid till 13-12-2027 is submitted. Product is available in free sale. DSL: DSL valid till 18-10-2028 is submitted. LOA: Copy of letter of authorization is submitted dated 29-09-2025
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies of three batches CBT/01062018, CBT/02062018 and CBT/03062018 25 ± 2°C / 60 ± 5% RH (in accelerated condition for 6 months), 5°C ± 3°C (in real time condition) for 24 months
	The status in reference regulatory authorities	MHRA approved (Pabal Injection 100mcg/ml by Ferring Pharmaceuticals)
	Evaluation Remarks	
	The application has been processed in compliance to the decision of 220th meeting DRAP AUthority. The firm has submitted Form 28-A (i.e loan license) The firm shall submit notarized LOA and apsstille/legalized CoPP.	
	Decision	
	Deferred for the policy decision for loan license.	
310	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	(B3U-UV6-ZSG1, 2024-10-29)
	Detail of Fee Submitted	37000.0, 2024-10-21,
	The proposed proprietary name / brand name	**Bestee Tablets 20mg**

	Label Claim	Each Tablet contains: Bilastine....20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 x 10's , 2 x 10's,-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store between 15°C to 30°C.
	For generic drugs (me-too Status)	Bistavo Tablets 20mg
	Pharmacotherapeutic Group of (API)	R06AX29 Other antihistamines for systemic use
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Metrochem API Pvt. Ltd., Unit -IV, Plot no. 34B, 40B & 60B, J.N., Pharma City, Thanam (V), Parawada (M), Visakhapatnam District 531021, Andhra Pradesh, India.
	Detail of stability batches of drug product	3 batches. 5000 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	Bistavo 20mg Tablet B. No. MKK002 M/s Sami Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Health Canada (HC)
	GMP status of the firm	SUbmitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Decision	
	Approved	
311	Case Category	Routine (Haleema Sharif)
	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	(613-PVD-JMBP, 2024-06-03)
	Detail of Fee Submitted	30000.0, 2024-05-20,
	The proposed proprietary name / brand name	**Trint 5mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: Vortioxetine HBr equivalent to vortioxetine 5mg
	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)	Vorti 5mg Tablet - CCL Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Antidepressant
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	No. 18 Zhenhua Road, Lianyungang City, Jiangsu Province, China and business head office with address Room 1216,Shimao Plaza, Xinbei district, Changzhou, China
	Detail of stability batches of drug product	Submitted by firm
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attested commercial invoice is submitted by firm

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per conditions of zone IVA is submitted by firm.
	The status in reference regulatory authorities	Brintellix 5mg Film Coated Tablet by Lundbeck Limited - MHRA
	GMP status of the firm	GMP inspection conducted on 25.03.2022 indicate tablet general section of firm.
	Evidence of approval of manufacturing facility	CLB letter dated 7th June 2022 indicated Tablet General section.
	Evaluation Remarks	
	Previously, the firm submitted its DML; however, vortioxetine hydrobromide was not included, while other APIs were listed. The firm was therefore asked to submit an API approval letter issued by either the Jiangsu Food and Drug Administration (Provincial Authority) or the National Medical Products Administration (NMPA) (Central Authority). In response, the firm has now submitted a GMP certificate for vortioxetine, issued by the Lianyungang Drug Administration, which is a local regulatory authority.	
	Decision	
	Approved Approved with innovator's specification. Firm shall submit fee for revision of specifications as per SRO 1324(I)/2024 dated 30-08- 2024 before issuance of Registration letter.	
312	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	(D5L-G1M-JXE8, 2024-09-27)
	Detail of Fee Submitted	37000.0, 2024-09-18,
	The proposed proprietary name / brand name	**TORICAB**
	Label Claim	Each Film Coated Tablet Contains: Etoricoxib..... 120mg (Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's, 10's, 14's, 20'-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 degree celsius
	For generic drugs (me-too Status)	STARCOX 120mg
	Pharmacotherapeutic Group of (API)	NSAID
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Prudence Pharma Chem
	Detail of stability batches of drug product	Stability data of three batches submitted by firm
	Documents for the procurement of API with approval from DRAP (in case of Import)	Submitted by firm
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted by Firm

	The status in reference regulatory authorities	Approved in MHRA
	GMP status of the firm	-
	Evidence of approval of manufacturing facility	CLB letter indicating Tablet General Section submitted by firm
	Evaluation Remarks	
	Decision	
	Approved Approved subject to submission of GMP certificate by drug product manufacturer.	
313	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	(ELA-P2S-XN5N, 2024-09-27)
	Detail of Fee Submitted	37000.0, 2024-09-18,
	The proposed proprietary name / brand name	**TORICAB**
	Label Claim	Each Film Coated Tablet Contains: Etoricoxib..... 60mg (Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's, 10's, 14's, 20'-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 degree celsius
	For generic drugs (me-too Status)	STARCOX 60mg
	Pharmacotherapeutic Group of (API)	NSAID
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Prudence Pharma Chem
	Detail of stability batches of drug product	Submitted by firm
	Documents for the procurement of API with approval from DRAP (in case of Import)	Submitted by firm
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted by firm
	The status in reference regulatory authorities	Approved in MHRA
	GMP status of the firm	-
	Evidence of approval of manufacturing facility	CLB letter Indicating Tablet General section is submitted by firm
	Evaluation Remarks	
	Decision	
	Approved Approved subject to submission of GMP certificate by drug product manufacturer.	
314	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	(VQ5-WHE-WX61, 2024-09-27)
	Detail of Fee Submitted	37000.0, 2024-09-18,

	The proposed proprietary name / brand name	**TORICAB**
	Label Claim	Each Film Coated Tablet Contains: Etoricoxib..... 90mg (Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's, 10's, 14's, 20'-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 degree celsius
	For generic drugs (me-too Status)	STARCOX 90mg
	Pharmacotherapeutic Group of (API)	NSAID
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Prudence Pharma Chem
	Detail of stability batches of drug product	Stability data for three batches submitted by firm
	Documents for the procurement of API with approval from DRAP (in case of Import)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Approved in MHRA
	GMP status of the firm	-
	Evidence of approval of manufacturing facility	CLB letter indicating Tablet General Section submitted by firm.
	Evaluation Remarks	
	Decision	
	Approved Approved subject to submission of GMP certificate by drug product manufacturer.	
315	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	**Global Pharmaceuticals Pakistan** Plot # 8, Street # S-8, RCCI, Industrial Estate Rawat, Islamabad-Pakistan **(000724)**
	Application Form Dy. No / Tracking ID & date of submission	(U2M-791-Z73Y, 2024-06-03)
	Detail of Fee Submitted	30000.0, 2024-05-06,
	The proposed proprietary name / brand name	**Acneris 1%w/w Gel**
	Label Claim	Each gram contains: Clindamycin phosphate eq to Clindamycin.....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10gm-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect from light.
	For generic drugs (me-too Status)	Clinagel 1% gel by GSK Pvt Ltd
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Name:M/s Zhejiang Tiantai Pharmaceutical Co., Ltd. Address: No. 588, Fengze Road, Tiantai County, Taizhou City, Zhejiang Province, China (317200)
	Detail of stability batches of drug product	Stability data of three batches submitted by firm
	Documents for the procurement of API with approval from DRAP	Submitted

	(in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE; Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided by firm
	The status in reference regulatory authorities	Approved in MHRA
	GMP status of the firm	GMP certificate attached inside dossier
	Evidence of approval of manufacturing facility	CLB letter indicating Gel General section indicated by firm.
	Evaluation Remarks	
	Decision	
	Approved	
316	Case Category	Routine (Haleema Sharif)
	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	(BNR-DJZ-VGHE, 2024-07-08)
	Detail of Fee Submitted	75000.0, 2024-06-11,
	The proposed proprietary name / brand name	**Acter 250mg**
	Label Claim	Each Tablet Contains: Terbinafine HCL equivalent to Terbinafine 250mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1x10's, 2x10's, 2x7'-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 °C
	For generic drugs (me-too Status)	Lamisil 250mg Tablet (Novartis Pharma Pakistan)
	Pharmacotherapeutic Group of (API)	Antifungal
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt Limited-Plot # 129, Sunder Industrial Estate Lahore-
	Name & address of API manufacturer	Saptagir Laboratories Pvt Ltd
	Detail of stability batches of drug product	Submitted by firm
	Documents for the procurement of API with approval from DRAP (in case of Import)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted by firm
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted by Firm
	The status in reference regulatory authorities	Terbinafine 250mg Tablets (Dr. Reddys laboratories UK Ltd.)
	GMP status of the firm	GMP certificate attached inside dossier
	Evidence of approval of manufacturing facility	CLB letter indicating Tablet General Section submitted by firm.
	Evaluation Remarks	
	Decision	
	Approved	
317	Case Category	Routine (Haleema Sharif)
	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	(UU2-BBR-VE1U, 2024-07-08)
	Detail of Fee Submitted	75000.0, 2024-06-11,
	The proposed proprietary name / brand name	**Acter 125mg**
	Label Claim	Each Tablet contains: Terbinafine HCl equivalent to Terbinafine.....125mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1x10's, 2x10's, 2x7'-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 °C
	For generic drugs (me-too Status)	Lamisil 125mg Tablet (Novartis Pharma Pakistan)
	Pharmacotherapeutic Group of (API)	Antifungal
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt Limited-Plot # 129, Sunder Industrial Estate Lahore-
	Name & address of API manufacturer	Saptagir Laboratories Pvt Ltd
	Detail of stability batches of drug product	Submitted by firm for three batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	Submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted by Firm
	The status in reference regulatory authorities	Terbinafine 125mg Tablets (Dr. Reddys laboratories UK Ltd.)/ Approved in MHRA
	GMP status of the firm	GMP certificate uploaded inside Dossier
	Evidence of approval of manufacturing facility	CLB letter indicating Tablet General Section submitted by firm.
	Evaluation Remarks	
	Decision	
	Approved	
318	Case Category	New Section (Haleema Sharif)
	Name, address of Applicant.	**VENUS PHARMA** 23-KM MULTAN ROAD, LAHORE **(000300)**
	Application Form Dy. No / Tracking ID & date of submission	(8A3-YL4-1WWB, 2026-02-06)
	Detail of Fee Submitted	38700, 2025-10-31,
	The proposed proprietary name / brand name	**Nor-est Injection**
	Label Claim	Each ml contains: Norethisterone Enanthate.....50mg Estradiol Valerate.....5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1ml x 1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Attached Module I P1.5.8
	Pharmacotherapeutic Group of (API)	Contraceptive Hormones
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhejiang Xianju Junye Pharmaceutical Co.,Ltd.

	Detail of stability batches of drug product	Stability Studies of drug product Attached M III 3.2 P.8
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached M III 3.2 P.8
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached Module III 3.2. P.2.2.1 (B)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached Module III P 3.2. S.7
	The status in reference regulatory authorities	Attached Module I P 1.5.9
	GMP status of the firm	Attached Module I P 1.3.4
	Evidence of approval of manufacturing facility	Attached Module I P 1.3.5

Evaluation Remarks

Queries	Response
1. Test for residual solvents has not been performed by drug substance manufacturer for estradiol valerate; Justification is required regarding this from drug substance manufacturer.	As per USP 2024, the applicable monograph does not include a requirement or specification for residual solvents. The attached reference is provided for verification. Our material complies fully with the current USP 2024 monograph requirements and specifications. *** The firm's response is inadequate. It should be expanded with an ICH Q3C-based risk assessment or scientific justification, not just USP monograph compliance.
2. Audit trail report of 21 CFR compliant system.	Audit trail report of 21 CFR compliant system is not submitted by firm

Decision

Deferred

Registration Board decided to defer the case for submission of following:

A comprehensive ICH Q3C-based risk assessment, including details of solvent usage (if any), classification, control measures, and/or supporting analytical data to demonstrate compliance.

Audit trail report of 21 CFR compliant system is not submitted by firm

319	Case Category	New Section (Haleema Sharif)
	Name, address of Applicant.	**VEGA PHARMACEUTICALS PVT LTD** PLOT # 4, PHARMA CITY 30KM MULTAN ROAD LAHORE **(000542)**
	Application Form Dy. No / Tracking ID & date of submission	(RNQ-U81-G6YG, 2025-08-05)
	Detail of Fee Submitted	37000.0, 2025-07-14,
	The proposed proprietary name / brand name	**Brimo 0.2% eye drops**
	Label Claim	Each ml contains: Brimonidine Tartrate ..... 2mg (0.2% w/v) (Manufacturer's specification
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 25°C; excursions permitted to 15-30°C
	For generic drugs (me-too Status)	Brimodine 0.2% by Sante (Private) Limited
	Pharmacotherapeutic Group of (API)	Alpha adrenergic agonists
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	

Detail of stability batches of drug product	3 batches BT T1-24, BT T2-24, BT T3-24 each having batch size of 400 bottles
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 23-07-2024 specifies import of 45g of Brimonidine Tartrate
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies are conducted against Brimodine 0.2% (Batch # GJ-018) by Sante (private) Limited
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches of API YQ0021121, YQ0031121, YQ0041121 as per Zone IV-A
The status in reference regulatory authorities	USFDA Approved Alphagan Eye drops by Allergan, Inc.
GMP status of the firm	Valid GMP certificate issued on the basis of inspection dated 08-05-2024
Evidence of approval of manufacturing facility	Eye/Ear Drops & Nasal Spray Section (General) II-New issued on 3rd June 2025

Evaluation Remarks

Queries	Response
In analytical method of drug substance wavelength for assay is 264nm and in analytical method of drug product wavelength for assay is 254 nm and on chromatograms wavelength is 254 nm. clarify this difference.	The difference in assay wavelength between drug substance (264 nm) and drug product (254 nm) is based on method optimization and specificity considerations. For Brimonidine Tartrate drug substance, 264 nm was selected as per supplier recommendation, corresponding to the absorbance maximum in pure solution. During development of the drug product analytical method, UV spectral evaluation and method optimization were performed in the presence of formulation excipients and preservatives. It was observed that at 264 nm, increased baseline noise and interference from formulation components and degradation products could occur during stability studies. Therefore, 254 nm was selected for drug product assay as it provided improved baseline stability, better specificity, and consistent response for Brimonidine Tartrate in the finished formulation. Adequate absorbance and sensitivity were maintained at this wavelength. The drug product method at 254 nm was fully validated in accordance with ICH Q2(R1) requirements, including specificity, linearity, accuracy, precision, robustness, and stability-indicating capability. All routine, validation, and stability testing up to 6 months has been successfully conducted at 254 nm. Hence, the difference in wavelength selection is scientifically justified and does not impact the quality, safety, or efficacy of the product. Please Note here the Verification of Drug substance API is done by the Vega Pharmaceuticals on same 264 nm.
	The previously issued GMP certificate for domestic and export purposes was valid until 05/07/2025. The firm was instructed to submit a valid GMP certificate; however, they have now submitted a GMP certificate issued for the export of the drug. Previous GMP issued to firm for Domestic and export purpose was valid Valid until:05/07/2025when firm was advised to submit valid GMP they now submitted GMP certificate issued for export of Drug

Decision

Approved

Approved with innovator's specification.

Firm shall submit 9,000/- fee for revision of specifications as per SRO 1324(I)/2024 dated 30-08-2024 before issuance of Registration letter.

320	Case Category	New Section (Haleema Sharif)
	Name, address of Applicant.	**VEGA PHARMACEUTICALS PVT LTD** PLOT # 4, PHARMA CITY 30KM MULTAN ROAD LAHORE **(000542)**
	Application Form Dy. No / Tracking ID & date of submission	(DJV-6W5-Z2H3, 2025-08-05)
	Detail of Fee Submitted	37000.0, 2025-07-14,
	The proposed proprietary name / brand name	**Brimotol 0.2%/ 0.5% ophthalmic solution**
	Label Claim	Each mL contains: Brimonidine Tartrate ..... 0.2% Timolol (as Timolol Maleate).... 0.5% (Manufacturer's Specifications)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store between 15 - 30°C, protect from light.
	For generic drugs (me-too Status)	Brimo-T by ATCO Laboratories Limited
	Pharmacotherapeutic Group of (API)	Alpha adrenergic agonists & Beta-Blocker
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches BTM T1-24, BTM T2-24, BTM T3-24 each having batch size of 400 bottles
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 24-08-2024 specifies import of 45g of Brimonidine Tartrate & dated 26-5-2024 specifies import of 3Kg of Timolol Maleate
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies are conducted against Brimo-T (Batch # KM003J) by ATCO Laboratories,
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches of API YQ0021121, YQ0031121, YQ0041121 of Brimonidine tartrate & 3 batches 0501052017 , 0502052017 ,0503102017 of Timolol Maleate as per Zone IV-A
	The status in reference regulatory authorities	USFDA Approved Combigan Eye drops by Allergan, Inc.
	GMP status of the firm	Valid GMP certificate issued on the basis of inspection dated 08-05-2024
	Evidence of approval of manufacturing facility	Eye/Ear Drops & Nasal Spray Section (General) II-New issued on 3rd June 2025

Evaluation Remarks

Queries	Response
1. GMP certificate for Brimonidine Tartrate other than export purpose, and evidence that stated drug substance is also used domestically in country of origin.	The previously issued GMP certificate for domestic and export purposes was valid until 05/07/2025. The firm was instructed to submit a valid GMP certificate; however, they have now submitted a GMP certificate issued for the export of the drug. Previous GMP issued to firm for Domestic and export purpose was valid Valid until:05/07/2025when firm was advised to submit valid GMP they now submitted GMP certificate issued for export of Drug
2. CoA of imported lot of API.	Firm has submitted COA of imported lot in other formulation containing Brimonidine Tartrate by same firm

Decision

Approved

Approved with innovator's specification.

Firm shall submit 9,000/- fee for revision of specifications as per SRO 1324(I)/2024 dated 30-08-2024 before issuance of Registration letter.

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Case Category	Routine (Haleema Sharif)
Name, address of Applicant.	**Pacific Pharmaceuticals Ltd.** Plot No.384, Sundar Industrial Estate, Raiwind Road, Lahore **(000902)**
Application Form Dy. No / Tracking ID & date of submission	(GJU-W4Q-RYY7, 2024-05-09)
Detail of Fee Submitted	30000.0, 2024-04-02,
The proposed proprietary name / brand name	**Ketorolac Tromethamine Injection 30mg/ml**
Label Claim	Each ml contains Ketorolac Tromethamine 30mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	5x1ml Ampoule-As per SRO
Shelf Life (Unit)	2 Year(s)Store below 30°C
For generic drugs (me-too Status)	Toradol Injection by Roche Pakistan Ltd.
Pharmacotherapeutic Group of (API)	Analgesic
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Satyadivis Pharmaceuticals Pvt. Ltd.
Detail of stability batches of drug product	provided
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted loan letter from Wimit
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE; Provided
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
The status in reference regulatory authorities	Ketorolac Trometamol 30 mg/ml solution for injection by Baxter Healthcare Ltd, UK-MHRA Approved
GMP status of the firm	GMP certificate issued to the firm based on GMP inspection conducted on 12.10.2023.
Evidence of approval of manufacturing facility	CLB letter No. 1-56/2011-Lic dated 24 June 2019 indicate SVP (General) section.

Evaluation Remarks

Registration Board has deferred the case in its 352nd meeting for submission of following:

Reason of deferment	Response of firm
1. The data logger records demonstrating the storage conditions of drug substance throughout transportation by drug product manufacturer as the stability data submitted by the firm actually corresponds to 25°C ± 2°C / 60% RH ± 5% RH, rather than Zone IVA conditions. 2. Real-time stability data of the product for at least one year, including degradation studies conducted on the drug product by drug product manufacturer.	Firm has submitted Long-term stability data from supplier as per zone IV-B (30°C ± 2°C / 75% RH ± 5% RH) to fulfill the requirements of storage conditions.

	Decision	
	Approved	
322	Case Category	New Section (Haleema Sharif)
	Name, address of Applicant.	**Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore **(000576)**
	Application Form Dy. No / Tracking ID & date of submission	(YG8-WRQ-BGAX, 2024-08-21)
	Detail of Fee Submitted	30000.0, 18500.0 2024-08-06, 2025-07-15
	The proposed proprietary name / brand name	**Danazol Capsule 100mg**
	Label Claim	Each Capsule contains: Danazol ... 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10’s , 15’s, 20’s, 3-As per SRO
	Shelf Life (Unit)	2 Year(s)Store between 15°C - 30°C
	For generic drugs (me-too Status)	Danzol 100mg Capsules of M/s Platinum Pharmaceuticals
	Pharmacotherapeutic Group of (API)	G03XA01, Antigonadotropins and similar agents
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	03 Batches, 1000 Capsules each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Copy AD (I&E) Lahore attested Invoice for Import of 1Kg API has been submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and CDP has been conducted against Danzol 100mg Capsules of M/s Platinum Pharmaceuticals.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Studies conducted at 25+2°C and 60% +5%RH by Drug Substance Manufacturer.
	The status in reference regulatory authorities	DANAZOL 100mg Capsules, USFDA approved.
	GMP status of the firm	Copy of GMP Certificate valid for three years from the date of inspection (14-04-2022) has been submitted.
	Evidence of approval of manufacturing facility	Copy of Section approval letter from Licensing Division for Tablet (General) Section has been submitted.

Evaluation Remarks

Registration has deferred the case in its 345th meeting for the following reasons, Response of firm is summarized below.

Reason of deferment	Response of firm.
1. Danazol is a synthetic steroid derived from ethisterone, whereas Section approval letter has been enclosed for Tablet (General) Section. Please justify (with supporting evidence), where the product is intended to be manufactured.	Firm has submitted CLB letter dated 16th April 2025 indicate Capsule Steroid Section
2. Please provide evidence of API approval of Drug Substance (Danazol) issued by regulatory authority of country of origin.	Previously, the firm submitted an API approval document that did not include a date or reference number, making it incomplete. The firm has now submitted a GMP certificate for the manufacturer, which mentions the production of bulk API (General category) in general but does not specifically refer to Danazol (Steroidal Drug Substance).

		Moreover address on submitted GMP certificate is not similar to the address of drug substance manufacturer mentioned in section 3.2.S.2.1. Address in Dossier: Micro Orgo Chem, India 44/2201, Pranav Co-Op HSG. Soc . Gandhi Nagar, Bandra (E), Mumbai- 400051, India. Address on GMP certificate: Micro Orgo Chem Shed No. C 1 B 57 LIC sector G.D.I.C, VAPI 396-195 District Valsad
	3. 3.2.S.7 Stability Studies (Real Time) have been conducted at 25+2°C and 60% +5%RH instead of Zone-IV. Please justify.	Firm has submitted stability studies data of drug substance as per conditions of zone IVA with following endorsement from drug substance manufacturer: We Micro Orgo Chem, would like to specify that we are performing stability study for both Zone IV A and Zone IV B as a long term stability study, but we are not including the same in DMF section 3.2.S.7.3 we are only including accelerated study along with most common storage condition which is 25°C +/- 2 degrees and RH of 60% +/- 5% as long term study, However we are providing the same per the customer requirements, Hence the same was not available th DMF section 3.2.S.7.3. Micro Orgo-Chem confirms the correctness and completeness of the data supplied:
	4. 3.2.P.8 Stability Studies were initiated in December 2023, whereas the material was imported in September 2020. Please clarify.	Following clarification submitted by firm: We would like to clarify that the stability batches were planned and manufactured considering our internal priorities and the availability of required equipment. We ensured that the manufacturing and initiation of stability studies were conducted well within the approved shelf life of the active pharmaceutical ingredient (API), thereby maintaining compliance with all regulatory requirements and ensuring product quality and integrity. We remain committed to adhering to all applicable guidelines and maintaining transparent communication with your esteemed department

	Decision
	Deferred Registration Board deferred the case for submission of valid, GMP certificate clearly referencing Danazol (Steroidal Drug Substance), and having similar address as mentioned in section 3.2.S.2.1 of dossier.

323	Case Category	Routine (Haleema Sharif)
	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	(UQR-HMM-2788, 2024-05-15)
	Detail of Fee Submitted	, 75000.0 , 2024-02-26
	The proposed proprietary name / brand name	**Artesun Injection 60mg**
	Label Claim	Each vial contains: Artesunate 60mg
	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 25 Degree Centigrade
	For generic drugs (me-too Status)	Misonate 60mg Injection (manufactured by Tabros Pharmaceutical) Reg. No. 057719
	Pharmacotherapeutic Group of (API)	Anti-malarial

	Name, address of Manufacturing site:	Palpax Pharmaceutical Pvt. Ltd.-Plot No. FD-46-A8, Street-1, Sector-38, Korangi Creek Industrial Park, Karachi-
	Name & address of API manufacturer	Arhihantanam Life Care Pvt. Ltd. India
	Detail of stability batches of drug product	Provided
	Documents for the procurement of API with approval from DRAP (in case of Import)	firm has submitted attested commercial invoice
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE; Provided
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
	The status in reference regulatory authorities	Artesunate Injection 60mg Manufactured by Ryvis Pharma (Canada)
	GMP status of the firm	GMP certificate issued to the firm based on inspection conducted on 08th November 2022.
	Evidence of approval of manufacturing facility	Sterile dry powder vial section is present on CLB letter No. 2-3/2011-Lic dated 12. 06. 2017

Evaluation Remarks

The Registration Board in its 352nd meeting has deferred the case for submission of following:

Reason for Deferment	Response of firm
1. The data logger records demonstrating the storage conditions throughout transportation by drug product manufacturer as the stability data submitted by the firm actually corresponds to 25°C ± 2°C / 60% RH ± 5% RH, rather than Zone IVA conditions. 2. Real-time stability data of the product for at least one year, including degradation studies conducted on the drug product by drug product manufacturer.	Firm has submitted stability data of drug substance as per conditions of Zone IVA. More over firm has also submitted following: We kept our product for stability study for 2 years in real time stability & Accelerated as per Zone IV-A (30 °C ± 2°C, 65% RH & 40°C ± 2°C 75% RH. We did not observe any degradation in two years our stability show that our product is stable under stress condition (Accelerated stability studies and real time stability) no change in assay, physical appearance & PH that why No degradation observed while some degradation test was performed in lab during the Test method verification.

Decision

Approved

Registration Board approved the product subject to the submission of in-use stability studies of the drug product using the same solvent as recommended by the WHO prequalified reference product. The firm shall also submit batch analysis report in accordance with IP monograph of Artesunate Injection.

324	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	**AUSPEC PHARMACEUTICALS PVT LTD** 21, Km, Raiwind Road, Lahore. **(000964)**
	Application Form Dy. No / Tracking ID & date of submission	(QLR-6B4-4W7N, 2024-05-27)
	Detail of Fee Submitted	75000.0, 2024-02-06,
	The proposed proprietary name / brand name	**K-Tol 30mg/ml Injection**
	Label Claim	Each 1ml ampoule Contains: Ketorolac Tromethamine....30mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1ml x 5's/As per SRO-As per SRO

	Shelf Life (Unit)	2 Year(s)Store below 30C
	For generic drugs (me-too Status)	Orkit Injection 30mg/ml by Aulton Pharmaceutical, Hattar
	Pharmacotherapeutic Group of (API)	Analgesic
	Name, address of Manufacturing site:	Aulton Pharmaceuticals-Plot # 84/1, Block A, Phase 5, Industrial Estate, Hattar, Pakistan-
	Name & address of API manufacturer	M/s SAURAV CHEMICALS LIMITED. by DerabassiBarwala Road, Village Bhagwanpura, Tehsil Derabassi, District Sahibzada Ajit Singh Nagar, Punjab, India
	Detail of stability batches of drug product	Submitted for three batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE; Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted by firm.
	The status in reference regulatory authorities	Ketorolac Trometamol 30 mg/ml solution for injection by Baxter Healthcare Ltd, Caxton Way, Thetford, Norfolk, IP24 3SE, UK
	GMP status of the firm	-
	Evidence of approval of manufacturing facility	-
	Evaluation Remarks	
	Decision	
	Approved	
325	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	**QADIR PHARMACEUTICALS** FATEH GHAR SAHUWALA ROAD SIALKOT **(000944)**
	Application Form Dy. No / Tracking ID & date of submission	(UEL-W8P-1MLB, 2024-10-07)
	Detail of Fee Submitted	37000.0, 2024-09-20,
	The proposed proprietary name / brand name	**Desloqad 5mg Tablet**
	Label Claim	Each film coated tablet contains; Desloratadine 5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 x 10’s -As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C , protect from light
	For generic drugs (me-too Status)	Desora 5mg Tablet
	Pharmacotherapeutic Group of (API)	Antihistamine
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Morepen Laboratories Limited
	Detail of stability batches of drug product	Stability data of three batches submitted by firm
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted by firm
	The status in reference regulatory authorities	FDA, MHRA, EMC
	GMP status of the firm	-
	Evidence of approval of manufacturing facility	-

Evaluation Remarks

Query	Response
Analytical method of drug substance manufacturer is different from USP? Why	The analytical method of the drug substance manufacturer may differ from the pharmacopeial method (USP) because manufacturers are allowed to develop and use in-house analytical procedures, provided these methods are scientifically justified and properly validated. In our case, the drug substance manufacturer utilizes an in-house analytical method that is specifically optimized for their manufacturing process, impurity profile, and instrumentation. This method ensures accurate, precise, and reproducible results for routine quality control of the API. Although the method differs from the USP monograph method, it has been fully validated in accordance with ICH Q2 (R1) guidelines, demonstrating equivalence or superiority in terms of specificity, accuracy, precision, linearity, and robustness. Where applicable, method verification or comparison with the USP method has been performed to ensure that the quality of the drug substance complies with pharmacopeial requirements

Decision

Approved

326	Case Category	Routine (Haleema Sharif)
	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	(3UB-LYD-9X5A, 2024-10-30)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-28, 2024-10-23
	The proposed proprietary name / brand name	**Zipras 80mg Capsules**
	Label Claim	Each Capsule contains: Ziprasidone (as HCl) .....80mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Zeldox 80mg Capsules
	Pharmacotherapeutic Group of (API)	antipsychotics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Stability data of three submitted by firm
	Documents for the procurement of API with approval from DRAP (in case of Import)	invoice submitted by firm
	Pharmaceutical Equivalence and Comparative Dissolution Profile	submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	submitted
	The status in reference regulatory authorities	Ziprasidone Hydrochloride Capsules 80mg (Registered inUSFDA)
	GMP status of the firm	-

	Evidence of approval of manufacturing facility	-
	Evaluation Remarks	
	The firm was advised to submit a valid GMP certificate. However, we have noted that the address of the manufacturer on the GMP certificate differs from the address mentioned on the Invoice, the Certificate of Analysis (COA), and in section 3.2.S.2.1 of the dossier.	
	Decision	
	Deferred Registration Board deferred the case for submission of the following: A GMP certificate ensuring consistency of the manufacturer's name and address across all regulatory documents, including the dossier (section 3.2.S.2.1), COA, and commercial invoice.	
327	Case Category	Routine (Haleema Sharif)
	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	(P6W-WGW-2JVA, 2024-10-30)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-28, 2024-10-08
	The proposed proprietary name / brand name	**Zipras 60mg Capsules**
	Label Claim	Each Capsule contains: Ziprasidone (as HCl) .....60mg (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 30ºC
	For generic drugs (me-too Status)	Xepex 60mg Capsules, Manufacturer: Danas Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Atypical Antipsychotic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Stability Studies data of three batches both accelerated and real time submitted by firm
	Documents for the procurement of API with approval from DRAP (in case of Import)	Invoice provied by firm
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stabilty data submitted by firm
	The status in reference regulatory authorities	Ziprasidone Hydrochloride Capsules 60mg, Manufacturer: LUPIN PHARMS, (NDA): 077560, (USFDA Approved)
	GMP status of the firm	-
	Evidence of approval of manufacturing facility	-
	Evaluation Remarks	
	The firm was advised to submit a valid GMP certificate. However, it is noted that the address of the manufacturer on the GMP certificate differs from the address mentioned in section 3.2.S.2.1 of the dossier.	
	Decision	
	Deferred	

