

**MINUTES OF 359TH MEETING OF REGISTRATION BOARD
HELD ON 09TH JUNE, 2026**

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

359th meeting of Registration Board was held on 09th June, 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
2.	Brig. Zahid Farooq Baig, Professor of Medicine/ General Medicine Nephrologist, Combined Military Hospital, Kharian.	Member (Virtual)
3.	Dr. Syed Asad Ali Shah, Principal Animal Husbandry In-Service Training Institute, Peshawar.	Member (Virtual)
4.	Dr. Tehseen Fatima, Dow College of Biotechnology, Dow University of Health Sciences, Karachi.	Member (Virtual)
5.	Syed Adnan Rizvi, Director Drugs Testing Laboratory, Govt. of Sindh, Karachi.	Member (Virtual)
6.	Mr. Imranullah Khan, Director Drugs Testing Laboratory, Govt. of Khyber Pakhtunkhuwa, Peshawar.	Member (Virtual)
7.	Mr. Muzzamil Waheed, Director, Drugs Testing Laboratory, Govt. of Punjab, Faisalabad.	Member (Virtual)
8.	Mr. Ghulam Mujtaba, Deputy Director, Representative of IPO, Islamabad.	Member (Virtual)
9.	Miss Sadia Mahwish, Deputy Director, Representative of Quality Assurance & Lab Testing Division, DRAP.	Member
10.	Dr. Ghazanfar Ali Khan, Director, of Biological Evaluation & Research Division, DRAP.	Member
11.	Hafiz M. Ali Tayyab, Additional Pharmaceutical Evaluation & Registration Division / Secretary Registration Board.	Member

Item No. I Confirmation of minutes of 358th meeting of Registration Board.

358th meetings of Registration Board were held on 12th May, 2026. Accordingly, draft minutes of the 358th meeting of Registration Board were prepared and circulated among the members through email for their perusal / approval / comments (if any). Following comments have been received;

i. Syed Adnan Rizvi, Director, Drugs Testing Laboratory, Govt. of Sindh, Karachi through email dated 23-05-2026 informed that;

I am submitting following concerns/reservations/observations/recommendations in respect of 358th Meeting of the Registration Board held on 12 May 2026;

1. Mandatory Submission of Risk Management Plan for New Molecules and Biological Entities

It is proposed that submission of a comprehensive Risk Management Plan (RMP) should be made mandatory for all new molecules and biological entities from now onwards.

The RMP should comprehensively address:

Pharmacovigilance activities

Risk minimization measures

Signal detection and safety monitoring mechanisms

Post marketing surveillance commitments

Periodic safety update reporting

Risk communication strategies

Additional pharmacovigilance activities where applicable

The proposed framework should align with internationally recognized regulatory principles and recommendations issued by the World Health Organization, European Medicines Agency, and International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.

Implementation of mandatory RMP requirements would significantly strengthen lifecycle safety monitoring and pharmacovigilance oversight for innovative therapies biologicals and novel therapeutic entities.

2. Strict Regulatory Action on Data Integrity Violations and Forged Data

The Board strongly emphasized that intentional manipulation fabrication concealment forgery or falsification of submitted data represents a grave violation of regulatory ethics scientific integrity and public health protection principles.

Such practices directly compromise the credibility of the national regulatory system and may expose patients to serious health risks due to reliance on inaccurate or misleading evidence.

Accordingly the following actions are recommended:

Issuance of an official regulatory advisory or circular regarding mandatory compliance with data integrity requirements

Strict regulatory and legal proceedings against companies or individuals involved in fabricated manipulated or forged submissions

Suspension blacklisting cancellation of registrations or debarment for repeat violations

Establishment of structured data integrity inspection and audit mechanisms

Verification of raw data analytical records manufacturing records and electronic data trails during evaluation and inspection processes

Alignment with internationally accepted ALCOA and ALCOA+ data integrity principles

These measures are necessary to preserve transparency scientific credibility and public confidence in the medicines regulatory system.

3. Concern Regarding Approval of Colistin Containing Veterinary Products

The Board extensively discussed cases related to veterinary formulations containing Colistin Sulphate and Colistimethate Sodium 2 MIU equivalent to Colistin base activity.

It was previously resolved that such cases should be referred to the Livestock and Dairy Development Board under the Ministry of National Food Security and Research for expert opinion considering the serious antimicrobial resistance implications associated with Colistin use.

However substantial inconsistency was observed in regulatory decision making.

In Case #367 quoting DRB 358 approval the Board specifically stated:

“The Board referred the case of Colistin containing products to the Sub Committee on Veterinary Drugs for their opinion on use of Colistin in veterinary formulations.”

Whereas in multiple other cases including Case #260 262 270 271 282 284 285 288 294 298 300 301 302 304 306 308 310 311 312 322 323 324 342 354 355 360 361 362 364 365 366 370 372 375 376 377 378 379 386 388 389 391 441 442 443 444 462 463 464 465 466 467 468 and 477 products were approved without referral for expert antimicrobial resistance or veterinary review.

This inconsistency raises serious scientific regulatory and public health concerns because Colistin is globally recognized as a critically important last line antimicrobial reserved for treatment of multidrug resistant Gram negative bacterial infections in humans.

The increasing emergence of carbapenem resistant organisms including resistance to Meropenem has further elevated the importance of preserving Colistin efficacy.

4. International Scientific Evidence and One Health Concerns

A major multidisciplinary study published in The Lancet Microbe titled:

“International manufacturing and trade in colistin its implications in colistin resistance and One Health global policies”

investigated microbiological economic anthropological and regulatory dimensions of Colistin use and resistance across several countries including Pakistan.

The study involved researchers from the University of Agriculture Faisalabad and the University of Oxford among other international institutions.

The investigators analyzed Colistin importation manufacturing farm level use and prevalence of colistin resistant Enterobacterales in humans animals and environmental sources.

The study concluded that despite global antimicrobial resistance commitments Colistin continues to be extensively used in food producing animals for:

Therapeutic use

Metaphylaxis

Prophylaxis

Growth promotion purposes

Pakistan was identified as a significant consumer of veterinary antimicrobials particularly in intensive poultry farming systems.

5. Emergence of MCR Mediated Colistin Resistance

Global concern intensified following discovery of the mobile colistin resistance gene MCR 1 in 2015 among *Escherichia coli* isolates obtained from pigs pork products and hospitalized patients in China.

The significance of MCR mediated resistance is particularly alarming because these organisms frequently co harbor additional multidrug resistance determinants rendering infections extremely difficult and in some instances nearly impossible to treat.

Subsequently multiple MCR variants have spread internationally across human animal food and environmental ecosystems representing a major One Health antimicrobial resistance threat.

Pakistani studies have also demonstrated emergence of colistin resistant Gram negative organisms among carbapenem resistant isolates further narrowing therapeutic options.

6. WHO Recommendations Regarding Antibiotic Use in Animals

The World Health Organization in its 2017 global guidance titled:

“Stop using antibiotics in healthy animals to prevent the spread of antibiotic resistance”

strongly recommended discontinuation of routine use of medically important antibiotics in healthy food producing animals for growth promotion and disease prevention purposes.

WHO Guidance on Antibiotic Use in Animals

WHO further classified polymyxins including Colistin among the “highest priority critically important antimicrobials” for human medicine.

WHO recommendations specifically include:

Restriction of antibiotics for growth promotion

Restriction of prophylactic use in healthy animals

Reduction of medically important antimicrobial consumption in food animals

Strengthening antimicrobial stewardship and surveillance systems

WHO also highlighted that approximately 80 percent of medically important antibiotic consumption in some countries occurs within the animal sector.

7. Pakistani Clinical Concerns Regarding Colistin Use

A Pakistani clinical guidance publication titled:

“Drug Use Recommendations for Colistin Injection in the Adult Population”

published in the Journal of Ayub Medical College Abbottabad highlighted growing concerns regarding irrational and unstandardized Colistin use within Pakistan.

Drug Use Recommendations for Colistin Injection in Adults

The guidance emphasized:

Colistin is a salvage therapy for severe multidrug resistant infections

Pakistan lacked standardized national Colistin use guidance

Rational prescribing administration and monitoring are critically necessary

Emergence of Colistin resistant pathogens threatens patient safety and therapeutic effectiveness

These findings reinforce the urgent need for national antimicrobial stewardship and tighter regulatory control.

8. International Regulatory Restrictions on Veterinary Colistin Use

International regulatory authorities have also initiated restrictions on veterinary and feed related Colistin use.

The National Agency for Food and Drug Administration and Control issued a regulatory directive prohibiting use of Colistin as a coccidiostat in animal feed due to growing antimicrobial resistance concerns.

NAFDAC Regulatory Directive on Colistin Use in Animal Feed

The directive acknowledged:

Colistin is a last resort antimicrobial for multidrug resistant infections in humans

Excessive veterinary antimicrobial exposure accelerates resistance emergence

Colistin resistance mechanisms are increasingly associated with carbapenem resistant organisms

Resistance to both carbapenems and Colistin may severely compromise available treatment options

These international developments demonstrate a growing global regulatory trend toward restriction and stewardship of Colistin use in veterinary sectors.

9. Recommendations

In light of the above scientific regulatory and public health concerns the following recommendations are proposed:

Mandatory expert review of all Colistin containing veterinary formulations by LDDB or an independent antimicrobial resistance committee

Immediate national policy review regarding continued veterinary use of Colistin particularly for growth promotion prophylaxis and non therapeutic purposes

Restriction of Colistin use solely for justified therapeutic indications under qualified veterinary supervision

Prohibition of Colistin use as growth promoter feed additive or routine prophylactic agent

Development of national DRAP guidelines for rational Colistin use in human and veterinary sectors

Establishment of national antimicrobial stewardship frameworks based on One Health principles

Enhanced pharmacovigilance and antimicrobial resistance surveillance systems for critically important antimicrobials

Reassessment of already approved Colistin containing veterinary products in light of emerging antimicrobial resistance evidence

Alignment of Pakistan's future regulatory policies with WHO antimicrobial resistance containment strategies and global stewardship frameworks.

ii. Dr. Ali Jan, Director, Drugs Testing Laboratory, Govt. of Baluchistan , Quetta through email dated 23-05-2026 informed that;

Keeping in view the registration of Colistin-containing products, I respectfully submit the following suggestion as Member of the Registration Board:

Registration of Colistin-containing products, particularly veterinary formulations, may be considered with caution in line with the recommendations of the World Health Organization, keeping in view the growing concern of antimicrobial resistance (AMR), as Colistin is an important last-resort therapeutic option in human medicine.

It is further suggested that both already registered products and new applications of Colistin may be dealt with uniformly under an across-the-board policy review. The cases may be

referred to the Expert Working Group for evaluation and suggestions, so that a consistent regulatory approach may be adopted and implemented across the board.

Accordingly, fair minutes of 358th meeting were processed to Chairman, Registration Board for perusal/approval. After approval from Chairman Registration Board, fair minutes of 358th meeting of Registration Board were circulated among concerned divisions/sections for implementation.

Decision:-

Registration Board confirmed the minutes of the 358th meeting along with following additional decisions:-

- 1. Submission of RMP before consideration of registration of new drug and biological.**
- 2. Issuance of advisory to pharmaceutical industry regarding mandatory compliance with data integrity requirements. DRAP is committed to ensuring accuracy in data review, however, inadvertent human errors may occur during disposal of pendency with limited human resource. Fictitious submissions pointed out at any stage even after regulatory approval will be dealt with strict regulatory actions.**
- 3. Referred the matter for use of Colistin in the veterinary formulation to already constituted Expert Working Group on Foot and Mouth Disease, for their consideration and recommendations.**
- 4. Recommendations to the Authority for allowing loaning of API with strict regulatory compliance. In case of any fictitious submissions, regulatory actions may be initiated against violators.**

Registration-II Section

Case. No.01: Request Of M/s CCL Pharmaceuticals (Pvt.) Ltd. 62-Quaid-E-Azam Industrial Estate, Kot Lakhpat, Lahore for De-Registration of Registered Product.

M/s CCL Pharmaceuticals (Pvt.) Ltd. 62-Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore was granted registration for bulk import and local blistering, packaging vide letter no. F.5-4/2019-Reg-II (M-291) dated 15th May 2020 for following products. Now the firm has requested for de-registration of their registered product as per details mentioned alongside.

Sr. No	Product(s) Name	Reg. No.	Reason for De-Reg. (stated by firm)	Name of the Manufacturer of Soft Gel
1.	Isotret 10mg Soft Gelatin Capsule Each softgel capsule contains: Isotretinoin 10mg (USP Specifications)	101805	The firm wants to shift the manufacturing of these products locally on contract manufacturing from M/s. Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi and same have been very kindly approved by DRB in its 353rd meeting held on 14th – 15th January 2026.	M/s Phil Inter Pharma Co. Ltd., No. 25, Street No. 8, VSIP, Thuan An District, Binh Duong, Vietnam.
2.	Isotret 20mg Soft Gelatin Capsule Each softgel capsule contains: Isotretinoin 20mg (USP Specifications)	101806	They requested to cancel registration of above said products for CCL Pharmaceuticals Pvt. Ltd., 62 Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore (DML000052) at your earliest and issue registration of product approved in 353rd meeting of DRB on contract manufacturing.	

Decision: Registration Board acceded to request of the firm and decided to cancel the registration of Isotret 10mg Soft Gelatin Capsule Reg. No. 101805 and Isotret 20mg Soft Gelatin Capsule Reg. No. 101806 in the name of M/s CCL Pharmaceuticals (Pvt.) Ltd. 62-Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.

Import & Vet Section

1.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Amazole-10 Oral Drench
	Composition	Each ml contains: Albendazole 100mg Cobalt Sulphate 0.75mg Sodium Selenite 0.35mg
	Diary No. Date of R& I & fee	Dy. No. 23289 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 65429873748)
	Pharmacological Group	Anthelmintic/minerals
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml; Decontrolled
	Me-too status	Could not be confirmed
	GMP status	New DML
	Remarks of the Evaluator ^X	Shortcomings:

		Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: :(M-331)Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. Firm submit generic status Reg. 075666 ALBA 10 SUSPENSION Decision: Approved.	
2.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Dairytone-M Powder
	Composition	Each Kg contains: Calcium as Dicalcium Phosphate...155gm Phosphorous as Dicalcium Phosphate...135gm Magnesium as Magnesium Oxide...55gm Sodium as Sodium Chloride...45gm Iron as Ferrous Sulphate...1gm Zinc as Zinc Sulphate...3gm Manganese as Manganese Sulphate...2gm Copper as Copper Sulphate.. 0.6gm Cobalt as Cobalt Chloride. 0.01gm Iodine as Potassium Iodide. 0.04gm Selenium as Sodium Selenite. 0.003gm
	Diary No. Date of R& I & fee	Dy.No 7379 dated 14-03-2023 Rs.30,000/- dated 14-03-2023 (slip No. 36358257072)
	Pharmacological Group	Dietary supplement of essential macro and micro minerals
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 200gm, 500gm, 1Kg, 5Kg, 10Kg, 20Kg; Decontrolled
	Me-too status	HS-Minerals Powder of M/s Mylab (Pvt) Ltd, Bahawalpur. (Reg. No. 112272)
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator	Target species:
		Cattle, calves, sheep, goats Oral Powder (General) section confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML renewal Shortcomings: The applied formulation contains different salt form of Sodium than the reference product. So, provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.

Decision: (M-339) Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.

Remarks:

The composition of the me-too product is the same in all aspects except for sodium: the applied product contains sodium as sodium chloride (45 g), whereas the me-too product contains sodium as sodium sulphate anhydrous (45g).

Decision: (M-358) Deferred for evidence of applied formulation/drug already approved by DRAP (generic/ me-too status) along with registration number, brand name and name of firm.

Firm requested on official website of DRAP composition of complete salt form is not mentioned, however they are agreed for composition as per generic.

Decision: Approved. Firm shall submit pre-registration variation fee for standardization of formulation.

RRR Section

Case No.1. M/s. Lisko Pakistan (Pvt) Ltd.L-10/D Block 21 Federal B Industrial Area Karachi.

1.	Brand Name + Dosage Form and Strength	Parapol DS 250mg/5ml
	Composition	Each 5ml contains: Paracetamol....250mg
	Dairy No. date of R &I fee	Rs.38700/- (Tracking ID: XP9-TPH-X6AW)
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	60ml and 120ml As per SRO.
	Me-too status	Fevonor Plus Suspension (Paracetamol 250mg/5ml) Company: Global Pharmaceuticals Pvt Ltd
	RRA Status	Medinol Over 6 250mg/5ml oral suspension. HPRA Approved
	GMP Status	Last GMP inspection conducted on 2nd June, 2024 DML renewal conducted on 17 th February 2025 wherein Oral Liquid (general) section is mentioned
	Remark of the Renewal section	Registration of Parapol DS 250mg/5ml (021880) invalid due to non-submission of renewal application within prescribe time period. Last renewal submitted in year 2008.
	Decision: Approved	
2.	Brand Name + Dosage Form and Strength	Kozypam Tablet 5mg
	Composition	Each tablet contains: Diazepam 5mg
	Dairy No. date of R &I fee	Rs.38700/- (Tracking ID: AQR-R1U-26JG)
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	28s,30s,42s,50s,56s,60s,84s,90s,100s,250s,500s & 100s As per SRO.
	Me-too status	1. VALIUM 5MG TAB (Diazepam 5mg) Company: Martin Dow Limited 2. APAURIN TABLET 5mg (Diazepam 5mg) Company: ISIS Pharmaceuticals & Chemical Works
	RRA Status	Anxicalm 5 mg Tablets .HPRA Approved
	GMP Status	Last GMP inspection conducted on 2nd June, 2024 DML renewal conducted on 17 th February 2025 wherein Tablet (Psychotropic) section is mentioned
	Remark of the Renewal section	Registration of Kozypam Tablet 5mg (006468) is invalid due to non-submission of renewal application within prescribe time period.

		Last renewal submitted in year 2017.
	Decision: Approved	
3.	Brand Name + Dosage Form and Strength	Diazepam tablet 2mg
	Composition	Each tablet contains: Diazepam.....2mg
	Dairy No. date of R &I fee	Rs.38700/- (Tracking ID: 792-MDR-J2D9)
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	30s,50s,90s,100s,250s,500s & 1000s As per SRO.
	Me-too status	1. VALIUM 2MG TAB (Diazepam 2mg) Company: Martin Dow Limited 2. VAZEPAM TABLET 2mg (Diazepam 2mg) Company: Valor Pharmaceuticals
	RRA Status	Anxicalm 2 mg Tablets HPRA approved
	GMP Status	Last GMP inspection conducted on 2nd June, 2024 DML renewal conducted on 17 th February 2025 wherein Tablet (Psychotropic) section is mentioned
	Remark of the Renewal section	Registration of Diazepam Tablet 2mg (006467) is invalid due to non-submission of renewal application within prescribe time period. Last renewal submitted in year 2017.
	Decision: Approved	

Case No.2. M/s. OPAL LABORATORIES (Pvt.) LIMITED of LC – 41, L.I.T.E., Landhi, Karachi.

1.	Brand Name + Dosage Form and Strength	BRADEx OPHTHALMIC SUSPENSION
	Composition	Each ml contains: Tobramycin.....3mg (0.3%) Dexamethasone.....1mg (0.1%)
	Dairy No. date of R &I fee	Rs.38700/- (Tracking ID: 2NN-RUZ-AY5V)
	Type of form	Fom-5
	Finished product specifications	USP
	Pack size and Demand Price	5ml As per SRO.
	Me-too status	Eyebradex Eye Drops 5ml by Barrett Hodgson Pakistan (Pvt) Ltd
	RRA Status	MHRA
	GMP Status	Last GMP inspection conducted on 23 rd July, 2025 Ophthalmic section is approved by CLB dated 31 st May 2021
	Remark of the Renewal section	Registration of Bradex ophthalmic suspension (031225) is invalid due to non-submission of renewal application within prescribed time period.
	Decision: Approved	

Pharmaceutical Evaluation Cell (PEC)

Case No. 01 M/s Otsuka Pakistan Ltd, No. F/4-9, Hub Industrial Trading Estate, Dist; Lasbela, Balochistan.