	Registration Board deferred the case for submission of the following: A GMP certificate ensuring consistency of the manufacturer's name and address across all regulatory documents, including the dossier (section 3.2.S.2.1), COA, and commercial invoice.	
328	Case Category	Routine (Haleema Sharif)
	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	(SMH-V63-PRP2, 2024-10-30)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-28, 2024-10-08
	The proposed proprietary name / brand name	**Zipras 40mg Capsules**
	Label Claim	Each Capsule contains: Ziprasidone (as HCl) .....40mg (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 30ºC
	For generic drugs (me-too Status)	Xepex 40mg Capsules, Manufacturer: Danas Pharmaceuticals
	Pharmacotherapeutic Group of (API)	atypical antipsychotic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Submitted by firm for three batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	Invoice submitted by firm
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE; Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Ziprasidone Hydrochloride Capsules 40mg, Manufacturer: LUPIN PHARMS, (NDA): 077560 (USFDA Approved)
	GMP status of the firm	-
	Evidence of approval of manufacturing facility	-
	Evaluation Remarks	
	The firm was advised to submit a valid GMP certificate. However, it is noted that the address of the manufacturer on the GMP certificate differs from the address mentioned in section 3.2.S.2.1 of the dossier.	
	Decision	
	Deferred Registration Board deferred the case for submission of the following: A GMP certificate ensuring consistency of the manufacturer's name and address across all regulatory documents, including the dossier (section 3.2.S.2.1), COA, and commercial invoice.	
329	Case Category	Routine (Haleema Sharif)
	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	(USY-VWX-Z6MT, 2024-10-30)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-28, 2024-10-08
	The proposed proprietary name / brand name	**Zipras 20mg Capsules**
	Label Claim	Each Capsule contains: Ziprasidone (as HCl) .....20mg (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 30ºC
	For generic drugs (me-too Status)	Xepex 20mg Capsules, Manufacturer: Danas Pharmaceuticals
	Pharmacotherapeutic Group of (API)	atypical antipsychotic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Stability Studies for three batches both accelerated and real time submitted by firm
	Documents for the procurement of API with approval from DRAP (in case of Import)	Submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	submitted .
	The status in reference regulatory authorities	Ziprasidone Hydrochloride Capsules 20mg, Manufacturer: LUPIN PHARMS, (NDA): 077560, (USFDA Approved)
	GMP status of the firm	-
	Evidence of approval of manufacturing facility	-
	Evaluation Remarks	
	The firm was advised to submit a valid GMP certificate. However, it is noted that the address of the manufacturer on the GMP certificate differs from the address mentioned in section 3.2.S.2.1 of the dossier.	
	Decision	
	Deferred Registration Board deferred the case for submission of the following: A GMP certificate ensuring consistency of the manufacturer's name and address across all regulatory documents, including the dossier (section 3.2.S.2.1), COA, and commercial invoice.	
330	Case Category	Routine (Haleema Sharif)
	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	(9VM-Z6D-M9X7, 2024-10-09)
	Detail of Fee Submitted	37000.0, 2024-09-12,
	The proposed proprietary name / brand name	**TICALOR**
	Label Claim	Each film coated tablet contains: Ticagrelor 90mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10-As per SRO,20-As per SRO,30-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 °C

	For generic drugs (me-too Status)	ANPLAG 90MG TABLET (PHARMEVO)
	Pharmacotherapeutic Group of (API)	Antiplatelet
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Jiangxi Synergy Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	Stability Study Submitted by firm
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearence Certificate submitted by firm.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	US-FDA (BRILINTA 90MG TABLET) (NDA: 022433)
	GMP status of the firm	-
	Evidence of approval of manufacturing facility	-
	Evaluation Remarks	
	Decision	
	Approved	
331	Case Category	Routine (Haleema Sharif)
	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	(L6M-WBH-9ST3, 2024-10-09)
	Detail of Fee Submitted	37000.0, 2024-09-12,
	The proposed proprietary name / brand name	**TICALOR**
	Label Claim	Each film coated tablet contains: Ticagrelor 60mg.
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10-As per SRO,20-As per SRO,30-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 °C
	For generic drugs (me-too Status)	ANPLAG 60MG TABLET (PHARMEVO)
	Pharmacotherapeutic Group of (API)	antiplatelet agent
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Jiangxi Synergy Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	Stability data of three batches submitted by firm
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearence certificate submitted by firm
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted by firm as per zone IVA
	The status in reference regulatory authorities	US-FDA (BRILINTA 60MG TABLET) (NDA: 022433)
	GMP status of the firm	Attached inside dossier
	Evidence of approval of manufacturing facility	CLB letter indicating Tablet General section submitted by firm
	Evaluation Remarks	

	Decision	
	Approved	
332	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	(1SE-ZZT-URE8, 2024-08-21)
	Detail of Fee Submitted	30000.0, 2024-07-08,
	The proposed proprietary name / brand name	**Tigrelor**
	Label Claim	Each Film coated tablet contains: Ticagrelor.....90mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	140 tablets [14 tabl-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)	ANPLAG 90mg Tablet
	Pharmacotherapeutic Group of (API)	Antiplatelet Agent
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	SUMAR BIOTECH LLP Plot-No.:112, 113,114 GIDC Estate Gozariya, Ta. & Dist.: Mehsana -382825, Gujarat.
	Detail of stability batches of drug product	Stability data of three batches submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	Submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Ssubmitted
	The status in reference regulatory authorities	Approved in USFDA
	GMP status of the firm	GMP certificate attached inside dossier
	Evidence of approval of manufacturing facility	CLB letter indicating Tablet General section submitted by firm.
	Evaluation Remarks	
	Decision	
	Approved	
333	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	(UZY-X34-N92S, 2024-08-19)
	Detail of Fee Submitted	30000.0, 2024-07-08,
	The proposed proprietary name / brand name	**Tigrelor**
	Label Claim	Each Film Coated Tablet contains: Ticagrelor.....60mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	140 Tablets [14 Tabl-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)	Anplag 60mg Tablet. Manufacturer: PHARMEVO (PVT) LTD
	Pharmacotherapeutic Group of (API)	Antiplatelet Agent
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	SUMAR BIOTECH LLP & Address: Plot-No.:112, 113,114 GIDC Estate Gozariya, Tal. & Dist.: Mehsana - 382 825, Gujarat, India.
	Detail of stability batches of drug product	Submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Approved in USFDA
	GMP status of the firm	GMP certificate attached inside dossier
	Evidence of approval of manufacturing facility	CLB letter indicating tablet general section submitted by firm
	Evaluation Remarks	
	Decision	
	Approved	
334	Case Category	Routine (Haleema Sharif)
	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	(2TE-18U-PWNJ, 2024-08-19)
	Detail of Fee Submitted	, ,
	The proposed proprietary name / brand name	**Proxen**
	Label Claim	Each 5ml contains: Naproxen 125mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100mL, 120mL, and 20-As per SRO
	Shelf Life (Unit)	24 Year(s)stored below 30°C
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	Analgesic
	Name, address of Manufacturing site:	Martin Dow Marker Limited -7- Jail Road, Quetta, Pakistan-
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Sumitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE; Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Naproxen Orion 25 mg/ml oral suspension by Orion Corporation Orionintie 1 FI-02200 Espoo

		Finland (MHRA)
	GMP status of the firm	-
	Evidence of approval of manufacturing facility	-
	Evaluation Remarks	
	Valid GMP Certificate of Unit I (as part of manufacturing is carried out here) & Unit II of drug substance manufacturer is required.	
	Decision	
	Approved Approved subject to submission of valid GMP Certificate of Unit I (as part of manufacturing is carried out here) & Unit II of drug substance manufacturer.	
335	Case Category	Routine (Haleema Sharif)
	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	(523-6VQ-WSPW, 2024-06-24)
	Detail of Fee Submitted	75000.0, 2024-06-24,
	The proposed proprietary name / brand name	**OLP 2mg/ml Eye Drops**
	Label Claim	Each ml Contains: Olopatadine as Hydrochloride (USP).....2mg (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)	Opat Forte Opthalmic Solution Alza Pharmaceuticals 081623
	Pharmacotherapeutic Group of (API)	Histamine receptor antagonist
	Name, address of Manufacturing site:	Winbrains Research Laboratories-Plot No. 69/1, Phase I-II, Industrial Estate, hattar, KPK-
	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)	-
	Pharmaceutical Equivalence and Comparative Dissolution Profile	-
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	-
	The status in reference regulatory authorities	UK MHRA Approved
	GMP status of the firm	-
	Evidence of approval of manufacturing facility	Not attached inside dossier
	Evaluation Remarks	
	Following shortcomings were conveyed to the firm: 1.Valid DML of both the applicant and manufacturer M/s. Weather and M/s. Winbrains. 2.Section approval letter of M/s. winbrains for eye drop section. 3.Drug substance imports documents like clearance certificate or attested invoice. 4.In analytical method of drug substance injection volume for assay is 30micrliter but in all chromatogram's injection volume is 20microliter. please clarify. 5.COA of imported lot of drug substance. 6.Valid GMP certificate of M/s. Winbrains. 7. Valid GMP certificate of drug substance manufacturer. t is submitted that firm has not responded to above shortcomings However firm has submitted following undertaing:1. We M/s Weather Folds Pharmaceuticals Plot No. 69/2, Phase II, Industrial Estate, Hattar, KPK would like to declare that we shall adopt the same sourceof drug	

	substance, drug product formulation, specification and container closureas submitted by M/s Winbrains Research Laboratories and approved in DRB 352nd Meeting for Product (OLOPATADINE 2MG/ML EYE DROPS).2. In case of any post-registration variation by the contract manufacturer, same shall be immediately applied by us for requisite approval by registration board. The request of firm is hereby placed for consideration of Board Please.	
	Decision	
	Approved	
336	Case Category	New Section (Haleema Sharif)
	Name, address of Applicant.	**World Biz Pharmaceuticals Company, Multan** 340, Phase-II, Industrial Estate, Multan **(000942)**
	Application Form Dy. No / Tracking ID & date of submission	(9GM-842-4D9R, 2024-12-11)
	Detail of Fee Submitted	30000.0, 7000.0 2024-06-04, 2024-10-31
	The proposed proprietary name / brand name	**Tabicox Tablet 60mg**
	Label Claim	Each Film Coated Tablet Contain:- Etoricoxib 60mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's, 5's, 10's,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)	Starcox Tablet by Getz Pharma Karachi (Reg. No. 075969
	Pharmacotherapeutic Group of (API)	NSAID
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Seutic labs private limited,Plot No 4 P2 Sy No 129 Gadwanthi village, Humnabad industrial area, Humnabad, bidar district, Karnataka-585330, India
	Detail of stability batches of drug product	Stability data of three batches submitted by firm
	Documents for the procurement of API with approval from DRAP (in case of Import)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted by firm
	The status in reference regulatory authorities	ARCOXIA 60mg Film-coated Tablets MHRA Approved
	GMP status of the firm	--
	Evidence of approval of manufacturing facility	CLB letter dated 21 December 2023 indicate Tablet General section of firm
	Evaluation Remarks	
	Firm has rectified other shortcomings however firm has not submitted valid GMP certificate of drug substance manufacturer, GMP certificate of drug substance manufacturer was valid till 21.8.2024.	
	Decision	
	Deferred Deferred for submission of Valid GMP certificate of Drug substance manufcaturer.	
337	Case Category	Routine (Haleema Sharif)

	Name, address of Applicant.	**Medwell Pharmaceuticals** 1 km, terbella road, lawrencepur, faqirabad Attock **(000699)**
	Application Form Dy. No / Tracking ID & date of submission	(HZ5-WHH-XJ2Z, 2024-07-08)
	Detail of Fee Submitted	75000.0, 2024-06-26,
	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 YearStore below 25°c
	For generic drugs (me-too Status)	Bina 1% Cream by Linta Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	winbrains Research Laboratories-Plot No. 69/1, Phase I-II, Industrial Estate, Hattar.-
	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	USFDA Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Following Querries were conveyed to he firm: Please attach/upload following at the earliest for further processing/evaluation of application: 1. Valid GMP certificate of drug substance manufacturer. 2. JP monograph of applied formulation. 3. Valid DML of M/s. Medwell & M/s. Winbrains, and valid GMP certificate and section approval letter of M/s. Winbrains (as firm has submitted evidence of Dry Powder Inhaler Capsule (General) Section and applied formulation is cream.). 4. Drug substance import documents like clearance certificate or DRAP attested invoice along with COA of imported lot of Drug substance. 5. Pl verify attached chromatogram from submitted audit trail. It is submitted that firm has not responded to above querries However firm has submitted following undertaking: Declaration for Application of Contract Manufacturing Terbinadine 1% Cream1. We M/s Medwell Pharmaceuticals would like to declare that we shall adopt the same source ofdrug substance, drug product formulation, specification and container closure as submitted by M/s Winbrains Research Laboratories and approved in DRB 350th Meeting.2. In case of any post-registration variation by the contract manufacturer, same shall beimmediately applied by us for requisite approval by registration board. The case is hereby place for consideration of Board. Please	
	Decision	
	Approved	
338	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	**Nagarsons Pharmaceuticals Pvt Ltd** Plot no 34 Street NS-2 National Industrial zone Rawat Islamabad **(000927)**

	Application Form Dy. No / Tracking ID & date of submission	(RA8-D8E-52ZU, 2025-07-24)
	Detail of Fee Submitted	37000.0, 2025-07-08,
	The proposed proprietary name / brand name	**R-Zole Cream**
	Label Claim	Each gram contains: Hydrocortisone Acetate eq. to Hydrocortisone.....10mg Clotrimazole.....10mg (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1,S-As per SRO
	Shelf Life (Unit)	2 Year(s)Store between 15C-30C
	For generic drugs (me-too Status)	Clozax H Cream
	Pharmacotherapeutic Group of (API)	Antifungal preparations with corticosteroids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	a. Name and address of API manufacturer of Clotrimazole BADRIVISHAL CHEMICALS AND PHARMACEUTICALS (710433), GAT NO. 29, VILLAGE JAMBWADE (INDURI), POST SUDUMBRE,, TAL - MAVAL, DIST-, PUNE - 412109, Dist - PUNE-ZONE6 b. Name and address of API manufact
	Detail of stability batches of drug product	Attached
	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
	GMP status of the firm	Attached
	Evidence of approval of manufacturing facility	Attached
	Evaluation Remarks	
	Firm is claiming BP specifications for applied product however applied formulation monograph is not found in BP available with me neither firm has provided it, firm may need to submit analytical method validation studies alongwith with fee for revision of specifications. Difference in excipients of applied product and reference product is recorded as under and firm has not submitted drug excipient compatibility studies.	

Excipients of reference product	Excipient of applied product
1. Ceto stearyl alcohol 2. Medium chain triglycerides 3. Tricetearet-4-phosphate	1. Cetyl alcohol 2. Cetyl palmitate 3. Isopropyl myristate 4. Polysorbate 60 5. Sorbitan monostearate 6. Stearly alcohol

	3.The firm initially submitted stability study data for the drug substance at 25 °C ± 2 and 60% RH. When requested to provide data at 30 °C ± 2 and 65% RH, the firm resubmitted the same data while only changing the stated conditions to 30 °C ± 2 and 65% RH. The firm has now again submitted the same data under the original conditions of 25 °C ± 2 and 60% RH. *** firm has regretted for this error and submitted new data as per zoneIVA conditions.	
	Decision	
	Rejected Registration Board rejected application due to concerns related to data integrity.	
339	Case Category	Routine (Haleema Sharif)

	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	(PTN-D6T-DU73, 2024-06-27)
	Detail of Fee Submitted	75000.0, 2024-06-24,
	The proposed proprietary name / brand name	**Fodic 2% Cream**
	Label Claim	COMPOSITION: Each gm 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°c
	For generic drugs (me-too Status)	Ucid 2% Cream by Ciba Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Winbrains Research Laboratories-Plot No. 69/1, Phase I-II, Industrial Estate, hattar, KPK-
	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	UK MHRA Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Following shortcomings were conveyed to thhe firm : 1. Valid DML and GMP certificate of M/s. Winbrains. 2. Link to verify the excipients of reference product also mention brand name of reference product. 3.Audit trail report of 21 CFR compliant system. 4. Drug substance import documents like clearance certificate or DRAP attested invoice. 5. Valid DML of drug substance manufacturer. 6. Drug substance import documents like clearance certificate or DRAP attested invoice. It is submitted that firm has not responded to above querries however firm has submitted following: Declaration for Application of Contract ManufacturingFUSIDIC ACID 2% CREAM1. We M/s Weather Folds Pharmaceuticals Plot No. 69/2, Phase II, IndustrialEstate, Hattar, KPK would like to declare that we shall adopt the same source of drug substance, drug product formulation, specification and container closureas submitted by M/s Winbrains Research Laboratories and approved in DRB 352nd Meeting.2. In case of any post-registration variation by the contract manufacturer, sameshall be immediately applied by us for requisite approval by registration board. The case is hereby placed for consideration of the Board plesae.	
	Decision	
	Approved	
340	Case Category	Routine (Haleema Sharif)
	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	(Q3Q-6MY-X2M5, 2024-06-27)

	Detail of Fee Submitted	75000.0, 2024-06-24,
	The proposed proprietary name / brand name	**OLP 1mg/ml Eye Drops**
	Label Claim	Each ml Contains: Olopatadine as Hydrochloride (USP).....1mg (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)	Opat Opthalmic Solution Alza Pharmaceuticals 081624
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Winbrains Research Laboratories-Plot No. 69/1, Phase I-II, Industrial Estate, hattar, KPK-
	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	UK MHRA Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	following shortcomings in thier application were conveyed to the firm: 1. Section approval letter, valid DML and GMP certificate of drug substance & drug product manufacturer. 2. Osmolality And Osmolarity 260±340 mOsmol/kg. Please explain this limit in specification of finished product. 3. In average volume or minimum fill please mention limit in volume instead of percentage. 4. Link to confirm that excipients of applied product are similar to reference product. 5. upload manufacturing method of applied formulation. 6. Drug substance imports documents like clearance certificate OR DRAP attested invoice. 7. verify chromatograms at page 312 and 331 from submitted audit trail & high light it. 8. Mention retest date or expiry date of drug substance. The firm has informed following : Declaration for Application of Contract ManufacturingOLOPATADINE 1% EYE DROPS1. We M/s Weather Folds Pharmaceuticals Plot No. 69/2, Phase II, IndustrialEstate, Hattar, KPK would like to declare that we shall adopt the same source of drug substance, drug product formulation, specification and container closure as submitted by M/s Wenovo Pharmaceuticals approved in DRB 352nd Meeting for thier product .2. In case of any post-registration variation by the contract manufacturer, same shall be immediately applied by us for requisite approval by registration board. It is submitted that M/s. Wnovo and M/s. Weather Fold both are getting thier product contract manufcatured by M/s. Winbrains. The case is hereby submitted for consideration of the Boad please.	
	Decision	
	Approved	
341	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Amson Vaccines & Pharma (Pvt.) Ltd.** Plot # 154, Industrial Triangle, Kahuta Road, **(000393)**
	Application Form Dy. No / Tracking ID & date of submission	(BPL-M3R-J2SM, 2024-02-23)
	Detail of Fee Submitted	75000.0, 2023-11-30,

	The proposed proprietary name / brand name	**Cesod 1g**
	Label Claim	Each Vial contains: Ceftriaxone sodium eq. to Ceftriaxone USP 1000mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	24 MonthAt 25 °C
	For generic drugs (me-too Status)	Oxidil 1g Injection (Reg. No. 022422)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Arreta Pharmaceuticals (Pvt) Ltd-Plot No. 13, Street No. N-5, RCCI, Industrial Estate Rawat-
	Name & address of API manufacturer	Sinopharm Weiqida Pharmaceutical Co., Ltd. First Medical Zone, Economic & Technological Development Zone, Datong, Shanxi, 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	FDA (Rocephin 1g Injection)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has requested that: We applied our Toll registration in PRV on 03-06-2025, and we were granted the CESOD IV INJECTION "CEFTRIAXONE SOIDUM" ON CONTRACT MANUFACTURING range in September 2025. Therefore, kindly withdraw/cancel our request, as we do not wish to pursue this application further.	
	Decision	
	Rejected The Registration Board acceded to the request of the applicant.	
342	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Amson Vaccines & Pharma (Pvt.) Ltd.** Plot # 154, Industrial Triangle, Kahuta Road, **(000393)**
	Application Form Dy. No / Tracking ID & date of submission	(RVR-BWG-H9H4, 2024-02-23)
	Detail of Fee Submitted	75000.0, 2023-11-30,
	The proposed proprietary name / brand name	**Cesod 500mg**
	Label Claim	Each vial contains: Ceftriaxone sodium eq. Ceftriaxone USP 500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	24 MonthAt 25 °C
	For generic drugs (me-too Status)	Oxidil 500mg Injection (Reg. No. 023393)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Arreta Pharmaceuticals (Pvt) Ltd-Plot No. 13, Street No. N-5, RCCI, Industrial Estate Rawat-

	Name & address of API manufacturer	Sinopharm Weiqida Pharmaceutical Co., 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	FDA (Rocephin 500mg Injection)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has submitted: "we are manufacturing Cesod 500mg IV Injection through M/s Seraph Pharmaceuticals under a contract manufacturing agreement. However, due to the limited production capacity of M/s Seraph Pharmaceuticals Islamabad, we have decided to also register this product for contract manufacturing with M/s Arreta Pharmaceuticals Islamabad".	
	Decision	
	Rejected The Registration Board acceded to the request of the applicant.	
343	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(14G-Q4P-7X6S, 2026-02-04)
	Detail of Fee Submitted	97200, 2026-01-30,
	The proposed proprietary name / brand name	**Talavil Tablet 5mg**
	Label Claim	Each film coated tablet contains: Tadalafil.....5mg (USP Specs.)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's, 5's 10's, 20's, 28's & 30's-De-Controlled
	Shelf Life (Unit)	2 YearStore below at 30°C
	For generic drugs (me-too Status)	Fildil 05mg Tablets
	Pharmacotherapeutic Group of (API)	PDE5 Inhibitor
	Name, address of Manufacturing site:	M/s Wimits Pharmaceutical-Plot No 129-Sunder Industrial Estate, Raiwind Road, Lahore, Pakistan-
	The status in reference regulatory authorities	EMA Approved/FDA Approved
	Detail of previous approval	Procial Tablet 05mg (M 351)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**PDH Laboratories (Pvt.) Ltd.** 9.5 Km Sheikhupura Road, Lahore **(000039)**
	Application Form Dy. No / Tracking ID & date of submission	(1EU-X5M-5DZM, 2026-03-04)
	Detail of Fee Submitted	97200, 2026-02-02,
	The proposed proprietary name / brand name	**PD-Met Tablet 400mg**
	Label Claim	Each Film Coated Tablet Contains: Metronidazole...400mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100's-Controlled
	Shelf Life (Unit)	2 Yearbelow 30°
	For generic drugs (me-too Status)	Flagyl 400 mg tab by Sanofi Aventis (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	General Antibiotic
	Name, address of Manufacturing site:	Variant Pharmaceuticals (Pvt.) Ltd.-PLOT # 5, M-2, PHARMAZONE, 26 KM MAIN SHARAQPUR ROAD DISTRICT SHEIKHUPURA PAKISTAN -
	The status in reference regulatory authorities	Metronidazole 400 mg Film-Coated Tablets by Special Concept Development (UK) Limited T/A RxFarma, Colonial Way, Watford, Hertfordshire, WD24 4YR HD House, Imperial Way, North Watford, Hertfordshire, WD24 4LQ, UK
	Detail of previous approval	Metvar 400mg tablet, This produc is approved at sr. no. 150 in Minutes of 339th Meeting of Registrat
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**LIVEN PHARMACEUTICALS** 49-KM MULTAN ROAD, PHOOL NAGAR, DISTRICT, KASUR PAKISTAN **(000881)**
	Application Form Dy. No / Tracking ID & date of submission	(1G1-Q7U-VU1Y, 2026-02-04)
	Detail of Fee Submitted	97200, 2026-01-16,
	The proposed proprietary name / brand name	**Beelive-T 800/26.6mg Tablet**
	Label Claim	Each Film Coated tablet contains: Ibuprofen.....800mg Famotidine.....26.6mg

	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Ibuprofen (analgesic & anti-inflammatory drug) Famotidine(Histamine-2 receptor antagonists (H2RAs))
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	DUEXIS (ibuprofen and famotidine 800mg/26.6mg) tablet of M/s Horizon Pharma USA, Inc. Lake Forest, IL 60045 (USFDA Approved)
	Detail of previous approval	Ibuprofen/Famotidine 800mg/26.6 Tablet approved in 343rd 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	
346	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	(1HR-DLL-GMTD, 2026-02-12)
	Detail of Fee Submitted	97200, 2026-01-27,
	The proposed proprietary name / brand name	**Deciti 6mg Tablet**
	Label Claim	Each film coated tablet contains: Deucravacitinib .....6 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 Yearstore at 20° to 25°C
	For generic drugs (me-too Status)	Hamaz pharmaceuticals (pvt)Ltd.
	Pharmacotherapeutic Group of (API)	Gansu Haotian pharma Tech Co., Ltd, Address: No.11, Chongqing Road, Small and Medium-sized Enterprise Business Base Baiyin Gansu P.R. China.
	Name, address of Manufacturing site:	Hamaz Pharmaceuticals (Pvt)Ltd.-13-KM Bosan Road Lutafabad Multan-
	The status in reference regulatory authorities	complies
	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	
347	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Indus Pharma (Pvt.) Ltd.** Plot No 26,27,63,64,65,66 & 67 Sector 27, Korangi Industrial Area, Karachi. **(000124)**
	Application Form Dy. No / Tracking ID & date of submission	(1YS-HAR-165Y, 2026-02-03)
	Detail of Fee Submitted	97200, 2025-12-03,
	The proposed proprietary name / brand name	**Indofer-CM Injection**
	Label Claim	Each ml contains: Ferric carboxymaltose equivalent to elemental iron.....50mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Fercari Injection 500mg /10ml
	Pharmacotherapeutic Group of (API)	Iron carbohydrate complexes
	Name, address of Manufacturing site:	NovaMed Pharmaceuticals (Pvt.) Ltd.-28-KM, Ferozepur Road, Lahore- Pakistan. -
	The status in reference regulatory authorities	Ferinject 50 mg iron/mL dispersion for injection/infusion.
	Detail of previous approval	Feroxyma injection 750mg/15ml, 348th 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	
348	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	(226-HX7-RNY9, 2025-08-22)
	Detail of Fee Submitted	93000.0, 2025-01-22,
	The proposed proprietary name / brand name	**sildiwell**
	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	
349	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	(26S-5U1-82Z1, 2026-03-06)
	Detail of Fee Submitted	97200, 2026-01-27,
	The proposed proprietary name / brand name	**SUREXX 5MG TABLET**
	Label Claim	Each Film-coated tablet contains: Suvorexant ...5mg (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 YearStore at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30ºC (59°F to 86ºF)
	For generic drugs (me-too Status)	Hamaz pharmaceuticals (pvt)Ltd.
	Pharmacotherapeutic Group of (API)	Shandong Kehui Pharmaceuticals Co., Ltd Address: No.9A1, Tianheng Road, Gaoqing City, Shangdong Province China-256300.
	Name, address of Manufacturing site:	Hamaz Pharmaceuticals (Pvt)Ltd.-13-KM Bosan Road Lutafabad Multan-
	The status in reference regulatory authorities	complies
	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	

350	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Maybush Pharmaceuticals (Pvt) Ltd** Plot # 249/A, Industrial Triangle, Kahuta Road Islamabad **(000501)**
	Application Form Dy. No / Tracking ID & date of submission	(295-1VX-29VZ, 2026-02-09)
	Detail of Fee Submitted	97200, 2026-02-06,
	The proposed proprietary name / brand name	**NORSET 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 Year30C
	For generic drugs (me-too Status)	Manufacture Name: OBS Pharma (Pvt.) Ltd. Manufacturer Address: 108, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore Brand Name & Strength: Primolut N (Norethisterone) 5mg Tablet Composition: Each
	Pharmacotherapeutic Group of (API)	Norethisterone, also known as norethindrone, is a synthetic progestational hormone belonging to the 19-nortestosterone-derived class of progestins. (Reference;Basic and Clinical Pharmacology By Bertram G. Katzung) (b) WHO ATC Code: For Norethisterone G03AC01
	Name, address of Manufacturing site:	SKYWIN PHARMACEUTICALS-Plot #01,Al Badar Industrial Estate, Phase II Sheikhupura Road Lahore-
	The status in reference regulatory authorities	Manufacture Name: Bayer plc Address: 400 South Oak Way, Reading, Berkshire, RG2 6AD Brand Name & Strength: Primolut N Tablet 5mg Composition: Each tablet contains: Norethisterone… 5mg Market Authorization Number: PL 00010/0553 Dosage Form: oral tablet Reference Regulatory Authority: MHRA Approved
	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	
351	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Health care pharmaceuticals** 40 km lahore Road multan **(000905)**
	Application Form Dy. No / Tracking ID & date of submission	(2A4-J9Y-73L3, 2026-02-17)

	Detail of Fee Submitted	97200, 2026-01-30,
	The proposed proprietary name / brand name	**FECAR Injection**
	Label Claim	500mg/10ml
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	3 YearBelow 25°C
	For generic drugs (me-too Status)	Ferinject aaproved IN USFDA
	Pharmacotherapeutic Group of (API)	Anti-anaemic
	Name, address of Manufacturing site:	Carer Pharmaceuticals Industries -Plot #27, Main Road, Industrial Estate, Rawat-
	The status in reference regulatory authorities	National Medical Products Administration China
	Detail of previous approval	Carbifer 500mg injection meeting no 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	
352	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**ANEEB PHARMACEUTICAL PVT LIMITED** 24 KM BEDIAN ROAD LAHORE **(000555)**
	Application Form Dy. No / Tracking ID & date of submission	(2E7-YWP-P4RE, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-11-20,
	The proposed proprietary name / brand name	**Amoxicillin Suspension 125mg/5ml**
	Label Claim	Each 5ml contains: Amoxicillin as Trihydrate ..... 125 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30 oC
	For generic drugs (me-too Status)	Amoxil 125mg/5ml dry suspension, GSK Karachi, Reg. No. 000508
	Pharmacotherapeutic Group of (API)	Beta-Lactam Antibacterial, Penicillin
	Name, address of Manufacturing site:	Fynk Pharmaceuticals-19-km G.T.Road, kala Shah Kaku, Lahore, Pakistan-
	The status in reference regulatory authorities	Amoxil-125mg/5ml, 250mg/5ml, USFDA approved
	Detail of previous approval	FAXCIL 125 mg/5ml suspension, Minutes of 331st Meeting of Registration Board held on 31st Oct – 2nd
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to	

	submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila **(000856)**
	Application Form Dy. No / Tracking ID & date of submission	(2N1-3TY-5YJP, 2026-03-06)
	Detail of Fee Submitted	97200, 2026-01-27,
	The proposed proprietary name / brand name	**SUREXX 20MG TABLET**
	Label Claim	Each Film-coated tablet contains: Suvorexant ...20mg (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 YearStore at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C to 30°C (59°F to 86°F). Keep in original package. The container closure system is child resistant.
	For generic drugs (me-too Status)	Hamaz pharmaceuticals (pvt)Ltd.
	Pharmacotherapeutic Group of (API)	Shandong Kehui Pharmaceuticals Co., Ltd Address: No.9A1, Tianheng Road, Gaoqing City, Shangdong Province China-256300.
	Name, address of Manufacturing site:	Hamaz Pharmaceuticals (Pvt)Ltd.-13-KM Bosan Road Lutafabad Multan-
	The status in reference regulatory authorities	complies
	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	
354	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	(2N5-13R-V4M6, 2026-02-04)
	Detail of Fee Submitted	97200, 2025-11-25,
	The proposed proprietary name / brand name	**Tazowl 4.5gm Injection**