Name and address of manufacturer / Applicant	M/s Otsuka Pakistan Ltd, No. F/4-9, Hub Industrial Trading Estate, Dist; Lasbela, Balochistan.
Brand Name +Dosage Form + Strength	Amiparen I.V Infusion
Diary No. Date of R& I & fee	Dy. NO. 19595 dated 31/10/2017 Fee Rs. 20,000/-
Composition	Each 100ml contains: L-Leucine... 1.40g L-isoleucine... 0.80g L-Valine... 0.80g L-Lysine acetate... 1.48g L-Threonine... 0.57g L-Tryptophan... 0.20g L-Methionine... 0.39g L-Phenylalanine... 0.70g L-Cysteine... 0.10g L-Tyrosine... 0.05g L-Arginine... 1.05g L-Histidine... 0.50g L-Alanine... 0.80g Proline... 0.50g L-Serine... 0.30g Aminoacetic Acid... 0.59g L-Aspartic Acid... 0.10g L-Glutamic acid... 0.10g Water for injection... q.s
Pharmacological Group	Amino acid
Type of Form	Form 5
Finished Product Specification	Mfg specs
Pack Size & Demanded Price	500ml plastic (LDPE) bottle, Rs. 575/-
Approval Status of Product in Reference Regulatory Authorities	Could not be confirmed
Me-too Status	could not be confirmed with same composition and strength.
GMP Status	Last inspection report dated 13/12/2017, the firm is found good and compliant as per GMP requirement.
Remarks of the Evaluator.	The firm had initially applied for 500ml glass bottle and then the firm applied for LDPE bottle. Provide evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275 th meeting and already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm in LDPE bottle with same strength, and filled volume.
Decision of 295th meeting: Deferred for following: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm in LDPE bottle with same strength, and filled volume. Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in LDPE bottle with same strength, and filled volume.	

Firm's reply: Firm has submitted following information: Amipalene infusion of M/s Otsuka Pharmaceutical Factory Sales alliance: Otsuka Pharmaceutical Co., Ltd., approved by PMDA of Japan. The reference product is available in 200ml, 300ml & 400ml bag. 高カロリー輸液用総合アミノ酸製剤 (pmda.go.jp) Firm has also submitted stability study record including summary sheets, batch manufacturing records and HPLC chromatograms. Decision of 333rd meeting: Registration Board deferred the case for submission of complete stability studies data as per the checklist approved in 293rd meeting of Registration Board. Response by the firm: The firm has submitted R&I receiving for submission of data in hard form dated 27-03-2025 is submitted and the stability data was submitted again on June 13th, 2025, 3:26 pm vide Tracking ID No. GJL-85V-N55Q. The initial application was submitted on form 5 for 500mL and the stability data is submitted for 400mL filled volume. The firm has submit fee (Rs. 9030/-) challan No. 13798581891 dated 12-06-2025.		
STABILITY STUDY DATA		
Drug	Amiparen 400mL /infusion	
	Name of API	Manufacturer
API Lot No.	L-Leucine (001-230903A)	Ms Shantou Jiahe Biologic Technology Co. Ltd China
	L-isoleucine (004-231102A)	Ms Shantou Jiahe Biologic Technology Co. Ltd China
	L-Valine (003-230902A)	Ms Shantou Jiahe Biologic Technology Co. Ltd China
	L-Lysine acetate (20701240117)	M/s Wuxi Jinghai Amino Acid Co., Ltd., China Not as per zone IV-A
	L-Threonine (005-231001A)	Ms Shantou Jiahe Biologic Technology Co. Ltd China
	L-Tryptophan (211978)	M/s Kyowa Hakko Bio Co., Ltd. Japan Kyowa Hakko was the Japanese manufacturing facility of Shanghai Kyowa Amino Acid Co., Ltd. However, the plant has now been closed.
	L-Methionine (1000001737)	M/s Ajinomoto Co., INC, Japan
	L-Phenylalanine (002-231104A)	M/s Shantou Jiahe Biologic Technology Co. Ltd China
	L-Cysteine (36BC5F1)	M/s Nippon Protein Co. Ltd., Japan Form 6 dated 16-04-2024 for 20grams of material is submitted. The submitted stability data of DS is not according to zone IV-A.
	L-Tyrosine (21401240202)	M/s Wuxi Jinghai Amino Acid Co., Ltd., China Form 6 dated 26-03-2024 for 25kg material is submitted. The submitted stability data of DS is not according to zone IV-A.
	L-Arginine (23063935)	Ms Shanghai Kyowa Amino Acid co. ltd.,China The name of the DS manufacturer has been changed to M/s Shanghai Plumino amino Acd Co. Ltd., China
	L-Histidine (23HB14A014)	M/s Shanghai Ajinomoto Amino Acid Co., Ltd., China Form 6 dated 16-04-2024 for 50kg material is submitted.

		GMP certificate is not submitted. Written confirmation for GMP is submitted. The submitted stability data of DS is not according to zone IV-A.
	L-Alanine (23AL17B087)	M/s Shanghai Ajinomoto Amino Acid Co., Ltd., China GMP certificate is not submitted. Written confirmation for GMP is submitted. The submitted stability data of DS is not according to zone IV-A. The DS is being used for manufacturing of the registered product Aminovel and Aminoleban already by the firm.
	L-Proline (22121756)	M/s Shanghai Kyowa Amino Acid Co., Ltd., China The name of the DS manufacturer has been changed to M/s Shanghai Plumino amino Acid Co. Ltd., China The submitted stability data of DS is not according to zone IV-A. The DS is being used for manufacturing of the registered product Aminovel and Aminoleban already by the firm.
	L-Serine (23061134)	M/s Shanghai Kyowa Amino Acid Co., Ltd., China The name of the DS manufacturer has been changed to M/s Shanghai Plumino amino Acid Co. Ltd., China The submitted stability data of DS is not according to zone IV-A. The DS is being used for manufacturing of the registered product Aminoleban already by the firm
	Aminoacetic acid (Glycine) (1000002485)	M/s Shanghai Ajinomoto Amino Acid Co., Ltd., China
	L-Aspartic Acid (1161231206)	M/s Evonik Rexim (Nanjing) Pharmaceutical Co. Ltd., China Form 6 dated 16-04-2024 for 50kg material is submitted.
	L-Glutamic acid (1121230101)	M/s Evonik Rexim SAS, France. GMP has not been submitted. Form 6 dated 16-04-2024 for 50kg material is submitted.
Description of Pack (Container closure system)	LDPE 400mL infusion bottle	
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%	
Time Period	Real time: 06 months Accelerated: 06 months	

Frequency		Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, (months)	
Batch No.		TAM107F24	TAM108F24 TAM108F24
Batch Size		1210	1210 1210
Manufacturing Date		24-06-2024	24-06-2024 24-06-2024
Date of Initiation		18-07-2024	18-07-2024 18-07-2024
No. of Batches		03	
Date of Submission		R&I receiving for submission of data in hard form dated 27-03-2025 is submitted. June 13th, 2025, 3:26 pm vide Tracking ID No. GJL-85V-N55Q .	
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			
Sr. No.	Documents to Be Provided		Status
1.	Reference of previous approval of applications with stability study data of the firm.		Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.		Submitted
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.		Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer submitted
4.	Stability study data of API from API manufacturer		Submitted as per zone IV-A
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		Submittd
6.	Documents for the procurement of API with approval from DRAP (in case of import).		Submitted.
7.	Protocols followed for conduction of stability study		submitted.
8.	Method used for analysis of FPP		Submitted.
9.	Drug-excipients compatibility studies (where applicable)		submitted
10.	Complete batch manufacturing record of three stability batches.		Submitted.
11.	Record of comparative dissolution data (where applicable)		NA
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.		Not Submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)		Not Submitted.
Decision: Approved with innovator’s specifications. The registration letter will be issued after submission of: 1. Applicable fee for revision of specifications from manufacturer’s to innovator’s 2. Forced degradation studies for drug product as per guidelines.			

100	Name and address of manufacturer / Applicant	M/s Otsuka Pakistan Ltd, No. F/4-9, Hub Industrial Trading Estate, Dist; Lasbela, Balochistan.
	Brand Name +Dosage Form + Strength	Kidmin I.V Infusion
	Diary No. Date of R& I & fee	Dy. NO. 19596 dated 31/10/2017 Fee Rs. 20,000/-
	Composition	Each 100ml contains: L-Leucine..... 1.40g L-isoleucine.....0.90g L-Valine..... 1.00g L-Lysine acetate.....0.71g L-Threonine... ..0.35g L-Tryptophan... ..0.25g L-Methionine... ..0.30g L-Phenylalanine... 0.50g L-Cysteine.....0.10g L-Tyrosine... ..0.05g L-Arginine... ..0.45g L-Histidine..... 0.35g L-Alanine..... 0.25g L-Proline.....0.30g L-Aspartic Acid... 0.10g L-Serine. 0.30g L-Glutamic acid... 0.10g Water for injection....q.s
	Pharmacological Group	Amino acid
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	100ml plastic (LDPE) bottle, Rs. 575/-
	Approval Status of Product in Reference Regulatory Authorities	Could not be confirmed
	Me-too Status	could not be confirmed with same composition and strength.
	GMP Status	Last inspection report dated 13/12/2017, the firm is found good and compliant as per GMP requirement.
	Remarks of the Evaluator.	Initially the product with filled volume of 200ml (which is already registered) in glass bottle was applied but now you have applied for 100ml in LDPE bottle, therefore, Provide evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting and already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm in LDPE bottle with same strength, and filled volume. Submit requisite fee for change in the filled volume.
	Decision of 295th meeting: Deferred for following: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm in LDPE bottle with same strength, and filled volume. Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in LDPE bottle with same strength, and filled volume. Submission of requisite fee for change in filled volume of the applied product.	
	Firm's reply: Firm has submitted following information: Kydomin infusion of M/s Otsuka Pharmaceutical Factory Sales alliance: Otsuka Pharmaceutical Co., Ltd., approved by PMDA of Japan. The reference product is available in 200ml & 300ml bag. 腎不全用アミノ酸製剤 (pmda.go.jp)	

Decision of 33rd meeting: Registration Board deferred the case for submission of complete stability studies data as per the checklist approved in 293rd meeting of Registration Board.

Response by the firm:

The firm has submitted R&I receiving for submission of data in hard form dated 27-03-2025 is submitted and the stability data was submitted again on June 13th, 2025, 3:26 pm vide Tracking ID No. **JYM-R8N-YAND**. The firm has submitted fee challan of Rs. 9030/- No. 84166685821 dated 12-06-2025.

STABILITY STUDY DATA

Drug	Kidmin Injection 200mL	
	Name of API	Manufacturer
API Lot No.	L-Leucine (001-230903A)	Ms Shantou Jiahe Biologic Technology Co. Ltd China
	L-isoleucine (004-231102A)	Ms Shantou Jiahe Biologic Technology Co. Ltd China
	L-Valine (003-230902A)	Ms Shantou Jiahe Biologic Technology Co. Ltd China
	L-Lysine acetate (20701240117)	M/s Wuxi Jinghai Amino Acid Co., Ltd., China Not as per zone IV-A
	L-Threonine (005-231001A)	Ms Shantou Jiahe Biologic Technology Co. Ltd China
	L-Tryptophan (211978)	M/s Kyowa Hakko Bio Co., Ltd. Japan Kyowa Hakko was the Japanese manufacturing facility of Shanghai Kyowa Amino Acid Co., Ltd. However, the plant has now been closed.
	L-Methionine (1000001737)	M/s Ajinomoto Co., INC, Japan
	L-Phenylalanine (002-231104A)	M/s Shantou Jiahe Biologic Technology Co. Ltd China
	L-Cysteine (36BC5F1)	M/s Nippon Protein Co. Ltd., Japan Form 6 dated 16-04-2024 for 20grams of material is submitted. The submitted stability data of DS is not according to zone IV-A.
	L-Tyrosine (21401240202)	M/s Wuxi Jinghai Amino Acid Co., Ltd., China Form 6 dated 26-03-2024 for 25kg material is submitted. The submitted stability data of DS is not according to zone IV-A.
	L-Arginine (23063935)	Ms Shanghai Kyowa Amino Acid co. ltd., China The name of the DS manufacturer has been changed to M/s Shanghai Plumino amino Acid Co. Ltd., China
	L-Histidine (23HB14A014)	M/s Shanghai Ajinomoto Amino Acid Co., Ltd., China Form 6 dated 16-04-2024 for 50kg material is submitted. GMP certificate is not submitted. Written confirmation for GMP is submitted. The submitted stability data of DS is not according to zone IV-A.
	L-Alanine (23AL17B087)	M/s Shanghai Ajinomoto Amino Acid Co., Ltd., China GMP certificate is not submitted. Written confirmation for GMP is submitted.

		The submitted stability data of DS is not according to zone IV-A. The DS is being used for manufacturing of the registered product Aminovel and Aminoleban already by the firm.	
	L-Proline (22121756)	M/s Shanghai Kyowa Amino Acid Co., Ltd., China The name of the DS manufacturer has been changed to M/s Shanghai Plumino amino Acd Co. Ltd., China The submitted stability data of DS is not according to zone IV-A. The DS is being used for manufacturing of the registered product Aminovel and Aminoleban already by the firm.	
	L-Serine (23061134)	M/s Shanghai Kyowa Amino Acid Co., Ltd., China The name of the DS manufacturer has been changed to M/s Shanghai Plumino amino Acd Co. Ltd., China The submitted stability data of DS is not according to zone IV-A. The DS is being used for manufacturing of the registered product Aminoleban already by the firm.	
	L-Aspartic Acid (1161231206)	M/s Evonik Rexim (Nanjing) Pharmaceutical Co. Ltd., China Form 6 dated 16-04-2024 for 50kg material is submitted.	
	L-Glutamic acid (1121230101)	M/s Evonik Rexim SAS, France. GMP has not been submitted. Form 6 dated 16-04-2024 for 50kg material is submitted.	
Description of Pack (Container closure system)	LDPE infusion bottle 200mL		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, (months)		
Batch No.	TKID04F24	TKID05F24	TKID06F24
Batch Size	2403	2403	3000
Manufacturing Date	24-06-2024	24-06-2024	24-06-2024
Date of Initiation	24-06-2024	24-06-2024	24-06-2024
No. of Batches	03		
Date of Submission	R&I receiving for submission of data in hard form dated 27-03-2025 is submitted. June 13th, 2025, 3:26 pm vide Tracking ID No. JYM-R8N-YAND.		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.	Submitted
4.	Stability study data of API from API manufacturer	Submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	Submitted
10.	Complete batch manufacturing record of three stability batches.	Submitted
11.	Record of comparative dissolution data (where applicable)	NA
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Decision: Approved with innovator's specifications. The registration letter will be issued after submission of:

1. Applicable fee for revision of specifications from manufacturer's to innovator's

2. Forced degradation studies for drug product as per guidelines.

Case No. 02 Cases of Medisynth on General Request

Registration Board in its 323rd meeting approved the following product(s) in the name of **M/s Medisynth Pharmaceuticals, Plot No.55, Street No.S-5, National Industrial Zone, Rawat, Islamabad.** Registration letter was pending due to brand name resemblance / submission of data / documents as per decision of Board. The firm has submitted requisite documents / data vide Dy.No, 28419 dated 08-12-2023, 120 dated 02-01-2024 and tracking ID: 3ZN-G9E-V47E on 13-08-2025. However, the address of the DML holder was changed i.e. **M/s Medisynth Pharmaceuticals, Khasra no 1028/1029 Mouza Jellyari Gujri Tehsil Gujar khan Rawalpindi.**

Accordingly the Board in its 351st meeting held on 23rd – 24th September, 2025 decided as follows:

“Registration Board decided that the applicant shall submit new registration applications on CTD format for abovementioned products along with applicable fee of registration. These applications shall be considered out of queue.”

However, the firm has applied the following on General Request of e-APP instead of applying as application for registration:

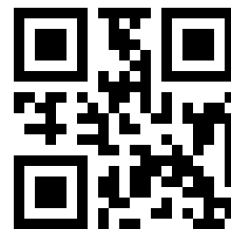
MEDISYNTH PHARMACEUTICALS Khasra No. 1028/1029, Mouza Jellyari Gujri, Tehsil Gujar Khan, District Rawalpindi DML No. 000718		
SNO	Application ID: DXV-LH4-EB4D	
1	The proposed proprietary name/brand name under which the drug is intended to be sold with trade mark certification/clearance.	Synprid 25mg Tablet
	Strength/concentration of Active Pharmaceutical ingredient (API) per unit. Each tablet contains:	Levosulpiride 25mg
	Application ID: J8N-8RW-38JQ	
2	The proposed proprietary name/brand name under which the drug is intended to be sold with trade mark certification/clearance.	Synprid 50mg Tablet
	Strength/concentration of Active Pharmaceutical ingredient (API) per unit. Each tablet contains:	Each tablet contains: Levosulpiride 50mg

Decision: Registration Board decided to consider cases of M/s. Medisynth Pharmaceuticals, Khasra no 1028/1029 Mouza Jellyari Gujri Tehsil Gujar khan Rawalpindi submitted on general request form for change of site and directed to refer the cases to PEC for evaluation.



Drug Regulatory Authority of Pakistan

(Pharmaceutical Evaluation & Registration Division)



Sr. No	Title	Description
1	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (000644)
	Application Form Dy. No / Tracking ID & date of submission	(X5T-PHB-A512, 2024-07-02)
	Detail of Fee Submitted	30000.0, 2024-05-14,
	The proposed proprietary name / brand name	Omiget 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-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°C
	For generic drugs (me-too Status)	Omaril Tablet by Genix Pharma
	Pharmacotherapeutic Group of (API)	dipeptidyl peptidase 4 (DPP-4) inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Data of three batches at 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	Performed; Omaril 12.5mg Tablet Batch No. O2654
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of three batches at long term and accelerated conditions
	The status in reference regulatory authorities	PMDA Japan
	GMP status of the firm	Required
	Evidence of approval of manufacturing facility	Drug Manufacturing License No. 000644
2	Evaluation Remarks	
	GMP required	
	Decision	
	Approved	
	Subject to provision of latest GMP report of the applicant	
	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Dr. Raza Pharma 44-C Hayatabad Industrial Estate Peshawar (000387)

	Application Form Dy. No / Tracking ID & date of submission	(B6E-L5T-768M, 2024-11-14)
	Detail of Fee Submitted	37000.0, 2024-10-24,
	The proposed proprietary name / brand name	Sita Plus
	Label Claim	Each film coated tablet contains: Sitagliptin Phosphate equivalent to sitagliptin.....50mg 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 YearBelow 30 degree C°
	For generic drugs (me-too Status)	Sitaphage (50-850)mg Tablet -
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	AURO LABORATORIES LIMITED ,M/S Pharmagen Limited
	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
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The data submitted for Analytical Method Validation of finished product, Comparative Dissolution Profile and Finished Product Stability is same as submitted by another firm vide application TID: 4UD-962-B55P	
3	Decision	
	Rejected	
	The Registration Board rejected the registration application for Sita Plus Tablet submitted by M/s Dr. Raza Pharma, Plot No. 44-C, Industrial Estate, Hayatabad, Peshawar for the following reasons:	
	a. submission of falsified data in Analytical method validation/verificaiton report and	
	b. submission of falsified data in stability of drug product	
	c. comparative dissolution profile report	
	Case Category	Routine (Abdul Mughees)
	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	(4UD-962-B55P, 2024-10-31)
	Detail of Fee Submitted	30000.0, 7000.0 2024-07-06, 2024-10-28

	The proposed proprietary name / brand name	Esa-Met (50-850)mg Tablet
	Label Claim	Each film coated Tablet contains: Sitagliptin Phosphate equivalent to sitagliptin 50mg Metformin HCl 850mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	2 YearBelow 30
	For generic drugs (me-too Status)	Sitaphage 50mg-850mg Tablet
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Aarti drugs 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	USFDA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The data submitted for Analytical Method Validation of finished product, Comparative Dissolution Profile and Finished Product Stability is same as submitted by another firm vide application TID: B6E-L5T-768M	
	Decision	
	Rejected	
4	The Registration Board rejected the registration application for Esa-Met (50-850)mg Tablet submitted by Naeem Pharmaceuticals (SMC-Pvt) Ltd., Plot No.95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan for the following reasons:	
	a. submission of falsified data in Analytical method validation/verificaiton report and	
	b. submission of falsified data in stability of drug product	
	c. comparative dissolution profile report	
	Case Category	Routine (Abdul Mughees)
	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	(V1S-532-LPRY, 2024-07-04)
	Detail of Fee Submitted	75000.0, 2024-06-26,
	The proposed proprietary name / brand name	RelaGen 50mg Tablet
	Label Claim	Each Film Coated Tablet containing: Trelagliptin Succinate eq. to 50 mg of Trelagliptin
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	4's-As per SRO

	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	Trelaget Tablet. (Getz Pharma)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Mark Pharmaceuticals -Plot # 527, Sundar Industrial Estate, Lahore-
	Name & address of API manufacturer	Anhui Haikang Pharmaceutical Co., Ltd. No. 21 Huancheng West Road Anqing Anhui 246000 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	Zafatec ® Teijin Pharma Ltd. Approved in PMDA Japan.
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	similar data as of another company with respect to AMV of ifnished drug product, stability testing, chromatograms (same file name and other attributes) etc. Same data as Q7R-63Y-GT2E	
	Decision	
	Rejected	
	The Registration Board rejected the registration application for RelaGen 50mg Tablet submitted by M/s Genetics Pharmaceuticals Pvt. Ltd, 539-A Sundar Industrial Estate Raiwind Road Lahore for the following reasons: a. submission of falsified data in Analytical method validation/verificaiton report and b. submission of falsified data in stability of drug product	
5	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Quaper pvt Ltd 26-A small industrial estate Lahore road Sargodha (000609)
	Application Form Dy. No / Tracking ID & date of submission	(Q7R-63Y-GT2E, 2024-07-10)
	Detail of Fee Submitted	30000.0, 2024-07-09,
	The proposed proprietary name / brand name	TRELA 50MG
	Label Claim	each film coated tablet contains:Trelagliptin succinate eq.to Trelagliptin.....50mg
	Reference to Finished product specifications	
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature 25 degree centigrade(excursions permitted from 15 to 30 degree centigrade)
	For generic drugs (me-too Status)	TRELGET 50MG TABLET
	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	PMDA Japan
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	similar data as of another company with respect to AMV of ifinished drug product, stability testing, chromatograms (same file name and other attributes) etc. Same data as V1S-532-LPRY	
	Decision	
	Rejected	
	The Registration Board rejected the registration application for TRELA 50MG submitted by M/s Quaper pvt Ltd., 26-A Small Industrial Estate, Lahore Road, Sargodha for the following reasons:	
	a. submission of falsified data in Analytical method validation/verificaition report and b. submission of falsified data in stability of drug product	
6	Case Category	Routine (Abdul Mughees)
	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	(LUM-631-PH6V, 2024-11-13)
	Detail of Fee Submitted	37000.0, 2024-10-09,
	The proposed proprietary name / brand name	T-Glip Tablet 100 mg
	Label Claim	T-Glip Tablet 100 mg Each Film Coated Tablet containing: Trelagliptin Succinate eq. to 100 mg of Trelagliptin.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearAccelerated 40 °C± 2°C/75% ± 5% RH, Long term 30 °C± 2°C /65% ± 5% RH
	For generic drugs (me-too Status)	Trelaget Tablet by Getz Pharma is DRAP Approved
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Shandong Xier Kangtai 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	Teijin Pharma Ltd 100 mg® Film Coated Tablet is Approved in PMDA Japan.
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The AMV submitted for finished product and the submitted stability chromatograms have same file names, retention time and injection time as submitted by other applicant, application TID U2Y-7NY-DSLZ	
	Decision	
	Rejected	
	The Registration Board rejected the registration application for T-Glip Tablet 100 mg submitted by M/s Cunningham Pharmaceuticals (Pvt.) Ltd. Plot No. 81 - Sunder Industrial Estate, Raiwind Road, Lahore- Pakistan for the following reasons:	
	a. submission of falsified data in stability of drug product	
7	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Quaper pvt Ltd 26-A small industrial estate Lahore road Sargodha (000609)
	Application Form Dy. No / Tracking ID & date of submission	(U2Y-7NY-DSLZ, 2024-07-10)
	Detail of Fee Submitted	,
	The proposed proprietary name / brand name	TRELA 100MG
	Label Claim	Each film coated tablet contains:Trelagliptin succinate eq.to Trelagliptin.....100mg
	Reference to Finished product specifications	
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature 25 degree centigrade(excursions permitted from 15 to 30 degree centigrade)
	For generic drugs (me-too Status)	TREAGET 100 MG TABLET
	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	PMDA Japan
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The AMV submitted for finished product and the submitted stability chromatograms have same file names, retention time and injection time as submitted by other applicant, application TID LUM-631-PH6V	

	Decision	
	Rejected	
	The Registration Board rejected the registration application for TRELA 100MG submitted by M/s Quaper pvt Ltd., 26-A Small Industrial Estate, Lahore Road, Sargodha for the following reasons: a. submission of falsified data in Analytical method validation/verificaiton report and b. submission of falsified data in stability of drug product	
8	Case Category	Routine (Abdul Mughees)
	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	(U1M-2LW-R4ML, 2024-10-09)
	Detail of Fee Submitted	37000.0, 2024-09-19,
	The proposed proprietary name / brand name	T-Glip Tablet 50 mg.
	Label Claim	T-GLIP TABLET 50 mg. Each Film Coated Tablet containing: Trelagliptin Succinate eq. to 50 mg of Trelagliptin.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearAccelerated 40 °C± 2°C/75% ± 5% RH, Long term 30 °C± 2°C /65% ± 5% RH
	For generic drugs (me-too Status)	Trelaget Tablet by Getz Pharma is DRAP Approved.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Shandong Xier Kangtai 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	Teijin Pharma Ltd 50 mg® Film Coated Tablet is Approved in PMDA Japan.
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The AMV submitted for finished product, CDP data submitted by the applicant and stability chromatograms have same file names, retention time and injection time as submitted by other applicant, application TIDs V1S-532-LPRY, Q7R-63Y-GT2E	
	Decision	
	Rejected	

The Registration Board rejected the registration application for T-Glip Tablet 100 mg submitted by M/s Cunningham Pharmaceuticals (Pvt.) Ltd. Plot No. 81 - Sunder Industrial Estate, Raiwind Road, Lahore- Pakistan for the following reasons:

- a. submission of falsified data in stability of drug product
- b. submission of falsified data in analytical method validation
- c. submission of falsified data in stability of drug product

9	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Scilife Pharma Private Limited FD-57/58-A2, Korangi Creek Industrial Park (KCIP) (000837)
	Application Form Dy. No / Tracking ID & date of submission	(58Q-MGJ-YDXQ, 2024-08-26)
	Detail of Fee Submitted	30000.0, 2024-08-06,
	The proposed proprietary name / brand name	Scilina-M XR Tablet 12.5/2.5/1000mg
	Label Claim	Each film-coated tablet contains: Empagliflozin.....12.5mg Linagliptin.....2.5mg Metformin HCl USP....1000mg (as extended release)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x7s (14s)-As per SRO,4x7s (28s)-As per SRO,8x7s (56s)-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 25°C. (Excursions permitted between 15°C to 30°C). Protect from Sunlight and moisture.
	For generic drugs (me-too Status)	Linjardy-M 12.5/2.5/1000mg Tablet
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Fuxin Long Rui Pharmaceutical Co.,Ltd. Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China,Shouguang Fukang Pharmaceutical Co., Ltd. Address: North-East of Dongwaihuan Road, Dongcheng Industrial Area China
	Detail of stability batches of drug product	03 batches of 3000 tablets at 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	Performed; Trijardy XR 12.5/2.5/1000mg by M/s Boehringer Ingelheim Pharmaceuticals, USA.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 batches at long-term and accelerated conditions
	The status in reference regulatory authorities	Trijardy XR 12.5/2.5/1000mg by M/s Boehringer Ingelheim Pharmaceuticals, USA. USFDA Approved
	GMP status of the firm	GMP certificate of 07th March 2023
	Evidence of approval of manufacturing facility	DML

	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
10	Approved	
	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Scilife Pharma Private Limited FD-57/58-A2, Korangi Creek Industrial Park (KCIP) (000837)
	Application Form Dy. No / Tracking ID & date of submission	(4SG-AJR-T86H, 2024-09-13)
	Detail of Fee Submitted	30000.0, 45000.0 2024-08-06, 2024-09-11
	The proposed proprietary name / brand name	Scilina-M XR 25/5/1000mg Tablet
	Label Claim	Each film-coated tablet contains: Empagliflozin.....25mg Linagliptin.....5mg Metformin HCl USP....1000mg (as extended release)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2 x 7 (14) -As per SRO, 4 x 7 (24) -As per SRO, 8 x 7 (56) -As per SRO
	Shelf Life (Unit)	2 Year(s) Store at 25°C. (Excursions permitted between 15°C to 30°C). Protect from Sunlight and moisture.
	For generic drugs (me-too Status)	Linjardy-M 25/5/1000mg Tablet
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Fuxin Long Rui Pharmaceutical Co.,Ltd, Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China, shouguang fukang Pharmaceuticals Co., Ltd. North-east of Dongwaihuan Dongheng industrial area, shougang shandong the people's republic of china
	Detail of stability batches of drug product	03 batches of 3000 tablets at 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	Trijardy XR 25/5/1000mg by M/s Boehringer Ingelheim Pharmaceuticals, USA.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 batches at long-term and accelerated conditions
	The status in reference regulatory authorities	Trijardy XR 25/5/1000mg by M/s Boehringer Ingelheim Pharmaceuticals, USA. USFDA Approved
	GMP status of the firm	GMP certificate of 07th March 2023
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
11	Case Category	Routine (Abdul Mughees)

	Name, address of Applicant.	Barrett Hodgson Pakistan (Pvt.) Ltd F/423, Site, Karachi (000457)
	Application Form Dy. No / Tracking ID & date of submission	(BTZ-6YP-A22S, 2024-09-25)
	Detail of Fee Submitted	37000.0, 2024-09-09,
	The proposed proprietary name / brand name	Emdimet XR Tablet 10mg+5mg+1000mg
	Label Claim	Each film coated tablet contains: Empagliflozin (as immediate release) 10mg Linagliptin (as immediate release) 5mg Metformin HCl (as extended release) 1000mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-De-Controlled
	Shelf Life (Unit)	24 Month(s)Store below 30°C
	For generic drugs (me-too Status)	Linjardy-M Tablets 10mg+5mg+1000mg
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Product Name: Trijardy XR Tablet 10mg+5mg+1000mg film coated. Manufacturer: Boehringer Ingelheim International GmbH, Germany.
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The applicaiton fulfills codal formalities.	
	Decision	
	Approved	
12	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Barrett Hodgson Pakistan (Pvt.) Ltd F/423, Site, Karachi (000457)
	Application Form Dy. No / Tracking ID & date of submission	(QBV-A8U-YS9J, 2024-11-12)
	Detail of Fee Submitted	37000.0, 2024-09-09,
	The proposed proprietary name / brand name	Emdimet XR Tablet 5mg+2.5mg+1000mg
	Label Claim	Each film coated tablet contains: Empagliflozin (as immediate release).....5mg Linagliptin (as immediate release).....2.5mg Metformin HCl (as extended release).....1000mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-De-Controlled

	Shelf Life (Unit)	24 Month(s) Preserve in tight containers. Store at controlled room temperature
	For generic drugs (me-too Status)	Linjardy-M Tablets 5mg+2.5mg+1000mg
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	-
	Detail of stability batches of drug product	three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Product Name: Trijardy XR Tablet 5mg+2.5mg+1000mg film coated. Manufacturer: Boehringer Ingelheim International GmbH, Germany.
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The applicaiton fulfills codal formalities.	
	Decision	
	Approved	
13	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Barrett Hodgson Pakistan (Pvt.) Ltd F/423, Site, Karachi (000457)
	Application Form Dy. No / Tracking ID & date of submission	(T22-8JG-SH4U, 2024-11-12)
	Detail of Fee Submitted	37000.0, 2024-09-09,
	The proposed proprietary name / brand name	Emdimet XR Tablet 12.5mg+2.5mg+1000mg
	Label Claim	Each film coated tablet contains: Empagliflozin (as immediate release)...12.5mg Linagliptin (as immediate release).....2.5mg Metformin HCl (as extended release).....1000mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-De-Controlled
	Shelf Life (Unit)	24 Month(s) Preserve in tight containers. Store at controlled room temperature.
	For generic drugs (me-too Status)	Linjardy-M Tablets 12.5mg+2.5mg+1000mg
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	-
	Detail of stability batches of drug product	three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Product Name: Trijardy XR Tablet 12.5mg+2.5mg+1000mg film coated. Manufacturer: Boehringer Ingelheim International GmbH, Germany.
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
14	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Barrett Hodgson Pakistan (Pvt.) Ltd F/423, Site, Karachi (000457)
	Application Form Dy. No / Tracking ID & date of submission	(2E6-1NL-LBNJ, 2024-10-28)
	Detail of Fee Submitted	37000.0, 2024-10-22,
	The proposed proprietary name / brand name	Emgly Plus Tablet 10mg+5mg
	Label Claim	Each film coated tablet contains: Empagliflozin.....10mg Linagliptin.....5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-De-Controlled
	Shelf Life (Unit)	24 Month(s) Preserve in tight containers. Store at controlled room temperature
	For generic drugs (me-too Status)	Linjardy Tablets 10mg+5mg
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	-
	Detail of stability batches of drug product	three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Product Name: Glyxambi Tablet 10mg+5mg film coated Manufacturer: Boehringer Ingelheim International GmbH
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	

	Approved	
15	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Barrett Hodgson Pakistan (Pvt.) Ltd F/423, Site, Karachi (000457)
	Application Form Dy. No / Tracking ID & date of submission	(6G1-GZU-1PSY, 2024-10-29)
	Detail of Fee Submitted	37000.0, 2024-10-02,
	The proposed proprietary name / brand name	Emgly Plus Tablet 25mg+5mg
	Label Claim	Each film coated tablet contains: Empagliflozin.....25mg Linagliptin.....5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-De-Controlled
	Shelf Life (Unit)	24 Month(s) Preserve in tight containers. Store at controlled room temperature.
	For generic drugs (me-too Status)	Linjardy Tablets 25mg+5mg
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	-
	Detail of stability batches of drug product	Three batches at long-term and accelreated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long-term and accelreated conditions
	The status in reference regulatory authorities	Product Name: Glyxambi Tablet 25mg+5mg film coated Manufacturer: Boehringer Ingelheim International GmbH, Germany.
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
16	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (000644)
	Application Form Dy. No / Tracking ID & date of submission	(SQ3-AH4-G58L, 2024-10-23)
	Detail of Fee Submitted	37000.0, 2024-10-18,
	The proposed proprietary name / brand name	Cal-D 1mcg Injection
	Label Claim	Each Ampoule (1mL) Contains: Calcitriol (USP).....1Mcg (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)	Calcijex Injection by Abbott Laboratories
	Pharmacotherapeutic Group of (API)	A11CC04; Vitamin D analog
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Three batches at 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	PE
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long-term and accelerated conditions
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
17	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (000644)
	Application Form Dy. No / Tracking ID & date of submission	(91A-86R-YJGV, 2024-10-23)
	Detail of Fee Submitted	37000.0, 2024-10-18,
	The proposed proprietary name / brand name	Cal-D 2mcg Injection
	Label Claim	Each Ampoule (1mL) Contains: Calcitriol (USP).....2mcg (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)	Calcijex Injection by Abbott Laboratories
	Pharmacotherapeutic Group of (API)	A11CC04; Vitamin D analog
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/S EAGLE CHEMICAL WORKS. PLOT NO. 29/A, 1ST PHASE G.I.D.C, VAPI CITY, -VAPI, 396 195, DIST-VALSAD, GUJARAT STATE, INDIA.
	Detail of stability batches of drug product	Three batches at 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	PE
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long-term and accelerated conditions
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Deferred	
	For submission of the following: i. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation. ii. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07 iii. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.	
18	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Platinum Pharmaceuticals A-20,North Western Industrial Zone Bin Qasim,Karachi (000415)
	Application Form Dy. No / Tracking ID & date of submission	(Y5Z-4EH-JPU4, 2024-10-28)
	Detail of Fee Submitted	37000.0, 2024-09-24,
	The proposed proprietary name / brand name	EMPANUM-M Tablet 5/500mg
	Label Claim	Each film-coated tablet contains: Empagliflozin..... 5mg Metformin HCl..... 500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10s-As per SRO,14s-As per SRO,20s-As per SRO,28s-As per SRO,30s-As per SRO,56s-As per SRO,7s-As per SRO,96s-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30C in a dry place and protect from sunlight
	For generic drugs (me-too Status)	Empaphage-M Tablet 5/500mg
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Aarti Drugs Limited,Jiangsu Yongan Pharmaceutical Co. Ltd.
	Detail of stability batches of drug product	Three batches at log 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	Performed

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at log term and accelerated conditions
	The status in reference regulatory authorities	Synjardy 5/500mg
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
19	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Platinum Pharmaceuticals A-20,North Western Industrial Zone Bin Qasim,Karachi (000415)
	Application Form Dy. No / Tracking ID & date of submission	(Z34-GN3-R4AT, 2024-10-28)
	Detail of Fee Submitted	37000.0, 2024-09-24,
	The proposed proprietary name / brand name	EMPANUM-M 5/1000MG
	Label Claim	Each film-coated tablet contains: Empagliflozin 5mg Metformin HCl.....1000mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10-As per SRO,14-As per SRO,20-As per SRO,28-As per SRO,30-As per SRO,56-As per SRO,7-As per SRO,96-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 °C
	For generic drugs (me-too Status)	EMPAPHAGE-M (Martin dow)
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	AARTI DRUGS LIMITED,Jiangsu Yongan Pharmaceutical Co., Ltd
	Detail of stability batches of drug product	Three batches at log 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at log term and accelerated conditions
	The status in reference regulatory authorities	SYNJARDY 5MG + 1GM (US-FDA)
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
20	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Platinum Pharmaceuticals A-20,North Western Industrial Zone Bin Qasim,Karachi (000415)
	Application Form Dy. No / Tracking ID & date of submission	(XN8-HV2-6513, 2024-10-28)

	Detail of Fee Submitted	37000.0, 2024-09-24,
	The proposed proprietary name / brand name	EMPANUM-M 12.5/500MG
	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	10-As per SRO,14-As per SRO,20-As per SRO,28-As per SRO,30-As per SRO,56-As per SRO,7-As per SRO,96-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 °C
	For generic drugs (me-too Status)	EMPAPHAGE-M (Martin dow)
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	AARTI DRUGS LIMITED,Jiangsu Yongan Pharmaceutical Co., Ltd
	Detail of stability batches of drug product	Three batches at log 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at log term and accelerated conditions
	The status in reference regulatory authorities	SYNJARDY 12.5MG + 500MG (US-FDA)
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
21	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Platinum Pharmaceuticals A-20,North Western Industrial Zone Bin Qasim,Karachi (000415)
	Application Form Dy. No / Tracking ID & date of submission	(B7M-PMP-4US4, 2024-10-28)
	Detail of Fee Submitted	37000.0, 2024-09-24,
	The proposed proprietary name / brand name	EMPANUM-M 12.5/850MG
	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	10-As per SRO,14-As per SRO,20-As per SRO,28-As per SRO,30-As per SRO,56-As per SRO,7-As per SRO,96-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 °C
	For generic drugs (me-too Status)	EMPAPHAGE-M (Martin dow)
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	AARTI DRUGS LIMITED,Jiangsu Yongan Pharmaceutical Co., Ltd

	Detail of stability batches of drug product	Three batches at log 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at log term and accelerated conditions
	The status in reference regulatory authorities	SYNJARDY 12.5MG + 850MG (EMA)
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
22	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Platinum Pharmaceuticals A-20,North Western Industrial Zone Bin Qasim,Karachi (000415)
	Application Form Dy. No / Tracking ID & date of submission	(3AY-DDL-M4VN, 2024-10-29)
	Detail of Fee Submitted	30000.0, 7000.0 2024-09-04, 2024-10-14
	The proposed proprietary name / brand name	Empagliflozin 10,mg Tablet
	Label Claim	Each Tablet contains Empagliflozin 10mg.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10s-As per SRO,14s-As per SRO,20s-As per SRO,30s-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30 C in a dry place
	For generic drugs (me-too Status)	Diampa 10mg Tablet
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Jiangsu Yongan Pharmaceutical Co.,Limited
	Detail of stability batches of drug product	Three batches at log 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at log term and accelerated conditions
	The status in reference regulatory authorities	Jardiance 10mg Tablet(FDA)
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
23	Case Category	Routine (Abdul Mughees)