	Label Claim	Tazowl 4.5gm Injection (Tazobactum + Piperacillin)
	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)	Tanzo Injection 4.5gm by Bosch Pharmaceuticals.
	Pharmacotherapeutic Group of (API)	β-Lactamase inhibitor
	Name, address of Manufacturing site:	M/s Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II , Sheikhupura Road Lahore. -
	The status in reference regulatory authorities	Zosyn ® Injection is Approved in USFDA
	Detail of previous approval	Tazopip Injection 4.5 g
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**Hygeia Pharmaceuticals** Plot NO 295, Industrial Triangles Kahuta Road Islamabad **(000523)**
	Application Form Dy. No / Tracking ID & date of submission	(2NH-45Y-GY9U, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-12-01,
	The proposed proprietary name / brand name	**HYDIN 7.5% Solution**
	Label Claim	HYDIN 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	450ml-Controlled,60ml-Controlled
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Poviwell 7.5% Solution (131734) Well Go Pharmaceuticals (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Well Go Pharmaceuticals (Pvt) Ltd-5-km, Raiwind Manga Road Lahore-
	The status in reference regulatory authorities	Pakistan
	Detail of previous approval	Poviwell 7.5% Solution (131734) 351 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	
356	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(2PN-6T9-59H5, 2026-03-04)
	Detail of Fee Submitted	97200, 2026-01-21,
	The proposed proprietary name / brand name	**Turam 75/ 650 mg Tablet**
	Label Claim	Each film coated tablet contains: Tramadol HCl.....75mg Paracetamol..... 650mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's,20's,30's,40's& 100's-As per SRO
	Shelf Life (Unit)	3 YearRoom Temperature
	For generic drugs (me-too Status)	Product Name: Tonoflex-P Forte Tablet Composition: Each film coated tablet contains; Tramadol HCl……. 75 mg Paracetamol……. 650 mg Sami Pharmaceutical Pakistan (Pvt.) ltd
	Pharmacotherapeutic Group of (API)	Analgesic & antipyretic
	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	PARADOL D 75/650mg Tablet, 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	
357	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	(2WQ-BNV-5E3Q, 2026-02-24)
	Detail of Fee Submitted	97200, 2026-02-09,
	The proposed proprietary name / brand name	**Cefotect**
	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 Year15 °C - 30 °C
	For generic drugs (me-too Status)	Cebac 1g Injection
	Pharmacotherapeutic Group of (API)	Cephalosporin's Antibiotics
	Name, address of Manufacturing site:	Aulton Pharmceuticals-Plot no 84/1, Block A, Phase V, Industrial estate hattar-
	The status in reference regulatory authorities	SULPERAZON
	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	
358	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	(3DX-S7R-TZXQ, 2026-02-12)
	Detail of Fee Submitted	97200, 2026-01-27,
	The proposed proprietary name / brand name	**Restab 60mg Tablet**
	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 YearStore at 20 °C to 25°C (68 °F to 77°F); excursions permitted to 15 °C to 30°C (59° F to 86°F)
	For generic drugs (me-too Status)	Hamaz pharmaceuticals (pvt)Ltd.
	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 Bosan Road Lutafabad Multan-
	The status in reference regulatory authorities	complies
	Detail of previous approval	345m
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the	

	above-mentioned notification. Furthermore, quality agreement 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.	**Kanel Pharma** Plot No. 6, Street No. SS-3, National Industrial Zone, Rawat **(000758)**
	Application Form Dy. No / Tracking ID & date of submission	(3JM-JMS-DEDZ, 2026-01-27)
	Detail of Fee Submitted	93000.0, 4200.0 2025-07-31, 2025-09-10
	The proposed proprietary name / brand name	**Norgin 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 YearControlled Room Temprature
	For generic drugs (me-too Status)	Primolut N (Norethisterone) 5mg Tablet of M/s OBS
	Pharmacotherapeutic Group of (API)	Synthetic Progestational Hormone
	Name, address of Manufacturing site:	M?S SKYWIN PHARMACEUTICALS-Plot # 01, Al Badar Industrial Estate, Phase II Sheikhupura Road Lahore.-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	JUST-N 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	
360	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	(3VV-EZW-YNNR, 2026-02-18)
	Detail of Fee Submitted	97200, 2026-01-27,
	The proposed proprietary name / brand name	**Atinib 50mg Tablet**
	Label Claim	Each film coated tablet contains: Abrocitinib.....50 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 YearStore at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C to 30°C

		(59°F to 86°F). Keep in original package. The container closure system is child resistant.
	For generic drugs (me-too Status)	Hamaz pharmaceuticals (pvt)Ltd.
	Pharmacotherapeutic Group of (API)	Gansu Hoatin Pharmatech Co., Ltd. Address: No. 11, Chongqing Road, small & medium sized enterprise business base baiyin gansu P.R, China.
	Name, address of Manufacturing site:	Hamaz Pharmaceuticals (Pvt)Ltd.-13-KM Bosan Road Lutafabad Multan-
	The status in reference regulatory authorities	complies
	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	
361	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Searle Pakistan Limited** C-14, Manghopir Road, SITE, Karachi **(000012)**
	Application Form Dy. No / Tracking ID & date of submission	(3WY-SRQ-LT84, 2026-03-04)
	Detail of Fee Submitted	97200, 2026-01-06,
	The proposed proprietary name / brand name	**NAPREX (Naproxen/Esomeprazole) 500mg/20mg Tablet**
	Label Claim	Each modified release tablet contains: Naproxen.....500mg (Enteric coated Core) Esomeprazole (as Magnesium Trihydrate).....20mg (Immediate Release Coat)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,28's-De-Controlled,30's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30°C.
	For generic drugs (me-too Status)	Glomov Tablets (Global Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	Naproxen (NSAID) & Esomeprazole (PPI).
	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	Approved by US FDA, MHRA UK and EMA.
	Detail of previous approval	Product Name: SNP (Naproxen/ Esomeprazole) 500mg/ 20mg Tablet. Meeting No.: 343rd 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	
362	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Tovida Pharmaceuticals (Pvt) Ltd** Plot No.7, Street No.S-07, RCCI Industrial Estate Islamabad **(000996)**
	Application Form Dy. No / Tracking ID & date of submission	(41U-X8D-X3E6, 2026-02-04)
	Detail of Fee Submitted	97200, 2025-10-28,
	The proposed proprietary name / brand name	**SECLO 40mg INJECTION**
	Label Claim	Each vial contains: Omeprazole sodium equ. to Omeprazole ..... 40mg (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO -De-Controlled
	Shelf Life (Unit)	2 Year30C+-
	For generic drugs (me-too Status)	Ruling 40mg Injection HIGH-Q International
	Pharmacotherapeutic Group of (API)	PPI
	Name, address of Manufacturing site:	SWERA PHARMACEUTICALS-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	343 MINUTES OF MEETING held on 8th & 10th Nov,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	
363	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**SATURN Pharmaceuticals Pvt Ltd** 23km Thorar Raiwind Road Lahore **(000734)**
	Application Form Dy. No / Tracking ID & date of submission	(42M-BV8-V9US, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-12-08,
	The proposed proprietary name / brand name	**ESOPRAZIN**
	Label Claim	Each Capsule contains: Enteric coated pellets of Esomeprazole Magnesium Trihydrate equivalent to Esomperazole ..... 20 mg
	Reference to Finished product specifications	United States Pharmacopeia

	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 centigrade. Protect from heat, moisture & sunlight
	For generic drugs (me-too Status)	Nexium 20mg capsule
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor (PPI)
	Name, address of Manufacturing site:	Variant Pharmaceuticals Pvt Ltd.-Plot no 5 M2 Pharmazone Sharqpur lahore-Road.-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Minutes of 297th 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	
364	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	(46Y-SBR-39N4, 2026-02-17)
	Detail of Fee Submitted	97200, 2026-01-27,
	The proposed proprietary name / brand name	**Carzee Capsule 4.5mg**
	Label Claim	Each Capsule contains: Cariprazine Hydrochloride eq, to cariprazine..... 4.5mg (As per 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 30°C. Protect from Heat & Light.
	For generic drugs (me-too Status)	Hamaz pharmaceuticals (pvt)Ltd.
	Pharmacotherapeutic Group of (API)	ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD. Address: CHUANNAN, DUQIAO, LINHAI ZHEJIANG 317016, CHINA.
	Name, address of Manufacturing site:	Hamaz Pharmaceuticals (Pvt)Ltd.-13-KM Bosan Road Lutafabad Multan-
	The status in reference regulatory authorities	complies
	Detail of previous approval	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	
365	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	(495-PA7-6SW6, 2026-03-09)
	Detail of Fee Submitted	97200, 2026-01-27,
	The proposed proprietary name / brand name	**Tenapex 50mg tablet**
	Label Claim	Each Film-coated tablet contains: Tenapanor as HCl...50mg (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 YearStore at room temperature, between 68°F and 77°F (20°C and 25°C).
	For generic drugs (me-too Status)	Hamaz pharmaceuticals (pvt)Ltd.
	Pharmacotherapeutic Group of (API)	Shandong Kehui Pharmaceuticals Co., Ltd Address: No.9A1, Tianheng Road, Gaoqing City, Shangdong Province China-256300.
	Name, address of Manufacturing site:	Hamaz Pharmaceuticals (Pvt)Ltd.-13-KM Bosan Road Lutafabad Multan-
	The status in reference regulatory authorities	complies
	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	
366	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**ANEEB PHARMACEUTICAL PVT LIMITED** 24 KM BEDIAN ROAD LAHORE **(000555)**
	Application Form Dy. No / Tracking ID & date of submission	(498-3VD-JX3J, 2026-02-11)
	Detail of Fee Submitted	97200, 2026-02-02,
	The proposed proprietary name / brand name	**IMIPEN-C 500 MG INJ**
	Label Claim	Each vial contains: Imipenem (as monohydrate).....500mg Cilastatin (as sodium).....500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30 oC

	For generic drugs (me-too Status)	Cilapen Injection 500mg by M/s Bosch Pharma
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Name, address of Manufacturing site:	M/s. Fynk Pharmaceuticals-19-km, G.T Road, kala Shah Kaku, Lahore, Pakistan-
	The status in reference regulatory authorities	USFDA approved
	Detail of previous approval	Imicil Injection 500mg, Minutes of 331st Meeting of Registration Board held on 31st Oct – 2nd Nov, 2
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**Health care pharmaceuticals** 40 km lahore Road multan **(000905)**
	Application Form Dy. No / Tracking ID & date of submission	(4A2-M7D-BTJL, 2026-03-04)
	Detail of Fee Submitted	97200, 2026-02-06,
	The proposed proprietary name / brand name	**Vonoz**
	Label Claim	Each Film coated tablet contains: Vonoprazan as Fumarate.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Yearbelow 30°C
	For generic drugs (me-too Status)	Fildil 10mg tablet by M/s Highnoon Laboratories
	Pharmacotherapeutic Group of (API)	Anti-ulcer
	Name, address of Manufacturing site:	Quaper (Pvt) Ltd-26-A, small Industrial Estate Lahore Road Sargodha-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	meeting No. 330, Quzan 10mg tablet
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**Tovida Pharmaceuticals (Pvt) Ltd** Plot No.7, Street No.S-07, RCCI Industrial Estate Islamabad **(000996)**
	Application Form Dy. No / Tracking ID & date of submission	(4A4-75Z-NEMY, 2026-02-10)
	Detail of Fee Submitted	97200, 2025-11-10,
	The proposed proprietary name / brand name	**Levidena 20mg tablets**
	Label Claim	Every film-coated tablet contains: Vardenafil (as hydrochloride trihydrate)..... 20mg. (USP Spec's.)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO -De-Controlled
	Shelf Life (Unit)	2 Year30C+-
	For generic drugs (me-too Status)	NA (New Molecule)
	Pharmacotherapeutic Group of (API)	Erectile dysfunction
	Name, address of Manufacturing site:	Solaris Life Sciences -Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, Rawalpindi-Pakistan-
	The status in reference regulatory authorities	USFDA approved
	Detail of previous approval	351th MInutes of meeting helad on 23rd to 24th Sep,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	
369	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Nexus Pharma (Pvt) Ltd** Plot No. 4/19-4/36, Sector 21 Korangi Industrial Area, Karachi - Pakistan **(000421)**
	Application Form Dy. No / Tracking ID & date of submission	(4EB-GA1-2GBJ, 2026-02-18)
	Detail of Fee Submitted	97200, 2026-02-04,
	The proposed proprietary name / brand name	**CIBANAC**
	Label Claim	Each ml of Suspension Contains: Nepafenac.....1mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	AS PER SRO-As per SRO
	Shelf Life (Unit)	2 YearDO NOT STORE ABOVE 30 DEGREE
	For generic drugs (me-too Status)	NEPANAC OPHTHALMIC SUSPENSION BY REMINGTON PHARMA
	Pharmacotherapeutic Group of (API)	Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

	Name, address of Manufacturing site:	WINTHROX LABORATORIES (PVT) LTD.-PLOT NO. K-219/A, PHASE-II, SITE, SUPER HIGHWAY, KARACHI-
	The status in reference regulatory authorities	MHRA, UK APPROVED
	Detail of previous approval	NEPTON, 333 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	
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	(4EY-3LA-QY75, 2025-08-22)
	Detail of Fee Submitted	93000.0, 2025-01-23,
	The proposed proprietary name / brand name	**DUM**
	Label Claim	Each Tablet Contains: Sildenafil (as Citrate) ---------- 50mg
	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 50mg 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.	**Alliance Pharmaceuticals (pvt) Ltd** 112-A Hayatabad Industrial Estate **(000594)**

	Application Form Dy. No / Tracking ID & date of submission	(4HZ-8EM-6TTE, 2026-03-04)
	Detail of Fee Submitted	97200, 2026-02-13,
	The proposed proprietary name / brand name	**Keto-Zee**
	Label Claim	Each film coated tablet contains: α-Ketoanalogue to isoleucine (Calcium-salt)... 67 mg α-Ketoanalogue to leucine (Calcium-salt)... 101 mg α-Ketoanalogue to phenylalanine (Calcium-Salt) 68 mg α-Ketoanalogue to valine (Calcium-Salt) 86 mg α-hydroxyanalogue to DL-methionine (Calcium-Salt)....59 mg L-lysine acetate...105mg corresponding to L-lysine 75 mg L-threonine 53 mg L-tryptophan 23 mg L-histidine 38 mg L-tyrosine 30 mg Total nitrogen content per tablet 36 mg Calcium content per tablet 1.25mmol = 50 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10x10s-As per SRO
	Shelf Life (Unit)	2 Year30 C
	For generic drugs (me-too Status)	Ketoalfa tablets
	Pharmacotherapeutic Group of (API)	M/S: Cleargreens Pharmaceuticals (Pvt.) Ltd.
	Name, address of Manufacturing site:	M/S Solaris Life Science Pharma (Pvt)Ltd-Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, Rawalpindi-PAKISTAN.-
	The status in reference regulatory authorities	Ketosteril Tablets of M/s Fresenius Kabi, Germany
	Detail of previous approval	Ketorein Tablet. 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	
372	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**ANEEB PHARMACEUTICAL PVT LIMITED** 24 KM BEDIAN ROAD LAHORE **(000555)**
	Application Form Dy. No / Tracking ID & date of submission	(4J4-927-B3AU, 2026-02-11)
	Detail of Fee Submitted	97200, 2026-02-02,
	The proposed proprietary name / brand name	**MERONEX 500 MG INJ**
	Label Claim	Each Vial contains: Meropenem as trihydrate ..... 500 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30 oC

	For generic drugs (me-too Status)	Meronem IV 500mg Injection, Pfizer Pakistan.
	Pharmacotherapeutic Group of (API)	Carbapenem
	Name, address of Manufacturing site:	M/s. Fynk Pharmaceuticals-19-km, G.T Road, kala Shah Kaku, Lahore, Pakistan-
	The status in reference regulatory authorities	USFDA approved
	Detail of previous approval	Morefen 500mg Dry Powder injection, Minutes of 333rd meeting of Registration Board (19th To 20th Dec
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**PDH Laboratories (Pvt.) Ltd.** 9.5 Km Sheikhupura Road, Lahore **(000039)**
	Application Form Dy. No / Tracking ID & date of submission	(4TH-X5A-5V84, 2026-03-04)
	Detail of Fee Submitted	97200, 2026-02-02,
	The proposed proprietary name / brand name	**PD-Pera Infusion 1gm/100ml**
	Label Claim	Each 100ml contains: Paracetamol.....1000 mg(1g)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 degree.
	For generic drugs (me-too Status)	BRAMOL 1000mg/100ml Infusion by M/s Brookes Pharma Private Ltd.., Reg. No. 089175
	Pharmacotherapeutic Group of (API)	analgesic and antipyretic
	Name, address of Manufacturing site:	Variant Pharmaceuticals (Pvt.) Ltd. -PLOT # 5, M-2, PHARMAZONE, 26 KM MAIN SHARAQPUR ROAD DISTRICT SHEIKHUPURA PAKISTAN -
	The status in reference regulatory authorities	Paracetamol 10 mg/ml solution for infusion, B. Braun Melsungen AG Carl-Braun-Straße 1 34212 Melsungen, Germany
	Detail of previous approval	Paracetamol 1000mg/100ml infusion, Sr. # 63, M-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	
374	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	(4UM-BZ8-EH67, 2026-02-26)
	Detail of Fee Submitted	97200, 2026-02-18,
	The proposed proprietary name / brand name	**Cithrox 125mg Suspension**
	Label Claim	Each reconstituted 5ml contains: Ciprofloxacin.....125mg (USP Spec's)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	60ml-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Novidat125mg/5ml Dry Suspension (by SAMI Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	Anti-infectives Floroquinolone Antibiotic
	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	CIPRO 125mg/5mlDry Suspension (Bayer Healthcare Ltd USFDA Approved)
	Detail of previous approval	Ciprocin 125mg/5ml Dry Suspension, 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	
375	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**SATURN Pharmaceuticals Pvt Ltd** 23km Thorar Raiwind Road Lahore **(000734)**
	Application Form Dy. No / Tracking ID & date of submission	(4WX-52D-LQVE, 2026-02-10)
	Detail of Fee Submitted	97200, 2025-12-09,
	The proposed proprietary name / brand name	**S-Mont**
	Label Claim	Each Sachet contains: Montelukast Sodium eq. to Montelukast 4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14's & 28's -As per SRO
	Shelf Life (Unit)	2 YearStore below 30 centigrade. Protect from heat, moisture & sunlight

	For generic drugs (me-too Status)	FLOAID 4mg Sachet
	Pharmacotherapeutic Group of (API)	leukotriene receptor antagonists (LTRAs)
	Name, address of Manufacturing site:	Variant Pharmaceuticals Pvt Ltd.-Plot no 5 M2 Pharmazone Sharqpur lahore-Road.-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	Minutes of 336th meeting of Registration Board (4th to 6th 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.	**LIVEN PHARMACEUTICALS** 49-KM MULTAN ROAD, PHOOL NAGAR, DISTRICT, KASUR PAKISTAN **(000881)**
	Application Form Dy. No / Tracking ID & date of submission	(52U-ZPU-A2NS, 2026-02-04)
	Detail of Fee Submitted	97200, 2026-01-16,
	The proposed proprietary name / brand name	**B-Penil 180mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Bempedoic acid -------180mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Bempedoic acid……. Adenosine triphosphate-citrate lyase (ACL) inhibitors.
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Nexletol 180mg Tablet of M/s Esperion Theurapeutics ,Inc. (USFDA Approved)
	Detail of previous approval	Nextol 180mg Tablet - 348th 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	

377	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Metro Pharmaceutical** Plot no 14 street no ss-2 industrial zone rawat Islamabad **(000772)**
	Application Form Dy. No / Tracking ID & date of submission	(53D-QYT-HQ1Z, 2026-02-27)
	Detail of Fee Submitted	97200.0, 2025-08-18,
	The proposed proprietary name / brand name	**Metovan 10mg Tablet**
	Label Claim	Each film coated Tablet contains; Vonoprazan.....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)Below 30°C
	For generic drugs (me-too Status)	Vonozan 10mg tablet
	Pharmacotherapeutic Group of (API)	inhibits gastric acid secretion by acting as a potassium-competitive acid blocker (P-CAB)
	Name, address of Manufacturing site:	M/S Linta Pharmaceuticals Pvt. Ltd.- Plot #3, Street S-5, National Industrial Zone, Rawat Islamabad.-
	The status in reference regulatory authorities	TAKECAB TAB by Takeda Pharmaceutical Company Limited JAPAN
	Detail of previous approval	Vonopraz 10mg Tablet , 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	
378	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	(563-68W-Q2A4, 2026-02-04)
	Detail of Fee Submitted	97200, 2026-01-21,
	The proposed proprietary name / brand name	**WINLAMOX TABLET**
	Label Claim	Each film coated tablet contains: Ammoxicillin trihydrate eq. to Amoxicillin.....875mg, Potassium clavulanate eq. to Clavulanic acid....125mg (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 Centigrade
	For generic drugs (me-too Status)	Augmentin 1000mg Tablets of M/s GSK Pakistan
	Pharmacotherapeutic Group of (API)	Antibiotic

	Name, address of Manufacturing site:	Skywin Pharmaceutical-Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road-
	The status in reference regulatory authorities	Augmentin 1000mg Tablet USFDA Approved
	Detail of previous approval	Amoxi 1000mg Tablet Approved in Minutes of 344th 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	
379	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Skywin Pharmaceuticals Pvt. Ltd** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road **(000971)**
	Application Form Dy. No / Tracking ID & date of submission	(5BW-TN8-QHYE, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-07,
	The proposed proprietary name / brand name	**Skyset ODT 8mg Tablet**
	Label Claim	Each Orodispersible tablet contains: Ondansetron.....8mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Ondansetron is used to prevent nausea and vomiting caused by cancer chemotherapy, radiation therapy, and surgery. Ondansetron is in a class of medications called serotonin 5-HT3 receptor antagonists. It works by blocking the action of serotonin, a natural substance that may cause nausea and vomiting.
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Ondansetron Bluefish 8mg orodispersible tablets of M/s Bluefish Pharmaceuticals AB Box 49013 100 28 Stockholm (EMA Approved)
	Detail of previous approval	Dysit ODT 8mg Tablet 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	
380	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**LIVEN PHARMACEUTICALS** 49-KM MULTAN ROAD, PHOOL NAGAR, DISTRICT, KASUR PAKISTAN **(000881)**
	Application Form Dy. No / Tracking ID & date of submission	(5EW-EEX-2G2W, 2026-02-11)
	Detail of Fee Submitted	97200, 2026-01-16,
	The proposed proprietary name / brand name	**Beelive 800mg/8ml Injection**
	Label Claim	Each ml contains: Ibuprofen..... 100mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	NSAIDs
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Caldolor 800mg/8ml injection of M/s Cumberland Pharmaceuticals, Nashville, TN, USA, 37203 80915536, R,2 (USFDA Approved)
	Detail of previous approval	Bropin 800mg/8ml Injection - 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	
381	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	(5LJ-NR2-S47P, 2026-03-09)
	Detail of Fee Submitted	97200, 2026-01-27,
	The proposed proprietary name / brand name	**SUREXX 10MG TABLET**
	Label Claim	Each Film-coated tablet contains: Suvorexant ...10mg (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 YearStore at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30ºC (59°F to 86ºF)
	For generic drugs (me-too Status)	Hamaz pharmaceuticals (pvt)Ltd.
	Pharmacotherapeutic Group of (API)	Shandong Kehui Pharmaceuticals Co., Ltd Address: No.9A1, Tianheng Road, Gaoqing City, Shangdong Province China-256300.
	Name, address of Manufacturing site:	Hamaz Pharmaceuticals (Pvt)Ltd.-13-KM Bosan Road Lutafabad Multan-
	The status in reference regulatory authorities	complies
	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	
382	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**LIVEN PHARMACEUTICALS** 49-KM MULTAN ROAD, PHOOL NAGAR, DISTRICT, KASUR PAKISTAN **(000881)**
	Application Form Dy. No / Tracking ID & date of submission	(5Q2-RS1-3EU7, 2026-02-11)
	Detail of Fee Submitted	97200, 2026-01-16,
	The proposed proprietary name / brand name	**Prazan 100/10mg Tablet**
	Label Claim	Each Film Coated Modified Release Tablet contains: Aspirin----------100mg (Enteric coated core) Vonopranzan 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 at room temperature below 30
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Vonoprazan Fumarate----------Potassium-competitive acid blocker (P-CAB) Aspirin----------NSAIDs
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Cabpirin 10mg/100mg Tablet of M/s Takeda Pharmaceutical Company Limited (PMDA Approved)
	Detail of previous approval	Vozan-AS 100/10mg Tablet - 340th 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	
383	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**PDH Laboratories (Pvt.) Ltd.** 9.5 Km Sheikhupura Road, Lahore **(000039)**
	Application Form Dy. No / Tracking ID & date of submission	(5V1-MB4-76HY, 2026-03-04)
	Detail of Fee Submitted	97200, 2026-02-02,
	The proposed proprietary name / brand name	**PD-Omi capsule 20mg**
	Label Claim	Each capsule contains: Omeprazole (enteric coated pellets) equivalent to Omeprazole.....20 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2x7's, 10's, 20's, 30's, 100's -Controlled
	Shelf Life (Unit)	2 Yearbelow 30°
	For generic drugs (me-too Status)	Risek Capsule 20mg by Getz Pharma
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor (PPI)
	Name, address of Manufacturing site:	Variant Pharmaceuticals (Pvt.) Ltd. -PLOT # 5, M-2, PHARMAZONE, 26 KM MAIN SHARAQPUR ROAD DISTRICT SHEIKHUPURA PAKISTAN -
	The status in reference regulatory authorities	OMEPRAZOLE 20 MG CAPSULE by Sandoz Limited Park View, Riverside Way Watchmoor Park Camberley, Surrey GU15 3YL United Kingdom
	Detail of previous approval	Varizole 20mg capsule. This produc is approved at sr. no. 1397 in Minutes of 297th Meeting of Regist
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**ISIS Pharmaceuticals & Chemical Works** 25/1-3, Sector 12-C, North Karachi Industrial Area **(000126)**
	Application Form Dy. No / Tracking ID & date of submission	(61B-RG5-5A5Q, 2026-02-06)

	Detail of Fee Submitted	97200, 2025-11-10,
	The proposed proprietary name / brand name	**CEFZYN INJECTION 1G**
	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	1g-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 C
	For generic drugs (me-too Status)	Cebac Injection (M/s Bosch Pharma)
	Pharmacotherapeutic Group of (API)	Third-generation cephalosporins
	Name, address of Manufacturing site:	NICHOLAS PHARMACEUTICALS-25/I-3, Sector 12C, North Karachi Industrial Area, Karachi-
	The status in reference regulatory authorities	Sulperazone Intravenous Injection 1g Pfizer PMDA Japan
	Detail of previous approval	Wincef 1gm Injection (333 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	
385	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	(622-T44-2W2W, 2026-02-18)
	Detail of Fee Submitted	97200, 2026-01-27,
	The proposed proprietary name / brand name	**Atinib 100mg Tablet**
	Label Claim	Each film coated tablet contains: Abrocitinib.....100 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 YearStore at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C to 30°C (59°F to 86°F). Keep in original package. The container closure system is child resistant.
	For generic drugs (me-too Status)	Hamaz pharmaceuticals (pvt)Ltd.
	Pharmacotherapeutic Group of (API)	Gansu Hoatin Pharmatech Co., Ltd. Address: No. 11, Chongqing Road, small & medium sized enterprise business base baiyin gansu P.R, China.
	Name, address of Manufacturing site:	Hamaz Pharmaceuticals (Pvt)Ltd.-13-KM Bosan Road Lutafabad Multan-
	The status in reference regulatory authorities	complies

	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	
386	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	(63H-YAY-9JHY, 2026-02-19)
	Detail of Fee Submitted	30000.0, 45000 2024-01-30, 2026-01-15
	The proposed proprietary name / brand name	**AviTazid**
	Label Claim	Each vial contains:Ceftazidime 2 gram (Equivalent to 2.635 grams sterile ceftazidime pentahydrate/sodium carbonate) And Avibactam 0.5 grams (Equivalent to 0.551 grams sterile avibactam Sodium).
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO,10's-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30ºC in dry cool environment
	For generic drugs (me-too Status)	Aviderm Injection by Novamed
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Novamed Pharmaceuticals(Pvt.)Ltd-28KM Ferozepur Road Lahore-
	The status in reference regulatory authorities	Avycaz 2g/0.5g byGlaxoSmithKline Manufacturing S.p.A. Verona, 37135 Italy
	Detail of previous approval	Aviderm Injection ,M- 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 subject to submission of differential fee for contract manufacturing as per applicable S.R.O.	
387	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)**

	Application Form Dy. No / Tracking ID & date of submission	(66J-BXM-65B2, 2026-02-04)
	Detail of Fee Submitted	97200, 2026-01-30,
	The proposed proprietary name / brand name	**Talavil Tablet 20mg**
	Label Claim	Each film coated tablet contains: Tadalafil.... 20mg (USP Specs.)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's, 5's 10's, 20's, 28's & 30's-De-Controlled
	Shelf Life (Unit)	2 YearStore below at 30°C
	For generic drugs (me-too Status)	Fildil 20mg Tablets
	Pharmacotherapeutic Group of (API)	PDE5 Inhibitor
	Name, address of Manufacturing site:	M/s Wimits Pharmaceutical-Plot no 129-Sunder Industrial Estate, Raiwind Road, Lahore, Pakistan-
	The status in reference regulatory authorities	EMA Approved/FDA Approved
	Detail of previous approval	Procial Tablet 20mg (M 351)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**SWERA PHARMACEUTICALS** PLOT# 27, STREET# S-4, INDUSTRIAL ESTATE, RAWAT **(000941)**
	Application Form Dy. No / Tracking ID & date of submission	(6B4-T8H-2W7T, 2026-02-06)
	Detail of Fee Submitted	97200, 2026-01-26,
	The proposed proprietary name / brand name	**Montinic Tablet 10mg**
	Label Claim	Each Film coated tablet contains: Montelukast Sodium (eq. to. Montelukast).....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 Year15-30c
	For generic drugs (me-too Status)	Attached
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt) Ltd-Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat-
	The status in reference regulatory authorities	Attached
	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	
389	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**SATURN Pharmaceuticals Pvt Ltd** 23km Thorar Raiwind Road Lahore **(000734)**
	Application Form Dy. No / Tracking ID & date of submission	(6BM-4WD-P8NW, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-12-08,
	The proposed proprietary name / brand name	**OMESTURN**
	Label Claim	Each Capsule contains: Omeprazole (as Omeprazole EC Pellets 8.5%) = 40 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2 X 7's, 10's, 20's,30's,&100's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 centigrade. Protect from heat, moisture & sunlight
	For generic drugs (me-too Status)	Risek 40mg Capsule
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor (PPI)
	Name, address of Manufacturing site:	Variant Pharmaceuticals Pvt Ltd.-Plot no 5 M2 Pharmazone Sharqpur lahore-Road.-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	Minutes of 297th 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	
390	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	(RLQ-2BS-3VU2, 2026-01-27)
	Detail of Fee Submitted	93000.0, 2025-05-07,
	The proposed proprietary name / brand name	**Progard-40mg Injection IV**