	Name, address of Applicant.	Platinum Pharmaceuticals A-20,North Western Industrial Zone Bin Qasim,Karachi (000415)
	Application Form Dy. No / Tracking ID & date of submission	(U3T-8RL-DJ8P, 2024-10-31)
	Detail of Fee Submitted	37000.0, 2024-09-24,
	The proposed proprietary name / brand name	EMPANUM-M 12.5/1000MG
	Label Claim	Each film-coated tablet contains: Empagliflozin.....12.5mg Metformin HCl.....1000mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10-As per SRO,14-As per SRO,20-As per SRO,28-As per SRO,30-As per SRO,56-As per SRO,7-As per SRO,96-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 °C
	For generic drugs (me-too Status)	EMPAPHAGE-M (Martin dow)
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	AARTI DRUGS LIMITED,Jiangsu Yongan Pharmaceutical Co., Ltd
	Detail of stability batches of drug product	Three batches at log 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at log term and accelerated conditions
	The status in reference regulatory authorities	SYNJARDY 12.5MG + 1000MG (EMA)
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
24	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Platinum Pharmaceuticals A-20,North Western Industrial Zone Bin Qasim,Karachi (000415)
	Application Form Dy. No / Tracking ID & date of submission	(LMQ-H12-Q8XD, 2024-10-31)
	Detail of Fee Submitted	37000.0, 2024-09-24,
	The proposed proprietary name / brand name	EMPANUM-M 5/850MG
	Label Claim	Each film-coated tablet contains: Empagliflozin.....5mg Metformin HCl.....850mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10-As per SRO,14-As per SRO,20-As per SRO,28-As per SRO,30-As per SRO,56-As per SRO,7-As per SRO,96-As per SRO

	Shelf Life (Unit)	2 Year(s)Store below 30 °C
	For generic drugs (me-too Status)	EMPAPHAGE-M (Martin dow)
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	AARTI DRUGS LIMITED,Jiangsu Yongan Pharmaceutical Co., Ltd
	Detail of stability batches of drug product	Three batches at log 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at log term and accelerated conditions
	The status in reference regulatory authorities	SYNJARDY 5MG + 850MG (EMA)
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
25	Case Category	Export Facilitation (Abdul Mughees)
	Name, address of Applicant.	Ferozsons Laboratories Limited PO Ferozsons, Amangarh (000038)
	Application Form Dy. No / Tracking ID & date of submission	(W6M-W6W-XVVB, 2025-01-30)
	Detail of Fee Submitted	75000.0, 2025-01-08,
	The proposed proprietary name / brand name	Verigard Tablets 10mg
	Label Claim	Each film coated tablet contains: Vericiguat.....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)Do not store above 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	C01DX22; guanylate cyclase (sGC) stimulator
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	NA
	Detail of stability batches of drug product	Three batches at long-term and accelerated conditionsq
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Verquvo Tablets 10mg
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long-term and accelerated conditionsq

	The status in reference regulatory authorities	Brand Name: Verquvo Tablets 10mg Manufacturer: Bayer AG, Kaiser-Wilhelm-Allee, 51368 Leverkusen, Germany - USFDA
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
26	Case Category	Export Facilitation (Abdul Mughees)
	Name, address of Applicant.	Atco Laboratories Limited B-18 SITE KARACHI (000188)
	Application Form Dy. No / Tracking ID & date of submission	(GX7-4D7-564G, 2025-04-29)
	Detail of Fee Submitted	75000.0, 2025-01-31,
	The proposed proprietary name / brand name	Linglip-M Tablet
	Label Claim	Each film coated tablet contains: Linagliptin 2.5mg Metformin Hydrochloride 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,5's-De-Controlled,60's-De-Controlled,7's-De-Controlled,90's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Don't store & transport above 30degree centigrade
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CTX LIFESCIENCES PVT. LTD,IPCA Laboratories Limited.,
	Detail of stability batches of drug product	Three batches of 2500 tablets at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long-term and accelerated conditions
	The status in reference regulatory authorities	JENTADUETO Tablets by Boehringer Ingelheim Pharmaceuticals, USA
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML 000181 dated 11.04.2021
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
27	Case Category	Export Facilitation (Abdul Mughees)

	Name, address of Applicant.	Atco Laboratories Limited B-18 SITE KARACHI (000188)
	Application Form Dy. No / Tracking ID & date of submission	(M7E-JSS-TVP8, 2025-05-12)
	Detail of Fee Submitted	75000.0, 2025-02-11,
	The proposed proprietary name / brand name	SOLIGIN TABLET
	Label Claim	Each film coated tablet contains: Sotagliflozin 200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,28's-De-Controlled,30's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Don't store & transport above 30degree centigrade
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	Anti-diabetic; A10BK06; dual sodium-glucose cotransporter 1 and 2 (SGLT1/SGLT2) inhibitor
	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	Three batches of 1500 tablets at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long-term and accelerated conditions
	The status in reference regulatory authorities	INPEFA Tablets by Lexicon Pharmaceuticals US
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
28	Case Category	Export Facilitation (Abdul Mughees)
	Name, address of Applicant.	Atco Laboratories Limited B-18 SITE KARACHI (000188)
	Application Form Dy. No / Tracking ID & date of submission	(4YA-MYY-L8JT, 2025-09-29)
	Detail of Fee Submitted	37000.0, 2025-07-16,
	The proposed proprietary name / brand name	Atcodap M XR Tablet
	Label Claim	Each film-coated tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg Metformin Hydrochloride (Extended-Release) 1000mg
	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,56's-De-Controlled,60's-De-Controlled,7's-De-Controlled

	Shelf Life (Unit)	24 Year(s)Not Store and Transport above 30 degree centigrade.
	For generic drugs (me-too Status)	Dapxiga-M XR 5mg/1gm Tablet manufactured by Ferozsans Laboratories Ltd.
	Pharmacotherapeutic Group of (API)	Antidiabetic Agent
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	IPCA Laboratories Limited, India.,Jiangsu Yongan Pharmaceutical Co., Ltd.,
	Detail of stability batches of drug product	06 Months Data of Accelerated Stability and 06 Months Data of Long-Term Stability
	Documents for the procurement of API with approval from DRAP (in case of Import)	API Procurement Document and Sale Invoice
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence Study Report and Comparative Dissolution Profile performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 Months Data of Accelerated Stability and 36 Months Data of Long-Term Stability of Dapagliflozin, 06 Months Data of Accelerated Stability and 60 Months Data of Long-Term Stability of Metformin HCl
	The status in reference regulatory authorities	XIGDUO XR Tablet Manufactured by: AstraZeneca Pharmaceuticals LP Wilmington, DE 19850.
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
29	Case Category	Export Facilitation (Abdul Mughees)
	Name, address of Applicant.	Atco Laboratories Limited B-18 SITE KARACHI (000188)
	Application Form Dy. No / Tracking ID & date of submission	(69G-3QM-HV4E, 2025-09-29)
	Detail of Fee Submitted	37000.0, 2025-07-16,
	The proposed proprietary name / brand name	Atcodap M XR Tablet
	Label Claim	Each film-coated tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 2.5mg Metformin Hydrochloride (Extended-Release) 1000mg
	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,56's-De-Controlled,60's-De-Controlled,7's-De-Controlled
	Shelf Life (Unit)	24 Year(s)Not Store and Transport above 30 degree centigrade.
	For generic drugs (me-too Status)	Dapa-Met 2.5mg/1gm Tablet manufactured by Hilton Pharma (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Antidiabetic Agent
	Name, address of Manufacturing site:	Self Manufacturing

	Name & address of API manufacturer	IPCA Laboratories Limited, India.,Jiangsu Yongan Pharmaceutical Co., Ltd.,
	Detail of stability batches of drug product	06 Months Data of Accelerated Stability and 06 Months Data of Long-Term Stability
	Documents for the procurement of API with approval from DRAP (in case of Import)	API Procurement Document and Sale Invoice is
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence Study Report and Comparative Dissolution Profile performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 Months Data of Accelerated Stability and 36 Months Data of Long-Term Stability of Dapagliflozin, 06 Months Data of Accelerated Stability and 60 Months Data of Long-Term Stability of Metformin HCl
	The status in reference regulatory authorities	XIGDUO XR Tablet Manufactured by: AstraZeneca Pharmaceuticals LP Wilmington, DE 19850.
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
30	Case Category	Export Facilitation (Abdul Mughees)
	Name, address of Applicant.	Atco Laboratories Limited B-18 SITE KARACHI (000188)
	Application Form Dy. No / Tracking ID & date of submission	(TWL-8H1-65HJ, 2025-10-20)
	Detail of Fee Submitted	37000.0, 2025-07-16,
	The proposed proprietary name / brand name	Atcodap M XR Tablet
	Label Claim	Each film-coated tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Metformin Hydrochloride (Extended-Release) 1000mg
	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,56's-De-Controlled,60's-De-Controlled,7's-De-Controlled
	Shelf Life (Unit)	24 Year(s)Not Store and Transport above 30 degree centigrade.
	For generic drugs (me-too Status)	Dapxiga-M XR 10mg/1gm Tablet manufactured by Ferozsans Laboratories Ltd.
	Pharmacotherapeutic Group of (API)	Antidiabetic Agent
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	IPCA Laboratories Limited, India.,Jiangsu Yongan Pharmaceutical Co., Ltd.,
	Detail of stability batches of drug product	03 Months Data of Accelerated Stability and 03 Months Data of Long-Term Stability
	Documents for the procurement of API with approval from DRAP	API Procurement Document and Sale Invoice

	(in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence Study Report and Comparative Dissolution Profile
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 Months Data of Accelerated Stability and 36 Months Data of Long-Term Stability of Dapagliflozin, 06 Months Data of Accelerated Stability and 60 Months Data of Long-Term Stability of Metformin HCl
	The status in reference regulatory authorities	XIGDUO XR Tablet Manufactured by: AstraZeneca Pharmaceuticals LP Wilmington, DE 19850.
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
31	Case Category	Export Facilitation (Abdul Mughees)
	Name, address of Applicant.	Atco Laboratories Limited B-18 SITE KARACHI (000188)
	Application Form Dy. No / Tracking ID & date of submission	(YPA-3Y3-Y9Z4, 2025-11-18)
	Detail of Fee Submitted	38700.0, 2025-09-05,
	The proposed proprietary name / brand name	Atcodap M XR Tablet
	Label Claim	Each film-coated tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg Metformin Hydrochloride (Extended-Release) 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,56's-De-Controlled,60's-De-Controlled,7's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Not Store and Transport above 30 degree centigrade.
	For generic drugs (me-too Status)	DaplozMet 5mg + 500mg per Tablet manufactured by Highnoon Laboratories Ltd.
	Pharmacotherapeutic Group of (API)	Dapagliflozin, "Sodium-Glucose Co-Transporter 2 (SGLT2) inhibitors" and Metformin, "Biguanides".
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Ipca Laboratories Limited,Jiangsu Yongan Pharmaceutical Co., Ltd.,
	Detail of stability batches of drug product	03 Months Data of Accelerated Stability and 03 Months Data of Long-Term Stability
	Documents for the procurement of API with approval from DRAP (in case of Import)	API Procurement Document and Sale Invoice
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence Study Report and Comparative Dissolution Profile

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 Months Data of Accelerated Stability and 36 Months Data of Long-Term Stability of Dapagliflozin, 06 Months Data of Accelerated Stability and 60 Months Data of Long-Term Stability of Metformin HCl
	The status in reference regulatory authorities	XIGDUO XR Tablet Manufactured by: AstraZeneca Pharmaceuticals LP Wilmington, DE 19850.
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
32	Case Category	Export Facilitation (Abdul Mughees)
	Name, address of Applicant.	Atco Laboratories Limited B-18 SITE KARACHI (000188)
	Application Form Dy. No / Tracking ID & date of submission	(UV2-R7X-X1YY, 2025-11-18)
	Detail of Fee Submitted	38700, 2025-09-05,
	The proposed proprietary name / brand name	Atcodap M XR Tablet
	Label Claim	Each film-coated tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Metformin Hydrochloride (Extended-Release) 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, 56's-De-Controlled, 60's-De-Controlled, 7's-De-Controlled
	Shelf Life (Unit)	2 Year(s) Not Store and Transport above 30 degree centigrade.
	For generic drugs (me-too Status)	Dapxiga-M XR Tablet 10mg + 500mg per Tablet manufactured by Ferozsans Laboratories Ltd.
	Pharmacotherapeutic Group of (API)	Dapagliflozin, "Sodium-Glucose Co-Transporter 2 (SGLT2) inhibitors". Metformin, "Biguanides".
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Ipca Laboratories Limited, Jiangsu Yongan Pharmaceutical Co., Ltd.,
	Detail of stability batches of drug product	03 Months Data of Accelerated Stability and 03 Months Data of Long-Term Stability
	Documents for the procurement of API with approval from DRAP (in case of Import)	API Procurement Document and Sale Invoice
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence Study Report and Comparative Dissolution Profile
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 Months Data of Accelerated Stability and 36 Months Data of Long-Term Stability of Dapagliflozin, 06 Months Data of Accelerated Stability and 60 Months Data of Long-Term Stability of Metformin HCl

	The status in reference regulatory authorities	XIGDUO XR Tablet Manufactured by: AstraZeneca Pharmaceuticals LP Wilmington, DE 19850.
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
33	Case Category	Export Facilitation (Abdul Mughees)
	Name, address of Applicant.	Atco Laboratories Limited B-18 SITE KARACHI (000188)
	Application Form Dy. No / Tracking ID & date of submission	(WV7-YD6-GJBY, 2025-10-24)
	Detail of Fee Submitted	38700.0, 2025-08-11,
	The proposed proprietary name / brand name	Syngab CR Tablets
	Label Claim	Each film coated extended-release tablet contains: Pregabalin 82.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled,7's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Not Store and Transport above 30 degree centigrade.
	For generic drugs (me-too Status)	Gablin CR Tablets manufactured by CCL Pharmaceuticals (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Gabapentinoid Medication, GABA Analogs
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CTX Lifesciences Pvt. Ltd.
	Detail of stability batches of drug product	03 Months Data of Accelerated Stability and 03 Months Data of Long-Term Stability
	Documents for the procurement of API with approval from DRAP (in case of Import)	API Procurement Document and Sale Invoice
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence Study Report and Comparative Dissolution Profile
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 Months Data of Accelerated Stability and 72 Months Data of Long-Term Stability of Pregabalin
	The status in reference regulatory authorities	LYRICA CR Tablets Manufactured by: Pfizer inc.7000 portage rd. Pharmacia & upjohn company llc.
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
34	Case Category	Export Facilitation (Abdul Mughees)

	Name, address of Applicant.	Atco Laboratories Limited B-18 SITE KARACHI (000188)
	Application Form Dy. No / Tracking ID & date of submission	(Z4Z-9JX-L19A, 2025-09-30)
	Detail of Fee Submitted	38700.0, 2025-08-11,
	The proposed proprietary name / brand name	Syngab CR Tablets
	Label Claim	Each film coated extended-release tablet contains: Pregabalin 165mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled,7's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Not Store and Transport above 30 degree centigrade.
	For generic drugs (me-too Status)	Gablin CR Tablets manufactured by CCL Pharmaceuticals (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Gabapentinoid Medication, GABA Analogs
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CTX Lifesciences Pvt. Ltd.
	Detail of stability batches of drug product	06 Months Data of Accelerated Stability and 06 Months Data of Long-Term Stability
	Documents for the procurement of API with approval from DRAP (in case of Import)	API Procurement Document and Sale Invoice
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence Study Report and Comparative Dissolution Profile
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 Months Data of Accelerated Stability and 72 Months Data of Long-Term Stability of Pregabalin
	The status in reference regulatory authorities	LYRICA CR Tablets Manufactured by: Pfizer inc.7000 portage rd. Pharmacia & upjohn company llc.
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
35	Case Category	Export Facilitation (Abdul Mughees)
	Name, address of Applicant.	Atco Laboratories Limited B-18 SITE KARACHI (000188)
	Application Form Dy. No / Tracking ID & date of submission	(E7X-RRV-WYUIJ, 2025-10-15)
	Detail of Fee Submitted	38700.0, 2025-08-11,
	The proposed proprietary name / brand name	Syngab CR Tablets
	Label Claim	Each film coated extended-release tablet contains: Pregabalin 330mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-

		Controlled,7's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Not Store and Transport above 30 degree centigrade.
	For generic drugs (me-too Status)	Gablin CR Tablets manufactured by CCL Pharmaceuticals (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Gabapentinoid Medication, GABA Analogs
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CTX Lifesciences Pvt. Ltd.
	Detail of stability batches of drug product	06 Months Data of Accelerated Stability and 06 Months Data of Long-Term Stability
	Documents for the procurement of API with approval from DRAP (in case of Import)	API Procurement Document and Sale Invoice
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence Study Report and Comparative Dissolution Profile
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 Months Data of Accelerated Stability and 72 Months Data of Long-Term Stability of Pregabalin
	The status in reference regulatory authorities	LYRICA CR Tablets Manufactured by: Pfizer inc.7000 portage rd. Pharmacia & upjohn company llc.
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
36	Case Category	Export Facilitation (Abdul Mughees)
	Name, address of Applicant.	Searle Pakistan Limited C-14, Manghopir Road, SITE, Karachi (000012)
	Application Form Dy. No / Tracking ID & date of submission	(ELE-1MA-3HX4, 2025-07-04)
	Detail of Fee Submitted	37000.0, 2025-02-03,
	The proposed proprietary name / brand name	VILDA 50MG TABLETS
	Label Claim	Each tablet contains: Vildagliptin 50 mg.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-De-Controlled,28's-De-Controlled,56's-De-Controlled
	Shelf Life (Unit)	24 Year(s)Store below 30°C. Protect from heat, light and moisture.
	For generic drugs (me-too Status)	Dialiptin 50 mg Tablets (Reg. No.: 100262)
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Drug Substance Source: Jiangxi Synergy Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Approved ny MHRA, EMA, etc.
	GMP status of the firm	Provided 19 July 2024
	Evidence of approval of manufacturing facility	DML 000012
	Evaluation Remarks	
	The applicaiton fulfills codal formalities.	
	Decision	
	Approved	
37	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	(3EV-PLH-E6WU, 2024-08-29)
	Detail of Fee Submitted	30000.0, 2024-08-06,
	The proposed proprietary name / brand name	ERTOXA-S (Ertugliflozin+Sitagliptin) 5mg/100mg Tablet
	Label Claim	Each film-coated tablet contains: Ertugliflozin L Pyroglutamic acid equivalent to Ertugliflozin...5mg Sitagliptin Phosphate Monohydrate equivalent to Sitagliptin....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)Store below 30 °C.
	For generic drugs (me-too Status)	Tiglozin-S Tablet 5mg/100mg, NABIQASIM (PVT) LTD.
	Pharmacotherapeutic Group of (API)	Sodium-glucose co-transporter 2 (SGLT2) inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	STEGLUJAN, Food & Drug Administration-FDA
	GMP status of the firm	Prrovided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	

38	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	(1NB-1MN-9J7G, 2024-10-18)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-06, 2024-10-14
	The proposed proprietary name / brand name	ERTOXA-S (Ertugliflozin+Sitagliptin) 15mg/100mg Tablet
	Label Claim	Each film-coated tablet contains: Ertugliflozin L Pyroglutamic acid equivalent to Ertugliflozin...15mg Sitagliptin Phosphate Monohydrate equivalent to Sitagliptin....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)Store below 30 °C.
	For generic drugs (me-too Status)	Tiglozin-S Tablet 15mg/100mg, NABIQASIM (PVT) LTD.
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	STEGLUJAN, Food & Drug Administration- FDA
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
39	Case Category	Export Facilitation (Abdul Mughees)
	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	(DXM-2NL-6TSG, 2025-11-06)
	Detail of Fee Submitted	38700, 2025-10-17,
	The proposed proprietary name / brand name	MIROHIL TABLETS 5mg
	Label Claim	Each film-coated tablet contains: Mirogabalin besylate eq.to Mirogabalin..... 5mg
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled,5's-De-Controlled,7's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect from sunlight & moisture. Keep out of reach of children.
	For generic drugs (me-too Status)	Mirogab (getz pharma)
	Pharmacotherapeutic Group of (API)	Gabapentinoid: Neuropathic Pain
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	--
	Detail of stability batches of drug product	Three batches at long term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	DIL -C-77FC60
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Tarlige Tablets 5 mg (Daiichi Sankyo Company, Limited)
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DMLNo. 000136
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
40	Case Category	Export Facilitation (Abdul Mughees)
	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	(95H-TEB-SW6E, 2026-02-12)
	Detail of Fee Submitted	38700, 2025-10-17,
	The proposed proprietary name / brand name	MIROHIL TABLETS 15mg
	Label Claim	Each film-coated tablet contains: Mirogabalin besylate eq.to Mirogabalin..... 15mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled,5's-De-Controlled,7's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect from sunlight & moisture. Keep out of reach of children.
	For generic drugs (me-too Status)	Mirogab (getz pharma)
	Pharmacotherapeutic Group of (API)	Gabapentinoid: Neuropathic Pain
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	--
	Detail of stability batches of drug product	Three batches at long term and accelerated conditions
	Documents for the procurement of API with approval from DRAP	DIL -C-77FC60

	(in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Tarlige Tablets 15 mg (Daiichi Sankyo Company, Limited)
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML No. 000136
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
41	Case Category	Export Facilitation (Abdul Mughees)
	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	(X2S-A16-TVJG, 2026-02-12)
	Detail of Fee Submitted	38700, 2025-10-17,
	The proposed proprietary name / brand name	MIROHIL TABLETS 10mg
	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	10's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled,5's-De-Controlled,7's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect from sunlight & moisture. Keep out of reach of children.
	For generic drugs (me-too Status)	Mirogab (getz pharma)
	Pharmacotherapeutic Group of (API)	Gabapentinoid: Neuropathic Pain
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	--
	Detail of stability batches of drug product	Three batches at long term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	DIL -C-77FC60
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Tarlige Tablets 10 mg (Daiichi Sankyo Company, Limited)
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML No. 000136
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	

	Approved	
42	Case Category	Export Facilitation (Abdul Mughees)
	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	(XP7-L4Q-B9U2, 2026-02-12)
	Detail of Fee Submitted	38700, 2025-10-17,
	The proposed proprietary name / brand name	MIROHIL TABLETS 2.5mg
	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	10's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled,5's-De-Controlled,7's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect from sunlight & moisture. Keep out of reach of children.
	For generic drugs (me-too Status)	Mirogab (getz pharma)
	Pharmacotherapeutic Group of (API)	Gabapentinoid: Neuropathic Pain
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	--
	Detail of stability batches of drug product	Three batches on long term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	DIL -C-77FC60
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches on long term and accelerated conditions
	The status in reference regulatory authorities	Tarlige Tablets 2.5 mg (Daiichi Sankyo Company, Limited)
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML No. 000136
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
43	Case Category	Export Facilitation (Abdul Mughees)
	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	(E9R-TBP-51QM, 2025-12-03)
	Detail of Fee Submitted	38700, 2025-11-19,
	The proposed proprietary name / brand name	ZABRO 15mg TABLET
	Label Claim	Each film coated tablet contains: Mirogabalin as Besylate ...15mg Innovator's Specification
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	10x10's-De-Controlled,1x10's-De-Controlled,2x10's-De-Controlled,2x7's-De-Controlled,5x10's-De-Controlled
	Shelf Life (Unit)	2 Year(s)STORE BELOW 30oC
	For generic drugs (me-too Status)	Miro Tablet Nabi Qasim Industries (Pvt) Ltd, Reg No.120267
	Pharmacotherapeutic Group of (API)	Gabapentinoids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	NA
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Tarlige 15mg Tablet Daiichi Sankyo Company Limited Approved PMDA Japan
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
44	Case Category	Export Facilitation (Abdul Mughees)
	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	(DZH-U81-3BTS, 2026-02-04)
	Detail of Fee Submitted	38700, 2025-11-19,
	The proposed proprietary name / brand name	ZABRO 10mg TABLET
	Label Claim	Each film coated tablet contains: Mirogabalin as Besylate ...10mg Innovator's Specification
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10x10's-De-Controlled,1x10's-De-Controlled,2x10's-De-Controlled,2x7's-De-Controlled,5x10's-De-Controlled
	Shelf Life (Unit)	2 Year(s)STORE BELOW 30oC
	For generic drugs (me-too Status)	Miro Tablet Nabi Qasim Industries (Pvt) Ltd,Reg No.120268
	Pharmacotherapeutic Group of (API)	Gabapentinoids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	NA
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Tarlige 10mg Tablet Daiichi Sankyo Company Limited Approved PMDA Japan
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
45	Case Category	Export Facilitation (Abdul Mughees)
	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	(PY5-EU2-DTPG, 2026-02-20)
	Detail of Fee Submitted	38700, 2025-11-19,
	The proposed proprietary name / brand name	ZABRO 5mg TABLET
	Label Claim	Each film coated tablet contains: Mirogabalin as Besylate ..5mg Innovator's Specification
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10x10's-De-Controlled, 1x10's-De-Controlled, 2x10's-De-Controlled, 2x7's-De-Controlled, 5x10's-De-Controlled
	Shelf Life (Unit)	2 Year(s)STORE BELOW 30oC
	For generic drugs (me-too Status)	Miro Tablet Nabi Qasim Industries (Pvt) Ltd, Reg No.120269
	Pharmacotherapeutic Group of (API)	Gabapentinoids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	NA
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Tarlige 5mg Tablet Daiichi Sankyo Company Limited Approved PMDA Japan
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
46	Case Category	Export Facilitation (Abdul Mughees)

	Name, address of Applicant.	Ferozsons Laboratories Limited PO Ferozsons, Amangarh (000038)
	Application Form Dy. No / Tracking ID & date of submission	(1RQ-SSA-1UWH, 2025-11-14)
	Detail of Fee Submitted	38700.0, 2025-08-26,
	The proposed proprietary name / brand name	Rezaid Tablets 80mg
	Label Claim	Each film coated tablet contains: Resmetirom.....80mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's(1x10's)-As per SRO,14's(1x14's)-As per SRO,20's(2x10's)-As per SRO,28's(2x14's)-As per SRO,30's(3x10's)-As per SRO,5's(1x5's)-As per SRO,7's(1x7's)-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store above 30°C
	For generic drugs (me-too Status)	Brand Name: Resmirom Tablets 80mg Manufacturer: M/s Getz Pharma (Pvt.) Ltd - Karachi
	Pharmacotherapeutic Group of (API)	Thyroid hormone receptor (THR)-beta agonists
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	NA
	Detail of stability batches of drug product	03 batches manufactured each having batch size i.e 733 tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form-06 (issued dated 17-12-2024, specifies 680g import of Resmetirom), Invoice , Packing List, Form-03 ,Form-07, GD
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP studies are conducted against Resmirom Tablets 80mg (Batch No: 001FR9, Exp. Date: 04/2027) of Getz Pharma (Pvt.) Ltd - Karachi,
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data studies of 03 batches is performed by Drug substane manufacturer
	The status in reference regulatory authorities	Brand Name: Rezdiffra Tablets Manufacturer: Madrigal Pharmaceuticals, Inc. West Conshohocken, PA
	GMP status of the firm	Complying cGMP as per Certificate No. F.11-10/2024-DRAP-435 Dated: 26-11-2024, valid till 09-08-2027.
	Evidence of approval of manufacturing facility	Tablet Section (General) Approval granted by DRAP (Central Licensing Board) via tracking ID: XWU-WU3-4VZM dated: 01-08-2025.
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
47	Case Category	Export Facilitation (Abdul Mughees)
	Name, address of Applicant.	Ferozsons Laboratories Limited PO Ferozsons, Amangarh (000038)
	Application Form Dy. No / Tracking ID & date of submission	(X97-4NZ-NTEZ, 2025-11-17)
	Detail of Fee Submitted	38700.0, 2025-08-26,
	The proposed proprietary name / brand name	Rezaid Tablets 60mg

	Label Claim	Each film coated tablet contains: Resmetirom.....60mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's(1x10's)-As per SRO,14's(1x14's)-As per SRO,20's(2x10's)-As per SRO,28's(2x14's)-As per SRO,30's(3x10's)-As per SRO,5's(1x5's)-As per SRO,7's(1x7's)-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store above 30°C
	For generic drugs (me-too Status)	Brand Name: Resmirom Tablets 60mg Manufacturer: M/s Getz Pharma (Pvt.) Ltd - Karachi
	Pharmacotherapeutic Group of (API)	Thyroid hormone receptor (THR)-beta agonists
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	NA
	Detail of stability batches of drug product	03 batches manufactured each having batch size i.e. 733 tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form-06 (issued dated 17-12-2024, specifies 680g import of Resmetirom), Invoice , Packing List, Form-03 ,Form-07, GD
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP studies are conducted against Resmirom Tablets 60mg (Batch No: 001FR8, Exp. Date: 04/2027) of Getz Pharma (Pvt.) Ltd - Karachi,
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data studies of 03 batches is performed by Drug substance manufacturer
	The status in reference regulatory authorities	Brand Name: Rezdiffra Tablets Manufacturer: Madrigal Pharmaceuticals, Inc. West Conshohocken, PA
	GMP status of the firm	Complying cGMP as per Certificate No. F.11-10/2024-DRAP-435 Dated: 26-11-2024, valid till 09-08-2027.
	Evidence of approval of manufacturing facility	Tablet Section (General) Approval granted by DRAP (Central Licensing Board) via tracking ID: XWU-WU3-4VZM dated: 01-08-2025.
Evaluation Remarks		
The application fulfills codal formalities.		
Decision		
Approved		
48	Case Category	Export Facilitation (Abdul Mughees)
	Name, address of Applicant.	Ferozsons Laboratories Limited PO Ferozsons, Amangarh (000038)
	Application Form Dy. No / Tracking ID & date of submission	(JDL-63J-XHAY, 2026-01-15)
	Detail of Fee Submitted	38700.0, 2025-08-26,
	The proposed proprietary name / brand name	Rezaid Tablets 100mg
	Label Claim	Each film coated tablet contains: Resmetirom.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's (1x10's)-As per SRO,14's (1x14's)-As per SRO,20's (2x10's) -As per SRO,28's (2x14's) -As per SRO,30's (3x10's)-As per SRO,5's (1x5's)-As per SRO,7's (1x7's)-As per SRO

	Shelf Life (Unit)	2 Year(s)Do not store above 30°C
	For generic drugs (me-too Status)	Brand Name: Resmirom Tablets 100mg Manufacturer: M/s Getz Pharma (Pvt.) Ltd - Karachi
	Pharmacotherapeutic Group of (API)	Thyroid hormone receptor (THR)-beta agonists
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	NA
	Detail of stability batches of drug product	03 batches manufactured each having batch size i.e 733 tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form-06 (issued dated 17-12-2024, specifies 680g import of Resmetirom), Invoice , Packing List, Form-03 ,Form-07, GD
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP studies are conducted against Resmirom Tablets 100mg (Batch No: 001FS1, Exp. Date: 04/2027) of Getz Pharma (Pvt.) Ltd - Karachi,
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data studies of 03 batches is performed by Drug substance manufacturer
	The status in reference regulatory authorities	Brand Name: Rezdiffra Tablets Manufacturer: Madrigal Pharmaceuticals, Inc. West Conshohocken, PA
	GMP status of the firm	Complying cGMP as per Certificate No. F.11-10/2024-DRAP-435 Dated: 26-11-2024, valid till 09-08-2027.
	Evidence of approval of manufacturing facility	Tablet Section (General) Approval granted by DRAP (Central Licensing Board) via tracking ID: XWU-WU3-4VZM dated: 01-08-2025.
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
49	Case Category	Export Facilitation (Abdul Mughees)
	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	(SGJ-SVU-788P, 2025-09-26)
	Detail of Fee Submitted	37000.0, 2025-05-26,
	The proposed proprietary name / brand name	RESTIROM
	Label Claim	Each Film Coated Tablet contains: Resmetirom 60 mg
	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 at room temperature below 25C
	For generic drugs (me-too Status)	Getz Pharma (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Nantong Chanyoo Pharmatech Co., Ltd
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Nantong Chanyoo Pharmatech Co., Ltd
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	24 months (Zone IVA)
	The status in reference regulatory authorities	UPM Pharmaceuticals (Bristol, TN)
	GMP status of the firm	Valid till June 2025
	Evidence of approval of manufacturing facility	Tablet section
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
50	Case Category	Export Facilitation (Abdul Mughees)
	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	(ZLX-YNY-VJYA, 2025-10-02)
	Detail of Fee Submitted	37000.0, 2025-05-26,
	The proposed proprietary name / brand name	RESTIROM
	Label Claim	Each Film Coated Tablet contains: Resmetirom 80 mg
	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 at room temperature below 25C
	For generic drugs (me-too Status)	Getz Pharma (Pvt.) Ltd.
	Pharmaceutical Group of (API)	Nantong Chanyoo Pharmatech Co., Ltd
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Nantong Chanyoo Pharmatech Co., Ltd
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	24 months (Zone IVA)
	The status in reference regulatory authorities	UPM Pharmaceuticals (Bristol, TN)
	GMP status of the firm	Valid till June 2027
	Evidence of approval of manufacturing facility	Tablet section
	Evaluation Remarks	
	Decision	
	Approved	
51	Case Category	Export Facilitation (Abdul Mughees)
	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	(QYV-U44-VBRA, 2025-10-03)
	Detail of Fee Submitted	37000.0, 2025-05-26,

	The proposed proprietary name / brand name	RESTIROM
	Label Claim	Each Film Coated Tablet contains: Resmetirom 100 mg
	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 at room temperature below 25C
	For generic drugs (me-too Status)	Getz Pharma (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Nantong Chanyoo Pharmatech Co., Ltd
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Nantong Chanyoo Pharmatech Co., Ltd
	Detail of stability batches of drug product	Three batches at long term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Performed
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	24 months (Zone IVA)
	The status in reference regulatory authorities	UPM Pharmaceuticals (Bristol, TN)
	GMP status of the firm	Valid till June 2027
	Evidence of approval of manufacturing facility	Tablet section
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
52	Case Category	Export Facilitation (Abdul Mughees)
	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	(XMA-6J7-4VUZ, 2026-01-28)
	Detail of Fee Submitted	38700, 2026-01-06,
	The proposed proprietary name / brand name	Zeegap CR Tablets 82.5mg
	Label Claim	Each extended-release tablet contains: Pregabalin, USP...82.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2X14's, -De-Controlled,1X10s , -De-Controlled,1X14's, -De-Controlled,1X7's , -De-Controlled,2X10's,-De-Controlled,2X7's, -De-Controlled,3X10's-De-Controlled,4X7's, -De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect from sunlight & moisture. Keep out of reach of children.
	For generic drugs (me-too Status)	Gabica CR 82.5mg Tablets: Getz Pharma
	Pharmacotherapeutic Group of (API)	N02BF02; Gabapentinoids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Three batches of 1000 tablets at long term and accelerated conditions

	Documents for the procurement of API with approval from DRAP (in case of Import)	DIL -C-19CF52
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed; Lyrica CR
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Lyrica CR Tablet 82.5mg: Manufactured by Pfizer Inc: https://www.accessdata.fda.gov/drugsatfda_docs/la
	GMP status of the firm	GMP certificate dated 20.01.2025
	Evidence of approval of manufacturing facility	DML No.. 000136 dated 23.10.2024
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
53	Case Category	Export Facilitation (Abdul Mughees)
	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	(JTJ-SZT-9GGX, 2026-01-28)
	Detail of Fee Submitted	38700, 2026-01-06,
	The proposed proprietary name / brand name	ZEEGAP CR TABLETS 330mg
	Label Claim	Each extended release tablet contains: Pregabalin, USP.....330mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1X10s , -De-Controlled, 2X14's,-De-Controlled, 2X7's, -De-Controlled, 4X7's, -De-Controlled,1X14's,-De-Controlled,1X7's ,-De-Controlled,2X10's,-De-Controlled,3X10's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect from sunlight & moisture. Keep out of reach of children.
	For generic drugs (me-too Status)	Gabica CR 330mg Tablets: Getz Pharma
	Pharmacotherapeutic Group of (API)	N02BF02; Gabapentinoids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Three batches of 1000 tablets at long term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	DIL -C-19CF52
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed; Lyrica CR
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Lyrica CR Tablet 330mg: Manufactured by Pfizer Inc.: https://www.accessdata.fda.gov/drugsatfda_docs/la
	GMP status of the firm	GMP certificate dated 20.01.2025

	Evidence of approval of manufacturing facility	DML No.. 000136 dated 23.10.2024
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
54	Case Category	Export Facilitation (Abdul Mughees)
	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	(MM8-GVR-WU2T, 2026-01-28)
	Detail of Fee Submitted	38700, 2026-01-06,
	The proposed proprietary name / brand name	ZEEGAP CR TABLETS 165 mg
	Label Claim	Each extended release tablet contains: Pregabalin, USP.....165mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1X10s , -De-Controlled,1X14's, -De-Controlled,1X7's , -De-Controlled,2X10's, -De-Controlled,2X14's, -De-Controlled,2X7's, -De-Controlled,3X10's-De-Controlled,4X7's, -De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect from sunlight & moisture. Keep out of reach of children.
	For generic drugs (me-too Status)	Gabica CR 165mg Tablets: Getz Pharma
	Pharmacotherapeutic Group of (API)	N02BF02; Gabapentinoids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Three batches of 1000 tablets at long term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	DIL -C-19CF52
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed; Lyrica CR
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Lyrica CR Tablet 165mg: Manufactured by Pfizer Inc: https://www.accessdata.fda.gov/drugsatfda_docs/ldr
	GMP status of the firm	GMP certificate dated 20.01.2025
	Evidence of approval of manufacturing facility	DML No.. 000136 dated 23.10.2024
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
55	Case Category	Export Facilitation (Abdul Mughees)
	Name, address of Applicant.	Highnoon Laboratories Ltd 17.5 KM, Multan Road, (000155)

	Application Form Dy. No / Tracking ID & date of submission	(R1T-SMZ-4ASV, 2026-04-21)
	Detail of Fee Submitted	38700, 2026-01-26,
	The proposed proprietary name / brand name	Sotafloz 400mg Tablets
	Label Claim	Each film coated Tablets contains: Sotagliflozin 400mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x10 Tablets-As per SRO,2x14's Tablets-As per SRO,2x5's Tablets-As per SRO,2x7's Tablets-As per SRO,3x10's Tablets-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not Store above 30°C. Protect from light and moisture.
	For generic drugs (me-too Status)	CCL Pharmaceuticals (Pvt.) Ltd Sotza 400mg Tablets Reg # 131934
	Pharmacotherapeutic Group of (API)	inhibitor of SGLT2 and SGLT1 ATC code: A10BK06
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	NA
	Detail of stability batches of drug product	RDP0078-01 RDP0078-02 RDP0078-03 Batch size 1764 tablets at long term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	RO-57801A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Study was conducted for Comparative Dissolution Profile of Sotagliflozin 400 mg Tablets with Inpefa™ 400 mg Tablets (reference product). Dissolution profile for both Sotagliflozin 400 mg Tablets with Inpefa™ 400 mg Tablets (reference product) found to be satisfactory
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Inpefa™ 400 mg Tablets USFDA
	GMP status of the firm	Valid upto 07-01-2029
	Evidence of approval of manufacturing facility	Renewal letter dated 17.11.2025 is submitted wherein Tablet General section is mentioned.
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
56	Case Category	Export Facilitation (Abdul Mughees)
	Name, address of Applicant.	Highnoon Laboratories Ltd 17.5 KM, Multan Road, (000155)
	Application Form Dy. No / Tracking ID & date of submission	(RJE-5PB-SU6T, 2026-04-21)
	Detail of Fee Submitted	38700, 2026-01-26,
	The proposed proprietary name / brand name	Sotafloz 200mg Tablet
	Label Claim	Each Film coated tablet contains; Sotagliflozin.....200mg