	Label Claim	Each vial contains: Pantoprazole Sodium eq. to. Pantoprazole.....40mg
	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)	Zentro Injection 40mg IV Reg. No. 045388 By: Bosch Pharma
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibiter (PPI)
	Name, address of Manufacturing site:	Akson Pharmaceuticals (Pvt.) Ltd,-Plot No. 9-B/1&2, Sector D-1, Old Industrial Estate, Mirpur-Azad Kashmir.-
	The status in reference regulatory authorities	ROTONIX® I.V. for Injection, USFDA Approved
	Detail of previous approval	PROGARD 40MG INJECTION IV Reg. No. 093296 PRVC (F-137-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. The PRV approval is dated 11.11.2024.	
	Decision	
	Approved	
391	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Dew-Max Pharmaceuticals (Pvt) Ltd** Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad **(000889)**
	Application Form Dy. No / Tracking ID & date of submission	(A9B-XBN-QXHA, 2026-03-02)
	Detail of Fee Submitted	97200, 2025-12-11,
	The proposed proprietary name / brand name	**Vonosen 10mg Tablet**
	Label Claim	Each film coated tablet contain: Vonoprazan (as fumarate).....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14s-As per SRO,20s-As per SRO,30s-As per SRO
	Shelf Life (Unit)	2 Year15-30c
	For generic drugs (me-too Status)	Attached
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Linta Pharmaceuticals (Pvt) Ltd-Plot.3 Street S-5 National Industrial Zone Rawat Islamabad-
	The status in reference regulatory authorities	Attached
	Detail of previous approval	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	
392	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Dew-Max Pharmaceuticals (Pvt) Ltd** Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad **(000889)**
	Application Form Dy. No / Tracking ID & date of submission	(5HD-45J-LM3B, 2026-03-02)
	Detail of Fee Submitted	97200, 2025-12-09,
	The proposed proprietary name / brand name	**Vonosen 20mg Tablet**
	Label Claim	Each film coated tablet contain: Vonoprazan (as fumarate).....20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14s-As per SRO,20s-As per SRO,30s-As per SRO
	Shelf Life (Unit)	2 Year15-30c
	For generic drugs (me-too Status)	Attached
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Linta Pharmaceuticals (Pvt) Ltd-Plot # 3, Street # S-5, National Industrial Zone Rawat, Islamabad-
	The status in reference regulatory authorities	Attached
	Detail of previous approval	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	
393	Case Category	Routine (Incharge Evaluation Cell)
	Name, address of Applicant.	**Martin Dow Marker Limited** 7, Jail Road Quetta. **(000028)**
	Application Form Dy. No / Tracking ID & date of submission	(T5E-JRZ-342B, 2025-11-11)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-22, 2025-02-06
	The proposed proprietary name / brand name	**Empagliflozin+ Linagliptin Tablet 10mg+5mg**
	Label Claim	Each tablet contains Empagliflozin...10mg Linagliptin.....5mg (Innovator Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14s-As per SRO
	Shelf Life (Unit)	2 Year(s)below 30
	For generic drugs (me-too Status)	Diampa LT

	Pharmacotherapeutic Group of (API)	Anti diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Linagliptin: Fuxin Long Rui Pharmaceutical CO.,Ltd Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China Empagliflozin:RUYUAN HEC Pharm Co., Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdon
	Detail of stability batches of drug product	Long-term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Glyxambi batch number 106532A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Long-term and accelerated conditions
	The status in reference regulatory authorities	USFDA
	GMP status of the firm	GMP certificate 18.03.2024
	Evidence of approval of manufacturing facility	DML 28.04.2020
	Evaluation Remarks	
	The application fulfills codal formalities and submitted for consideration of the Board.	
	Decision	
	Approved	
394	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**De-Mont Research Laboratories (Pvt.) Ltd.** 20 Km, Lahore-Sharikpur Road, Sheikhupura **(000844)**
	Application Form Dy. No / Tracking ID & date of submission	(6JL-53R-7BSA, 2026-02-12)
	Detail of Fee Submitted	97200, 2026-01-30,
	The proposed proprietary name / brand name	**Clotricon 1% Topical Lotion**
	Label Claim	Each ml contains: Clotrimazole.....10mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	60ml-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 25°C
	For generic drugs (me-too Status)	Canix 1% Lotion, Crystolite Pharmaceuticals, Islamabad
	Pharmacotherapeutic Group of (API)	Anti-Fungal
	Name, address of Manufacturing site:	M/s Bio Labs Pvt Ltd.-Plot # 145, Industrial Triangle, Kahuta Road, Islamabad-
	The status in reference regulatory authorities	LOTRIMIN AF 1% Topical Lotion USFDA Approved
	Detail of previous approval	Biotrim 1% Topical Lotion, 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	
395	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**PDH Laboratories (Pvt.) Ltd.** 9.5 Km Sheikhupura Road, Lahore **(000039)**
	Application Form Dy. No / Tracking ID & date of submission	(BPL-4JQ-J39Z, 2026-03-04)
	Detail of Fee Submitted	97200, 2026-02-02,
	The proposed proprietary name / brand name	**PD-Omi IV Injection 40mg**
	Label Claim	Each Vial contains: Omeprazole Sodium equivalent to Omperazole ..... 40 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's, 25's -Controlled
	Shelf Life (Unit)	2 Yearbelow 30°
	For generic drugs (me-too Status)	Risek injection 40mg IV by Getz Pharma
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor (PPI)
	Name, address of Manufacturing site:	Variant Pharmaceuticals (Pvt.) Ltd. -PLOT # 5, M-2, PHARMAZONE, 26 KM MAIN SHARAQPUR ROAD DISTRICT SHEIKHUPURA PAKISTAN -
	The status in reference regulatory authorities	Omeprazole 40 mg Powder for Solution for Infusion by Sandoz Ltd Park View, Riverside Way Watchmoor Park Camberley, Surrey GU15 3YL United Kingdom
	Detail of previous approval	Varizole 40mg IV injection. This produc is approved at sr. no. 217 in Minutes of 312th Meeting of Re
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**PDH Laboratories (Pvt.) Ltd.** 9.5 Km Sheikhupura Road, Lahore **(000039)**
	Application Form Dy. No / Tracking ID & date of submission	(MMR-QX5-3SQH, 2026-03-04)
	Detail of Fee Submitted	97200, 2026-02-02,
	The proposed proprietary name / brand name	**PD-Omi capsule 40mg**

	Label Claim	Each capsule contains: Omeprazole (enteric coated pellets) equivalent to Omeprazole.....40 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2x7's, 10's-Controlled
	Shelf Life (Unit)	2 Yearbelow 30°
	For generic drugs (me-too Status)	Risek Capsule 40mg by Getz Pharma
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor (PPI)
	Name, address of Manufacturing site:	Variant Pharmaceuticals (Pvt.) Ltd.-PLOT # 5, M-2, PHARMAZONE, 26 KM MAIN SHARAQPUR ROAD DISTRICT SHEIKHUPURA PAKISTAN-
	The status in reference regulatory authorities	Omeprazole 40mg Capsules by Sandoz Limited Park View, Riverside Way Watchmoor Park Camberley, Surrey GU15 3YL United Kingdom
	Detail of previous approval	Varizole 40mg capsule. This produc is approved at sr. no. 1398 in Minutes of 297th Meeting of Regist
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**PDH Laboratories (Pvt.) Ltd.** 9.5 Km Sheikhupura Road, Lahore **(000039)**
	Application Form Dy. No / Tracking ID & date of submission	(MR8-Z9U-UWT7, 2026-03-04)
	Detail of Fee Submitted	97200, 2026-02-02,
	The proposed proprietary name / brand name	**PD-Esso Capsule 20mg**
	Label Claim	Each Capsule contains: Enteric Coated Esomeprazole Magnesium Trihydrate Pellets equivalent to Esomeprazole = 20 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2x7's, 10's -De-Controlled
	Shelf Life (Unit)	2 Yearbelow 30°
	For generic drugs (me-too Status)	Nexum capsule 20mg by Getz pharma
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor (PPI)
	Name, address of Manufacturing site:	Variant Pharmaceuticals (Pvt.) Ltd-PLOT # 5, M-2, PHARMAZONE, 26 KM MAIN SHARAQPUR ROAD DISTRICT SHEIKHUPURA PAKISTAN -
	The status in reference regulatory authorities	NEXIUM 20mg CAPSULE by AstraZeneca AB (Sodertalje, Sweden) Marketing Authorization

		Number: PL 17901/0068 Reference Regulatory Authority: FDA Approved
	Detail of previous approval	This produc is approved at sr. no. 1399 in Minutes of 297th Meeting of Registration Board (12-14 Jan
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**PDH Laboratories (Pvt.) Ltd.** 9.5 Km Sheikhupura Road, Lahore **(000039)**
	Application Form Dy. No / Tracking ID & date of submission	(PT8-557-AD1D, 2026-03-04)
	Detail of Fee Submitted	97200, 2026-02-02,
	The proposed proprietary name / brand name	**PD-Esso Capsule 40mg**
	Label Claim	Each Capsule contains: Enteric Coated Esomeprazole Magnesium Trihydrate Pellets equivalent to Esomeprazole = 40 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2x7's, 10's -De-Controlled
	Shelf Life (Unit)	2 Yearbelow 30°
	For generic drugs (me-too Status)	Nexum capsule 40mg by Getz pharma
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor (PPI)
	Name, address of Manufacturing site:	Variant Pharmaceuticals (Pvt.) Ltd.-PLOT # 5, M-2, PHARMAZONE, 26 KM MAIN SHARAQPUR ROAD DISTRICT SHEIKHUPURA PAKISTAN -
	The status in reference regulatory authorities	This produc is approved at sr. no. 1400 in Minutes of 297th Meeting of Registration Board (12-14 Jan, 2021)
	Detail of previous approval	ESOVAR capsule 40mg. This produc is approved at sr. no. 1400 in Minutes of 297th Meeting of Registra
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**PDH Laboratories (Pvt.) Ltd.** 9.5 Km Sheikhupura Road, Lahore **(000039)**
	Application Form Dy. No / Tracking ID & date of submission	(Q3B-Y2B-YS2Y, 2026-03-04)
	Detail of Fee Submitted	97200, 2026-02-02,
	The proposed proprietary name / brand name	**PD-Moxi tablet 400mg**
	Label Claim	Each film coated tablet contains: Moxifloxacin HCl equivalent to Moxifloxacin.....400 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5's-Controlled
	Shelf Life (Unit)	2 Yearbelow 30°
	For generic drugs (me-too Status)	MOXIGET 400 mg tab by Getz pharma (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Quinolone Antibiotic
	Name, address of Manufacturing site:	Variant Pharmaceuticals (Pvt.) Ltd. -PLOT # 5, M-2, PHARMAZONE, 26 KM MAIN SHARAQPUR ROAD DISTRICT SHEIKHUPURA PAKISTAN -
	The status in reference regulatory authorities	Moxifloxacin 400 mg film-coated tablets by Brown & Burk UK Limited, 5 Marryat Close, Hounslow, TW4 5DQ, United Kingdom
	Detail of previous approval	MOXIVAR 400mg Tablet, This produc is approved at sr. no. 117 in Minutes of 313th Meeting of Registra
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
400	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**PDH Laboratories (Pvt.) Ltd.** 9.5 Km Sheikhupura Road, Lahore **(000039)**
	Application Form Dy. No / Tracking ID & date of submission	(VVY-X1S-ASA6, 2026-03-04)
	Detail of Fee Submitted	97200, 2026-02-02,
	The proposed proprietary name / brand name	**PD-Moxi infusion 400mg/250ml**
	Label Claim	Each 250ml contains: Moxifloxacin as HCl.....400 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's -Controlled
	Shelf Life (Unit)	2 Yearbelow 30°

	For generic drugs (me-too Status)	Avelox 400mg/250ml Infusion by Bayer Health care
	Pharmacotherapeutic Group of (API)	Quinolone Antibiotic
	Name, address of Manufacturing site:	Variant Pharmaceuticals (Pvt.) Ltd. -PLOT # 5, M-2, PHARMAZONE, 26 KM MAIN SHARAQPUR ROAD DISTRICT SHEIKHUPURA PAKISTAN -
	The status in reference regulatory authorities	Moxifloxacin 400 mg/250 ml Solution for Infusion by Fresenius Kabi Deutschland GmbH Else-Kroener Strasse 1 Bad Homburg v.d.H 61352 Germany
	Detail of previous approval	Moxivar 400 mg/250ml Infusion, This produc is approved at sr. no. 1593 in Minutes of 331th Meeting o
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**PDH Laboratories (Pvt.) Ltd.** 9.5 Km Sheikhupura Road, Lahore **(000039)**
	Application Form Dy. No / Tracking ID & date of submission	(X1R-G86-L7J4, 2026-03-04)
	Detail of Fee Submitted	97200, 2026-02-02,
	The proposed proprietary name / brand name	**PD-Met infusion 500mg/100ml**
	Label Claim	Each 100ml contains: Metronidazole.....500 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-Controlled
	Shelf Life (Unit)	2 Yearbelow 30°
	For generic drugs (me-too Status)	Flagyl 500mg/100ml Infusion by Sanofi Aventis (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	General Antibiotic
	Name, address of Manufacturing site:	Variant Pharmaceuticals (Pvt.) Ltd. -PLOT # 5, M-2, PHARMAZONE, 26 KM MAIN SHARAQPUR ROAD DISTRICT SHEIKHUPURA PAKISTAN -
	The status in reference regulatory authorities	Metronidazole 500mg/100ml Intravenous Infusion by Baxter Healthcare Ltd.Caxton Way, Thetford Norfolk, IP24 3SE, UK
	Detail of previous approval	Metzole 500mg/100ml infusion. This produc is approved at sr. no. 930 in Minutes of 326th Meeting of
	Evaluation Remarks	

	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**PDH Laboratories (Pvt.) Ltd.** 9.5 Km Sheikhupura Road, Lahore **(000039)**
	Application Form Dy. No / Tracking ID & date of submission	(ZXE-G9Y-LQ81, 2026-03-04)
	Detail of Fee Submitted	97200, 2026-02-02,
	The proposed proprietary name / brand name	**PD-Esso IV injection 40mg**
	Label Claim	Each Capsule contains: Pre-lyophillized Sterile Powder for solution for I.V injection or infusion of Esomperazole Sodium eq. to Esomperazole ..... 40 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	2 Yearbelow 30°
	For generic drugs (me-too Status)	Nexum Injection 40mg IV by Getz Pharma
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor (PPI)
	Name, address of Manufacturing site:	Variant Pharmaceuticals (Pvt.) Ltd. -PLOT # 5, M-2, PHARMAZONE, 26 KM MAIN SHARAQPUR ROAD DISTRICT SHEIKHUPURA PAKISTAN -
	The status in reference regulatory authorities	Esomeprazole 40 mg powder for injection/infusion by Ranbaxy (UK) Limited a Sun Pharmaceutical Company
	Detail of previous approval	ESOVAR 40mg IV Injection.This produc is approved at sr. no. 216 in Minutes of 312 Meeting of Registr
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**Genetics Pharmaceuticals Pvt. Ltd** 539-A Sundar Industrial Estate Raiwind Road Lahore **(000845)**

	Application Form Dy. No / Tracking ID & date of submission	(1NG-3XB-G483, 2025-09-03)
	Detail of Fee Submitted	93000.0, 2025-07-23,
	The proposed proprietary name / brand name	**Revigra 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 YearBelow 25°C
	For generic drugs (me-too Status)	Hilagra (Hilton Pharma)
	Pharmacotherapeutic Group of (API)	M/S: Century Pharmaceuticals Limited, Address: 103-106, GIDC, Halol Dist. Panchmahals- 389 350, India
	Name, address of Manufacturing site:	M/s Focus & Rulz Pharmaceuticals Pvt (Ltd)-44-Industrial Triangle, Kahuta Road Islamabad-Pakistan. -
	The status in reference regulatory authorities	Viagra 50mg Tablet (Upjohn EESV, The Netherlands)
	Detail of previous approval	Silpah 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	
404	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(5G6-EXD-RT2N, 2025-04-21)
	Detail of Fee Submitted	93000.0, 2024-11-28,
	The proposed proprietary name / brand name	**Revito (Tadalafil) Tablets 5mg**
	Label Claim	Each film coated tablets contains: Tadalafil 5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4's, 1x5's, 1x10's-De-Controlled
	Shelf Life (Unit)	2 YearSrore below 30°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals (Pvt.) Ltd.-Plot # 129, Sundar Industrial Estate Lahore, Pakistan-
	The status in reference regulatory authorities	US FDA
	Detail of previous approval	
	Evaluation Remarks	

	The firm initially selected NO in the data already and then submitted pre-registration variation fee along with extract of minutes of the Registration Board for approval of their cross-referred product. 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.	
	Decision	
	Approved	
405	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(7Q3-VN1-6AUU, 2025-04-21)
	Detail of Fee Submitted	93000.0, 2024-11-28,
	The proposed proprietary name / brand name	**Revito Tablets 20mg**
	Label Claim	Each film coated tablet contains: Tadalafil 20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4's, 1x5's, 1x10's-De-Controlled
	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:	Wimits Pharmaceuticals (Pvt.) Ltd.-Plot No. 129, Sunder Industrial Estate Raiwind Road, Lahore.-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	
	Evaluation Remarks	
	The firm initially selected NO in the data already and then submitted pre-registration variation fee along with extract of minutes of the Registration Board for approval of their cross-referred product. 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.	
	Decision	
	Approved	
406	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(96S-T16-R9YL, 2025-04-21)

	Detail of Fee Submitted	93000.0, 2024-11-28,
	The proposed proprietary name / brand name	**Revito (Tadalafil) Tablets 2.5mg**
	Label Claim	Each film coated tablets contains: Tadalafil 2.5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4's, 1x5's, 1x10's-De-Controlled
	Shelf Life (Unit)	2 YearSrore below 30°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceutical (Pvt.) Ltd.-Plot # 129, Sundar Industrial Estate Lahore, Pakistan-
	The status in reference regulatory authorities	US FDA
	Detail of previous approval	
	Evaluation Remarks	
	The firm initially selected NO in the data already and then submitted pre-registration variation fee along with extract of minutes of the Registration Board for approval of their cross-referred product. 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.	
	Decision	
	Approved	
407	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Mediate Pharmaceutical Pvt Ltd** Plot # 150-151 Sector 24, Korangi Industrial Area **(000167)**
	Application Form Dy. No / Tracking ID & date of submission	(G3P-J3R-EVJ5, 2026-01-27)
	Detail of Fee Submitted	38700, 58500 2025-12-24, 2026-03-03
	The proposed proprietary name / brand name	**Medform capsule**
	Label Claim	Each capsule contains: Budesonide.....200mcg Formoterol Fumarate Dihydrate.....6mcg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30'S-As per SRO
	Shelf Life (Unit)	2 Year25
	For generic drugs (me-too Status)	Venticort Rotacaps 200mg + 6mcg
	Pharmacotherapeutic Group of (API)	Budesonide + Formoterol fumarate dihydrate belongs to a pharmaceutical group known as an inhaled corticosteroid (ICS) and long-acting beta2-adrenergic agonist (LABA) combinatio
	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	EMC/FDA Approved
	Detail of previous approval	DRAP , Meeting 336th Page # 1832-1833
	Evaluation Remarks	

	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**Bosch Pharmaceuticals (Pvt) Ltd.** Plot No. 221-223, Sector-23, Korangi Industrial Area **(000350)**
	Application Form Dy. No / Tracking ID & date of submission	(ZU7-8ZQ-ERVJ, 2025-01-28)
	Detail of Fee Submitted	93000.0, 2024-11-28,
	The proposed proprietary name / brand name	**Revito Tablets 10mg**
	Label Claim	Each film coated tablet contains: Tadalafil 10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4's, 1x5's, 1x10's-De-Controlled
	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:	Wimits Pharmaceuticals (Pvt.) Ltd.-Plot No. 129, Sunder Industrial Estate Raiwind Road, Lahore.-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	
	Evaluation Remarks	
	The firm initially selected NO in the data already and then submitted pre-registration variation fee along with extract of minutes of the Registration Board for approval of their cross-referred product. 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.	
	Decision	
	Approved	
409	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	(UWY-2NU-X2VP, 2025-06-05)
	Detail of Fee Submitted	93000.0, 2025-05-09,

	The proposed proprietary name / brand name	**Aksofos 500mg/10ml Injection**
	Label Claim	Each ml contains: Ferric carboxymaltose Equivalent to Elemental Iron 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10ml, 1x2ml, 1x20m-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	IZER (Ferric carboxymaltose) 500mg/10ml Injection of M/s Pharmasol
	Pharmacotherapeutic Group of (API)	Iron replacement products
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	Ferinject 50mg/ml Injection of M/s Vifor Pharma (MHRA Approved)
	Detail of previous approval	
	Evaluation Remarks	
	The applicant initially selected No in the data already approved column of the application. After submission of pre-registration variation fee, they have requested for consideration against the already approved cross-referred product. 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.	
	Decision	
	Approved	
410	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Mediate Pharmaceutical Pvt Ltd** Plot # 150-151 Sector 24, Korangi Industrial Area **(000167)**
	Application Form Dy. No / Tracking ID & date of submission	(AEL-B92-68X8, 2026-01-13)
	Detail of Fee Submitted	38700, 58500 2025-12-24, 2026-03-03
	The proposed proprietary name / brand name	**PIPAZO 4.5gm Injection**
	Label Claim	Each vial contains: Piperacillin as Sodium ...4gm Tazobactum as Sodium ..500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1'S-As per SRO
	Shelf Life (Unit)	2 Year25
	For generic drugs (me-too Status)	Zosyn 4.5gm INJECTION Regent Karachi by Cirin Pharma Hattar 4.5gm
	Pharmacotherapeutic Group of (API)	Beta Lactam Antibiotics
	Name, address of Manufacturing site:	Wallace Pharma Evolutions-Kala Wala Stop 20-KM, LAHORE JARANWALA ROAD, LAHORE -
	The status in reference regulatory authorities	EMC/FDA Approved
	Detail of previous approval	DRAP Meeting 331 Page # 1084-1093
	Evaluation Remarks	

	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**Genetics Pharmaceuticals Pvt. Ltd** 539-A Sundar Industrial Estate Raiwind Road Lahore **(000845)**
	Application Form Dy. No / Tracking ID & date of submission	(GMB-YMG-VDXL, 2025-09-03)
	Detail of Fee Submitted	93000.0, 2025-07-23,
	The proposed proprietary name / brand name	**Revigra 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 YearBelow 25°C
	For generic drugs (me-too Status)	Hilagra (Hilton Pharma)
	Pharmacotherapeutic Group of (API)	M/S: Century Pharmaceuticals Limited, Address: 103-106, GIDC, Halol Dist. Panchmahals- 389 350, India
	Name, address of Manufacturing site:	M/s Focus & Rulz Pharmaceuticals Pvt (Ltd)-44-Industrial Triangle, Kahuta Road Islamabad-Pakistan. -
	The status in reference regulatory authorities	Viagra 100mg Tablet (Upjohn EESV, The Netherlands)
	Detail of previous approval	Silpah 100mg Tablet, 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	
412	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(HNZ-XXN-5RP4, 2025-06-05)
	Detail of Fee Submitted	93000.0, 2025-05-23,

	The proposed proprietary name / brand name	**Tadala Tablet 2.5mg**
	Label Claim	Each film coated tablet contains: Tadalafil.....2.5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-De-Controlled,10's-De-Controlled,100's-De-Controlled,14's-De-Controlled,2's-De-Controlled,20's-De-Controlled,28's-De-Controlled,3's-De-Controlled,30's-De-Controlled,4's-De-Controlled,40's-De-Controlled,5's-De-Controlled,50's-De-Controlled,7's-De-Controlled,8's-De-Controlled
	Shelf Life (Unit)	2 YearDo not store above 30C.
	For generic drugs (me-too Status)	Procial 2.5mg Tablet, Wimits Pharmaceuticals Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	ULTRA TECH INDIA LTD.
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals Pvt. Limited.-Plot # 129, Sunder Industrial Estate Lahore.-
	The status in reference regulatory authorities	Tadalafil. Company: Ajanta Pharma USA Inc. (USFDA)
	Detail of previous approval	Procial 2.5mg 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	
413	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	(MTQ-M7J-VZ6J, 2025-09-30)
	Detail of Fee Submitted	93000.0, 2025-07-10,
	The proposed proprietary name / brand name	**Tadlo 20mg**
	Label Claim	Eachfilm coated tablet contains: Tadalafil...20mg
	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)	Tadalafil 20mg Tablets
	Pharmacotherapeutic Group of (API)	Phosphodiesterase inhibitors
	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	Procial 20mg 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	
414	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	(T1W-EU1-XBAV, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-10-27,
	The proposed proprietary name / brand name	**Diblay-M**
	Label Claim	Each Film-coated Tablet Contains: Empagliflozin..... 12.5mg Metformin HCl.....850mg
	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)	• Manufactured By: Solaris Pharma Brand name: Emform 12.5/850mg Tablets Strength: Empagliflozin 12.5mg + Metformin HCl 850mg Composition: Each Film-coated Tablet contains: E
	Pharmacotherapeutic Group of (API)	Anti Diabetic
	Name, address of Manufacturing site:	Name: Solaris Life Sciences (Pvt.) Ltd. Address: P-Address: Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat - Pakistan -
	The status in reference regulatory authorities	Registration Status: USFDA Approved New Drug Application (NDA): 212362. Company: MSN LABS PVT LTD Brand Name: Empagliflozin + Metformin Hydrochloride Marketing status: Over-the-counter
	Detail of previous approval	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	
415	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

	Name, address of Applicant.	**LEAMA CHEMI PHARMA (PVT) LTD** 37-A HAYATABAD INDUSTRIAL ESTATE PESHAWAR **(000404)**
	Application Form Dy. No / Tracking ID & date of submission	(WS4-9TL-S1TT, 2026-03-09)
	Detail of Fee Submitted	97200, 2026-01-21,
	The proposed proprietary name / brand name	**Lemafil 25mg**
	Label Claim	Each film coated Tablet contains: Sildenafil Citrate 35.127 mg eq. to sildenafil 25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4s and 1x10s-As per SRO
	Shelf Life (Unit)	2 Year30 C
	For generic drugs (me-too Status)	ripple 25 mg tablets
	Pharmacotherapeutic Group of (API)	phosphodiesterase type 5 (PDE5) 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	USFDA Approved
	Detail of previous approval	Ripple 25mg Tablets, (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	
416	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(4XT-81U-VSYT, 2025-01-23)
	Detail of Fee Submitted	93000.0, 2024-11-28,
	The proposed proprietary name / brand name	**Stamix (Sildenafil) Tablets 50mg**
	Label Claim	Each film coated tablets contains: Sildenafil Citrate equivalent to Sildenafil 50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x5's, 1x10's,2x10"-De-Controlled
	Shelf Life (Unit)	2 YearSrore below 30°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals (Pvt.) Ltd.-Plot # 129, Sundar Industrial Estate Lahore, Pakistan-
	The status in reference regulatory authorities	US FDA
	Detail of previous approval	

	Evaluation Remarks	
	The applicant initially selected No in the data already approved column of the application. After submission of pre-registration variation fee, they have requested for consideration against the already approved cross-referred product. 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.	
	Decision	
	Approved	
417	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(B2R-2N9-AS4Y, 2025-01-23)
	Detail of Fee Submitted	93000.0, 2024-11-28,
	The proposed proprietary name / brand name	**Stamix (Sildenafil) Tablets 100mg**
	Label Claim	Each film coated tablets contains: Sildenafil Citrate equivalent to Sildenafil 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x5's, 1x10's, 2x10-De-Controlled
	Shelf Life (Unit)	2 YearSrore below 30°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals (Pvt.) Ltd.-Plot # 129, Sundar Industrial Estate Lahore, Pakistan-
	The status in reference regulatory authorities	US FDA
	Detail of previous approval	
	Evaluation Remarks	
	The applicant initially selected No in the data already approved column of the application. After submission of pre-registration variation fee, they have requested for consideration against the already approved cross-referred product. 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.	
	Decision	
	Approved	
418	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(XEU-DM3-MA54, 2025-01-23)
	Detail of Fee Submitted	93000.0, 2024-11-28,
	The proposed proprietary name / brand name	**Stamix (Sildenafil) Tablets 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	1x5's, 1x10's, 2x10-De-Controlled
	Shelf Life (Unit)	2 YearSrore below 30°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals (Pvt.) Ltd.-Plot # 129, Sundar Industrial Estate Lahore, Pakistan-
	The status in reference regulatory authorities	US FDA
	Detail of previous approval	
	Evaluation Remarks	
	The applicant initially selected No in the data already approved column of the application. After submission of pre-registration variation fee, they have requested for consideration against the already approved cross-referred product. 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.	
	Decision	
	Approved	
419	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Maybush Pharmaceuticals (Pvt) Ltd** Plot # 249/A, Industrial Triangle, Kahuta Road Islamabad **(000501)**
	Application Form Dy. No / Tracking ID & date of submission	(6LA-J6R-SGYQ, 2026-02-12)
	Detail of Fee Submitted	97200, 2026-02-04,
	The proposed proprietary name / brand name	**MAYTRO2/0.5mg Tablet**
	Label Claim	Each of the 11 white tablets contains: Estradiol Valerate.....2mg Each of the 10 light brown tablets contains: Estradiol Valerate.....2mg Norgestrel 0.5mg
	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)	Manufacture Name: Bayer Weimar GmbH und Co., KG, Weimar, Germany. Marketed by: Bayer Pakistan (Pvt.) Limited, Plot No. 23, Sector No. 22, Korangi industrial Area, 74900, Karachi-Pakistan. Brand Name &

	Pharmacotherapeutic Group of (API)	(a) Pharmacological class of API : Estradiol is in a class of medications called estrogen hormones. It works by replacing estrogen that is normally produced by the body. Norgestrel is a progestin, or a synthetic progestogen, and hence is an agonist of the progesterone receptor, the biological target of progestogens like progesterone. (Reference;Basic and Clinical Pharmacology By Bertram G. Katzung)
	Name, address of Manufacturing site:	SKYWIN PHARMACEUTICALS-Plot #01,Al Badar Industrial Estate, Phase II Sheikhupura Road Lahore. Phone:042-111 116 366-
	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. 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 Registration number of the medicine in the National Drug Registry of the Ministry of Health: 032 90 22502 00 Dosage Form: coated oral tablet Reference Regulat
	Detail of previous approval	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	
420	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**LIVEN PHARMACEUTICALS** 49-KM MULTAN ROAD, PHOOL NAGAR, DISTRICT, KASUR PAKISTAN **(000881)**
	Application Form Dy. No / Tracking ID & date of submission	(6M2-LGY-7UT8, 2026-02-04)
	Detail of Fee Submitted	97200, 2026-01-16,
	The proposed proprietary name / brand name	**Prostocare 50mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Biclutamide.....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Casodex 50mg Tablet of M/s ICI, Pakistan
	Pharmacotherapeutic Group of (API)	Bicalutamide is in a class of medications called nonsteroidal antiandrogens

	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Bicalutamide 50 mg film-coated tablets of M/s Sun Pharmaceutical Industries Europe B.V. Polarisavenue 872132 JH Hoofddorp, Netherlands (USFDA Approved)
	Detail of previous approval	Casodex 50mg Tablet - 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	
421	Case Category	Routine (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	(UA4-2AT-7Q8A, 2026-01-14)
	Detail of Fee Submitted	38700, 2025-10-22,
	The proposed proprietary name / brand name	**Dpsyl 50mg Sachet**
	Label Claim	Each Sachet contains: Diclofenac potassium .....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 Year(s)Below 30°C
	For generic drugs (me-too Status)	Maxit 50mg sachet
	Pharmacotherapeutic Group of (API)	NSAID
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	At long-term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	API loan from Global Pharmaceuticals
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Maxit Sachet 50mg Batch #158582
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	At long-term and accelerated conditions
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	DML dated 17-01-2024
	Evidence of approval of manufacturing facility	DML dated 17-01-2024
	Evaluation Remarks	
	The firm has requested to consider application under new-license and submitted the fee.	
	Decision	
	Approved	