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2×10's-As per SRO,2×14's-As per SRO,2×5's-As per SRO,2×7's-As per SRO,3×10's-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not Store above 30°C. Protect from light and moisture
	For generic drugs (me-too Status)	CCL Pharmaceuticals (Pvt.) Ltd. Sotza 200mg Tablets Reg # 131933
	Pharmacotherapeutic Group of (API)	Inhibitor of SGLT2 and SGLT1 ATC Code: A10BK06
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Fuxin Long Rui Pharmaceutical CO., Ltd Address: Fluoride Industrial Park, Fumeng County (YiMaTu), Fuxin City, Liaoning Province, China
	Detail of stability batches of drug product	RDP0077-02, RDP0077-03, RDP0077-04 at long term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	RO-57801A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Study was conducted for Comparative Dissolution Profile of Sotafloz 200mg Tablet & Inpefa 200mg tablets (reference product). Dissolution profile for both Sotafloz 200mg Tablet & Inpefa 200mg tablets (reference product) found to be satisfactory.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	SOTAGLIFLOZIN 200mg Tablets USFDA
	GMP status of the firm	Validity 07-01-2029
	Evidence of approval of manufacturing facility	Fuxin Long Rui Pharmaceutical CO., Ltd Address: Fluoride Industrial Park, Fumeng County (YiMaTu), Fuxin City, Liaoning Province, China
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
57	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Cell Health Sciences , Plot No 217, Industrial Triangle, Kahuta Road, Islamabad (000711)
	Application Form Dy. No / Tracking ID & date of submission	(T65-1PM-XX65, 2024-05-21)
	Detail of Fee Submitted	30000.0, 2024-05-06,
	The proposed proprietary name / brand name	MELGU XR 50/1000MG TABLET
	Label Claim	Each extended release film coated tablet contains: Sitagliptin phosphate monohydrate eq. to Sitagliptin....50mg Metformin hydrochloride 1000mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO -As per SRO
	Shelf Life (Unit)	2 Year(s)30C

	For generic drugs (me-too Status)	Sitaglu- Met XR 50/1000mg Tablet(Hilton Pharma (PVT) LTD) 098819
	Pharmacotherapeutic Group of (API)	Anti diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Janumet XR 50/1000mg Tablet(Merck & Co INC, White house Station, NJ 08889 , USA.)USFDA Approved Drug.
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	6- Justification of Manufacturing ApproachMetformin and sitagliptin have different physicochemical properties; therefore, theirgranulation/wetting was performed separately to ensure optimal flow, compressibility, and uniformity. After achieving suitable granules for each component, both masses were blended together to obtain a uniform mixture prior to compression of the extended-release tablets. Sir In future, we undertake that we shall separately mix the both APIs that is Sitagliptin and metformin.	
	Decision	
	Deferred	
	The Registration Board deferred the product for submission of Pharmaceutical Development and stability studies for the formulations manufactured in accordance with the innovator's method of manufacturing	
58	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Cell Health Sciences, Plot No 217, Industrial Triangle, Kahuta Road, Islamabad (000711)
	Application Form Dy. No / Tracking ID & date of submission	(RAR-9SL-2QWD, 2024-05-23)
	Detail of Fee Submitted	30000.0, 2024-05-06,
	The proposed proprietary name / brand name	MELGU 50/850MG TABLET
	Label Claim	Each film coated tablet contains: Sitagliptin phosphate monohydrate eq. to Sitagliptin....50mg Metformin hydrochloride 850mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO -As per SRO
	Shelf Life (Unit)	2 Year(s)30C
	For generic drugs (me-too Status)	Sitaglu- Met 50/850mg Tablet(Hilton Pharma (PVT) LTD)088218
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	

	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Janumet 50/850mg Tablet(Merck Sharp & Dohme B.V. Waarderweg 39 2031 BN Haarlem, The Netherlands)Netherland Approved Drug.
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	6- Justification of Manufacturing ApproachMetformin and sitagliptin have different physicochemical properties; therefore, their granulation/wetting was performed separately to ensure optimal flow, compressibility, and uniformity. After achieving suitable granules for each component, both masses were blended together to obtain a uniform mixture prior to compression of the extended-release tablets. Sir In future, we undertake that we shall separately mix the both APIs that is Sitagliptin and metformin.	
	Decision	
	Deferred	
	The Registration Board deferred the product for submission of Pharmaceutical Development and stability studies for the formulations manufactured in accordance with the innovator's method of manufacturing	
59	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Seraph Pharmaceutical Plot No 210, Industrial Triangle Kahuta Road, Islamabad. (000860)
	Application Form Dy. No / Tracking ID & date of submission	(PSJ-4US-66TU, 2024-07-10)
	Detail of Fee Submitted	30000.0, 2024-06-11,
	The proposed proprietary name / brand name	Celampa-M XR 12.5/1000mg Tablet
	Label Claim	Each extended release film coated tablet contains: Empagliflozin....12.5mg Metformin hydrochloride 1000mg
	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)	Diampa- M XR 12.5/1000mg Tablet by Getz Pharma
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Aarti Drugs Limited,Fuxin Long Rui Pharmaceutical China
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	FDA approved drug
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The applicaiton fulfills codal formalities.	
	Decision	
	Approved	
60	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Pharmedic Laboratories (Pvt.) Ltd Lahore 16-Km Multan Road, Lahore (000228)
	Application Form Dy. No / Tracking ID & date of submission	(D3M-PVA-MWUT, 2024-08-09)
	Detail of Fee Submitted	30000.0, 2024-05-20,
	The proposed proprietary name / brand name	Artu-S Tablet
	Label Claim	Each film coated tablet contains: 19.43mg Ertugliflozin L-Pyroglutamic Acid (Equivalent to 15mg of Ertugliflozin) 128.5mg of Sitagliptin phosphate (equivalent to 100mg of Sitagliptin)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	A blister pack of 1 -As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store above 30 C, store in the original package in order to protect from moisture.
	For generic drugs (me-too Status)	Trevia R2
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Fuxin Long Rui Pharmaceutical CO., Ltd,Zhejiang Hongyuan Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Steglujan tablets Merck & Co., Inc. USA
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML dated 07.04.2025
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
61	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	(8Z4-ZMS-6YD7, 2024-08-19)
	Detail of Fee Submitted	30000.0, 2024-07-30,
	The proposed proprietary name / brand name	Emflox-M XR Tablets 12.5MG/1000MG
	Label Claim	Each extended-release tablet contains: Empagliflozin.....12.5mg Metformin HCl 1000mg (Innovator Specifications)
	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)	Erli plus XR Tablets, Manufacturer: Pharm Evo (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	Empagliflozin Metformin Hydrochloride 12.5MG/1000MG XR Tablets, Manufacturer: MSN LABS PVT LTD (USFDA Approved) (NDA): 212362
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The applicant has withdrawn this application as it was approved in Registration Board meeting (347) for contract manufacturing Seraph Pharma and the applicant acquired approval of change in manufacturing site to their name of already registered drug product.	
	Decision	
	Rejected	
	The Registration Board rejected the application as withdrawn by the applicant.	
62	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	(A4X-A3G-8NEX, 2024-08-20)
	Detail of Fee Submitted	30000.0, 2024-07-30,
	The proposed proprietary name / brand name	Emflox 10mg Tablets
	Label Claim	Each film coated tablet contains: Empagliflozin 10mg (Innovator Specifications)

	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)	Diampa 10mg tablets, Manufacturer: Getz Pharma Private Limited
	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	Jardiance 10mg tablets, Manufacturer: Boehringer Ingelheim Pharmaceutical company (USFDA Approved)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The applicant has withdrawn this application as it was approved in Registration Board meeting (347) for contract manufacturing Seraph Pharma and the applicant acquired approval of change in manufacturing site to their name of already registered drug product.	
	Decision	
	Rejected	
	The Registration Board rejected the application as withdrawn by the applicant.	
63	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	(W4U-SU8-N7BA, 2024-08-21)
	Detail of Fee Submitted	30000.0, 2024-07-30,
	The proposed proprietary name / brand name	Emflox-M Tablets 12.5MG/500MG
	Label Claim	Each film coated tablet contains; Empagliflozin.....12.5mg Metformin HCl 500mg (Innovator Specifications)
	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)	Diampa-M Tablets, Manufacturer: Getz Pharma Pvt. Limited
	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	Empagliflozin Metformin Hydrochloride Tablets, Company: MSN LABS PVT LTD. (NDA): 212362, (USFDA Approved)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The applicant has withdrawn this application as it was approved in Registration Board meeting (347) for contract manufacturing Seraph Pharma and the applicant acquired approval of change in manufacturing site to their name of already registered drug product.	
	Decision	
	Rejected	
	The Registration Board rejected the application as withdrawn by the applicant.	
64	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	(B74-BDZ-B1LU, 2024-08-26)
	Detail of Fee Submitted	30000.0, 2024-07-30,
	The proposed proprietary name / brand name	Emflox-M Tablets 12.5MG/ 850MG
	Label Claim	Each film coated tablet contains; Empagliflozin.....12.5mg Metformin HCl 850mg (Innovator Specifications)
	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)	Diampa-M Tablets, Manufacturer: Getz Pharma Pvt. Limited
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Synjardy 12.5/850mg, (EM approved) Manufacturer: Boehringer Ingelheim Pharma

		GmbH & Co. KG Binger Strasse 173 55216 Ingelheim am Rhein Germany
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The applicant has withdrawn this application as it was approved in Registration Board meeting (347) for contract manufacturing Seraph Pharma and the applicant acquired approval of change in manufacturing site to their name of already registered drug product.	
	Decision	
	Rejected	
	The Registration Board rejected the application as withdrawn by the applicant.	
65	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	(EEP-28Q-G18Y, 2024-08-30)
	Detail of Fee Submitted	30000.0, 2024-07-30,
	The proposed proprietary name / brand name	Emflox 25mg Tablets (Film Coated Tablet)
	Label Claim	Each film coated tablet contains: Empagliflozin 25mg (Innovator Specifications)
	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)	Diampa 25mg Tablets, Manufacturer: Getz Pharma Private Limited
	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	Jardiance 25mg tablets, Manufacturer: Boehringer Ingelheim Pharmaceutical company
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The applicant has withdrawn this application as it was approved in Registration Board meeting (347) for contract manufacturing Seraph Pharma and the applicant acquired approval of change in manufacturing site to their name of already registered drug product.	
	Decision	
	Rejected	
	The Registration Board rejected the application as withdrawn by the applicant.	

66	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	(67G-MP9-A4GD, 2024-10-03)
	Detail of Fee Submitted	30000.0, 7000.0 2024-07-30, 2024-09-25
	The proposed proprietary name / brand name	Emflox-L 5mg Tablets
	Label Claim	Each film coated tablet contains; Linagliptin 5mg (Innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Lina Tablets, Manufacturer: CCL Pharma Pvt. Limited
	Pharmaceutical Group of (API)	Anti-diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Three batches at long term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided; API on loan from Novamed
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Linagliptin Tablets 5mg, Company: Aurobindo Pharma Ltd., (NDA): 208415 (USFDA Approved)
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
67	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	(RS2-Z9S-H8Z3, 2024-10-03)
	Detail of Fee Submitted	30000.0, 7000.0 2024-07-30, 2024-09-25
	The proposed proprietary name / brand name	Emflox-LT Tablets 10mg/5mg
	Label Claim	Each film coated tablet contains; Empagliflozin/ Linagliptin.....10mg/ 5mg (Innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO

	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Diampa-LT Tablets, Manufacturer: Getz Pharma Pvt. Limited
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Empagliflozin and Linagliptin Tablet 10mg/5mg, Company: Prinston Pharma INC. (NDA): 212264 (USFDA Approved)
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
68	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	(W25-V28-2X85, 2024-10-30)
	Detail of Fee Submitted	30000.0, 7000.0 2024-07-30, 2024-10-08
	The proposed proprietary name / brand name	Emflox-LTM XR Tablets 25mg/ 5mg/ 1000mg
	Label Claim	Each film coated tablet contains: Empagliflozin/Linagliptin/Metformin HCl.....25mg/5mg/ 1000mg (Innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Exempa-Lin Met XR Tablet, Manufacturer: HIGH-Q
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Three batches at long term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided; API on loan from Novamed

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Empagliflozin , Linagliptin, Metformin Hydrochloride Tablets, Company: Lupin Ltd., (NDA): 215072, (USFDA Approved)
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
69	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	(89H-H2H-M19J, 2024-12-19)
	Detail of Fee Submitted	37000.0, 2024-11-14,
	The proposed proprietary name / brand name	Dabitek 100mg Tablets
	Label Claim	Each film coated tablet contains: Trelagliptin Succinate equivalent to Trelagliptin.....100mg (Innovator Spec's)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Trelaget 100mg Tablet (Getz pharmaceutical pvt. (ltd))
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Zafatek 100mg Tablet (PMDA Approved) Registered in Japan
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	

	Approved	
70	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	(MMW-9J5-1W1X, 2024-12-19)
	Detail of Fee Submitted	37000.0, 2024-11-14,
	The proposed proprietary name / brand name	DABITEK 50MG TABLET
	Label Claim	Each film coated tablet contains: Trelagliptin Succinate equivalent to Trelagliptin.....50mg (Innovator Spec's)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Trelaget 50mg Tablet (Getz pharmaceutical pvt. (ltd))
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Zafatek 50mg Tablet (Registered in Japan)
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
71	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi (000333)
	Application Form Dy. No / Tracking ID & date of submission	(6XN-1V2-GD1A, 2024-08-21)
	Detail of Fee Submitted	30000.0, 2023-12-18,
	The proposed proprietary name / brand name	ERSITA 5/100mg TABLETS
	Label Claim	Ech film coatede tablet contains: Ertugliflozin as LPGA.....5mg Sitagliptin as Phosphate Monohydrate.....100mg

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x7's-As per SRO
	Shelf Life (Unit)	2 Year(s)store in a cool and dry place below 30
	For generic drugs (me-too Status)	TREVIA R2 5+100mg
	Pharmacotherapeutic Group of (API)	Sodium-Glucose Co-Transporter 2 (SGLT2) inhibitor class of drugs
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Fuxin Long Rui Pharmaceuticals,India
	Detail of stability batches of drug product	Three batches 1500 tablets at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Setaglujan (MERK USA)
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML renewal submiited vide A44-6E8-X92H
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
72	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi (000333)
	Application Form Dy. No / Tracking ID & date of submission	(NS1-PYT-EX6X, 2024-08-28)
	Detail of Fee Submitted	30000.0, 2023-12-18,
	The proposed proprietary name / brand name	ERSITA 15/100mg TABLETS
	Label Claim	Each film coated tablet contains: Ertugliflozin as LPGA.....15mg Sitagliptin as Phosphate Monohydrate.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x7's-As per SRO
	Shelf Life (Unit)	2 Year(s)store in a cool and dry place below 30
	For generic drugs (me-too Status)	TREVIA R2 15+100mg TABLETS
	Pharmacotherapeutic Group of (API)	Sodium-Glucose Co-Transporter 2 (SGLT2) inhibitor class of drugs
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Fuxin Long Rui Pharmaceuticals,India
	Detail of stability batches of drug product	Three batches 1500 tablets at 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	Performed

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	STEGLUJAN 15/100mg TABLETS (Merk USA)
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML renewal submitted vide A44-6E8-X92H
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
73	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi (000333)
	Application Form Dy. No / Tracking ID & date of submission	(USP-63V-HA84, 2024-09-10)
	Detail of Fee Submitted	75000.0, 2024-08-26,
	The proposed proprietary name / brand name	E-Linamet XR 10mg/5mg/1000mg Tablets
	Label Claim	Each film coated tablet contains: Empagliflozin.....10mg Linagliptin.....5mg (immediate release) Metformin HCl.....1000mg (Extended release)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x7's-As per SRO
	Shelf Life (Unit)	2 Year(s)store in a cool and dry place below 30
	For generic drugs (me-too Status)	-
	Pharmacotherapeutic Group of (API)	Sodium-Glucose Co-Transporter 2 (SGLT2) inhibitor class of drugs with Metformin
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Exemed Pharmaceuticals,Fuxin Long Rui Pharmaceuticals,India,Jiangsu Yongan Pharmaceuticals Co. Ltd. China
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Trijardy XR 10mg/5mg/1000mg Tablets
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML renewal submitted vide A44-6E8-X92H
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
74	Case Category	Routine (Abdul Mughees)

	Name, address of Applicant.	Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi (000333)
	Application Form Dy. No / Tracking ID & date of submission	(G6Q-R2G-VZB9, 2024-09-20)
	Detail of Fee Submitted	75000.0, 2024-08-26,
	The proposed proprietary name / brand name	E-LINAMET XR 25mg/5mg/1000mg Tablets
	Label Claim	Each film coated tablet contains: Empagliflozin.....25mg Linagliptin.....5mg (immediate release) Metformin HCl.....1000mg (Extended release)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x7's-As per SRO
	Shelf Life (Unit)	2 Year(s)store in a cool and dry place below 30
	For generic drugs (me-too Status)	-
	Pharmacotherapeutic Group of (API)	Sodium-Glucose Co-Transporter 2 (SGLT2) inhibitor class of drugs with Metformin
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Exemed Pharmaceuticals,Fuxin Long Rui Pharmaceuticals,India,Jiangsu Yongan Pharmaceuticals Co. Ltd. China
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Trijardy XR 25mg/5mg/1000mg Tablets
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML renewal submitted vide A44-6E8-X92H
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
75	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi (000333)
	Application Form Dy. No / Tracking ID & date of submission	(5JY-ASP-6715, 2024-10-10)
	Detail of Fee Submitted	75000.0, 2024-07-24,
	The proposed proprietary name / brand name	E-LINAMET XR 5/2.5/1000mg Tablets
	Label Claim	Empagliflozin.....5mg Linagliptin.....2.5mg (Immediate release) Metformin HCl.....1000mg (Extended release)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x7's-As per SRO

	Shelf Life (Unit)	2 Year(s)store below 30
	For generic drugs (me-too Status)	nil
	Pharmacotherapeutic Group of (API)	Sodium-Glucose Co-Transporter 2 (SGLT2) inhibitor class of drugs with Metformin
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Exemed pharmaceuticals ,Fuxin Long Rui Pharmaceuticals,India,Jiangsu Yongan Pharmaceuticals Co. Ltd. China
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Trijardy XR Tablets
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML renewal submitted vide A44-6E8-X92H
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
76	Case Category	Contract Manufacturing (Abdul Mughees)
	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	(GDV-RT1-PZHE, 2024-08-22)
	Detail of Fee Submitted	75000.0, 2024-08-09,
	The proposed proprietary name / brand name	Trafen 100mg Tablet
	Label Claim	: Each film coated tablet contains: Trelagliptin as Trelagliptin Succinate.....100mg Innovator's Specification
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's-As per SRO,1x4's -As per SRO,2x10's-As per SRO,2x7's-As per SRO,3x10's-As per SRO,4x7's-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30 Degree
	For generic drugs (me-too Status)	Trelaget 100mg Tablet, M/s. Getz Pharma Pakistan (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceutical Pvt. Ltd.-Plot # 129, Sundar Industrial Estate Raiwind Road, Lahore, Pakistan.-
	The status in reference regulatory authorities	Zafatek Tablet 100mg, M/s Takeda Pharmaceuticals Company Limited PMDA Approved
	Detail of previous approval	
	Evaluation Remarks	

	The application was considered in routine. However, the applicant has informed that the said product has been approved for Wimitis (Contract acceptor) in 353rd meeting of the Registration Board. Accordingly, the applicant has submitted differential fee and declarations.	
	Decision	
	Approved	
77	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Welmark Pharmaceuticals Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan (000614)
	Application Form Dy. No / Tracking ID & date of submission	(GH1-L7B-HJ8Q, 2024-08-27)
	Detail of Fee Submitted	30000.0, 2024-07-30,
	The proposed proprietary name / brand name	DAPZIN M XR 10/1000mgTABLET
	Label Claim	Each Film Coated bilayer Tablet Contains: Metformin Hydrochloride (USP).....1000mg (Extended release) DapagliflozinPropanediol Monohydrate.....10mg (Immediate release) (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
	For generic drugs (me-too Status)	Dapa-Met TABLET XR 10/1000mg Manufacturer Hilton Pharma Pvt Ltd Strength 10/1000mg Tablet
	Pharmacotherapeutic Group of (API)	A10BK01; Sodium-glucose co-transporter 2 (SGLT2) inhibitor with Metformin
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	https://www.accessdata.fda.gov/drugsatfda_docs/labeling/2024/01/01/20240101.pdf
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
78	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Welmark Pharmaceuticals Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan (000614)

	Application Form Dy. No / Tracking ID & date of submission	(ZWA-L2J-HQJN, 2024-11-12)
	Detail of Fee Submitted	30000.0, 7000.0 2024-07-24, 2024-10-29
	The proposed proprietary name / brand name	DAPZIN M XR 5/1000mg TABLET
	Label Claim	Each Film Coated bilayer Tablet Contains: Metformin Hydrochloride (USP).....1000mg (Extended release) DapagliflozinPropanediol Monohydrate.....5mg (Immediate release) (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
	For generic drugs (me-too Status)	Dapa-Met TABLET XR 5/1000mg Manufacturer Hilton Pharma Pvt Ltd Strength 5/1000mg Tablet
	Pharmacotherapeutic Group of (API)	A10BK01; Sodium-glucose co-transporter 2 (SGLT2) inhibitor with Metformin
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	https://www.medicines.org.uk/emc/product/5293/s
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
79	Case Category	Contract Manufacturing (Abdul Mughees)
	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	(TET-P19-6XMW, 2024-09-12)
	Detail of Fee Submitted	75000.0, 18000.0 2024-08-09, 2024-09-10
	The proposed proprietary name / brand name	Trafen 50mg Tablet
	Label Claim	Each film coated tablet contains: Trelagliptin as Trelagliptin Succinate.....50mg Innovator's Specification
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's -As per SRO,1x4's-As per SRO,2x10's-As per SRO,2x7's-As per SRO,3x10's-As per SRO,4x7's-As per SRO

	Shelf Life (Unit)	2 Year(s)Store Below 30 Degree
	For generic drugs (me-too Status)	Trelaget 50mg Tablet, M/s. Getz Pharma Pakistan (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Name, address of Manufacturing site:	Wimits Pharmaceutical Pvt. Ltd.-Plot # 129, Sundar Industrial Estate Raiwind Road, Lahore, Pakistan.-
	The status in reference regulatory authorities	Zafatek Tablet 50mg, M/s Takeda Pharmaceuticals Company Limited PMDA Approved.
	Detail of previous approval	
	Evaluation Remarks	
	The applicant has informed that the said product has already been approved and accordingly submitted declaration and differential fee.	
	Decision	
	Approved	
80	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Nabiqasim Industries (Pvt) Ltd., 17/24, Korangi Industrial Area, Karachi. (000105)
	Application Form Dy. No / Tracking ID & date of submission	(65M-JD7-XHNU, 2024-11-13)
	Detail of Fee Submitted	75000.0, 2024-10-31,
	The proposed proprietary name / brand name	Sotaloz Tablet 200mg
	Label Claim	Each film-coated tablet contains: Sotagliflozin.....200mg (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°C
	For generic drugs (me-too Status)	Not available
	Pharmacotherapeutic Group of (API)	A10BK06; Sodium-glucose co-transporter 2 (SGLT2) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Fuxin Long Rui Pharmaceutical CO., Ltd.
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long-term and accelerated conditions
	The status in reference regulatory authorities	US FDA Approved (INPEFA 200mg tablet byLexicon Pharmaceuticals, Inc., USA & MHRA Approved (Zynquista 200 mg tablets by DLRC Ltd., UK)
	GMP status of the firm	Provided 2023
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	

	The application fulfills codal formalities.	
	Decision	
	Approved	
81	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Nabiqasim Industries (Pvt) Ltd., 17/24, Korangi Industrial Area, Karachi. (000105)
	Application Form Dy. No / Tracking ID & date of submission	(T5A-WAE-V9L1, 2024-11-13)
	Detail of Fee Submitted	75000.0, 2024-10-31,
	The proposed proprietary name / brand name	Sotaloz Tablet 400mg
	Label Claim	Each film-coated tablet contains: Sotagliflozin.....400mg (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°C
	For generic drugs (me-too Status)	Not available
	Pharmacotherapeutic Group of (API)	A10BK06; Sodium-glucose co-transporter 2 (SGLT2) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Fuxin Long Rui Pharmaceutical CO., Ltd.
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long-term and accelerated conditions
	The status in reference regulatory authorities	US FDA Approved (INPEFA 400mg tablet by Lexicon Pharmaceuticals, Inc., USA
	GMP status of the firm	Provided 2023
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
82	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Dr. Raza Pharma 44-C Hayatabad Industrial Estate Peshawar (000387)
	Application Form Dy. No / Tracking ID & date of submission	(PWV-XAM-PH7G, 2024-11-14)
	Detail of Fee Submitted	37000.0, 2024-10-24,
	The proposed proprietary name / brand name	Sita Plus
	Label Claim	Each film coated tablet contains: Sitagliptin Phosphate equivalent to sitagliptin.....50mg Metformin HCl.....500mg

	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 degree C°
	For generic drugs (me-too Status)	Sitaphage (50-500)mg Table
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	AURO LABORATORIES LIMITED ,M/S Pharmagen Limited
	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
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has stated as follows: Due to ongoing higher prices of API, and market fluctuations, we want to withdraw our product.	
	Decision	
	Rejected	
	The Registration Board rejected the application as withdrawn by the applicant.	
83	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Swiss Pharmaceuticals Pvt. Ltd. A/159, S.I.T.E.-II, Super Highway (000438)
	Application Form Dy. No / Tracking ID & date of submission	(NV6-298-E5ZZ, 2024-11-18)
	Detail of Fee Submitted	37000.0, 2024-10-31,
	The proposed proprietary name / brand name	EmpzaGlo Tablet 10mg
	Label Claim	Each film coated tablet contains: Empagliflozin.....10 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)Store below 30°C
	For generic drugs (me-too Status)	Diampa Tablets 10mg by Getz Pharma (Pvt) Ltd., 29-30 Sector 27 Korangi Industrial Area Karachi., (093073)
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Fuxin Long Rui Pharmaceutical CO. Ltd. Fluoride Industrial Park, Fumeng County(Yi Ma Tu), Fuxin City, Liaoning Province -123000, China.
	Detail of stability batches of drug product	Three batches at long term and accelerated conditions

	Documents for the procurement of API with approval from DRAP (in case of Import)	API on loan from Seraph Pharmaceuticals
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Jardiance by Boehringer Ingelheim Pharmaceuticals, Inc. approved by USFDA
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML Renewal dated 08-09-2024
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
84	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Werrick Pharmaceuticals Plot No. 216 - 217, I-10/3, Industrial Area Islambad (000340)
	Application Form Dy. No / Tracking ID & date of submission	(97M-DEG-HJTW, 2024-11-30)
	Detail of Fee Submitted	37000.0, 2024-11-04,
	The proposed proprietary name / brand name	Empamet 5/850mg Tablets
	Label Claim	Each film coated tablet contains:- Empagliflozin.....5mg, Metformin HCl.....850mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled,7's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Xenglu-Met 5/850mg Tablets, By Hilton, Pakistan By Hilton
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	N/A
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Synjardy Tablets 5/850mg FDA Approved
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	

	Approved	
85	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Werrick Pharmaceuticals Plot No. 216 - 217, I-10/3, Industrial Area Islambad (000340)
	Application Form Dy. No / Tracking ID & date of submission	(P59-JRQ-24AV, 2024-11-30)
	Detail of Fee Submitted	37000.0, 2024-11-04,
	The proposed proprietary name / brand name	Empamet 12.5/850mg Tablets
	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	10's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled,7's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	DIAMPA-M 12.5/850mg By Getz Pakistan
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	N/A
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Synjardy Tablets 12.5/850mg FDA Approved
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
86	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Werrick Pharmaceuticals Plot No. 216 - 217, I-10/3, Industrial Area Islambad (000340)
	Application Form Dy. No / Tracking ID & date of submission	(PSD-NS1-UB1M, 2024-11-30)
	Detail of Fee Submitted	37000.0, 2024-11-13,
	The proposed proprietary name / brand name	Trepinol 50mg Tablets
	Label Claim	Each film coated tablet contains: Tapentadol (as HCl).....50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-

		Controlled, 7's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Tapento IR Tablets By SAMI, Pakistan
	Pharmacotherapeutic Group of (API)	Other opioids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	N/A
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Nucunta Tablets FDA Approved
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	US FDA has reviewed and stated for the 200533Orig1s000 Nucynta™ (tapentadol) Extended Release Tablets that the labeling indicates that the drug product is to be used by patients 18 years of age or older for the management of moderate to severe chronic pain.	
	Decision	
	Approved	
	Approved with following labelling requirement:	
	"This drug product is to be used by patients 18 years of age or older for the management of moderate to severe chronic pain"	
87	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Nabiqasim Industries (Pvt) Ltd., 17/24, Korangi Industrial Area, Karachi. (000105)
	Application Form Dy. No / Tracking ID & date of submission	(4GP-RL1-6LHV, 2024-12-09)
	Detail of Fee Submitted	37000.0, 2024-12-05,
	The proposed proprietary name / brand name	Trelatek Tablet 100mg
	Label Claim	Each film-coated tablet contains: Trelagliptin Succinate equivalent to Trelagliptin.....100mg (Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	4's, 8's, 10's, 16's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Yes
	Pharmacotherapeutic Group of (API)	A10BH (Dipeptidyl peptidase 4 [DPP-4] 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	Three batches at long term and accelerated conditions
	Documents for the procurement of API with approval from DRAP	Provided

	(in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	PMDA, Japan Approved (Zafatek Tablets 100mg by Teijin Pharma Co. Ltd., Japan)
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
88	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Nabiqasim Industries (Pvt) Ltd., 17/24, Korangi Industrial Area, Karachi. (000105)
	Application Form Dy. No / Tracking ID & date of submission	(469-2UA-2L92, 2024-12-09)
	Detail of Fee Submitted	37000.0, 2024-12-05,
	The proposed proprietary name / brand name	Trelatek Tablet 50mg
	Label Claim	Each film-coated tablet contains: Trelagliptin Succinate equivalent to Trelagliptin.....50mg (Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	4's, 8's, 10's, 16's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Yes
	Pharmacotherapeutic Group of (API)	A10BH (Dipeptidyl peptidase 4 [DPP-4] 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	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	PMDA, Japan Approved (Zafatek Tablets 50mg by Teijin Pharma Co. Ltd., Japan)
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
89	Case Category	Routine (Abdul Mughees)

	Name, address of Applicant.	Werrick Pharmaceuticals Plot No. 216 - 217, I-10/3, Industrial Area Islambad (000340)
	Application Form Dy. No / Tracking ID & date of submission	(47S-NZ1-BMDT, 2024-12-17)
	Detail of Fee Submitted	37000.0, 2024-11-25,
	The proposed proprietary name / brand name	Regain 500mg Tablets
	Label Claim	Each film coated tablet contains: Metformin HCl.....500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-Controlled,14's-Controlled,20's-Controlled,28's-Controlled,30's-Controlled,50's-Controlled,7's-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Glucophage 500mg Tablets By Martin Dow Marker Ltd, Pakistan
	Pharmacotherapeutic Group of (API)	A10BA02; Biguanides
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	N/A
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Glucophage 500mg Tablets By Merck, KGaA, Germany
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
90	Case Category	Contract Manufacturing (Abdul Mughees)
	Name, address of Applicant.	Martin Dow Limited Plot no. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan (000267)
	Application Form Dy. No / Tracking ID & date of submission	(XEY-PPP-ZMRE, 2025-05-15)
	Detail of Fee Submitted	93000.0, 2025-03-13,
	The proposed proprietary name / brand name	Mirocare ODT 10mg
	Label Claim	Each orally disintegrating tablet contains: Mirogabalin (as Besylate) 10mg.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-As per SRO,28's-As per SRO,7's-As per SRO

	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	Gabapentinoids
	Name, address of Manufacturing site:	Martin Dow Marker Limited-07-Jail Road, Quetta, Pakistan-
	Name & address of API manufacturer	Not Applicable
	Detail of stability batches of drug product	Batch No: PDS-348-24, Batch No: PDS-349-24, Batch No: PDS-350-24
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 attached mentioning import of Mirogabalin Besylate (1.2000kg) from Shandong Kehui Pharmaceutical Co., Ltd,China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence established with Innovator Product Tarlige OD Tablet 10mg
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
	The status in reference regulatory authorities	Tarlige OD Tablet 10mg by PMDA Japan
	GMP status of the firm	GMP Certificate Valid till 16th January 2027
	Evidence of approval of manufacturing facility	Tablet (General) Section Approval issued via letter dated 17th June 2021
	Evaluation Remarks	
	Under export facilitation as per letter dated 30 April 2026.	
	Decision	
	Approved	
91	Case Category	Contract Manufacturing (Abdul Mughees)
	Name, address of Applicant.	Martin Dow Limited Plot no. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan (000267)
	Application Form Dy. No / Tracking ID & date of submission	(1NX-EP8-US21, 2025-05-29)
	Detail of Fee Submitted	93000.0, 2025-03-13,
	The proposed proprietary name / brand name	Mirocare ODT
	Label Claim	Each orally disintegrating tablet contains: Mirogabalin (as Besylate) 2.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-As per SRO,28's-As per SRO,7's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	Gabapentinoids
	Name, address of Manufacturing site:	Martin Dow Marker Limited-07-Jail Road, Quetta, Pakistan.-
	Name & address of API manufacturer	Not Applicable
	Detail of stability batches of drug product	Batch No: PDS-348-24, Batch No: PDS-349-24, Batch No: PDS-350-24
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 attached mentioning import of Mirogabalin Besylate (1.2000kg) from Shandong Kehui Pharmaceutical Co., Ltd,China

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence established with Innovator Product Tarlige OD Tablet 10mg
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
	The status in reference regulatory authorities	Tarlige OD Tablet 2.5mg by Japan
	GMP status of the firm	GMP Certificate Valid till 16th January 2027
	Evidence of approval of manufacturing facility	Tablet (General) Section Approval issued via letter dated 17th June 2021
	Evaluation Remarks	
	Under export facilitation as per letter dated 30 April 2026.	
	Decision	
	Approved	
92	Case Category	Contract Manufacturing (Abdul Mughees)
	Name, address of Applicant.	Martin Dow Limited Plot no. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan (000267)
	Application Form Dy. No / Tracking ID & date of submission	(8R1-TPB-RNXM, 2025-05-29)
	Detail of Fee Submitted	93000.0, 2025-03-13,
	The proposed proprietary name / brand name	Mirocare ODT
	Label Claim	Each orally disintegrating tablet contains: Mirogabalin (as Besylate) 5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-As per SRO, 28's-As per SRO, 7's-As per SRO
	Shelf Life (Unit)	2 Year(s) Store below 30°C
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	Gabapentinoids
	Name, address of Manufacturing site:	Martin Dow Marker Limited-07-Jail Road, Quetta, Pakistan.-
	Name & address of API manufacturer	Not Applicable
	Detail of stability batches of drug product	Batch No: PDS-348-24, Batch No: PDS-349-24, Batch No: PDS-350-24
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 attached mentioning import of Mirogabalin Besylate (1.2000kg) from Shandong Kehui Pharmaceutical Co., Ltd, China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence established with Innovator Product Tarlige OD Tablet 10mg
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
	The status in reference regulatory authorities	Tarlige OD Tablet 5mg by PMDA Japan
	GMP status of the firm	GMP Certificate Valid till 16th January 2027
	Evidence of approval of manufacturing facility	Tablet (General) Section Approval issued via letter dated 17th June 2021
	Evaluation Remarks	
	Under export facilitation as per letter dated 30 April 2026.	
	Decision	

	Approved	
93	Case Category	Contract Manufacturing (Abdul Mughees)
	Name, address of Applicant.	Martin Dow Limited Plot no. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan (000267)
	Application Form Dy. No / Tracking ID & date of submission	(EJX-QMJ-XP8T, 2025-07-15)
	Detail of Fee Submitted	93000.0, 2025-03-13,
	The proposed proprietary name / brand name	Mirocare ODT 15mg
	Label Claim	Each orally disintegrating tablet contains: Mirogabalin (as Besylate) 15mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-As per SRO, 28's-As per SRO, 7's-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30°C
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	Gabapentinoids
	Name, address of Manufacturing site:	Martin Dow Marker Limited-07-Jail Road, Quetta, Pakistan.-
	Name & address of API manufacturer	Not Applicable
	Detail of stability batches of drug product	Batch No: PDS-345-24, Batch No: PDS-346-24, Batch No:PDS-347-24
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 attached mentioning import of Mirogabalin Besylate (1.2000kg) from Shandong Kehui Pharmaceutical Co., Ltd, China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence established with Innovator Product Tarlige OD Tablet 15mg
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
	The status in reference regulatory authorities	Tarlige OD Tablet 15mg by Japan
	GMP status of the firm	GMP certificate valid till 16th January 2027
	Evidence of approval of manufacturing facility	Tablet (General)
	Evaluation Remarks	
	Under export facilitation as per letter dated 30 April 2026.	
	Decision	
	Approved	
94	Case Category	Import (Abdul Mughees)
	Name, address of Applicant.	Al Habib Pharmaceuticals. Plot 81 SMCHS BLOCK B (0414)
	Application Form Dy. No / Tracking ID & date of submission	(UAS-HM4-573Y, 2026-02-04)
	Detail of Fee Submitted	313500, 2025-11-10,
	The proposed proprietary name / brand name	GEMCIT 200mg Lyophilized Injection USP
	Label Claim	Each vial contains: Gemcitabine Hydrochloride USP Eq. to Gemcitabine 200mg Excipients q.s.

	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	12 Month(s)Store below 30°C
	For generic drugs (me-too Status)	Manufacturer name: BF Biosciences Limited Brand name : Pamigen 200mg Strength : 200mg Composition : Sterile lyophilized Gemcitabine Hydrochloride equivalent to Gemcitabine... 200mg Registration number :
	Pharmacotherapeutic Group of (API)	Aspen Biopharma Labs Pvt Ltd Biotech Park, Phase-Ii, Plot-10, Lalgadi Malakpet, Shameerpet, Medchal Malkajgiri, T.S., India.
	Name, address of Manufacturing site:	KWALITY PHARMACEUTICALS LTD. - KWALITY PHARMACEUTICALS LTD. 1-A, Industrial Area, Raja Ka Bagh, Tehsil Nurpur, Kangra-176201, (HP) (INDIA)-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Z-CITA-200mg , Flagship Biotech International Private Limited, India
	Name, address of Marketing Authorization Holder:	Al Habib Pharmaceuticals, Plot 81, Block B, SMCHS, Karachi , Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	DP: M/s Kwaliti Pharmaceuticals Ltd.. DCA Dist Solan (HP), India
	Details of Authorization Letter :	Finished drug product import
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 batches on long term and accelerated conditions
	The status in reference regulatory authorities	GEMCITABINE AN, ARTG 177642, TGA APPROVED – Australia : Company: Juno Pharmaceuticals Pty Ltd
	Evaluation Remarks	
	Subject to legalized CoPP and Letter of Authorization	
	Decision	
	Approved	
	Approved subject to provision of legalized CoPP and Letter of Authorization	
95	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi (000333)
	Application Form Dy. No / Tracking ID & date of submission	(EQJ-3YQ-PY5X, 2024-08-28)
	Detail of Fee Submitted	30000.0, 2023-12-18,
	The proposed proprietary name / brand name	E-LINA 10/5mg Tablets
	Label Claim	Each film coated tablet contains: Empagliflozin.....10mg Linagliptin.....5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x7-As per SRO
	Shelf Life (Unit)	2 Year(s)store in a cool and dry place below 30
	For generic drugs (me-too Status)	DIAMPA-LT (Getz Pharma
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Fuxin Long Rui Pharmaceuticals,India,Jiangsu Yongan Pharmaceuticals Co. Ltd. China

	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	GLYXAMBI Tablets (Boehringer Ingelheim Germany)
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
96	Case Category	Export Facilitation (Abdul Mughees)
	Name, address of Applicant.	Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi (000333)
	Application Form Dy. No / Tracking ID & date of submission	(T86-HWS-RLTR, 2025-04-07)
	Detail of Fee Submitted	75000.0, 2025-01-21,
	The proposed proprietary name / brand name	MIROGAB 15mg Tablets
	Label Claim	Each film coated tablet contains: Mirogabalin besylate equivalent to mirogabalin.....15mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	2 Year(s)store in a cool and dry place below 30
	For generic drugs (me-too Status)	nil
	Pharmacotherapeutic Group of (API)	Gabapentinoids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Kehui Pharmaceuticals Co.Ltd
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long-term and accelerated conditions
	The status in reference regulatory authorities	Tarlige 15mg Tablets
	GMP status of the firm	GMP certificate 20 Feb 2024
	Evidence of approval of manufacturing facility	DML 000333 dated 07-01-2021
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	

	Approved	
97	Case Category	Export Facilitation (Abdul Mughees)
	Name, address of Applicant.	Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi (000333)
	Application Form Dy. No / Tracking ID & date of submission	(QVR-DSU-ZBYB, 2025-04-07)
	Detail of Fee Submitted	75000.0, 2025-02-19,
	The proposed proprietary name / brand name	MIROGAB 10mg Tablets
	Label Claim	Each film coated tablet contains: Mirogabalin Besylate equivalent to Mirogabalin.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	2 Year(s)store in a cool and dry place below 30
	For generic drugs (me-too Status)	nil
	Pharmacotherapeutic Group of (API)	Gabapentinoids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Kehui Pharmaceuticals Co.Ltd
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long-term and accelerated conditions
	The status in reference regulatory authorities	Tarlige 10mg Tablets
	GMP status of the firm	GMP certificate 20 Feb 2024
	Evidence of approval of manufacturing facility	DML 000333 dated 07-01-2021
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
98	Case Category	Contract Manufacturing (Abdul Mughees)
	Name, address of Applicant.	Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi (000333)
	Application Form Dy. No / Tracking ID & date of submission	(5WW-JJR-LDEG, 2025-04-07)
	Detail of Fee Submitted	75000.0, 2025-02-19,
	The proposed proprietary name / brand name	MIROGAB 5mg Tablets
	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	10's-As per SRO
	Shelf Life (Unit)	2 Year(s)store in a cool and dry place below 30
	For generic drugs (me-too Status)	nil

	Pharmacotherapeutic Group of (API)	Gabapentinoids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Kehui Pharmaceuticals Co.Ltd
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long-term and accelerated conditions
	The status in reference regulatory authorities	Tarlige 5mg Tablets
	GMP status of the firm	GMP certificate 20 Feb 2024
	Evidence of approval of manufacturing facility	DML 000333 dated 07-01-2021
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
99	Case Category	Export Facilitation (Abdul Mughees)
	Name, address of Applicant.	Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi (000333)
	Application Form Dy. No / Tracking ID & date of submission	(RSA-VT1-XBM7, 2025-04-21)
	Detail of Fee Submitted	75000.0, 2025-01-21,
	The proposed proprietary name / brand name	MIROGAB 2.5mg Tablets
	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	10's-As per SRO
	Shelf Life (Unit)	2 Year(s)store in a cool and dry place below 30
	For generic drugs (me-too Status)	nil
	Pharmacotherapeutic Group of (API)	Gabapentinoids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Kehui Pharmaceuticals Co.Ltd
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long-term and accelerated conditions
	The status in reference regulatory authorities	Tarlige 2.5mg Tablets
	GMP status of the firm	GMP certificate 20 Feb 2024
	Evidence of approval of manufacturing facility	DML 000333 dated 07-01-2021
	Evaluation Remarks	
	The application fulfills codal formalities.	