422	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	(YWY-HWS-NGYR, 2026-03-26)
	Detail of Fee Submitted	97200, 2026-02-17,
	The proposed proprietary name / brand name	**MYNAP 500mg/20mg MR Tablet**
	Label Claim	Each Modified release Tablet contains: Naproxen .....500mg (as Enteric Coated Core) Esomeprazole as Magnesium Trihydrate .....20mg (as Immediate Release Coat) (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3x10's-De-Controlled
	Shelf Life (Unit)	2 YearBelow 30C Degree
	For generic drugs (me-too Status)	Glomov 20/500mg tablet by M/s Global Pharmaceutical (Pakistan) Reg No 109338
	Pharmacotherapeutic Group of (API)	Esomeprazole is Proton Pump Inhibitor (PPI) & Naproxen belongs to NSAID
	Name, address of Manufacturing site:	M/s WnsFeild Pharmaceuticals-Plot #122, Block A, Phase-V, Industrial Estate, Hattar, Haripur, KPK-
	The status in reference regulatory authorities	Vimovo delayed release tablet 20/500mg USFDA
	Detail of previous approval	Minutes of 324th meeting of Registration Board (24th to 26th January, 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	
423	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	(ZBU-7Q8-TSRB, 2026-02-17)
	Detail of Fee Submitted	97200, 2026-02-16,
	The proposed proprietary name / brand name	**C-DEX 60mg Capsules**
	Label Claim	Each Hard Gelatin Capsule Contains: Dexlansoprazole dual delayed release pallets eq. to Dexlansoprazole...60mg (Source of Pallets: Vision Pharmaceuticals)

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	4*7's, As per SRO-De-Controlled
	Shelf Life (Unit)	2 YearBelow 30C Degree
	For generic drugs (me-too Status)	Dexloprot DDR 30mg Capsule of Nabiqasim Industries (Pvt) Ltd.
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor (PPI)
	Name, address of Manufacturing site:	CELL HEALTH SCIENCES-Plot # 217 Industrial Triangle Kahuta Road, Islamabad-
	The status in reference regulatory authorities	Dexilant 60mg delayed release Capsule, US FDA approved.
	Detail of previous approval	Dexcell 60mg Capsule, Minutes for 340th meeting of Registration Board (1st October to 2nd October, 2
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**Crown Pharmaceuticals** Plot 286, Kahuta industrial Triangle, Kahota Road, Islamabad **(000456)**
	Application Form Dy. No / Tracking ID & date of submission	(6M4-WBV-QMDX, 2026-03-04)
	Detail of Fee Submitted	97200, 2026-02-16,
	The proposed proprietary name / brand name	**C-DEX 30mg Capsules**
	Label Claim	Each hard gelatin capsule contains: Dexlansoprazole dual delayed release pellets eq. to Dexlansoprazole...30mg (Source of Pallets: Vision Pharmaceuticals)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	4*7's, As per SRO-De-Controlled
	Shelf Life (Unit)	2 YearBelow 30C Degree
	For generic drugs (me-too Status)	Dexloprot DDR 30mg Capsule of Nabiqasim Industries (Pvt) Ltd.
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor (PPI)
	Name, address of Manufacturing site:	CELL HEALTH SCIENCES-Plot No 217, Industrial triangle, Kahuta road, Islamabad-Pakistan-
	The status in reference regulatory authorities	Dexilant 30mg delayed release Capsule, US FDA approved.
	Detail of previous approval	Dexcell 30mg Capsule, Minutes for 340th meeting of Registration Board (1st October to 2nd October, 2
	Evaluation Remarks	

	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**Crown Pharmaceuticals** Plot 286, Kahuta industrial Triangle, Kahota Road, Islamabad **(000456)**
	Application Form Dy. No / Tracking ID & date of submission	(MVQ-LJL-Q19Y, 2026-03-05)
	Detail of Fee Submitted	97200, 2026-03-02,
	The proposed proprietary name / brand name	**Kanzo 4.5g Injection**
	Label Claim	Each Vial Contains: Piperacillin Sodium eq. to Piperacillin 4gm, Tazobactum Sodium eq. to Tazobactum 0.5gm
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-Controlled
	Shelf Life (Unit)	2 YearBelow 30C Degree
	For generic drugs (me-too Status)	PIPRAL-T 4.5gm INJECTION I.V
	Pharmacotherapeutic Group of (API)	Piperacillin Class: Extended-spectrum penicillin & Tazobactam Class: β-lactamase inhibitor
	Name, address of Manufacturing site:	RSK Pharmaceuticals-Plot # 13A, Street # N-5, Rawat Industrial Estate, Rawalpindi-
	The status in reference regulatory authorities	ANDA APPROVED
	Detail of previous approval	Minutes of 350th Meeting of Registration Board (29th – 30th July, 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	
426	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	(6N2-ZRB-RY6J, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-11-11,

	The proposed proprietary name / brand name	**Traphen Plus Tablet 37.5mg/ 325mg**
	Label Claim	Each film coated tablet contains: Tramadol Hydrochloride.....37.5mg Paracetamol.....325mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's, 20's, 30's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Brand Name: Tonoflex-P Tablet Registration holder: Sami Pharmaceuticals, Registration No: 067163
	Pharmacotherapeutic Group of (API)	other analgesics and antipyretics: Anilides,
	Name, address of Manufacturing site:	Swiss Pharmaceuticals Pvt. Ltd.-A-159, S.I.T.E. Super Highway, Karachi-Pakistan-
	The status in reference regulatory authorities	Brand Name: Tramadol Hydrochloride/ Paracetamol 37.5mg /325mg film-coated tablets Marketing Authorization holder: Strandhaven Ltd t/a Somex Pharma Ilford, Essex IG3 8BS .UK
	Detail of previous approval	Approved data in PRVC Meeting for APPROVAL OF CHANGE IN MANUFACTURING SITE OF ALREADY REGISTERED DRU
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The product was approved in PRV dated 27-August, 2025 against Application TID: NN1-PVX-YMA1.	
	Decision	
	Approved	
427	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	(9WN-J3M-1J1A, 2026-03-04)
	Detail of Fee Submitted	97200, 2026-01-22,
	The proposed proprietary name / brand name	**Midolin 5mg Tablet**
	Label Claim	Each Tablet Contains Midodrine Hydrochloride 5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	20s-As per SRO
	Shelf Life (Unit)	2 Year15° to 30°C
	For generic drugs (me-too Status)	Midotab 5mg of M/S Wnsfeild Pharma
	Pharmacotherapeutic Group of (API)	Alpha 1 receptor agonist
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot #122, Block A, Phase V, Industrial Estate, Hattar, Haripur, KPK -
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	DRAP Registation Board Meeting No 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	
428	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	(RYN-TQ9-EW3V, 2026-03-05)
	Detail of Fee Submitted	97200, 2026-02-04,
	The proposed proprietary name / brand name	**Unigolix 200mg Tablet**
	Label Claim	Each film coated tablet contains Linzagolix as choline salt 200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 degree centigrade temperature
	For generic drugs (me-too Status)	Linxara tablet of M/S Acumen pharma
	Pharmacotherapeutic Group of (API)	Linzagolix is a selective, non-peptide gonadotropin-releasing hormone (GnRH) receptor antagonist
	Name, address of Manufacturing site:	Medizan Laboratories Pvt Ltd-Plot No.313, Industrial Triangle, Kahuta Road Islamabad. -
	The status in reference regulatory authorities	Yselty tablet MHRA approved
	Detail of previous approval	DRAP registration board Meeting no M-351
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**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	(THS-DT6-815N, 2026-03-10)

	Detail of Fee Submitted	97200, 2026-02-04,
	The proposed proprietary name / brand name	**Unigolix 100mg Tablet**
	Label Claim	Each film-coated tablet contains Linzagolix as choline salt 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10s-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 degree centigrade temperature
	For generic drugs (me-too Status)	Linxara tablet of M/S Acumen pharma
	Pharmacotherapeutic Group of (API)	Linzagolix is a selective, non-peptide gonadotropin-releasing hormone (GnRH) receptor antagonist
	Name, address of Manufacturing site:	Medizan Laboratories Pvt Ltd-Plot No.313, Industrial Triangle, Kahuta Road Islamabad. -
	The status in reference regulatory authorities	Yselty tablet MHRA approved
	Detail of previous approval	DRAP registration board Meeting no M-351
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)**
	Application Form Dy. No / Tracking ID & date of submission	(7DG-A3T-S1NJ, 2026-03-09)
	Detail of Fee Submitted	93000.0, 2025-01-15,
	The proposed proprietary name / brand name	**Silda**
	Label Claim	Each Silda 50mg Tablet Contains Sildenafil 50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Normal
	For generic drugs (me-too Status)	M/S Medizan Laboratories
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/S Medizan Laboratories - PlotNo.313,IndustrialTriangle,KahutaRoadIslamab Pakistan.-
	The status in reference regulatory authorities	https://www.fda.gov
	Detail of previous approval	293
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the	

	above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The cross-referred product was approved in PRV dated 30-January, 2026 vide application TID: DV9-RME-6JB8.	
	Decision	
	Approved	
431	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)**
	Application Form Dy. No / Tracking ID & date of submission	(NZX-W29-GB6N, 2026-03-09)
	Detail of Fee Submitted	93000.0, 2025-01-15,
	The proposed proprietary name / brand name	**Silda**
	Label Claim	Each Silda 100mg Tablet contains: Sildenafil Citrate
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Normal
	For generic drugs (me-too Status)	M/S Medizan Laboratories
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/S Medizan Laboratories - PlotNo.313,IndustrialTriangle,KahutaRoadIslamab Pakistan.-
	The status in reference regulatory authorities	https://www.fda.gov
	Detail of previous approval	293
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The cross-referred product was approved in PRV dated 30-January, 2026 vide application TID: 882-QQY-J4Y2.	
	Decision	
	Approved	
432	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)**
	Application Form Dy. No / Tracking ID & date of submission	(4P6-AV4-E7SV, 2026-03-18)
	Detail of Fee Submitted	93000.0, 2025-01-15,
	The proposed proprietary name / brand name	**Varda 10mg**
	Label Claim	Each Varda 10mg Tablet Contains Vardenafil Hydrochloride 10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Normal

	For generic drugs (me-too Status)	M/S Medizan Laboratories
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/S Medizan Laboratories -Plot No.313, Industrial Triangle, Kahuta Road Islamabad. -
	The status in reference regulatory authorities	https://www.fda.gov
	Detail of previous approval	Varda 10mg (Vardenafil) 293 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	
433	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)**
	Application Form Dy. No / Tracking ID & date of submission	(ZX9-VUL-Q72H, 2026-03-19)
	Detail of Fee Submitted	93000.0, 2025-01-15,
	The proposed proprietary name / brand name	**Varda**
	Label Claim	Each Varda 20mg Tablet Contains: Vardenafil 20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO -As per SRO
	Shelf Life (Unit)	2 Year(s)Normal
	For generic drugs (me-too Status)	M/S Medizan Laboratories
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/S Medizan Laboratories -Plot No.313, Industrial Triangle, Kahuta Road Islamabad-Pakistan-
	The status in reference regulatory authorities	https://www.fda.gov
	Detail of previous approval	293
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**LIVEN PHARMACEUTICALS** 49-KM MULTAN ROAD, PHOOL NAGAR, DISTRICT,

		KASUR PAKISTAN **(000881)**
	Application Form Dy. No / Tracking ID & date of submission	(6S4-3V7-9URJ, 2026-02-11)
	Detail of Fee Submitted	97200, 2026-01-16,
	The proposed proprietary name / brand name	**Dino-P 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	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Opioid analgesic
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	VIAGRA 50mg TABLET of M/s Upjohn EESV Rivium Westlaan 142 2909 LD Capelle aan den IJssel (EMA Approved)
	Detail of previous approval	Neogra 50mg Tablet - 350th 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	
435	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**LIVEN PHARMACEUTICALS** 49-KM MULTAN ROAD, PHOOL NAGAR, DISTRICT, KASUR PAKISTAN **(000881)**
	Application Form Dy. No / Tracking ID & date of submission	(BN2-DWE-AX4L, 2026-02-11)
	Detail of Fee Submitted	97200, 2026-01-16,
	The proposed proprietary name / brand name	**Dino-P 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	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Sildenafil is a medication used in the management and treatment of erectile dysfunction and pulmonary arterial hypertension. It is in the phosphodiesterase-5 inhibitor (PDE5-I) class of medications
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-

	The status in reference regulatory authorities	VIAGRA 100mg TABLET of M/s Upjohn EESV Rivium Westlaan 142 2909 LD Capelle aan den IJssel (EMA Approved)
	Detail of previous approval	Neogra 100mg Tablet - 350th 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.	**LIVEN PHARMACEUTICALS** 49-KM MULTAN ROAD, PHOOL NAGAR, DISTRICT, KASUR PAKISTAN **(000881)**
	Application Form Dy. No / Tracking ID & date of submission	(D5N-487-MNZ9, 2026-02-11)
	Detail of Fee Submitted	97200, 2026-01-16,
	The proposed proprietary name / brand name	**B-Pesart 5/80mg Tablet**
	Label Claim	Each Film Coated tablet contains: Nebivolol as HCl.....5mg Valsartan 80mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Nebivolol HCl (Beta Blocking Agent & Is used to treat Hypertension) Valsartan(ACE Inhibitor & Is used to treat Hypertension)
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Byvalson (Nebivolol HCl and Valsartan 5mg/80mg) tablet of M/s Actavis Pharma, Inc., Parsippany, NJ 07054 USA (USFDA Approved)
	Detail of previous approval	Nebicard-V 5/80 mg 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	
437	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

	Name, address of Applicant.	**LIVEN PHARMACEUTICALS** 49-KM MULTAN ROAD, PHOOL NAGAR, DISTRICT, KASUR PAKISTAN **(000881)**
	Application Form Dy. No / Tracking ID & date of submission	(S9N-V3T-AUJE, 2026-02-11)
	Detail of Fee Submitted	97200, 2026-01-16,
	The proposed proprietary name / brand name	**Augusta 20/375mg Tablet**
	Label Claim	Each Modified release tablet contains: Naproxen.....375mg (Enteric coated core) Esomeprazole as magnesium trihydrate .....20mg(Immediate released coat)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Glomov 375mg/20mg Tablet of M/s Global Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Naproxen belongs to a class of drugs NSAIDS. Esomeprazole belongs to a class of drugs Proton Pump Inhibitor
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Vimovo 375/20mg modified-release tablet of M/s Grunenthal Ltd (USFDA Approved)
	Detail of previous approval	Napsom 20/375mg Tablet 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	
438	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**LIVEN PHARMACEUTICALS** 49-KM MULTAN ROAD, PHOOL NAGAR, DISTRICT, KASUR PAKISTAN **(000881)**
	Application Form Dy. No / Tracking ID & date of submission	(SXU-WQ6-HLDA, 2026-02-11)
	Detail of Fee Submitted	97200, 2026-01-16,
	The proposed proprietary name / brand name	**Beelive 400mg/4ml Injection**
	Label Claim	Each ml contains: Ibuprofen..... 100mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30

	For generic drugs (me-too Status)	Rappifen 400mg/4ml Injection of M/s Aman Pharma
	Pharmacotherapeutic Group of (API)	NSAID,s
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Ibuprofen 400mg /4ml (100mg/ml) Injection of M/s POLİFARMA İLAÇ SAN. VE TİC. A.Ş. Vakıflar OSB Mahallesi, Sanayi Caddesi, No: 22/1 Ergene/Tekirdağ/TURKEY Eu & medicine Authority Approved
	Detail of previous approval	Bropin 400mg/4ml Injection - 331st 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	
439	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**LIVEN PHARMACEUTICALS** 49-KM MULTAN ROAD, PHOOL NAGAR, DISTRICT, KASUR PAKISTAN **(000881)**
	Application Form Dy. No / Tracking ID & date of submission	(WN8-YRW-21DT, 2026-02-11)
	Detail of Fee Submitted	97200, 2026-01-16,
	The proposed proprietary name / brand name	**Benam 100mg Tablet**
	Label Claim	Each Film coated tablet contains: Rebamipide 100mg
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Mucosta 100mg Tablet of M/s Otsuka Pakistan Limited
	Pharmacotherapeutic Group of (API)	Rebamipide belongs to the Antacids or anti-reflux agent's acts as a Prostaglandin E2
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	REBAMIPIDE TAB 100mg of M/s OHARA Pharmaceutical Co., Ltd (PMDA Approved)
	Detail of previous approval	Rebadec 100mg Tablet - 348th 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.	**LIVEN PHARMACEUTICALS** 49-KM MULTAN ROAD, PHOOL NAGAR, DISTRICT, KASUR PAKISTAN **(000881)**
	Application Form Dy. No / Tracking ID & date of submission	(XAU-BL1-X4S3, 2026-02-11)
	Detail of Fee Submitted	97200, 2026-01-16,
	The proposed proprietary name / brand name	**Lepride 12.5mg/ml Injection**
	Label Claim	Each ml contains: Levosulpiride 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 at room temperature below 30
	For generic drugs (me-too Status)	Levopraid 25mg/2ml injection of M/s Pacific Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Prokinetic agent
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	DISLEP 25 mg solution for injection/infusion of M/s Doppel Farmaceutici S.r.l. Via Volturno, 48-20089 Quinto dè Stampi Rozzano (MI) Italy (EU & Medicines Authority Approved)
	Detail of previous approval	LSP 12.5mg/ml Injection - 340th 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	
441	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**ANEEB PHARMACEUTICAL PVT LIMITED** 24 KM BEDIAN ROAD LAHORE **(000555)**
	Application Form Dy. No / Tracking ID & date of submission	(6YE-VNL-75P3, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-11-20,
	The proposed proprietary name / brand name	**Amotril Capsules 500mg**
	Label Claim	Each Capsule Contains: Amoxicillin as Trihydrate 500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100's-As per SRO

	Shelf Life (Unit)	24 Monthstore below 30 oC
	For generic drugs (me-too Status)	Amoxil 500mg, GSK Karachi, Reg. No. 006669
	Pharmacotherapeutic Group of (API)	Beta-Lactam Antibacterial, Penicillin
	Name, address of Manufacturing site:	Fynk Pharmaceuticals-19-km G.T.Road, kala Shah Kaku, Lahore, Pakistan-
	The status in reference regulatory authorities	Amoxil-500 mg, USFDA approved
	Detail of previous approval	FAXCIL Capsule 500 mg, Minutes of 323rd meeting of Registration Board (6th to 8th December, 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	
442	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**ANEEB PHARMACEUTICAL PVT LIMITED** 24 KM BEDIAN ROAD LAHORE **(000555)**
	Application Form Dy. No / Tracking ID & date of submission	(BL9-7WS-HZW8, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-11-20,
	The proposed proprietary name / brand name	**Amotril Capsules 250mg**
	Label Claim	Each Capsule Contains: Amoxicillin as Trihydrate 250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10-As per SRO,100-As per SRO,20-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30 oC
	For generic drugs (me-too Status)	Amoxil capsules 250mg by GSK Karachi
	Pharmacotherapeutic Group of (API)	Beta-Lactam Antibacterial, Penicillin.
	Name, address of Manufacturing site:	M/s Fynk Pharmaceuticals-19-km G.T.Road, kala Shah Kaku, Lahore, Pakistan-
	The status in reference regulatory authorities	USFDA approved
	Detail of previous approval	FAXCIL Cap 250 mg, 323rd meeting of Registration Board (6th to 8th December, 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	

443	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**ANEEB PHARMACEUTICAL PVT LIMITED** 24 KM BEDIAN ROAD LAHORE **(000555)**
	Application Form Dy. No / Tracking ID & date of submission	(Q4L-5PT-XU5G, 2026-02-11)
	Detail of Fee Submitted	97200, 2026-02-02,
	The proposed proprietary name / brand name	**MERONEX 1G INJ**
	Label Claim	Each Vial contains: Meropenem as trihydrate 1gm
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30 oC
	For generic drugs (me-too Status)	Meronem IV 1gm Injection, Pfizer Pakistan
	Pharmacotherapeutic Group of (API)	Carbapenem.
	Name, address of Manufacturing site:	M/s. Fynk Pharmaceuticals-19-km, G.T Road, kala Shah Kaku, Lahore, Pakistan-
	The status in reference regulatory authorities	USFDA approved
	Detail of previous approval	Morefen 1gm Dry Powder injection, Minutes of 333rd meeting of Registration Board (19th To 20th Decem
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**ANEEB PHARMACEUTICAL PVT LIMITED** 24 KM BEDIAN ROAD LAHORE **(000555)**
	Application Form Dy. No / Tracking ID & date of submission	(TS1-8A9-ABHN, 2026-02-11)
	Detail of Fee Submitted	97200, 2026-02-02,
	The proposed proprietary name / brand name	**AMOCLAVIN 1.2GM INJ**
	Label Claim	Each vial contains: Amoxicillin as Sodium ..... 1000mg. Potassium Clavulanate eq. Clavulanic Acid.....200mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30 oC
	For generic drugs (me-too Status)	Co Amoxi Injection 1.2 gm, Macter International Ltd., Reg. No. 070882.
	Pharmacotherapeutic Group of (API)	Penicillin Antibiotic + beta-lactamase inhibitor

	Name, address of Manufacturing site:	M/s. Fynk Pharmaceuticals-19-km, G.T Road, kala Shah Kaku, Lahore, Pakistan-
	The status in reference regulatory authorities	MHRA approved
	Detail of previous approval	Falamox 1.2gm for injection, Minutes for 339th meeting of Registration Board (6th August to 8th Augu
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**ANEEB PHARMACEUTICAL PVT LIMITED** 24 KM BEDIAN ROAD LAHORE **(000555)**
	Application Form Dy. No / Tracking ID & date of submission	(WZ3-1ZJ-GZDG, 2026-02-11)
	Detail of Fee Submitted	97200, 2026-02-02,
	The proposed proprietary name / brand name	**PIPRAV-TZ 4.5 GM INJ**
	Label Claim	Each vial contains: Pirperacillin (as Piperacillin sodium).....4g Tazobactam (as Tazobactam Sodium).....0.5g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30 oC
	For generic drugs (me-too Status)	Tanzo 4.5g Injection by M/s Bosch Pharmaceutical Pvt. Ltd. Karachi
	Pharmacotherapeutic Group of (API)	Antibiotics Penicillin: Broad-spectrum beta-lactam, Tazobactam: Beta-lactamase inhibitor
	Name, address of Manufacturing site:	M/s. Fynk Pharmaceuticals-19-km, G.T Road, kala Shah Kaku, Lahore, Pakistan-
	The status in reference regulatory authorities	USFDA approved
	Detail of previous approval	Tazomac Injection 4.5gram, Minutes of 330th meeting of Registration Board (24th to 26th July, 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	

446	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**ANEEB PHARMACEUTICAL PVT LIMITED** 24 KM BEDIAN ROAD LAHORE **(000555)**
	Application Form Dy. No / Tracking ID & date of submission	(48Q-ULS-DX1B, 2026-03-31)
	Detail of Fee Submitted	97200, 2026-03-03,
	The proposed proprietary name / brand name	**AMPNEX 125mg/5ml Dry Susp**
	Label Claim	Each 5ml contains: Ampicillin as trihydrate 125mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	60ml-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30 oC
	For generic drugs (me-too Status)	Ampcin 15 mg Dry Suspension, CSH Pharmaceuticals, Reg. No. 071538.
	Pharmacotherapeutic Group of (API)	Beta-Lactam Antibacterial, Penicillin.
	Name, address of Manufacturing site:	M/s. Fynk Pharmaceuticals-19-km, G.T Road, kala Shah Kaku, Lahore, Pakistan-
	The status in reference regulatory authorities	MHRA approved
	Detail of previous approval	Ampiwell Dry Powder Suspension 125mg/5ml, Minutes of 336th meeting of Registration Board (4th to 6th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**ANEEB PHARMACEUTICAL PVT LIMITED** 24 KM BEDIAN ROAD LAHORE **(000555)**
	Application Form Dy. No / Tracking ID & date of submission	(DSB-VRX-X9DA, 2026-03-31)
	Detail of Fee Submitted	97200, 2026-03-03,
	The proposed proprietary name / brand name	**AMPNEX 250mg/5ml Dry Susp.**
	Label Claim	Each 5ml contains: Ampicillin Trihydrate eq. Ampicillin.....250mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	60ml-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30 oC
	For generic drugs (me-too Status)	Ampicillin Suspension 250mg by M/s Amros Pharma
	Pharmacotherapeutic Group of (API)	Beta-Lactam Antibacterial, Penicillin.

	Name, address of Manufacturing site:	M/s. Fynk Pharmaceuticals-19-km, G.T Road, kala Shah Kaku, Lahore, Pakistan-
	The status in reference regulatory authorities	USFDA approved
	Detail of previous approval	Ampiwell Dry suspension 250mg/5ml, 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	
448	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**SWERA PHARMACEUTICALS** PLOT# 27, STREET# S-4, INDUSTRIAL ESTATE, RAWAT **(000941)**
	Application Form Dy. No / Tracking ID & date of submission	(6ZT-N7T-WN2P, 2026-02-18)
	Detail of Fee Submitted	97200, 2026-02-13,
	The proposed proprietary name / brand name	**CEFERA INJECTION 1g**
	Label Claim	Each vial contains: Ceftriaxone as Ceftriaxone Sodium.....1g (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO / DPC -As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Cefnig Injection 1g
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Name, address of Manufacturing site:	M/s Bloom Pharmaceuticals Pvt Ltd.-Plot# 30, Phase I&II, Industrial Estate Hattar-
	The status in reference regulatory authorities	US FDA Approved
	Detail of previous approval	M-307
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**SWERA PHARMACEUTICALS** PLOT# 27, STREET# S-4, INDUSTRIAL ESTATE, RAWAT **(000941)**

	Application Form Dy. No / Tracking ID & date of submission	(M9V-4Y5-T44Q, 2026-03-05)
	Detail of Fee Submitted	97200, 2026-01-26,
	The proposed proprietary name / brand name	**PREFIZER 75mg CAPSULE**
	Label Claim	Each Capsule Contains; Pregabalin 75mg (BP Spec's)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO / DPC -As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Gabica 75mg capsules Getz Pharma (pvt) Limited
	Pharmacotherapeutic Group of (API)	Gamma amino butyric acid (GABA)
	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	Lyrica® 75 mg hard capsules Pfizer Service Company BV, Hoge Wei 10, 1930 Zaventem, Belgium
	Detail of previous approval	M-352
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**SWERA PHARMACEUTICALS** PLOT# 27, STREET# S-4, INDUSTRIAL ESTATE, RAWAT **(000941)**
	Application Form Dy. No / Tracking ID & date of submission	(NBG-PJV-4BL2, 2026-02-18)
	Detail of Fee Submitted	97200, 2026-02-09,
	The proposed proprietary name / brand name	**SOFOMYCIN 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 / DPC -As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Focin Ultra sachet Tabros Pharma (Pvt.) Ltd
	Pharmacotherapeutic Group of (API)	Pharmacotherapeutic Group: antibiotics. WHO ATC Code: J01XX01
	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	Monurol 3g Sachet Zambon Switzerland Ltd.,
	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	
451	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**SWERA PHARMACEUTICALS** PLOT# 27, STREET# S-4, INDUSTRIAL ESTATE, RAWAT **(000941)**
	Application Form Dy. No / Tracking ID & date of submission	(SGR-8ZV-D57W, 2026-02-18)
	Detail of Fee Submitted	97200, 2026-02-13,
	The proposed proprietary name / brand name	**FIXIME 400mg CAPSULE**
	Label Claim	Each capsule contains: Cefixime as trihydrate .....400mg (Manufacturer's Specifications)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	As per SRO / DPC -As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Biozil 400mg Capsule Bio-Labs (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Name, address of Manufacturing site:	M/s Bloom Pharmaceuticals Pvt Ltd.-Plot#30, Phase I&II, Industrial Estate, Hattar-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	M-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	
452	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**SWERA PHARMACEUTICALS** PLOT# 27, STREET# S-4, INDUSTRIAL ESTATE, RAWAT **(000941)**
	Application Form Dy. No / Tracking ID & date of submission	(W1S-41R-HB4Y, 2026-02-18)
	Detail of Fee Submitted	97200, 2026-02-09,
	The proposed proprietary name / brand name	**SEWFIL TABLETS**

	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	As per SRO / DPC -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)	Pharmacotherapeutic Group: Selective inhibitor of cyclic GMP-specific phosphodiesterase (Type V) with vasodilator action; Urologicals; Drugs used in erectile dysfunction. WHO ATC Code: G04B E03
	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	US FDA 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	
453	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**SWERA PHARMACEUTICALS** PLOT# 27, STREET# S-4, INDUSTRIAL ESTATE, RAWAT **(000941)**
	Application Form Dy. No / Tracking ID & date of submission	(X8G-694-E7AQ, 2026-03-05)
	Detail of Fee Submitted	97200, 2026-01-26,
	The proposed proprietary name / brand name	**PREFIZER 50mg CAPSULE**
	Label Claim	Each Capsule Contains; Pregabalin 50mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO / DPC -As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Gabica 50mg capsules Getz Pharma (pvt) Limited
	Pharmacotherapeutic Group of (API)	Gamma amino butyric acid(GABA)
	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	Lyrica® 50 mg hard capsules Pfizer Service Company BV, Hoge Wei 10, 1930 Zaventem, Belgium
	Detail of previous approval	M-352

	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**SWERA PHARMACEUTICALS** PLOT# 27, STREET# S-4, INDUSTRIAL ESTATE, RAWAT **(000941)**
	Application Form Dy. No / Tracking ID & date of submission	(H93-BB8-T3NH, 2026-03-10)
	Detail of Fee Submitted	97200, 2026-02-16,
	The proposed proprietary name / brand name	**DYON TABLETS**
	Label Claim	EACH FILM COATED TABLET CONTAINS: DYDROGESTERONE.....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO / DPC -As per SRO
	Shelf Life (Unit)	3 YearBelow 30°C
	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 #01,Al Badar Industrial Estate, Phase II Sheikhupura Road Lahore.-
	The status in reference regulatory authorities	HPRA of Ireland.
	Detail of previous approval	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	
455	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**SWERA PHARMACEUTICALS** PLOT# 27, STREET# S-4, INDUSTRIAL ESTATE, RAWAT **(000941)**
	Application Form Dy. No / Tracking ID & date of submission	(LBT-12Q-E1MS, 2026-03-10)

	Detail of Fee Submitted	97200, 2026-02-18,
	The proposed proprietary name / brand name	**EMIPIME INJECTION**
	Label Claim	Each vial contains: Cefepime hydrochloride eq to Cefepime.....1gm With L-Arginine
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO / DPC -As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Cefstar Injection 1g Reg No. 076007
	Pharmacotherapeutic Group of (API)	Fourth-generation cephalosporin antibiotic
	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-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	
456	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	(76Y-D4U-5RQV, 2026-02-03)
	Detail of Fee Submitted	93000, 2025-07-04,
	The proposed proprietary name / brand name	**Vigorex 25 mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: Sildenafil as Citrate (USP).....25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4's; 1x10's; 1x14's 2x10's; 2x14's, 3x10's-De-Controlled
	Shelf Life (Unit)	24 MonthBelow 30C
	For generic drugs (me-too Status)	Seagra 25mg Tablet by Weather Folds Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 inhibitor (PDE5-I)
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot # 69/2. Phase-II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	MHRA, UK (Viagra 25mg film-coated tablets)
	Detail of previous approval	Seagra Tablet 25mg.Registration Board Meeting No. 351
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to	

	submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**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	(3PP-ZMV-8X1R, 2025-12-31)
	Detail of Fee Submitted	97200, 2025-12-11,
	The proposed proprietary name / brand name	**Metflozin Tablet 12.5mg/500mg**
	Label Claim	Each Film Coated Tablet Contains; Empagliflozin.....12.5mg Metformin HCl.....500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2*7's blister, As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore between 15 to 30C
	For generic drugs (me-too Status)	Diampa-M Tablets by Getz Pharma
	Pharmacotherapeutic Group of (API)	Empagliflozin is Sodium-glucose cotransporter-2 (SGLT2) inhibitors, Metformin HCl is Biguanides
	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	Empagliflozin Metformin Hydrochloride by MSN LABS PVT LTD (USFDA Approved)
	Detail of previous approval	Emform-M 12.5/500 Tablet by Seraph pharma
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The cross-referred product was approved in PRV dated 05-December 2025 vide application TID: PGB-UUG-GSES.	
	Decision	
	Approved	
458	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	(4NL-MSU-B8WM, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-11-20,

	The proposed proprietary name / brand name	**Nalphine 20mg/ml Injection**
	Label Claim	Each ml contains; Nalbuphine hydrochloride .....20mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2*5 Ampoules, 2 Ampoules, As per SRO-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.
	For generic drugs (me-too Status)	Bunail 20mg/ml injection by Bosch pharmaceuticals (pvt) ltd
	Pharmacotherapeutic Group of (API)	opioid agonist-antagonist analgesic
	Name, address of Manufacturing site:	SERAPH PHARMACEUTICAL-Plot # 210, Industrial Triangle, Kahuta Road, Islamabad, Pakistan-
	The status in reference regulatory authorities	NUBAIN Injection…..20mg/ml by Par Pharmacutical USA, Approved in FDA
	Detail of previous approval	Sernaib 20mg/ml Injection , meeting no. 351, approved in 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. The cross-referred product was approved in PRV dated 16-May-2024 vide letter F.119-PRVC/2024(PR-II).	
	Decision	
	Approved	
459	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	(77N-YR6-5WTY, 2026-02-26)
	Detail of Fee Submitted	97200, 2026-02-18,
	The proposed proprietary name / brand name	**Cithrox 250mg Suspension**
	Label Claim	Each reconstituted 5ml contains: Ciprofloxacin.....250mg (Usp Spec's)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	60ml-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Novidat250mg/5ml Dry Suspension (by SAMI Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	Anti-infectives Floroquinolone Antibiotic
	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	CIPRO 250mg/5mlDry Suspension (Bayer Healthcare Ltd USFDA Approved)
	Detail of previous approval	Ciprocin 250mg/5ml Dry Suspension, 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	
460	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	(7R5-8PU-PPVA, 2025-12-31)
	Detail of Fee Submitted	97200, 2025-12-11,
	The proposed proprietary name / brand name	**Metflozin Tablet 12.5mg/850mg**
	Label Claim	Each Film-Coated Tablet Contains; Empagliflozin ..... 12.5mg Metformin HCl 850mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2*7's Alu Alu blister, As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore between 15 to 30C
	For generic drugs (me-too Status)	Diampa-M Tablets by Getz Pharma
	Pharmacotherapeutic Group of (API)	Empagliflozin is Sodium-glucose cotransporter-2 (SGLT2) inhibitors,
	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	Synjardy 12.5/850mg, EM approved
	Detail of previous approval	Emform-M 12.5/850 Tablet (Solaris Life Sciences)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The cross-referred product was approved in PRV dated : 03-June, 2025 vide application TID: BM7-LNL-SBRH.	
	Decision	
	Approved	
461	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	(B2R-EH8-6MDY, 2026-02-09)
	Detail of Fee Submitted	97200, 2026-01-23,
	The proposed proprietary name / brand name	**Geosil 10mg Cream**
	Label Claim	Each gm Contains; Terbinafine Hydrochloride ..... 10mg (JP Spec's)
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	10 gram, 15 gram, 20 gram-As per SRO
	Shelf Life (Unit)	3 YearStore below 25 Centigrade. Do not refrigerate
	For generic drugs (me-too Status)	LamisilCream1% (GlaxoSmithKlinePakistanPvt. Ltd)
	Pharmacotherapeutic Group of (API)	Antifungal
	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	Lamisil 1% w/w Cream (Haleon Ireland Limited)
	Detail of previous approval	Xfin 1% Cream, DRB 352
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**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	(BH1-MGX-XWGN, 2026-02-04)
	Detail of Fee Submitted	97200, 2026-01-23,
	The proposed proprietary name / brand name	**Motig 2mg Tablet**
	Label Claim	Each film coated tablet contains: Prucalopride Succinate eq. to Prucalopride.....2mg (Innovator Spec's)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1*10's, 2*10's-As per SRO
	Shelf Life (Unit)	3 YearStore below 30 Centigrade
	For generic drugs (me-too Status)	Prulevity 2mg Tablet (Ferozsons Laboratries Ltd)
	Pharmacotherapeutic Group of (API)	Dihydro-benzofuran-carboxamide
	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	Prucalopride Succinate 2mg tablets (USFDA Approved)
	Detail of previous approval	Kaloprid 2mg Tablet
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The cross-referred product was approved in PRV dated 03-June, 2025 vide application TID: SVW-2L1-MBUP.	
	Decision	
	Approved	
463	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	(D4A-WXX-6Y6A, 2026-02-26)
	Detail of Fee Submitted	97200, 2026-02-18,
	The proposed proprietary name / brand name	**Klaronil 125mg Suspension**
	Label Claim	Each 5ml Contains; Clarithromycin..... 125mg (USP Spec's)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	60ml-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Klaricid 125mg/5ml Dry Suspension (Abbott Laboratories pakistan, Ltd)
	Pharmacotherapeutic Group of (API)	Macrolide 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	Clarithromycin suspension (SANDOZ USFDA Approved)
	Detail of previous approval	Clarisol Oral Dry Suspension 125mg/5ml, 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	

464	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	(DM8-2WS-8VAM, 2026-02-09)
	Detail of Fee Submitted	97200, 2026-02-02,
	The proposed proprietary name / brand name	**Urostate 8mg Capsule**
	Label Claim	Each Capsule Contains; Silodosin .....8mg (InnovatorSpec's)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1*10's, 2*10's-As per SRO
	Shelf Life (Unit)	3 YearStore below 30 Centigrade
	For generic drugs (me-too Status)	Silorap8mg capsules (GetzPharma (pvt) Limited)
	Pharmacotherapeutic Group of (API)	alpha-adrenoreceptor antagonists
	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	Rapaflo (Allergan, USFDA Approved)
	Detail of previous approval	Silodin 8mg Capsules, 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	
465	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	(EBV-A71-YVT4, 2026-03-02)
	Detail of Fee Submitted	97200, 2026-02-18,
	The proposed proprietary name / brand name	**Clotim Cream 2% w/w**
	Label Claim	Each gram cream contains; Clotrimazole ..... 20mg (USP Spec's)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	35gram (with applicator)-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 25 C.
	For generic drugs (me-too Status)	Gynosporin cream2% (Nabiqasim Industries(Pvt.)Ltd)
	Pharmacotherapeutic Group of (API)	Imidazole category of azole antifungals WHO
	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	Canesten Vaginal Cream 2% (Bayer PLC UK Ltd) MHRA Approved
	Detail of previous approval	Clovagizol Vaginal Cream (2%w/w), 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	
466	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	(G2J-D99-RH5A, 2026-03-02)
	Detail of Fee Submitted	97200, 2026-02-18,
	The proposed proprietary name / brand name	**Klaronil 250mg Suspension**
	Label Claim	Each 5ml Contains; Clarithromycin..... 250mg (USP Spec's)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	60ml-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Klaricid 250mg/5ml Dry Suspension (Abbott Laboratories pakistan, Ltd)
	Pharmacotherapeutic Group of (API)	Macrolide 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	Clarithromycin suspension (SANDOZ USFDA Approved)
	Detail of previous approval	Clarisol Oral Dry Suspension 250mg/5ml, 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	
467	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	(GTB-2Y6-P2BB, 2026-02-17)
	Detail of Fee Submitted	97200, 2026-02-12,
	The proposed proprietary name / brand name	**Cholest 4g Sachet**
	Label Claim	Each sachet contains Anhydrous Cholestyramine.....4gm (USP Spec's)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's, 20's, 30's, 50's Plastic Aluminium Foil-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Questran 4gm sachet
	Pharmacotherapeutic Group of (API)	Bile acid sequetrants
	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	Cholestyramine light (TEVA Pharmaceuticals USFDA Approved)
	Detail of previous approval	Lyster- 4g Sachet, DRB 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	
468	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	(J6D-3HZ-N398, 2025-12-31)
	Detail of Fee Submitted	97200, 2025-12-11,
	The proposed proprietary name / brand name	**Metflozin Tablet 12.5mg/1000mg**
	Label Claim	Each extended-release tablet contains: 12.5 mg of empagliflozin and 1000 mg of metformin hydrochloride
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2*7's Alu Alu blister, As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore between 15 to 30C
	For generic drugs (me-too Status)	Erli plus XR Tablets by Pharm Evo (Pvt.)Ltd Pakistan
	Pharmacotherapeutic Group of (API)	Empagliflozin is Sodium-glucose cotransporter-2 (SGLT2) inhibitors,

	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	Empagliflozin Metformin Hydrochloride by MSN LABS PVT LTD (USFDA Approved)
	Detail of previous approval	Emform-M 12.5/1000 Tablet (Solaris Life Sciences)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The cross-referred product was approved in PRV dated 05-December 2025 vide application TID: W2P-7PQ-MDJM.	
	Decision	
	Approved	
469	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	(JHE-PJM-XS8N, 2025-10-22)
	Detail of Fee Submitted	97200, 2025-09-24,
	The proposed proprietary name / brand name	**K-Zan 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 30C
	For generic drugs (me-too Status)	Vonozan Tablets 20 mg by Getz pharma
	Pharmacotherapeutic Group of (API)	potassium-competitive acid blockers (PCAB).
	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	Voquezna 20mg Tablet (USFDA Approved)
	Detail of previous approval	Vonop 20mg Tablet
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The cross-referred product was approved in PRV dated 03-June, 2025 vide application TID: T8X-VYQ-YRB2.	
	Decision	
	Approved	

470	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	(JV5-789-NRXQ, 2026-02-04)
	Detail of Fee Submitted	97200, 2026-01-23,
	The proposed proprietary name / brand name	**Muspam 10mg tablet**
	Label Claim	Each Film Coated Tablet Contains; Cyclobenzaprine HCl.....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1*10's, 2*10's-As per SRO
	Shelf Life (Unit)	3 YearStore in a dry place, protected from light, at a temperature below 30ºC
	For generic drugs (me-too Status)	Comforta Tablets (Genome Pharmaceuticals pvt. Limited)
	Pharmacotherapeutic Group of (API)	cyclical antidepressants
	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	Cyclobenzaprine Hydrochloride (Actavis Labs FL INC, USFDA Approved)
	Detail of previous approval	Zaparine 10mg Tablets
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The cross-referred product was approved in PRV dated 03-June 2025 vide application TID: 67A-AR2-NV4H.	
	Decision	
	Approved	
471	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	(LTJ-AM4-BT48, 2026-02-17)
	Detail of Fee Submitted	97200, 2026-02-12,
	The proposed proprietary name / brand name	**Finer 10mg Tablet**
	Label Claim	Each Film Coated Tablet Contains; Finerenone ..... 10mg (Innovator Spec's)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1*10's, 2*10's, 3*10's-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	NA

	Pharmacotherapeutic Group of (API)	Diuretics, Aldosterone Antagonists
	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	Kerendia 10mg Tablet (BAYER HLTHCARE USFDA Approved)
	Detail of previous approval	Finen 10mg Tablets, DRB 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	
472	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	(MS7-YZJ-MQZY, 2026-02-04)
	Detail of Fee Submitted	75000.0, 18000.0 2024-08-02, 2025-06-20
	The proposed proprietary name / brand name	**Cartin 1G injection**
	Label Claim	Each ampoule contains: Levocarnitine ..... 1g (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	as per SRO/DPC-As per SRO
	Shelf Life (Unit)	-2 Year15-25°C
	For generic drugs (me-too Status)	Carnitor injection
	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	FDA Approved Drug.
	Detail of previous approval	L-Carnit,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	
473	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	(PNL-S3S-ZYR6, 2026-02-16)
	Detail of Fee Submitted	97200, 2026-02-02,
	The proposed proprietary name / brand name	**Lowtens 25mg tablet**
	Label Claim	Each Film Coated Tablet Contains; Losartan Potassium.....25mg (USP Spec's)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2*10's-As per SRO
	Shelf Life (Unit)	3 YearStore below 25C
	For generic drugs (me-too Status)	Eziday Tablets 25mg (Werrick Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	Angiotensin II receptor blockers (ARBs)
	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	COZAAR 25mg Tablet (Merck & Co., Inc)
	Detail of previous approval	Losart 25mg Tablets, DRB 352
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**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	(PVB-376-REAJ, 2026-02-09)
	Detail of Fee Submitted	97200, 2026-01-23,
	The proposed proprietary name / brand name	**Trideram Cream**
	Label Claim	Each gram cream contains: Fluocinolone Acetonide.....0.1mg Hydroquinone..... 40mg Tretinoin.....0.5mg (Innovator Spec's)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	20 gram, 30 gram-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Siton Plus Cream (Shaigan Pharmaceuticals Pvt. Ltd)
	Pharmacotherapeutic Group of (API)	Corticosteroid, Depigmenting Agents, Retinoid
	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	Triluma Cream (Galderma Laboratories LP)
	Detail of previous approval	Tritilon 0.01%+4% ,0.05% Cream, DRB 352
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**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	(PW8-WYY-MRL8, 2026-02-11)
	Detail of Fee Submitted	97200, 2026-02-06,
	The proposed proprietary name / brand name	**Gepep 40mg/5ml Suspension**
	Label Claim	Each 5ml Contains; Famotidine.....40mg (USP Spec's)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50ml, 60ml, 120ml-As per SRO
	Shelf Life (Unit)	2 YearStore dry powder and reconstituted suspension at 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F)
	For generic drugs (me-too Status)	Polypep 40mg/5ml Dry Suspension (Wilson's PharmaceuticalsPvt., Ltd.)
	Pharmacotherapeutic Group of (API)	Histamine H2 receptor antagonist
	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	Pepcid for oral suspension (Salix Pharma USA)
	Detail of previous approval	Famodin 40mg/5ml Dry Suspension, 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	
476	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	(X78-BUX-U3ZU, 2026-02-16)
	Detail of Fee Submitted	97200, 2026-02-02,
	The proposed proprietary name / brand name	**Lowtens 50mg tablet**
	Label Claim	Each Film Coated Tablet Contains; Losartan Potassium.....50mg (USP Spec's)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2*10's-As per SRO
	Shelf Life (Unit)	3 YearStore below 25 Centigrade
	For generic drugs (me-too Status)	Eziday Tablets 50mg (Werrick Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	Angiotensin II receptor blockers (ARBs)
	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	COZAAR 50mg Tablet (Merck & Co., Inc)
	Detail of previous approval	Losart 50mg Tablets, DRB 352
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**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	(XNZ-VND-JJDY, 2026-02-17)
	Detail of Fee Submitted	97200, 2026-02-12,
	The proposed proprietary name / brand name	**Finer 20mg Tablet**
	Label Claim	Each Film Coated Tablet Contains; Finerenone ..... 20mg (Innovator Spec's)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1*10's, 2*10's, 3*10's-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Diuretics, Aldosterone Antagonists
	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	Kerendia 20mg Tablet (BAYER HLTHCARE USFDA Approved)

	Detail of previous approval	Finen 20mg Tablets, DRB 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	
478	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	(YZE-M7P-D576, 2026-02-09)
	Detail of Fee Submitted	97200, 2026-02-02,
	The proposed proprietary name / brand name	**Urostate 4mg Capsule**
	Label Claim	Each Capsule Contains; Silodosin .....4mg (InnovatorSpec's)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1*10's, 2*10's-As per SRO
	Shelf Life (Unit)	3 YearStore below 30 Centigrade
	For generic drugs (me-too Status)	Silorap4mg capsules (GetzPharma (pvt) Limited)
	Pharmacotherapeutic Group of (API)	alpha-adrenoreceptor antagonists
	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	Rapaflo (Allergan, USFDA Approved)
	Detail of previous approval	Silodin 4mg Capsules, 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	
479	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	(Z6L-YM4-SHQM, 2025-12-04)

	Detail of Fee Submitted	97200, 2025-11-20,
	The proposed proprietary name / brand name	**Nalphine 10mg/ml Injection**
	Label Claim	Each ml contains; Nalbuphine hydrochloride .....10mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2*5 Ampoules, 2 Ampoules, As per SRO-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.
	For generic drugs (me-too Status)	Bunail 10mg/ml injection by Bosch pharmaceuticals (pvt) ltd
	Pharmacotherapeutic Group of (API)	opioid agonist-antagonist analgesic
	Name, address of Manufacturing site:	SERAPH PHARMACEUTICAL-Plot # 210, Industrial Triangle, Kahuta Road, Islamabad, Pakistan-
	The status in reference regulatory authorities	NUBAIN Injection…..10mg/ml by Par Pharmacutical USA, Approved in FDA
	Detail of previous approval	Sernaib 10mg/ml Injection , meeting no. 351, approved in 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. The cross-referred product was approved in PRV.	
	Decision	
	Approved	
480	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Rotex Pharma Pvt Ltd** Plot No 206 207 Industrial Triangle Kahuta Road **(000651)**
	Application Form Dy. No / Tracking ID & date of submission	(79V-HMV-HPH6, 2026-03-04)
	Detail of Fee Submitted	97200, 2026-01-14,
	The proposed proprietary name / brand name	**Vonza**
	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	10's-As per SRO
	Shelf Life (Unit)	24 MonthBelow 30C
	For generic drugs (me-too Status)	Vonozan Tablets 20 mg, Getz Pharmaceutical (Pvt)Limited
	Pharmacotherapeutic Group of (API)	Potassium Competitive Acid Blocker
	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	USFDA Approved, Voquezna 20mg Tablet, Phathom
	Detail of previous approval	Tracking ID: 64U-JMV-63MP
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The cross-referred product was approved in PRV dated 03-June, 2025 vide application TID: T8X-VYQ-YRB2.	
	Decision	
	Approved	
481	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Rotex Pharma Pvt Ltd** Plot No 206 207 Industrial Triangle Kahuta Road **(000651)**
	Application Form Dy. No / Tracking ID & date of submission	(UVW-XGV-AV5R, 2026-02-12)
	Detail of Fee Submitted	97200, 2025-11-04,
	The proposed proprietary name / brand name	**Flowmax-D**
	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)	24 MonthBelow 30C
	For generic drugs (me-too Status)	Maxflow-D Capsule, CCL Pharmaceuticals (Pvt.) Ltd. Registration No.091571
	Pharmacotherapeutic Group of (API)	Alpha-adrenoreceptor antagonists
	Name, address of Manufacturing site:	M/S Biogen Life Sciences -8-Kilometer 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	Dutaride-T Capsule, Minutes of meeting 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	
482	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

	Name, address of Applicant.	**Rotex Pharma Pvt Ltd** Plot No 206 207 Industrial Triangle Kahuta Road **(000651)**
	Application Form Dy. No / Tracking ID & date of submission	(5DJ-7S9-V8GS, 2026-03-09)
	Detail of Fee Submitted	97200, 2025-11-28,
	The proposed proprietary name / brand name	**VIANEX**
	Label Claim	Each film coated tablet contains: Sildenafil (as Citrate) 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's, 10's-As per SRO
	Shelf Life (Unit)	2 YearBelow 30C
	For generic drugs (me-too Status)	Getfil Tablet 100mg,Registration No: 130599,Getz Pharma (Pvt) Limited
	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 No. 08, street No. S-1, RCCI Industrial estate Rawat, Rawalpindi- Pakistan-
	The status in reference regulatory authorities	Viagra 100mg Tablet, US FDA Approved, VIATRIS Pharmaceuticals.(NDA): 020895,
	Detail of previous approval	Ripple 100mg Tablet, Minutes of meeting 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	
483	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	(7NA-3Z6-N7MR, 2026-02-17)
	Detail of Fee Submitted	97200, 2026-01-27,
	The proposed proprietary name / brand name	**Carzee Capsule 3mg**
	Label Claim	Each Capsule contains: Cariprazine as Hydrochloride eq. to cariprazine..... 3mg (As per 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 30°C. Protect from Heat & Light.
	For generic drugs (me-too Status)	Hamaz pharmaceuticals (pvt)Ltd.

	Pharmacotherapeutic Group of (API)	ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD. Address: CHUANNAN, DUQIAO, LINHAI ZHEJIANG 317016, CHINA.
	Name, address of Manufacturing site:	Hamaz Pharmaceuticals (Pvt)Ltd.-13-KM Bosan Road Lutafabad Multan-
	The status in reference regulatory authorities	complies
	Detail of previous approval	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	
484	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	(7PB-9N8-U2HP, 2026-02-12)
	Detail of Fee Submitted	97200, 2026-01-27,
	The proposed proprietary name / brand name	**Restab 80mg Tablet**
	Label Claim	Each Film-coated tablet contains: Resmetirom.....80mg (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 YearStore at 20 °C to 25°C (68 °F to 77°F); excursions permitted to 15 °C to 30°C (59° F to 86°F)
	For generic drugs (me-too Status)	Hamaz pharmaceuticals (pvt)Ltd.
	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 Bosan Road Lutafabad Multan-
	The status in reference regulatory authorities	complies
	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	
485	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	(839-VA5-57T1, 2026-02-03)
	Detail of Fee Submitted	97200, 2026-01-07,
	The proposed proprietary name / brand name	**Avagra 100mg**
	Label Claim	Each tablet contains: Avanafil...100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	AS PER SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature
	For generic drugs (me-too Status)	MEDIZAN LABORATORIES (PVT.) LTD.
	Pharmacotherapeutic Group of (API)	CENTURY PHARMACEUTICAL LTD Corporate Office Address: 406, World Trade Centre, Sayajigunj,Vadodara – 390005, Gujarat, India. Phone No.: (0265) 2361581 / 2361978 / 2362509 Mobile No.: +91 – 7574851067
	Name, address of Manufacturing site:	MEDIZAN LABORATORIES (PVT.) LTD.-Plot No.313, Industrial Triangle, Kahuta Road Islamabad-Pakistan-
	The status in reference regulatory authorities	complies
	Detail of previous approval	351
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**Horizon HealthCare (Pvt) Ltd** plot no 33 sunder industrial estate lahore **(000782)**
	Application Form Dy. No / Tracking ID & date of submission	(92J-NZY-3SWE, 2026-03-09)
	Detail of Fee Submitted	93000.0, 2025-01-15,
	The proposed proprietary name / brand name	**silda 50mg**
	Label Claim	each tablet contains;sildenafil..50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	AS PER SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)normal
	For generic drugs (me-too Status)	M/S MEDIZAN LABORATORIES PVT.LTD
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	M/S MEDIZAN LABORATORIES OVT.LTD-PLOT 313 INDUSTRIAL TRIANGLE KAHUTA ROAD ISLAMABAD-
	The status in reference regulatory authorities	https://www.accessdata.fda.gov/drugsatfda_docs/l
	Detail of previous approval	silda 50mg (sildenafil) 293 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. The cross-referred product was approved in PRV dated 30-January, 2026 vide application TID: DV9-RME-6JB8.	
	Decision	
	Approved	
487	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	(AV3-MQA-T24Q, 2026-02-09)
	Detail of Fee Submitted	97200, 2026-01-27,
	The proposed proprietary name / brand name	**Retinib 50mg capsule**
	Label Claim	Each capsule contains 50 mg Ritlecitinib (equivalent to 80.13 mg Ritlecitinib tosylate) (As per Innovators specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	AS PER SRO-As per SRO
	Shelf Life (Unit)	2 Yearat 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C to 30°C (59°F to 86°F)
	For generic drugs (me-too Status)	Hamaz pharmaceuticals (pvt)Ltd.
	Pharmacotherapeutic Group of (API)	Gansu Hoatin Pharmatech Co., Ltd. Address: No. 11, Chongqing Road, small &
	Name, address of Manufacturing site:	Hamaz Pharmaceuticals (Pvt)Ltd.-13-KM Bosan Road Lutafabad Multan-
	The status in reference regulatory authorities	complies
	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.	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila **(000856)**
	Application Form Dy. No / Tracking ID & date of submission	(B66-X9B-W6G4, 2026-02-17)
	Detail of Fee Submitted	97200, 2026-02-17,
	The proposed proprietary name / brand name	**Carzee capsule 6mg**
	Label Claim	Each capsule contains: Cariprazine HCl eq. to Cariprazine ... 6mg (As per Innovators 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 30°C. Protect from Heat & Light.
	For generic drugs (me-too Status)	Hamaz pharmaceuticals (pvt)Ltd.
	Pharmacotherapeutic Group of (API)	ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD. Address: CHUANNAN, DUQIAO, LINHAI ZHEJIANG 317016, CHINA.
	Name, address of Manufacturing site:	Hamaz Pharmaceuticals (Pvt)Ltd.-13-KM Bosan Road Lutafabad Multan-
	The status in reference regulatory authorities	complies
	Detail of previous approval	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	
489	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	(MB5-GYG-RM8E, 2026-02-09)
	Detail of Fee Submitted	97200, 2026-01-27,
	The proposed proprietary name / brand name	**Gefazee 45mg Tablet**
	Label Claim	Each film coated tablet contains: Gefapixant citrate equivalent to Gefapixant .....45 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 YearStore Below 30°C. Protect from Heat & Light.
	For generic drugs (me-too Status)	Hamaz pharmaceuticals (pvt)Ltd.
	Pharmacotherapeutic Group of (API)	Gansu Hoatin Pharmatech Co., Ltd. Address: No. 11, Chongqing Road, small & medium sized enterprise business base baiyin gansu P.R, China.

	Name, address of Manufacturing site:	Hamaz Pharmaceuticals (Pvt)Ltd.-13-KM Bosan Road Lutafabad Multan-
	The status in reference regulatory authorities	complies
	Detail of previous approval	345M, GEFAXA
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**Horizon HealthCare (Pvt) Ltd** plot no 33 sunder industrial estate lahore **(000782)**
	Application Form Dy. No / Tracking ID & date of submission	(N51-RBA-8J3Q, 2026-03-09)
	Detail of Fee Submitted	93000.0, 2025-01-15,
	The proposed proprietary name / brand name	**silda 100mg**
	Label Claim	each tablet contains: 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)normal
	For generic drugs (me-too Status)	M/S MEDIZAN LABORATORIES PVT.LTD
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/S MEDIZAN LABORATORIES OVT.LTD-PLOT 313 INDUSTRIAL TRIANGLE KAHUTA ROAD ISLAMABAD-
	The status in reference regulatory authorities	https://www.accessdata.fda.gov/drugsatfda_docs/la
	Detail of previous approval	silda 100mg (sildenafil) 293 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. The cross-referred product was approved in PRV dated 30-January, 2026 vide application TID: 882-QQY-J4Y2.	
	Decision	
	Approved	
491	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	(QDZ-VD2-8AYH, 2026-02-04)

	Detail of Fee Submitted	97200, 2026-01-07,
	The proposed proprietary name / brand name	**Avagra 50mg**
	Label Claim	Each tablet contains: Avanafil ...50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	AS PER SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature
	For generic drugs (me-too Status)	MEDIZAN LABORATORIES (PVT.) LTD.
	Pharmacotherapeutic Group of (API)	CENTURY PHARMACEUTICAL LTD Corporate Office Address: 406, World Trade Centre, Sayajigunj,Vadodara – 390005, Gujarat, India. Phone No.: (0265) 2361581 / 2361978 / 2362509 Mobile No.: +91 – 7574851067
	Name, address of Manufacturing site:	MEDIZAN LABORATORIES (PVT.) LTD.-Plot No.313, Industrial Triangle, Kahuta Road Islamabad-Pakistan-
	The status in reference regulatory authorities	complies
	Detail of previous approval	351
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila **(000856)**
	Application Form Dy. No / Tracking ID & date of submission	(RSW-U1E-M7QJ, 2026-02-18)
	Detail of Fee Submitted	97200, 2026-01-27,
	The proposed proprietary name / brand name	**Atinib 200mg Tablet**
	Label Claim	Each film coated tablet contains: Abrocitinib.....200 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 YearSTORE at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C to 30°C (59°F to 86°F)
	For generic drugs (me-too Status)	Hamaz pharmaceuticals (pvt)Ltd.
	Pharmacotherapeutic Group of (API)	Gansu Hoatin Pharmatech Co., Ltd. Address: No. 11, Chongqing Road, small & medium sized enterprise business base baiyin gansu P.R, China.
	Name, address of Manufacturing site:	Hamaz Pharmaceuticals (Pvt)Ltd.-13-KM Bosan Road Lutafabad Multan-
	The status in reference regulatory authorities	complies

	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	
493	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	(VRA-ZX6-T84H, 2026-03-04)
	Detail of Fee Submitted	97200, 2026-01-27,
	The proposed proprietary name / brand name	**Fezotant Tablet**
	Label Claim	Each Film-coated tablet contains: Fezolinetant.....45mg (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 YearStore below 30°C in Cool & Dry Place
	For generic drugs (me-too Status)	Hamaz pharmaceuticals (pvt)Ltd.
	Pharmacotherapeutic Group of (API)	Gansu Haotian pharma Tech Co., Ltd, China Address: 11 Chongqinq road, small and medium-sized enterprise Business Base baiyin Gansu PR, CHINA. Tel: + 0931-8238232
	Name, address of Manufacturing site:	Hamaz Pharmaceuticals (Pvt)Ltd.-13-KM Bosan Road Lutafabad Multan-
	The status in reference regulatory authorities	complies
	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	
494	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	(XXU-LEB-ZV92, 2026-02-16)

	Detail of Fee Submitted	97200, 2026-01-27,
	The proposed proprietary name / brand name	**Restab 100mg tablet**
	Label Claim	Each Film-coated tablet contains Resmetirom....100mg (As per 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 at 20 °C to 25°C (68 °F to 77°F); excursions permitted to 15 °C to 30°C (59° F to 86°F)
	For generic drugs (me-too Status)	Hamaz pharmaceuticals (pvt)Ltd.
	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 Bosan Road Lutafabad Multan-
	The status in reference regulatory authorities	complies
	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	
495	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	(ZR1-ZGQ-ZS7P, 2026-02-17)
	Detail of Fee Submitted	97200, 2026-01-27,
	The proposed proprietary name / brand name	**Carzee Capsule 1.5mg**
	Label Claim	Each capsule contains: Cariprazine HCl eq. to Cariprazine ..... 1.5mg (As per Innovators 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. Protect from Heat & Light.
	For generic drugs (me-too Status)	Hamaz pharmaceuticals (pvt)Ltd.
	Pharmacotherapeutic Group of (API)	ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD. Address: CHUANNAN, DUQIAO, LINHAI ZHEJIANG 317016, CHINA.
	Name, address of Manufacturing site:	Hamaz Pharmaceuticals (Pvt)Ltd.-13-KM Bosan Road Lutafabad Multan-

	The status in reference regulatory authorities	complies
	Detail of previous approval	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	
496	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	(M6J-P2Y-VVTL, 2026-03-09)
	Detail of Fee Submitted	97200, 2026-01-27,
	The proposed proprietary name / brand name	**SUREXX 15MG TABLET**
	Label Claim	Each Film-coated tablet contains: Suvorexant ...15mg (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 YearStore at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30ºC (59°F to 86ºF)
	For generic drugs (me-too Status)	Hamaz pharmaceuticals (pvt)Ltd.
	Pharmacotherapeutic Group of (API)	Shandong Kehui Pharmaceuticals Co., Ltd Address: No.9A1, Tianheng Road, Gaoqing City, Shangdong Province China-256300.
	Name, address of Manufacturing site:	Hamaz Pharmaceuticals (Pvt)Ltd.-13-KM Bosan Road Lutafabad Multan-
	The status in reference regulatory authorities	complies
	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	
497	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	(V5E-WGQ-9PY2, 2026-03-09)
	Detail of Fee Submitted	93000.0, 2025-01-15,
	The proposed proprietary name / brand name	**VARDA 10MG**
	Label Claim	each 10mg varda contains : vardenafil Hcl....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	AS PER SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)normal
	For generic drugs (me-too Status)	M/S MEDIZAN LABORATORIES PVT.LTD
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/S MEDIZAN LABORATORIES OVT.LTD-PLOT 313 INDUSTRIAL TRIANGLE KAHUTA ROAD ISLAMABAD-
	The status in reference regulatory authorities	https://www.fda.gov
	Detail of previous approval	VARDA 10MG (VARDENAFIL HCL) 293 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	
498	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(7SV-V2R-MPA8, 2026-02-04)
	Detail of Fee Submitted	97200, 2026-01-30,
	The proposed proprietary name / brand name	**Talavil Tablet 2.5mg**
	Label Claim	Each film coated tablet contains: Tadalafil.....2.5mg (USP Specs.)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's, 5's 10's, 20's, 28's & 30's-De-Controlled
	Shelf Life (Unit)	2 YearStore below at 30°C
	For generic drugs (me-too Status)	Fildil 2.5mg Tablets
	Pharmacotherapeutic Group of (API)	PDE5 Inhibitor
	Name, address of Manufacturing site:	M/s Wimits Pharmaceutical-Plot No 129-Sunder Industrial Estate, Raiwind Road, Lahore, Pakistan-
	The status in reference regulatory authorities	EMA Approved/FDA 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	
499	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(HVN-9TS-QZNU, 2026-02-04)
	Detail of Fee Submitted	97200, 2026-01-30,
	The proposed proprietary name / brand name	**Talavil Tablet 10mg**
	Label Claim	Each film coated tablet contains: Tadalafil.....10mg (USP Specs.)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's, 5's 10's, 20's, 28's & 30's-De-Controlled
	Shelf Life (Unit)	2 YearStore below at 30°C
	For generic drugs (me-too Status)	Fildil 10mg Tablets
	Pharmacotherapeutic Group of (API)	PDE5 Inhibitor
	Name, address of Manufacturing site:	M/s Wimits Pharmaceutical-Plot No 129-Sunder Industrial Estate, Raiwind Road, Lahore, Pakistan-
	The status in reference regulatory authorities	EMA Approved/FDA Approved
	Detail of previous approval	Procial Tablet 10mg (M 351)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**Platinum Pharmaceuticals** A-20,North Western Industrial Zone Bin Qasim,Karachi **(000415)**
	Application Form Dy. No / Tracking ID & date of submission	(7SY-3TX-L6WD, 2026-02-06)
	Detail of Fee Submitted	97200, 2026-01-20,
	The proposed proprietary name / brand name	**CARBEX SYRUP 750 MG/5ML**
	Label Claim	Each 5ml contains: Carbocisteine.....750mg
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	100-As per SRO,120-As per SRO,200-As per SRO,60-As per SRO
	Shelf Life (Unit)	2 Year Do not Store Above 25°C
	For generic drugs (me-too Status)	muflex 750 mg / 5 ml syrup (Kaizen Pharmaceuticals (Pvt) Ltd.,)
	Pharmacotherapeutic Group of (API)	mucolytics
	Name, address of Manufacturing site:	Kaizen Pharmaceuticals (Pvt) Ltd-Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi-
	The status in reference regulatory authorities	EMC
	Detail of previous approval	Muflex 750 mg/ 5ml Syrup, meeting min 348 (tracking ID D58-APT-VVQD)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**Platinum Pharmaceuticals** A-20,North Western Industrial Zone Bin Qasim,Karachi **(000415)**
	Application Form Dy. No / Tracking ID & date of submission	(MAQ-NWL-BNBJ, 2026-03-26)
	Detail of Fee Submitted	97200, 2026-01-20,
	The proposed proprietary name / brand name	**Carbex 100 mg/ml Oral solution**
	Label Claim	Each ml contains: Carbocisteine.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	120 ml-As per SRO,240 ml-As per SRO,60 ml-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C. Protect from moisture and heat.
	For generic drugs (me-too Status)	Muflex 100 mg/ml oral solution (Kaizen pharmaceutical)
	Pharmacotherapeutic Group of (API)	mucolytics
	Name, address of Manufacturing site:	Kaizen Pharmaceuticals (Pvt) Ltd-Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi-
	The status in reference regulatory authorities	SOLUCIS 100mg/ml Syrup (AIFA)
	Detail of previous approval	muflex oral solution 100 mg/ml, meeting min 348 (tracking ID N13-UXV-XJY4)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the	

	above-mentioned notification. Furthermore, quality agreement 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.	**Platinum Pharmaceuticals** A-20,North Western Industrial Zone Bin Qasim,Karachi **(000415)**
	Application Form Dy. No / Tracking ID & date of submission	(LU5-US2-796V, 2025-12-31)
	Detail of Fee Submitted	97200, 2025-12-01,
	The proposed proprietary name / brand name	**Cholenum 5mg/ml injection (200000 IU)**
	Label Claim	Each ml contains: Cholecalciferol.....5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO,5's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C. Protect from light, heat, moisture & freezing
	For generic drugs (me-too Status)	Nac-D 5mg/ml Injection (UniMark Pharmaceuticals Pvt. Ltd.)
	Pharmacotherapeutic Group of (API)	Vitamin D analogues
	Name, address of Manufacturing site:	Swiss Pharmaceuticals Pvt. Ltd.-A/159, S.I.T.E. II, Super Highway, Karachi – Pakistan-
	The status in reference regulatory authorities	ANSM (France)
	Detail of previous approval	Nac-D 5mg/ml Injection Oral/IM (Tracking ID: 9PD-TU5-8VVX)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**Xenon Pharmaceuticals (Pvt.) Ltd** 9.5 Km Sheikhupura Road Lahore **(000077)**
	Application Form Dy. No / Tracking ID & date of submission	(V48-RNT-MVQT, 2025-12-04)
	Detail of Fee Submitted	93000, 4200 2025-04-09, 2025-10-22
	The proposed proprietary name / brand name	**Vetrox 250mg IM**
	Label Claim	Each Vial contains: Ceftriaxone Sodium eq. to Ceftriaxone .....250mg (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 in a cool and dry place.

	For generic drugs (me-too Status)	Ceftriaxone For Injection 250mg by Mehran International karachi
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Name, address of Manufacturing site:	Synchro Pharmaceuticals-77-Industrial Estate, Kot Lakhpat, Lahore.-
	The status in reference regulatory authorities	Rocephin Injection 250mg IM Injection F.Hoffman-La Roche Ltd. Switzerland USFDA Approved
	Detail of previous approval	Triomor 250mg IM Injection Approved in Post Registration Variation Committee in its 130th meeting of
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The cross-referred product was approved in PRV dated 16 September 2024.	
	Decision	
	Approved	
504	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Xenon Pharmaceuticals (Pvt.) Ltd** 9.5 Km Sheikhupura Road Lahore **(000077)**
	Application Form Dy. No / Tracking ID & date of submission	(7VG-TR6-GH1S, 2025-12-04)
	Detail of Fee Submitted	93000, 4200 2025-04-09, 2025-10-22
	The proposed proprietary name / brand name	**Vetrox 500mg IM Injection**
	Label Claim	Vetrox 500mg IM Injection Each Vial contains: Ceftriaxone Sodium eq. to Ceftriaxone .....500mg (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 in a cool and dry place.
	For generic drugs (me-too Status)	Oxidil 500mg IM Injection by Sami Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Name, address of Manufacturing site:	Synchro Pharmaceuticals-77-Industrial Estate, Kot Lakhpat, Lahore.-
	The status in reference regulatory authorities	Rocephin Injection 500mg IM Injection F.Hoffman-La Roche Ltd. Switzerland USFDA Approved
	Detail of previous approval	Triomor 500mg IM Injection Approved in Post Registration Variation Committee in its 130th meeting of
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product	

	formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The cross-referred product was approved in PRV dated 16 September 2024.	
	Decision	
	Approved	
505	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(5PE-M5M-UBJU, 2026-04-13)
	Detail of Fee Submitted	97200, 2026-01-20,
	The proposed proprietary name / brand name	**HYLINUM GEL**
	Label Claim	Each gram contains: Hyaluronic acid sodium salt ..... 2 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30g -As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C.
	For generic drugs (me-too Status)	Hyalinfa Gel, Kaizen Pharmaceuticals (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	Tissue Lubricant
	Name, address of Manufacturing site:	Kaizen Pharmaceuticals (Pvt) Ltd.-Plot no. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi-75020, Pakistan.-
	The status in reference regulatory authorities	Connettivina 0.2% Gel, AIFA (Italian Medicines Agency)
	Detail of previous approval	Hyalinfa Gel , 351
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**Platinum Pharmaceuticals** A-20,North Western Industrial Zone Bin Qasim,Karachi **(000415)**
	Application Form Dy. No / Tracking ID & date of submission	(WUN-U2E-HQLZ, 2026-04-13)
	Detail of Fee Submitted	97200, 2026-01-20,
	The proposed proprietary name / brand name	**SYNALGO MOUTHWASH 0.25% W/V**
	Label Claim	Each 100ml of solution contains.....Flurbiprofen 0.25gm
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	100ml-As per SRO,200ml-As per SRO,250ml -As per SRO,300ml -As per SRO
	Shelf Life (Unit)	2 YearMouthwash: This medicine should not be stored above 25°C
	For generic drugs (me-too Status)	Tornil Mouthwash 0.25% (Kaizen Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	Nonsteroidal anti-inflammatory drugs (NSAIDs)
	Name, address of Manufacturing site:	M/s KAIZEN PHARMACEUTICALS (PVT) LTD.-Plot no. E-127, E-128 & E-129 North Western, Industrial Zone, Port Qasim Authority Karachi-
	The status in reference regulatory authorities	(AIFA MEDICINES) FROBEN GOLA 250MG/100ML MOUTHWASH (COOPER CONSUMER HEALTH BV)
	Detail of previous approval	Tornil Mouthwash 0.25%, 331th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**De-Mont Research Laboratories (Pvt.) Ltd.** 20 Km, Lahore-Sharikpur Road, Sheikhupura **(000844)**
	Application Form Dy. No / Tracking ID & date of submission	(86J-5V5-WBT4, 2026-02-16)
	Detail of Fee Submitted	97200, 2026-01-30,
	The proposed proprietary name / brand name	**Tacoma Lotion**
	Label Claim	Each gram contains: Terbinafine as HCl.....10mg (JP Specifications)
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	20ml-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 25°C
	For generic drugs (me-too Status)	Terbiderm lotion, M/s Atco Lab.B-18, SITE Karachi
	Pharmacotherapeutic Group of (API)	Anti-Fungal
	Name, address of Manufacturing site:	M/s Bio Labs Pvt Ltd.-Plot # 145, Industrial Triangle, Kahuta Road, Islamabad-
	The status in reference regulatory authorities	Lamisil, Novartis Pharmaceuticals Canada INC.
	Detail of previous approval	Funasole 1% Lotion, 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	
508	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**De-Mont Research Laboratories (Pvt.) Ltd.** 20 Km, Lahore-Sharikpur Road, Sheikhupura **(000844)**
	Application Form Dy. No / Tracking ID & date of submission	(WZG-32B-2A3A, 2026-02-16)
	Detail of Fee Submitted	97200, 2026-01-30,
	The proposed proprietary name / brand name	**Ketocon 2% Lotion**
	Label Claim	Each gram contains: Ketoconazole.....20mg (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100ml-As per SRO,120ml-As per SRO,30ml-As per SRO,60ml-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 25°C
	For generic drugs (me-too Status)	KT - Zole Lotion, Bio-Labs (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Anti-Fungal
	Name, address of Manufacturing site:	M/s Bio Labs Pvt Ltd.-Plot # 145, Industrial Triangle, Kahuta Road, Islamabad-
	The status in reference regulatory authorities	Nizoral Shampoo; MHRA approved
	Detail of previous approval	IVIZO 2% LOTION, 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	
509	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**TN PHARMACEUTICALS** 264-C SUNDAR INDUSTRIAL ESTATE LAHORE **(000868)**
	Application Form Dy. No / Tracking ID & date of submission	(8AQ-ZNA-WEH7, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-11-13,
	The proposed proprietary name / brand name	**Axeon Injection 1g IV**
	Label Claim	Each Vial contains: Ceftriaxone Sodium eq. to Ceftriaxone .....1g (USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1'S-As per SRO
	Shelf Life (Unit)	2 YearStore at room temprature

	For generic drugs (me-too Status)	Oxidil 1g IV Injection
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Name, address of Manufacturing site:	Himedic Pharmaceuticals Pvt Ltd-19-Km link Multan Road Lahore-
	The status in reference regulatory authorities	Provided in Module 1
	Detail of previous approval	Basocef 1g injection IV
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The cross-referred product was approved in PRV dated 06-November, 2025 vide application TID: XX5-EPY-35RX.	
	Decision	
	Approved	
510	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**TN PHARMACEUTICALS** 264-C SUNDAR INDUSTRIAL ESTATE LAHORE **(000868)**
	Application Form Dy. No / Tracking ID & date of submission	(QWQ-G8J-E721, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-10-30,
	The proposed proprietary name / brand name	**KETOTAN 30mg/mL Injection**
	Label Claim	Each ml of ampoule contains: Ketorolac tromethamine ..... 30 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 in a cool and dry place.
	For generic drugs (me-too Status)	Ketrodil Injection 30 mg
	Pharmacotherapeutic Group of (API)	NSAIDs
	Name, address of Manufacturing site:	GT Pharma (Pvt.) Ltd.-Plot # 713 Sundar Industrial Estate, Lahore-
	The status in reference regulatory authorities	USFDA approved
	Detail of previous approval	APOLAC Injection Minutes of 333rd meeting of Registration Board (19th To 20th December, 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	
511	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

	Name, address of Applicant.	**Maybush Pharmaceuticals (Pvt) Ltd** Plot # 249/A, Industrial Triangle, Kahuta Road Islamabad **(000501)**
	Application Form Dy. No / Tracking ID & date of submission	(8BU-QHN-ZNRD, 2026-02-16)
	Detail of Fee Submitted	97200, 2026-02-04,
	The proposed proprietary name / brand name	**DACINIB15mg PR Tablet**
	Label Claim	Each Film Coated Extended-Release Tablet contains: Upadacitinib Hemihydrate equivalent to Upadacitinib 15mg
	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)	Wimits Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Upadacitinib is in a class of medications called Janus kinase (JAK) inhibitors (Reference;Basic and Clinical Pharmacology By Bertram G. Katzung)
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd-Plot # 129,Sunder Industrial Estate Lahore, Pakistan.,-
	The status in reference regulatory authorities	Manufacturer Name: AbbVie Inc. Product of Ireland Brand Name & Strength: Rinvoq (upadacitinib) 15mg Extended-release Tablet Composition: Each tablet contains 15.4mg Upadacitinib hemihydrate equivalent to upadacitinib… 15mg NDC 0074-2306-30 Dosage Form: Oral Solid Dosage Form Reference Regulatory Authority: USFDA Approved
	Detail of previous approval	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	
512	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Maybush Pharmaceuticals (Pvt) Ltd** Plot # 249/A, Industrial Triangle, Kahuta Road Islamabad **(000501)**
	Application Form Dy. No / Tracking ID & date of submission	(A2D-GET-6MN1, 2026-02-09)
	Detail of Fee Submitted	97200, 2026-02-04,
	The proposed proprietary name / brand name	**MAYBALIN 2.5mgTablet**
	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 Year30C
	For generic drugs (me-too Status)	Wimits Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Mirogabalin belongs to the class of gamma amino acids and its derivatives. Mirogabalin selectively binds α2δ subunits of voltage-gated calcium channels (VGCCs). It reduces calcium (Ca2+) influx and neurotransmission which inhibits neurotransmitter release in presynaptic neuron endings. (Reference;Basic and Clinical Pharmacology By Bertram G. Katzung)
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd-Plot # 129,Sunder Industrial Estate Lahore, Pakistan.,-
	The status in reference regulatory authorities	Manufacturer Name: Daiichi Sankyo Co., Ltd Brand Name & Strength: Tarlige Tablets 2.5mg Composition: Each Film coated tablet contains Mirogabalin besilate equivalent to Mirogabalin 2.5mg Dosage Form: Oral Solid Dosage Form Reference Regulatory Authority: PMDA Approved
	Detail of previous approval	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	
513	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Maybush Pharmaceuticals (Pvt) Ltd** Plot # 249/A, Industrial Triangle, Kahuta Road Islamabad **(000501)**
	Application Form Dy. No / Tracking ID & date of submission	(JX1-2HS-G85B, 2026-02-09)
	Detail of Fee Submitted	97200, 2026-02-04,
	The proposed proprietary name / brand name	**MAYBALIN 5mgTablet**
	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 Year30C
	For generic drugs (me-too Status)	Wimits Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Mirogabalin belongs to the class of gamma amino acids and its derivatives. Mirogabalin selectively binds α2δ subunits of voltage-gated calcium channels (VGCCs). It reduces calcium (Ca2+) influx and neurotransmission which inhibits neurotransmitter release in presynaptic neuron

		endings. (Reference;Basic and Clinical Pharmacology By Bertram G. Katzung)
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd-Plot # 129,Sunder Industrial Estate Lahore, Pakistan.,-
	The status in reference regulatory authorities	Manufacturer Name: Daiichi Sankyo Co., Ltd Brand Name & Strength: Tarlige Tablets 5mg Composition: Each Film coated tablet contains Mirogabalin besilate equivalent to Mirogabalin 5mg Dosage Form: Oral Solid Dosage Form Reference Regulatory Authority: PMDA Approved
	Detail of previous approval	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	
514	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Maybush Pharmaceuticals (Pvt) Ltd** Plot # 249/A, Industrial Triangle, Kahuta Road Islamabad **(000501)**
	Application Form Dy. No / Tracking ID & date of submission	(P9X-MAN-JVPR, 2026-02-12)
	Detail of Fee Submitted	97200, 2026-02-06,
	The proposed proprietary name / brand name	**ESTRANOR-D 75mg/25mgTablet**
	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	as per sro-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Wimits Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Tramadol HCl (is a synthetic analgesic drug exhibiting opioid and non-opioid properties, acting mainly on the central nervous system) Dexketoprofen trometamol (nonsteroidal anti-inflammatory drug (NSAID))
	Name, address of Manufacturing site:	Wimits Pharmaceutical Pvt Ltd-Plot # 129,Sunder Industrial Estate Lahore, Pakistan.,-
	The status in reference regulatory authorities	Manufactured by: Menarini – Von Heyden GmbH Leipziger Strasse 7-13 01097 Dresden Germany Brand Name & Strength: Skudexa 75 mg/25 mg film-coated tablets Composition: Each tablet contains: 75 mg of Tramadol hydrochloride 25 mg Dexketoprofen. Batch # DR-XY46409 Dosage Form:Film coated oral solid tablet

		Reference Regulatory Authority: HPRA Approved.
	Detail of previous approval	351th 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	
515	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Maybush Pharmaceuticals (Pvt) Ltd** Plot # 249/A, Industrial Triangle, Kahuta Road Islamabad **(000501)**
	Application Form Dy. No / Tracking ID & date of submission	(SBV-EA7-1YWS, 2026-02-12)
	Detail of Fee Submitted	97200, 2026-02-04,
	The proposed proprietary name / brand name	**DEUMAY 6mg TABLETS**
	Label Claim	Each film coated tablet contains; Deucravacitinib 6mg
	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: Dvanib 6mg Tablets Manufacturer Name: Hamaz Pharmaceuticals Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	Pharmacotherapeutic Group: Immunosuppressants, selective immunosuppressants
	Name, address of Manufacturing site:	GENOME PHARMACEUTICALS (PVT.) LTD.-16/I, Phase IV , Industrial Estate Hattar Pakistan-
	The status in reference regulatory authorities	SRA Registration Status: Japan Brand Name: SOTYKTU 6 mg film-coated tablets Manufacturer Name: Bristol-Myers Squibb Pharma Enclosed on page number 17(a)
	Detail of previous approval	351th 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	

516	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Maybush Pharmaceuticals (Pvt) Ltd** Plot # 249/A, Industrial Triangle, Kahuta Road Islamabad **(000501)**
	Application Form Dy. No / Tracking ID & date of submission	(T8S-R57-5LEG, 2026-02-09)
	Detail of Fee Submitted	97200, 2026-02-04,
	The proposed proprietary name / brand name	**PARAMINE 500mg+25mg Tablet**
	Label Claim	Each Film Coated tablet contains: Paracetamol 500mg Diphenhydramine Hydrochloride 25mg
	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)	Manufactured by : Haleon Pakistan Limited, Petro road, Jamshoro Brand Name & Strength: PANADOL NIGHT TABLET Composition: Each tablet contains Paracetamol 500 mg Diphenhydramine hydrochloride 25 mg Bat
	Pharmacotherapeutic Group of (API)	Paracetamol (central analgesic effect that is mediated through activation of descending serotonergic pathways) Diphenhydramine Hydrochloride (Antihistamines)
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd-Plot # 129,Sunder Industrial Estate Lahore, Pakistan.,-
	The status in reference regulatory authorities	PARAMINE 500mg+25mg Tablet
	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	
517	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Maybush Pharmaceuticals (Pvt) Ltd** Plot # 249/A, Industrial Triangle, Kahuta Road Islamabad **(000501)**
	Application Form Dy. No / Tracking ID & date of submission	(V14-L1G-TJLY, 2026-02-09)
	Detail of Fee Submitted	97200, 2026-02-06,
	The proposed proprietary name / brand name	**STERON10mg Tablet**
	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 Year30C
	For generic drugs (me-too Status)	Brand Name: Dydrogest 10mg Tablet. Registration holder: OBS Pakistan (Pvt) Ltd., C-14 Mangopir Road SITE Karachi. , Karachi. Status in regulatory authorities Dydrogest 10mg Tablet is DRAP Approved
	Pharmacotherapeutic Group of (API)	Genito Urinary system and sex hormones.
	Name, address of Manufacturing site:	SKYWIN PHARMACEUTICALS-Plot #01,Al Badar Industrial Estate, Phase II Sheikhupura Road Lahore-
	The status in reference regulatory authorities	Brand Name Duphaston 10 mg film-coated tablets. Marketing Authorization holder: Mylan IRE Healthcare Limited. Regulatory Authority: Duphaston 10 mg film-coated tablets ® is Approved in HPRA of Ireland.
	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	
518	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**SATURN Pharmaceuticals Pvt Ltd** 23km Thorar Raiwind Road Lahore **(000734)**
	Application Form Dy. No / Tracking ID & date of submission	(8EG-3YY-8HGB, 2026-02-10)
	Detail of Fee Submitted	97200, 2025-12-08,
	The proposed proprietary name / brand name	**LEVOSAT**
	Label Claim	Each film coated tablet contains: Levofloxacin hemihydrate eq. to Levofloxacin....250mg (USP SPECIFICATIONS)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's -As per SRO
	Shelf Life (Unit)	2 YearStore below 30 centigrade. Protect from heat, moisture & sunlight
	For generic drugs (me-too Status)	TAVANIC 250 mg tab
	Pharmacotherapeutic Group of (API)	Quinolone antibiotic
	Name, address of Manufacturing site:	Variant Pharmaceuticals Pvt Ltd.-Plot no 5 M2 Pharmazone Sharqpur lahore-Road.-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	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	
519	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**SATURN Pharmaceuticals Pvt Ltd** 23km Thorar Raiwind Road Lahore **(000734)**
	Application Form Dy. No / Tracking ID & date of submission	(BUX-UEX-E5BM, 2026-02-10)
	Detail of Fee Submitted	97200, 2025-12-08,
	The proposed proprietary name / brand name	**ESOPRAZIN**
	Label Claim	Each Vial contains: Esomeprazole Sodium equivalent to Esomeprazole .....40 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's -As per SRO
	Shelf Life (Unit)	2 YearStore below 30 centigrade. Protect from heat, moisture & sunlight
	For generic drugs (me-too Status)	NEXUM 40 mg IV
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor (PPI)
	Name, address of Manufacturing site:	Variant Pharmaceuticals Pvt Ltd.-Plot no 5 M2 Pharmazone Sharqpur lahore-Road.-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Minutes of 312th 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	
520	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Hygeia Pharmaceuticals** Plot NO 295, Industrial Triangles Kahuta Road Islamabad **(000523)**
	Application Form Dy. No / Tracking ID & date of submission	(8RN-9U8-PG26, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-12-01,
	The proposed proprietary name / brand name	**HYMOL 1gm/100ml INFUSION**
	Label Claim	Each 100ml contains: Paracetamol 1gm
	Reference to Finished product specifications	British Pharmacopeia

	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Parawell 1g/100ml Infusion (131733) M/s Well Go Pharmaceuticals (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Well Go Pharmaceuticals (Pvt) Ltd-5-km, Raiwind Manga Road Lahore-
	The status in reference regulatory authorities	Pakistan
	Detail of previous approval	Parawell 1g/100ml Infusion (131733) 351 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	
521	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Hygeia Pharmaceuticals** Plot NO 295, Industrial Triangles Kahuta Road Islamabad **(000523)**
	Application Form Dy. No / Tracking ID & date of submission	(RXN-5L7-YZH1, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-12-01,
	The proposed proprietary name / brand name	**HYDIN10% Solution**
	Label Claim	HYDIN10% Solution Each 1ml Contains: - Povidone Iodine 100mg equivalent to 10mg Iodine (USP Specification).
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	450ml-Controlled,60ml-Controlled
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Poviwell 10% Solution (131735) Well Go Pharmaceuticals (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Well Go Pharmaceuticals (Pvt) Ltd-5-km, Raiwind Manga Road Lahore-
	The status in reference regulatory authorities	Pakistan
	Detail of previous approval	Poviwell 10% Solution (131735) 351 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	
522	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	(8S7-A36-LQ1T, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-12-31,
	The proposed proprietary name / brand name	**Ketokar Tablet**
	Label Claim	Each film coated tablet contains: α-Ketoanalogue to isoleucine (Calcium-salt)... 67 mg α-Ketoanalogue to leucine (Calcium-salt)... 101 mg α-Ketoanalogue to phenylalanine (Calcium-Salt) 68 mg α-Ketoanalogue to valine (Calcium-Salt) 86 mg α-hydroxyanalogue to DL-methionine (Calcium-Salt)....59 mg L-lysine acetate...105mg corresponding to L-lysine 75 mg L-threonine 53 mg L-tryptophan 23 mg L-histidine 38 mg L-tyrosine 30 mg Total nitrogen content per tablet 36 mg Calcium content per tablet 1.25mmol = 50 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year15 °C - 30 °C
	For generic drugs (me-too Status)	Ketoalfa tablet
	Pharmacotherapeutic Group of (API)	Aminoacids
	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	Ketosteril Tablet M/sFreseniusKabi,Germany
	Detail of previous approval	Ketorein Tablet (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	
523	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	(L58-X9M-43DG, 2026-02-24)
	Detail of Fee Submitted	97200, 2026-02-09,

	The proposed proprietary name / brand name	**Cefotect**
	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 Year15 °C - 30 °C
	For generic drugs (me-too Status)	Cebac 2g Injection
	Pharmacotherapeutic Group of (API)	Cephalosporin's Antibiotics
	Name, address of Manufacturing site:	Aulton Pharmceuticals-Plot no 84/1, Block A, Phase V, Industrial estate hattar-
	The status in reference regulatory authorities	SULPERAZON
	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	
524	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	(UJP-YAD-E6X2, 2026-02-24)
	Detail of Fee Submitted	97200, 2026-02-06,
	The proposed proprietary name / brand name	**Esnapro**
	Label Claim	Each modified release tablet contains: Naproxen.....500mg (Enteric coated Core) Esomeprazole as Magnesium Trihydreate.....20mg (Immediate Release Coat) (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 Year15 °C - 30 °C
	For generic drugs (me-too Status)	Glomov Tablets
	Pharmacotherapeutic Group of (API)	Nonsteroidal Anti-inflammatory Drug (NSAID) and Proton Pump Inhibitor
	Name, address of Manufacturing site:	Solaris Life Sciences (pvt) Ltd-Plot No 08, Street S-1, RCCI , Rawat-
	The status in reference regulatory authorities	Vimovo modified release tablets
	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	
525	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	(5XQ-1EV-WDSV, 2026-03-02)
	Detail of Fee Submitted	93000, 4200 2024-12-04, 2025-12-18
	The proposed proprietary name / brand name	**Rig 12.5mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Omarigliptin.....12.5mg (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-De-Controlled
	Shelf Life (Unit)	2 YearStore below 25°c
	For generic drugs (me-too Status)	Omatin Tablet by Helix Pharma
	Pharmacotherapeutic Group of (API)	DPP-4 inhibitor
	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	Omergo Tablet, DRB 352
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**Trigon Pharmaceuticals (Private) Ltd** 8-k.m thokar raiwind road Lahore **(000342)**
	Application Form Dy. No / Tracking ID & date of submission	(91S-U9N-Y624, 2026-01-27)
	Detail of Fee Submitted	93000, 4200 2024-12-04, 2025-12-18
	The proposed proprietary name / brand name	**Fae 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 25°c
	For generic drugs (me-too Status)	Jakcib Tablet by Wnsfeild Pharmaceuticals
	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	
527	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	(DTA-MLY-H6GQ, 2026-03-19)
	Detail of Fee Submitted	93000.0, 2024-10-15,
	The proposed proprietary name / brand name	**MPA**
	Label Claim	Each Film Coated Tablet contains: Empagliflozin.....5mg Metformin Hydrochloride.....1000mg (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1* 14's-As per SRO
	Shelf Life (Unit)	2 YearBelow 25
	For generic drugs (me-too Status)	Empoli Plus (Empagliflozin + Metformin HCI) By Sami Pharmaceuticals (Pvt) Ltd.
	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	02456591 SYNJARDY EMPAGLIFLOZIN; METFORMIN HYDROCHLORIDE 5 MG; 1000 MG TABLET ORAL
	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	
528	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	(96B-GBH-AJU7, 2026-03-04)
	Detail of Fee Submitted	97200, 2026-02-13,
	The proposed proprietary name / brand name	**Xabrin 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 / DPC-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Miro 2.5mg tablet by NABI QASIM Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Anti convulsants
	Name, address of Manufacturing site:	Wimits Pharmaceuticals (Pvt.) Ltd.-Address Plot # 129, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan-
	The status in reference regulatory authorities	TARLIGE 2.5 mg film-coated tablets by DAIICHI SANKYO COMPANY (THAILAND) LTD.
	Detail of previous approval	Mirogab 2.5mg Tablet (Registration No. 127677) approved in 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	
529	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	(NNE-N25-S5DE, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-11-10,
	The proposed proprietary name / brand name	**Altafer 500mg/10ml Injection**
	Label Claim	Each 10ml Vial Contains: Iron as Ferric Carboxymaltose.....500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's (10ml)-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C

	For generic drugs (me-too Status)	Fercari Injection by Hilton Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Anti-Enemic
	Name, address of Manufacturing site:	WnsFeild Pharmaceuticals-Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar-
	The status in reference regulatory authorities	Ferinject 500mg/10ml by M/s Vifor Pharma UK Limited, EMA Approved.
	Detail of previous approval	FERRINA 500mg/10ml Injection approved in 343 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	
530	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	(PUY-ABE-E4NM, 2026-03-04)
	Detail of Fee Submitted	97200, 2026-02-13,
	The proposed proprietary name / brand name	**Xabrin 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 / DPC-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Miro 5mg tablet by NABI QASIM Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Anti convulsants
	Name, address of Manufacturing site:	Wimits Pharmaceuticals (Pvt.) Ltd.-Address Plot # 129, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan-
	The status in reference regulatory authorities	TARLIGE 5 mg film-coated tablets by DAIICHI SANKYO COMPANY (THAILAND) LTD. PMDA Approved
	Detail of previous approval	Mirogab 5mg Tablet (Registration No. 127678) approved in 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	
531	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Aspin Pharma** Plot # 10 & 25 Sector 20 Korangi Industrial Area Karachi 74900 Pakistan **(000045)**
	Application Form Dy. No / Tracking ID & date of submission	(9SP-UZJ-R5HY, 2026-02-16)
	Detail of Fee Submitted	97200, 2026-01-15,
	The proposed proprietary name / brand name	**Ivizo 2% Lotion**
	Label Claim	Ivizo 2% Lotion: (2% w/w) Each gm contains: Ketoconazole .....20mg (BP Specification)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100ml -De-Controlled,120ml -De-Controlled,30ml -De-Controlled,60ml -De-Controlled
	Shelf Life (Unit)	2 YearStore in the original package. There is no special temperature precaution for storage.
	For generic drugs (me-too Status)	Ketrazole Lotion
	Pharmacotherapeutic Group of (API)	Imidazole and triazole 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	Nizoral 2% shampoo (MHRA Approved)
	Detail of previous approval	KT-Zole Lotion, 336th 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	
532	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Searle Pakistan Limited** C-14, Manghopir Road, SITE, Karachi **(000012)**
	Application Form Dy. No / Tracking ID & date of submission	(M2J-37Z-X2QW, 2026-02-18)
	Detail of Fee Submitted	97200, 2025-12-31,
	The proposed proprietary name / brand name	**ANAFIL (Vardenafil) 20 mg Tablet**
	Label Claim	Each film coated tablet contains: Vardenafil as Hydrochloride Trihydrate 20mg
	Reference to Finished product specifications	United States Pharmacopeia

	Proposed Pack Size	1x10's-De-Controlled,1x2's-De-Controlled,1x4's-De-Controlled,1x6's-De-Controlled,2x4's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30°C.
	For generic drugs (me-too Status)	Vardena 20mg Tablets (M/s. M/s Solaris Life Sciences Private Limited)
	Pharmacotherapeutic Group of (API)	Urologicals, Drugs used in erectile dysfunction.
	Name, address of Manufacturing site:	M/s Solaris Life Sciences Private Limited-Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat.-
	The status in reference regulatory authorities	Approved by US FDA, MHRA UK and EMA.
	Detail of previous approval	Product Name: Vardena 20mg Tablet, Meeting No.: 351st 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	
533	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Searle Pakistan Limited** C-14, Manghopir Road, SITE, Karachi **(000012)**
	Application Form Dy. No / Tracking ID & date of submission	(4DM-SWM-3LZL, 2026-02-04)
	Detail of Fee Submitted	97200, 2026-01-06,
	The proposed proprietary name / brand name	**TIAFIL (Tadalafil) 20 mg Tablet**
	Label Claim	Each film coated tablet contains: Tadalafil 20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 x 10's-De-Controlled,1 x 2's-De-Controlled,1 x 4's-De-Controlled,2 x 4's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30°C.
	For generic drugs (me-too Status)	Tadalis 20mg Tablet (Hilton Pharma)
	Pharmacotherapeutic Group of (API)	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	Approved by MHRA UK.
	Detail of previous approval	Product Name: DALAFIL 20mg Tablet, Meeting No.: 352nd 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	
534	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Searle Pakistan Limited** C-14, Manghopir Road, SITE, Karachi **(000012)**
	Application Form Dy. No / Tracking ID & date of submission	(9VQ-H8T-TJ3J, 2026-02-18)
	Detail of Fee Submitted	97200, 2026-01-06,
	The proposed proprietary name / brand name	**TIAFIL (Tadalafil) 5 mg Tablet**
	Label Claim	Each film coated tablet contains: Tadalafil 5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's-De-Controlled,1x2's-De-Controlled,1x4's-De-Controlled,2x4's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30°C.
	For generic drugs (me-too Status)	Tadalis 5mg Tablet (Hilton Pharma)
	Pharmacotherapeutic Group of (API)	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	Approved by MHRA UK.
	Detail of previous approval	Product Name: DALAFIL 5mg Tablet, Meeting No.: 352nd 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	
535	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Searle Pakistan Limited** C-14, Manghopir Road, SITE, Karachi **(000012)**
	Application Form Dy. No / Tracking ID & date of submission	(64Z-TLP-73BE, 2026-03-10)
	Detail of Fee Submitted	97200, 2026-01-06,
	The proposed proprietary name / brand name	**NAPREX (Naproxen/ Esomeprazole) 375mg/20mg Tablet**
	Label Claim	Each modified release tablet contains: Naproxen.....375mg (Enteric coated Core) Esomeprazole as Magnesium

		Trihydrate.....20mg (Immediate Release Coat)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,28's-De-Controlled,30's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30°C.
	For generic drugs (me-too Status)	Glomov Tablets (Global Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	Naproxen (NSAID) & Esomeprazole (PPI).
	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	Approved by US FDA and Health Canada
	Detail of previous approval	Product Name: SNP 375mg/ 20mg Tablets, Meeting No.: 343rd 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	
536	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	(A2H-Q33-Z2XU, 2026-02-09)
	Detail of Fee Submitted	97200, 2026-02-02,
	The proposed proprietary name / brand name	**SBT 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 Year20-25°C
	For generic drugs (me-too Status)	pproved Medicines Aerotec 200mcg Capsule Highnoon Laboratories (Reg# 044593)
	Pharmacotherapeutic Group of (API)	bronchodilators
	Name, address of Manufacturing site:	M/s Winbrains Research Laboratories-Plot No. 69/1, Block B, Phase-I&II, Industrial Area, Hattar.-
	The status in reference regulatory authorities	Applied as Cross Refer Product against Already Approved CTD
	Detail of previous approval	SBT Rota capsule | Minutes of 336th meeting of Registration Board (4th to 6th 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	
537	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	(PH1-S2D-LMRY, 2026-03-05)
	Detail of Fee Submitted	97200, 2026-02-19,
	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 Year20-25°C
	For generic drugs (me-too Status)	Brand Name of Approved Medicines Bina 1% Cream Manufacturer Linta Pharmaceuticals Strength 1% Composition Each gram of cream contains:- Terbinafine as HCl .10mg (1.0%) Registration Number 080268 Dosag
	Pharmacotherapeutic Group of (API)	Organic compound
	Name, address of Manufacturing site:	M/s Winbrains Research Laboratories-Plot No. 69/1, Block B, Phase-I&II, Industrial Area, Hattar.-
	The status in reference regulatory authorities	https://www.medicines.org.uk/emc/product/12831/
	Detail of previous approval	Terbiwin 1% Cream | Minutes of 350th 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	
538	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	(YD7-J7Q-14GG, 2026-02-09)
	Detail of Fee Submitted	97200, 2026-02-02,

	The proposed proprietary name / brand name	**TYBRO 18MCG Rota Capsule**
	Label Claim	Each RotaCapsule contains: Tiotropium as Bromide Monohydrate.....18 Mcg (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 Year20-25°C
	For generic drugs (me-too Status)	Brand Name of Approved Medicines Apollo-F Capsule Nexus Pharma Karachi. (Reg# 076149)
	Pharmacotherapeutic Group of (API)	anticholinergics
	Name, address of Manufacturing site:	M/s Winbrains Research Laboratories-Plot No. 69/1, Block B, Phase-I&II, Industrial Area, Hattar.1-
	The status in reference regulatory authorities	Applied as Cross Refer Product against Already Approved CTD
	Detail of previous approval	Titropium 18mcg DPi Capsule DRB 336 Minutes Reference
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**Welwrd Pharmaceuticals** Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar **(000574)**
	Application Form Dy. No / Tracking ID & date of submission	(ZXJ-Z6N-JMD5, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-12-10,
	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 Year20-25°C
	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)	Janus kinase (JAK) inhibitors
	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	https://www.medicines.org.uk/emc/landing?status=1#gref

	Detail of previous approval	Tofocib 5mg Tablet 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	
540	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	(AR2-236-Z6QL, 2026-03-26)
	Detail of Fee Submitted	97200, 2026-02-26,
	The proposed proprietary name / brand name	**METHYLL 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 Year20-25°C
	For generic drugs (me-too Status)	Brand Name of Approved Medicines Solu Medrol Injection Manufacturer Pfizer Pakistan Strength 40mg, 125mg, 500mg, 1gm Composition Each vial contains:- Methylprednisolone Sodium succinate…….
	Pharmacotherapeutic Group of (API)	Corticosteroids
	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	Applied as Cross Refer Product against Already Approved CTD
	Detail of previous approval	Methyll 125mg Injection | 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	
541	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	(JHS-LWY-VH9Y, 2026-03-26)
	Detail of Fee Submitted	97200, 2026-02-26,
	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 Year20-25°C
	For generic drugs (me-too Status)	Brand Name of Approved Medicines Solu Medrol Injection Manufacturer Pfizer Pakistan Strength 40mg, 125mg, 500mg, 1gm Composition Each vial contains:- Methylprednisolone Sodium succinate…….
	Pharmacotherapeutic Group of (API)	Corticosteroids
	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	Applied as Cross Refer Product against Already Approved CTD
	Detail of previous approval	Methyll 500mg Injection | 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	
542	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	(QDY-DAJ-Z4J9, 2026-03-26)
	Detail of Fee Submitted	97200, 2026-02-26,
	The proposed proprietary name / brand name	**METHYLL 1000mg 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 Year20-25°C

	For generic drugs (me-too Status)	Brand Name of Approved Medicines Solu Medrol Injection Manufacturer Pfizer Pakistan Strength 40mg, 125mg, 1000mg, 1gm Composition Each vial contains:- Methylprednisolone Sodium succinate……
	Pharmacotherapeutic Group of (API)	Corticosteroids
	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	Applied as Cross Refer Product against Already Approved CTD
	Detail of previous approval	Methyll 1g Injection | 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	
543	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Dew-Max Pharmaceuticals (Pvt) Ltd** Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad **(000889)**
	Application Form Dy. No / Tracking ID & date of submission	(D1X-8ZA-DZQ1, 2026-03-02)
	Detail of Fee Submitted	97200, 2025-12-16,
	The proposed proprietary name / brand name	**Dewdex 30mg Capsule**
	Label Claim	Each hard gelatin Capsule contains: DDR Pellets of Dexlansoprazole Eq. to Dexlansoprazole..... 30mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30s-As per SRO
	Shelf Life (Unit)	2 Year15-30c
	For generic drugs (me-too Status)	Attached
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Swera Pharmaceutical -Plot No. 27, Street No. S-4, National Industrial Zone Rawat, Islamabad-
	The status in reference regulatory authorities	Attached
	Detail of previous approval	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	
544	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Dew-Max Pharmaceuticals (Pvt) Ltd** Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad **(000889)**
	Application Form Dy. No / Tracking ID & date of submission	(QHU-DUG-VS66, 2026-03-02)
	Detail of Fee Submitted	97200, 2025-12-16,
	The proposed proprietary name / brand name	**Dewdex 60mg Capsule**
	Label Claim	Each hard gelatin Capsule contains: DDR Pellets of Dexlansoprazole Eq. to Dexlansoprazole..... 60mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30s-As per SRO
	Shelf Life (Unit)	2 Year15-30c
	For generic drugs (me-too Status)	Attached
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Swera Pharmaceutical -Plot No. 27, Street No. S-4, National Industrial Zone Rawat, Islamabad-
	The status in reference regulatory authorities	Attached
	Detail of previous approval	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	
545	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Dew-Max Pharmaceuticals (Pvt) Ltd** Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad **(000889)**
	Application Form Dy. No / Tracking ID & date of submission	(1SG-627-VTTM, 2026-03-11)
	Detail of Fee Submitted	97200, 2026-02-19,
	The proposed proprietary name / brand name	**G-D3 Injection**
	Label Claim	Each ml contains: Cholecalciferol 5mg (2000001U)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year15-30c
	For generic drugs (me-too Status)	Attached
	Pharmacotherapeutic Group of (API)	Attached

	Name, address of Manufacturing site:	Islam Pharmaceutical-7-km Pasrur Road Sialkot -
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-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	
546	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Dew-Max Pharmaceuticals (Pvt) Ltd** Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad **(000889)**
	Application Form Dy. No / Tracking ID & date of submission	(7VD-7WM-VE19, 2026-03-11)
	Detail of Fee Submitted	97200, 2025-12-16,
	The proposed proprietary name / brand name	**Dezolid 600mg Tablet**
	Label Claim	Each Film coated Tablet contains:
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year15-30c
	For generic drugs (me-too Status)	Attached
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Islam Pharmaceutical-7-km Pasrur Road Sialkot -
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-352
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**Dew-Max Pharmaceuticals (Pvt) Ltd** Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad **(000889)**
	Application Form Dy. No / Tracking ID & date of submission	(MY2-WV9-DZ2U, 2026-03-11)
	Detail of Fee Submitted	97200, 2025-12-09,

	The proposed proprietary name / brand name	**Remobect 2g Injection**
	Label Claim	Each vial contains:
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year15-30c
	For generic drugs (me-too Status)	Attached
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Seraph Pharmaceuiticals-Plot No 210, Industrial triangle, Kahuta road, Islamabad-
	The status in reference regulatory authorities	Attached
	Detail of previous approval	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	
548	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Dew-Max Pharmaceuticals (Pvt) Ltd** Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad **(000889)**
	Application Form Dy. No / Tracking ID & date of submission	(ZA2-PEW-5NZ3, 2026-03-11)
	Detail of Fee Submitted	97200, 2025-12-09,
	The proposed proprietary name / brand name	**Ondew Injection**
	Label Claim	Each 4ml contains:
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year15-30c
	For generic drugs (me-too Status)	Attached
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Islam Pharmaceutical-7-km Pasrur Road Sialkot -
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-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	

549	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Dew-Max Pharmaceuticals (Pvt) Ltd** Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad **(000889)**
	Application Form Dy. No / Tracking ID & date of submission	(MX7-R3X-5MYY, 2026-03-26)
	Detail of Fee Submitted	97200, 2026-02-19,
	The proposed proprietary name / brand name	**G-DOL Injection**
	Label Claim	Each ampoule (1ml) contains
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year15-30c
	For generic drugs (me-too Status)	Attached
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Islam Pharmaceutical-7-km Pasrur Road Sialkot -
	The status in reference regulatory authorities	Attached
	Detail of previous approval	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	
550	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Mediate Pharmaceutical Pvt Ltd** Plot # 150-151 Sector 24, Korangi Industrial Area **(000167)**
	Application Form Dy. No / Tracking ID & date of submission	(HBB-B43-P9SM, 2026-03-18)
	Detail of Fee Submitted	38700, 58500 2025-12-24, 2026-02-03
	The proposed proprietary name / brand name	**MEDFORM 400mcg + 12mcg Rota Capsule**
	Label Claim	Each capsule contains: Budesonide.....400mcg Formoterol Fumarate Dihydrate.....12mcg Each delivered dose contains: Budesonide.....320mcg Formoterol Fumarate Dihydrate.....9mcg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30'S-As per SRO
	Shelf Life (Unit)	2 Year25
	For generic drugs (me-too Status)	Venticort Rotacaps 400mg + 12mcg
	Pharmacotherapeutic Group of (API)	Budesonide + Formoterol fumarate dihydrate belongs to a pharmaceutical group known as an inhaled corticosteroid (ICS) and long-acting beta2-adrenergic agonist (LABA) combinatio

	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	EMC/FDA Approved
	Detail of previous approval	DRAP , Meeting 339th Page # 1477
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**Genetics Pharmaceuticals Pvt. Ltd** 539-A Sundar Industrial Estate Raiwind Road Lahore **(000845)**
	Application Form Dy. No / Tracking ID & date of submission	(AS4-8AE-4EHE, 2026-02-04)
	Detail of Fee Submitted	97200, 2025-11-20,
	The proposed proprietary name / brand name	**Diblay-M XR**
	Label Claim	Each Extended-release Tablet Contains: Empagliflozin..... 12.5mg Metformin HCl.....1000mg
	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)	Reference Regulatory country: DRAP, Pakistan Manufacturer name: • Manufactured By: Getz Pharma Brand name: Diampa-M Strength: Empagliflozin 5mg + Metformin HCl 1000mg Composition: Each Extended-rel
	Pharmacotherapeutic Group of (API)	Medicinal products used in diabetes, Combinations of oral blood glucose lowering medicinal products, ATC code: A10BD07
	Name, address of Manufacturing site:	Solaris Life Sciences-Metformin HCl M/S: Aarti Drugs Limited. Address: (unit 11) plot No,211,213, Road No 2 GIDC,Sarigam ,TAL,Umbergaon Dist valsad(Gujrat india)-
	The status in reference regulatory authorities	Registration Status: USFDA Approved New Drug Application (NDA): 212362. Company: MSN LABS PVT LTD Brand Name: Empagliflozin + Metformin Hydrochloride
	Detail of previous approval	PRV approval vide Tracking ID: W2P-7PQ-MDJM dated 05-December, 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. The cross-referred product was approved in PRV dated 05-December 2025 vide application TID: W2P-7PQ-MDJM.	
	Decision	
	Approved	
552	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Medisynth Pharmaceuticals** Khasra No. 1028/1029, Mouza Jellyari Gujri, Tehsil Gujar Khan, District Rawalpindi **(000718)**
	Application Form Dy. No / Tracking ID & date of submission	(B8B-W43-8VBZ, 2026-03-04)
	Detail of Fee Submitted	97200, 2026-02-21,
	The proposed proprietary name / brand name	**K-Syn**
	Label Claim	Each ml Contains: Ketorolac Tromethamine.....30mg/ml USP specification
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5s-De-Controlled
	Shelf Life (Unit)	2 Year15C-30C
	For generic drugs (me-too Status)	Toradol by Martin Dow
	Pharmacotherapeutic Group of (API)	Product approved in 333rd meeting
	Name, address of Manufacturing site:	Carer Pharmaceuticals Industries-Plot No 27 Main road rawat Industiral Estate rawat-
	The status in reference regulatory authorities	Product approved in 333rd meeting
	Detail of previous approval	Ketocar 30mg/ml 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	
553	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	(NLR-B8S-BZT6, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-11-25,
	The proposed proprietary name / brand name	**Linzowl 100mg/5ml Dry Powder Suspension**
	Label Claim	Each 5ml contains: Linezolid 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1*120ml-As per SRO,1*60ml-As per SRO,1*90ml-As per SRO

	Shelf Life (Unit)	2 YearStore below 25 Degree Centigrade
	For generic drugs (me-too Status)	NEZKIL (linezolid) 100mg/5ml Powder for Oral Suspension of M/s S.J. & G. Fazul Ellahie (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Oxazolidinones
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II , Sheikhupura Road Lahore. -
	The status in reference regulatory authorities	Zyvox 100 mg/5 ml Granules for Oral Suspension of M/s Pfizer Limited (HPRA Approved)
	Detail of previous approval	Dilozen 100mg/5ml Powder for Suspension Minutes of 350th Meeting of Registration Board (29th – 30th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**Medwell Pharmaceuticals** 1 km, terbella road, lawrencepur, faqirabad Attock **(000699)**
	Application Form Dy. No / Tracking ID & date of submission	(BJ7-V2B-HVRW, 2026-02-12)
	Detail of Fee Submitted	97200, 2025-11-25,
	The proposed proprietary name / brand name	**Dextek 75/25mg 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	1x10's-As per SRO,10*10's-As per SRO,2*10's-As per SRO,2*7's-As per SRO,3*10's-As per SRO,5*10's-As per SRO,7*4's-As per SRO
	Shelf Life (Unit)	2 YearStore below 25 Degree Centigrade
	For generic drugs (me-too Status)	N.A
	Pharmacotherapeutic Group of (API)	Analgesic
	Name, address of Manufacturing site:	Wimits Pharmaceuticals (Pvt) Ltd.-Plot No 129, Sundar Estate, Raiwind Road, Lahore.-
	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
	Detail of previous approval	DEXTRAM 75MG/25MG TABLET Minutes of 351st Meeting of Registration Board (23rd – 24th September, 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	
555	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	(UV9-S21-7QJN, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-11-25,
	The proposed proprietary name / brand name	**MIZO TABLET**
	Label Claim	Mizo 200mcg Tablet (Misoprostol)
	Reference to Finished product specifications	The International Pharmacopeia
	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 YearStore below 25 Degree Centigrade
	For generic drugs (me-too Status)	BREEKY 200mcg Tablets of SAMI Pharmaceuticals (Pvt.) Limited.
	Pharmacotherapeutic Group of (API)	Synthetic prostaglandin E1 analog
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt) Ltd.-Plot No 129, Sundar Estate, Raiwind Road, Lahore.-
	The status in reference regulatory authorities	CYTOTEC 0.2mg Tablet, USFDA approved.
	Detail of previous approval	Minutes for 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	
556	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	(TQL-Z1P-1BJ3, 2026-03-09)
	Detail of Fee Submitted	97200, 2026-02-09,
	The proposed proprietary name / brand name	**Meddol 500mg/200mg Tablet**

	Label Claim	Each Film Coated tablet contains: Paracetamol .....500mg Ibuprofen.....200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 degree CELSIUS
	For generic drugs (me-too Status)	Provas Duo Tablet 500mg/200mg ,SAMI Pharmaceuticals Pvt. Ltd.Registration number: 108579
	Pharmacotherapeutic Group of (API)	Paracetamol (Analgesic and Antipyretics) Ibuprofen (Non-steroidal Anti-inflammatory Drug)
	Name, address of Manufacturing site:	Wimits Pharmaceuticals-Plot # 129 Sunder Industrial Estate, Raiwind Road, Lahore, Pakistan-
	The status in reference regulatory authorities	MHRA GOV UK 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	
557	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	(Z8G-ZMT-S697, 2026-03-26)
	Detail of Fee Submitted	97200, 2026-02-09,
	The proposed proprietary name / brand name	**Famowl 800MG/26.6MG Tablet**
	Label Claim	Each Film Coated tablet contains: Ibuprofen... 800mg Famotidine 26.6mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 degree Celsius
	For generic drugs (me-too Status)	M/s Wimits Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Ibuprofen (analgesic & anti-inflammatory drug) Famotidine(Histamine-2 receptor antagonists (H2RAs))
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals-Plot # 129, Sunder Industrial Estate Lahore.-
	The status in reference regulatory authorities	M/S Horizon Pharma USA, Inc. Lake Forest, IL 60045 USFDA 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	
558	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	(RA2-TV2-1AA7, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-11-17,
	The proposed proprietary name / brand name	**weltose injection**
	Label Claim	Each ml contains:- Iron as Ferric Carboxymaltose 50mg
	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)	biolab pharma
	Pharmacotherapeutic Group of (API)	Haematinics
	Name, address of Manufacturing site:	bio-labs pvt ltd-PLOT NO 145 KAHUTA INDUSTRIAL TRIANGLE ISLAMABAD-
	The status in reference regulatory authorities	FDA APPORVED
	Detail of previous approval	M-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	
559	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	(BT1-4TX-83SM, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-11-11,
	The proposed proprietary name / brand name	**Panixo Inj 40mg**
	Label Claim	Each vial contains: Pantoprazole sodium equivalent to Pantoprazole 40mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1,S-As per SRO
	Shelf Life (Unit)	2 YearStore BELOW 27 c0

	For generic drugs (me-too Status)	Zopent 40mg Injection, Hilton Pharma Karachi
	Pharmacotherapeutic Group of (API)	PPI
	Name, address of Manufacturing site:	SWERA PHARMACEUTICALS -Plot# 27, Street No. S-4, RCCI-Rawat, Islamabad-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Pantoera (Pantoprazole) 40mg 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	
560	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	(E5R-4BD-JN17, 2026-02-09)
	Detail of Fee Submitted	97200, 2026-01-21,
	The proposed proprietary name / brand name	**WINLAMOX DRY SUSPENSION**
	Label Claim	Each 5ml of reconstituted suspension contains: Ammoxicillin trihydrate eq. to Amoxicillin.....250mg Potassium clavulanate eq. to Clavulanic acid....62.5mg (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 Centigrade
	For generic drugs (me-too Status)	Augmentin 312.5mg/5ml Dry suspension of M/s GSK Pakistan
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	Skywin Pharmaceutical-Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road-
	The status in reference regulatory authorities	Augmentin 312.5mg/5ml Dry Suspension of M/s GlaxoSmithKline Research Triangle Park, NC 27709 (USFDA Approved)
	Detail of previous approval	Amoxi 312.5mg/5ml Dry Suspension Approved in Minutes of 344th 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	
561	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	(GZR-T4P-ZGYR, 2026-02-09)
	Detail of Fee Submitted	97200, 2026-01-21,
	The proposed proprietary name / brand name	**WINLAMOX DRY SUSPENSION**
	Label Claim	Each 5ml of reconstituted suspension contains: Ammoxicillin trihydrate eq. to Amoxicillin.....125mg Potassium clavulanate eq. to Clavulanic acid....31.25mg (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 Centigrade
	For generic drugs (me-too Status)	Augmentin 156.25mg/5ml Dry suspension of M/s GSK Pakistan
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	Skywin Pharmaceutical-Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road-
	The status in reference regulatory authorities	Augmentin 156.25mg/5ml Dry Suspension of M/s GlaxoSmithKline Research Triangle Park, NC 27709 (USFDA Approved)
	Detail of previous approval	Amoxi 156.25mg/5ml Dry Suspension Approved in 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	
562	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	(H9D-QSE-LM41, 2026-03-04)
	Detail of Fee Submitted	97200, 2026-02-02,
	The proposed proprietary name / brand name	**PARAMIN TABLET 500mg+25mg**

	Label Claim	Each Film Coated Tablet Contains: Paracetamol...500mg Diphenylhydramine HCl...25mg (Manufacturer's specifications)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25 degree Centigrade
	For generic drugs (me-too Status)	Panadol night tablets of M/s Haleon
	Pharmacotherapeutic Group of (API)	Paracetamol, Combinations excluding Psycholeptics
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Lahore.-
	The status in reference regulatory authorities	TYLENOL PM EXTRA STRENGTH, approved as Human OTC Drug in US
	Detail of previous approval	Peradol-D 500/25 mg Tablet Approved in Minutes of 343rd Meeting of Registration Board (01st – 02nd J
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**Winthrox Laboratories Pvt. Ltd** K-219-A, SITE, Super Highway Phase II, Karachi **(000807)**
	Application Form Dy. No / Tracking ID & date of submission	(HHP-B1Z-XPQB, 2026-02-17)
	Detail of Fee Submitted	97200, 2026-02-02,
	The proposed proprietary name / brand name	**MIROWIN TABLET 10mg**
	Label Claim	Each film-coated tablet contains: Mirogabalin besylate equivalent to Mirogabalin.....10mg (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 Centigrade.
	For generic drugs (me-too Status)	Mirogab 10mg Tablet
	Pharmacotherapeutic Group of (API)	Neuropathic pain
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Lahore.-
	The status in reference regulatory authorities	Tarlige Tablets 10mg of M/s Daiichi Sankyo Co., Ltd (PMDA Approved)
	Detail of previous approval	Mirogab Tablet 10mg Approved in Minutes of 344th 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	
564	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	(LAX-54R-WX3A, 2026-02-09)
	Detail of Fee Submitted	97200, 2026-01-21,
	The proposed proprietary name / brand name	**WINLAMOX TABLET 625mg**
	Label Claim	Each film coated tablet contains: Amoxicillin trihydrate eq. to Amoxicillin.....500mg Potassium clavulanate eq. to Clavulanic acid....125mg (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 Centigrade
	For generic drugs (me-too Status)	Augmentin 625mg Tablets of M/s GSK Pakistan
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	Skywin Pharmaceutical-Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road-
	The status in reference regulatory authorities	AUGMENTIN (amoxicillin/clavulanate potassium) M/s GlaxoSmithKline USFDA APPROVED
	Detail of previous approval	Amoxi 625mg Tablet Approved in Minutes of 344th Meeting of Registration Board (31st 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	
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	(TUS-118-H7AR, 2026-02-17)
	Detail of Fee Submitted	97200, 2026-02-11,

	The proposed proprietary name / brand name	**MIROWIN TABLET 2.5mg**
	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 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Mirogab 2.5mg Tablet BY Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore(000789)
	Pharmacotherapeutic Group of (API)	Gabapentinoids indicated for Neuropathic pain
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd-129-Sunder 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 Tablet 2.5mg Approved Minutes of 344th meeting of Registration Board (31st 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	
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	(UP6-VZV-HELR, 2026-02-17)
	Detail of Fee Submitted	97200, 2026-02-02,
	The proposed proprietary name / brand name	**MIROWIN TABLET 5mg**
	Label Claim	Each Film coated tablet containsMirogabalin besilate equivalent to Mirogabalin..... 5mg (As per Innovators Specification)
	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 Centigrade
	For generic drugs (me-too Status)	Mirogab 5mg Tablet by WIMITS PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	Gabapentinoids indicated for Neuropathic pain
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Lahore.-
	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 Approved in Minutes of 344th 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	
567	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Aurik Pharmaceuticals Pvt Ltd** PLOT # 6 & 7 ST # S-9 NATIONAL INDUSTRIAL ZONE, RAWAT, RAWALPINDI **(000802)**
	Application Form Dy. No / Tracking ID & date of submission	(HGP-TB6-3QHY, 2026-02-11)
	Detail of Fee Submitted	97200, 2026-01-21,
	The proposed proprietary name / brand name	**Anotin 20 mg Capsule**
	Label Claim	Each capsule contains: Isotretinoin..... 20mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10'S-As per SRO
	Shelf Life (Unit)	2 YearRoom Condition
	For generic drugs (me-too Status)	soft gelatin capsule shell Crystolite Pharmaceutical
	Pharmacotherapeutic Group of (API)	Retinoids for treatment of Acne
	Name, address of Manufacturing site:	BIOGEN LIFE SCIENCES-8Km,Chakbeli Road Rawat, Rawalpindi-
	The status in reference regulatory authorities	DRAP
	Detail of previous approval	BIOTAN 20MG CAPSULE Minutes of 3l2th 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	
568	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Health care pharmaceuticals** 40 km lahore Road multan **(000905)**
	Application Form Dy. No / Tracking ID & date of submission	(J4H-NQ1-DVWU, 2026-02-17)
	Detail of Fee Submitted	97200, 2026-02-06,

	The proposed proprietary name / brand name	**Vonoz**
	Label Claim	Each film coated tablet contains: Vonoprazan as Fumarate.....20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Yearbelow 30°C
	For generic drugs (me-too Status)	Fildil 20mg tablet by M/s Highnoon Laboratories
	Pharmacotherapeutic Group of (API)	Anti-ulcer
	Name, address of Manufacturing site:	Quaper (Pvt) Ltd-26-A, small Industrial Estate Lahore Road Sargodha-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	meeting No. 330, Quzan 20mg tablet (extract of meeting is attached)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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.	**Kanel Pharma** Plot No. 6, Street No. SS-3, National Industrial Zone, Rawat **(000758)**
	Application Form Dy. No / Tracking ID & date of submission	(LGY-4QU-TR9J, 2026-01-27)
	Detail of Fee Submitted	93000.0, 4200.0 2025-07-31, 2025-09-10
	The proposed proprietary name / brand name	**Gestofin 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-As per SRO
	Shelf Life (Unit)	2 YearControlled Room Temprature
	For generic drugs (me-too Status)	Duphaston 10 mg Tablets by Abbott
	Pharmacotherapeutic Group of (API)	GENITO URINARY SYSTEM AND SEX HORMONES
	Name, address of Manufacturing site:	M/S SKYWIN PHARMACEUTICALS-Plot # 01, Al Badar Industrial Estate, Phase II Sheikhupura Road Lahore.-
	The status in reference regulatory authorities	HPRA Ireland Approved
	Detail of previous approval	TABLET D-GEST 10 MG, 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	