	Decision	
	Approved	
100	Case Category	Export Facilitation (Abdul Mughees)
	Name, address of Applicant.	Martin Dow Marker Limited 7, Jail Road Quetta. (000028)
	Application Form Dy. No / Tracking ID & date of submission	(MTY-GXZ-H6NU, 2026-04-01)
	Detail of Fee Submitted	75000, 2026-01-13,
	The proposed proprietary name / brand name	Setriga Tablet 50mg
	Label Claim	Each film coated tablet contains: Suzetrigine..... 50mg (Innovator's Specification).
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per DPC-As per SRO
	Shelf Life (Unit)	2 YearBelow 30
	For generic drugs (me-too Status)	Not Available
	Pharmaceutical Group of (API)	sodium channel blockers
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Chongqing Asincan Biotech Co., Ltd. 2-2 No. 8 Gangqiao Branch Road, Jiangbei District, Chongqing, P.R of Chin
	Detail of stability batches of drug product	Enclosed
	Documents for the procurement of API with approval from DRAP (in case of Import)	Enclosed
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Enclosed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Enclosed
	The status in reference regulatory authorities	USFDA
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	DML NO;000028
	Evaluation Remarks	
	DS long term stability data is only 12 months	
	Decision	
	Approved	
101	Case Category	New Molecule/Formulation (Abdul Mughees)
	Name, address of Applicant.	Solaris Life Sciences Private Limited, Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992)
	Application Form Dy. No / Tracking ID & date of submission	(QP6-N6V-X9WH, 2026-05-07)
	Detail of Fee Submitted	38700, 36300 2026-02-20, 2026-04-01
	The proposed proprietary name / brand name	SOZET 50MGTABLETS
	Label Claim	Each film coated tablet contains: Suzetrigine.... 50mg (Innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C

	For generic drugs (me-too Status)	N/A (New Molecule)
	Pharmacotherapeutic Group of (API)	Sodium channel blocker
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	Notificaiton to Pharmacy Services	
	Decision	
	Approved	
	Approved subject to provision of evidence of notificaiton of pharmacovigilance officer to Pharmacy Services Division of DRAP	
102	Case Category	New Molecule/Formulation (Abdul Mughees)
	Name, address of Applicant.	Atco Laboratories Limited B-18 SITE KARACHI (000188)
	Application Form Dy. No / Tracking ID & date of submission	(J8W-J1W-QUMH, 2026-02-10)
	Detail of Fee Submitted	75000, 2026-01-08,
	The proposed proprietary name / brand name	JOURGINE Tablet
	Label Claim	Each film coated tablet contains: Suzetrigine 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 strip x 10 Tablets-De-Controlled,1 strip x 14 Tablets-De-Controlled,2 strips x 10 Tablets-De-Controlled,2 strips x 14 Tablets-De-Controlled
	Shelf Life (Unit)	24 MonthDo not store and transport above 30 degree centigrade.
	For generic drugs (me-too Status)	Not Available.
	Pharmacotherapeutic Group of (API)	Suzetrigine, “Selective Voltage-Gated Sodium Channel Inhibitor; Non-Opioid Analgesic”.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Chongqing Asincan Biotech Co., Ltd.
	Detail of stability batches of drug product	03 Months Accelerated Stability Data and 03 months Long-Term Stability are attached in Module 03.
	Documents for the procurement of API with approval from DRAP (in case of Import)	API Procurement Document is attached.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence Report and Comparative Dissolution Profile are attached in

		Module 03.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months Accelerated Stability Data of Suzetrigine and 12 months Long-Term Stability Data of Suzetrigine are attached in Module 03.
	The status in reference regulatory authorities	JOURNAVX 50mg Film coated Tablet manufactured by Vertex Pharmaceuticals Incorporated; 50 Northern Avenue, Boston, MA 02210.
	GMP status of the firm	GMP Status is attached in Module 01.
	Evidence of approval of manufacturing facility	Manufacturing Facility Evidence is provided.
	Evaluation Remarks	
	DS long term stability data is upto 18 months	
	Decision	
	Approved	
	Subject to submission of Stress Testing of Drug Substance.	
103	Case Category	New Molecule/Formulation (Abdul Mughees)
	Name, address of Applicant.	Nabiqasim Industries (Pvt) Ltd., 17/24, Korangi Industrial Area, Karachi. (000105)
	Application Form Dy. No / Tracking ID & date of submission	(AVQ-B2X-TJGN, 2026-02-10)
	Detail of Fee Submitted	75000, 2026-01-07,
	The proposed proprietary name / brand name	Zetrixia 50mg Tablet
	Label Claim	Each film-coated tablet contains: Suzetrigine.....50mg (Innovator's Specs.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's, 10's, 14's, 20's, 28's, 30's, 50's and 100's- De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below at 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Non-Opioid Analgesic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Chongqing Asincan Biotech Co,Ltd
	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 3 months (ongoing) and the real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 03months.(ongoing)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Submitted copy of commercial invoice with Clearance Certificate dated 17-07-2025 issued by AD, DRAP, Karachi Specifying 0.6000kg of Suzetrigine
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted Pharmaceutical Equivalence of our product against the product Journavx by (Vertex Pharmaceutical) Submitted CDP results of our product against the product Journavx 50mg Tablet by (Vertex Pharmaceutical)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted stability study data of 3 batches of Suzetrigine at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6

		months. The real time stability data is conducted at 30°C ± 2°C + 65%RH ± 5% for 24 months.
	The status in reference regulatory authorities	FDA Approved
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	RMP of innovator	
	Decision	
	Approved	
	Approved subject to provision of innovator's Risk Management Plan	
104	Case Category	New Molecule/Formulation (Abdul Mughees)
	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	(78H-HBZ-E4B1, 2026-02-10)
	Detail of Fee Submitted	75000, 2025-11-24,
	The proposed proprietary name / brand name	Suzet 50mg Tablet
	Label Claim	Each film coated tablet contains: Suzetrigine..... 50 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,100'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)	Sodium channel blocker
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	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.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence and CDP has been provided,
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
	The status in reference regulatory authorities	Food and Drug Administration
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	Provided
	Evaluation Remarks	
	DS long term stability is upto 12 months	
	Decision	
	Approved	
	Subject to submission of Stress Testing of Drug Substance.	
105	Case Category	New Molecule/Formulation (Abdul Mughees)

	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	(1GU-8LU-NN9P, 2026-02-06)
	Detail of Fee Submitted	75000, 2026-01-21,
	The proposed proprietary name / brand name	Painze 50mg Tablets
	Label Claim	Each film coated tablet contains: Suzetrigine 50mg (Innovators Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C and 65 % ± 5% RH
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Non-opioid Analgesics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Chongqing Asincan Biotech Co., Ltd.
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	US-FDA Approved
	GMP status of the firm	GMP Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	DS stability is upto 12 months	
	Decision	
	Approved	
	Subject to submission of Stress Testing of Drug Substance.	
106	Case Category	Contract Manufacturing (Abdul Mughees)
	Name, address of Applicant.	Martin Dow Limited Plot no. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan (000267)
	Application Form Dy. No / Tracking ID & date of submission	(XD3-Q8X-NVMZ, 2026-02-09)
	Detail of Fee Submitted	97200, 2026-01-29,
	The proposed proprietary name / brand name	Suzetrix Tablets 50mg
	Label Claim	Each film coated tablet contains: Suzetrigine.....50mg
	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 YearStore below 30°C
	For generic drugs (me-too Status)	Not Applicable

	Pharmacotherapeutic Group of (API)	Sodium Channel Blocker
	Name, address of Manufacturing site:	Martin Dow Marker Limited-07-Jail Road, Quetta, Pakistan.-
	Name & address of API manufacturer	Not Applicable
	Detail of stability batches of drug product	Batch No: PDS-457-25, Batch No: PDS-458-25, Batch No: PDS-459-25
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 attached mentioning import of Suzetrigine (2.5000kg) from Chongoing Asincan BioTech Co., Ltd
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence established with Innovator Product Journavx Tablet 50mg
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
	The status in reference regulatory authorities	Journavx by US-FDA
	GMP status of the firm	GMP certificate valid till 16th January 2027
	Evidence of approval of manufacturing facility	Tablet (General)
	Evaluation Remarks	
	Decision	
	Approved	
107	Case Category	New Molecule/Formulation (Abdul Mughees)
	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	(8L3-P3N-9HEP, 2026-05-07)
	Detail of Fee Submitted	75000, 2026-02-02,
	The proposed proprietary name / brand name	Suzet Tablets 50mg
	Label Claim	Each film-coated tablet contains: Suzetrigine 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled, 14's-De-Controlled, 20's-De-Controlled, 28's-De-Controlled, 30's-De-Controlled, 7's-De-Controlled
	Shelf Life (Unit)	24 Year(s) Do not store above 30°C. Protect from sunlight and moisture.
	For generic drugs (me-too Status)	-
	Pharmacotherapeutic Group of (API)	Non – Opioid Analgesic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	-
	Detail of stability batches of drug product	The 03 batches of both long term and accelerated stability data of drug product
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and Comparative Dissolution Profile
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	The 03 batches of both long term and accelerated stability data of drug substance with long term for only 09 months

	The status in reference regulatory authorities	Journavx Tablets 50mg by M/s Vertex Pharmaceuticals Incorporated, USA.
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	This is to share with your good office Suzetrigene is a New Molecule and Stability is under development. We can share stability studies with updated interval once received	
	Decision	
	Approved	
	Subject to submission of Stress Testing of Drug Substance.	
108	Case Category	Export Facilitation (Dr. Farhad Ullah)
	Name, address of Applicant.	Ferozsons Laboratories Limited PO Ferozsons, Amangarh (000038)
	Application Form Dy. No / Tracking ID & date of submission	(55R-Q55-ZN9J, 2025-05-05)
	Detail of Fee Submitted	37000.0, 2025-04-30,
	The proposed proprietary name / brand name	Tizole D Cream 1%/0.1%
	Label Claim	Each gram contains: Isoconazole Nitrate.....10mg Diflucortolone Valerate.....1mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10gram-As per SRO,15gram-As per SRO,30gram-As per SRO,50gram-As per SRO,5gram-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store above 30°C
	For generic drugs (me-too Status)	Travocort Cream 1%/0.1% Manufacturer: Bayer Pakistan (Pvt) Limited
	Pharmacotherapeutic Group of (API)	Corticosteroid and imidazole antifungals
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Gufic Biosciences Limited,Stermone Chemicals Private Limited
	Detail of stability batches of drug product	3 batches having batch size of 800gm (53 tubes) each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of form 6 issued dated 27-01-2022 specifying 35gm+1gm Diflucortolone Valerate. Firm has also submitted copy of invoice, packing list, airway bill and goods declaration for procurement of API. Firm has submitted copy of form 6 issued dated 01-02-2022 specifying 200gm+45gm Isoconazole Nitrate. Firm has also submitted copy of invoice, form 3, form 7 and DHL receipt for procurement of API.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Travocort Cream by M/s Bayer Pakistan (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	Travocort Cream 1%/0.1% Manufacturer: Leo Pharma - HPRA Approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 09-08-2024.

	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 26-10-2020 specifying Cream/ointment/Gel section (steroid).
	Evaluation Remarks	
	Shortcomings	Firm's Response
	Valid copy of cGMP certificate or DML of API manufacturer for Diflucortolone and Isoconazole Nitrate issued by relevant regulatory authority of country of origin is required	Diflucortolone Firm has submitted copy of cGMP certificate of API manufacturer valid upto 02-06-2027. Isoconazole Nitrate Firm has submitted copy of cGMP certificate of API manufacturer valid upto 12-08-2028.
	The application fulfills codal formalities and is submitted for consideration of Registration Board.	
	Decision	
	Approved	
109	Case Category	Routine (Dr. Farhad Ullah)
	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	(HA2-LE2-V7Q7, 2024-11-12)
	Detail of Fee Submitted	37000.0, 2024-10-31,
	The proposed proprietary name / brand name	Spaz-D Injection 40mg/2ml
	Label Claim	Each 2ml ampoule contains: Drotaverine HCl 40mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	25'S-As per SRO
	Shelf Life (Unit)	24 Year(s)Below 30 degree
	For generic drugs (me-too Status)	No-Spa Injection (40mg/2ml) by Hoechst Pakistan Limited (008296)
	Pharmacotherapeutic Group of (API)	Antispasmodics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Integrin Life Sciences Pvt. Ltd.Plot No. 69-71 & 75-77, APIIC Industrial Park, Tirumalagiri Village, Jaggaiahpetta Mandal, Krishna District – 521 175. Andhra Pradesh, INDIA.
	Detail of stability batches of drug product	3 batches having batch size of 2000 injections each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Not submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against NOSPA 40mg/2ml Injection by M/s Sanofi-Aventis Pakistan
	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 (Hungary, Romania, Bulgaria)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 03-04-2015 specifying Liquid Injection Ampoule (General) [Filling of one dosage form i.e. ampoule or vials at one time].
	Evaluation Remarks	

Shortcomings	Firm's Response
Valid copy of cGMP certificate or DML of API manufacturer issued by relevant regulatory authority of country of origin is required	Firm has submitted of cGMP certificate of API manufacturer valid upto 22-05-2024
Documents for procurement API with approval from DRAP shall be submitted	Firm has submitted copy of loan letter from M/s Venus pharma for 1.5kg Drotaverine HCl. Firm has also submitted copy of loan intimation submitted in DRAP Firm has also submitted copy of clearance certificate in the name of M/s Venus pharma specifying 50kg Drotaverine HCl.
The application fulfills codal formalities and submitted for consideration of Registration Board	
Decision	
Approved	
Registration Board further decided that the Registration Letter shall be issued after; 1. Submission of valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin 2. Verification of the loan documents of API.	
Case Category	New Section (Dr. Farhad Ullah)
Name, address of Applicant.	Neutro Pharma (Pvt.) Ltd., 9.5-Km, Sheikhpura Road, Lahore (000576)
Application Form Dy. No / Tracking ID & date of submission	(99J-XNP-VXNB, 2025-11-07)
Detail of Fee Submitted	38700.0, 2025-08-19,
The proposed proprietary name / brand name	Neupred EC 5mg Tablet
Label Claim	Each enteric coated tablet contains: Prednisolone B.P.....5mg BP Specifications
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	10x10's/As per SROs-As per SRO
Shelf Life (Unit)	2 Year(s)Store below 30 °C.
For generic drugs (me-too Status)	Deltacortril 5mg Enteric Coated Tablet by Lucycore Industries Registration No. 053218
Pharmacotherapeutic Group of (API)	Glucocorticoids
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Tianjin Tianyao Pharmaceuticals Co., Ltd.
Detail of stability batches of drug product	2 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 final clearance certificate issued dated 12-02-2025 specifying 50kg Prednisolone Base.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Deltacortril 5mg EC Tablet manufactured by Pfizer 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	Deltacortril® 5mg Gastro-resistant Tablets MHRA Approved
GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 04-08-2025.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 16-04-2025 specifying Tablet (Steroid) Section.

Evaluation Remarks																																					
Shortcomings	Firm's Response																																				
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 DML of API manufacturer valid upto 11-10-2025.																																				
Submit the analytical record of CDP studies as 0% drug release is recorded in acid media and acetate buffer	Submitted																																				
Stability study data of applied product at 6th month time point shall be submitted	Submitted																																				
The application fulfils codal formalities and is submitted for consideration of Registration Board																																					
Decision																																					
Approved																																					
Registration Board further decided that the Registration Letter shall be issued after submission of valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin																																					
111	<table> <tr> <td>Case Category</td><td>Routine (Dr. Farhad Ullah)</td></tr> <tr> <td>Name, address of Applicant.</td><td>Platinum Pharmaceuticals A-20,North Western Industrial Zone Bin Qasim,Karachi (000415)</td></tr> <tr> <td>Application Form Dy. No / Tracking ID & date of submission</td><td>(AYQ-6DQ-2RV1, 2024-07-23)</td></tr> <tr> <td>Detail of Fee Submitted</td><td>75000.0, 225000.0 2024-05-10, 2024-06-24</td></tr> <tr> <td>The proposed proprietary name / brand name</td><td>Memantine HCl SR Capsule 7mg</td></tr> <tr> <td>Label Claim</td><td>7mg</td></tr> <tr> <td>Reference to Finished product specifications</td><td>As per Innovators Specification</td></tr> <tr> <td>Proposed Pack Size</td><td>10s-As per SRO,14s-As per SRO,20s-As per SRO,30s-As per SRO,40s-As per SRO,50s-As per SRO</td></tr> <tr> <td>Shelf Life (Unit)</td><td>2 Year(s)store below 30C in a dry place and protect from sunlight</td></tr> <tr> <td>For generic drugs (me-too Status)</td><td>Excineur ER Capsule 7mg by M/s Kaizen Pharma</td></tr> <tr> <td>Pharmacotherapeutic Group of (API)</td><td>NMDA receptor antagonist. ATC Code; N06DX01</td></tr> <tr> <td>Name, address of Manufacturing site:</td><td>Self Manufacturing</td></tr> <tr> <td>Name & address of API manufacturer</td><td>Pellets Pharma Ltd.</td></tr> <tr> <td>Detail of stability batches of drug product</td><td>3 batches having batch size of 1000 capsule each</td></tr> <tr> <td>Documents for the procurement of API with approval from DRAP (in case of Import)</td><td>Firm has submitted copy of form 6 issued dated 10-02-2023 specifying 04kg Memantine HCl 16% SR Pellets . Firm has submitted copy of goods declaration, commercial invoice, airway bill, packing list, form 3 and form 7 for procurement of API.</td></tr> <tr> <td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>PE and CDP studies performed against Memantine HCl capsule ER by Amneal Pharma</td></tr> <tr> <td>Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)</td><td>Firm has submitted stability study data of 3 batches of drug substance as per Zone IV</td></tr> <tr> <td>The status in reference regulatory authorities</td><td>NAMENDA XR 7mg capsule USFDA Approved. Discontinued**Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**</td></tr> </table>	Case Category	Routine (Dr. Farhad Ullah)	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	(AYQ-6DQ-2RV1, 2024-07-23)	Detail of Fee Submitted	75000.0, 225000.0 2024-05-10, 2024-06-24	The proposed proprietary name / brand name	Memantine HCl SR Capsule 7mg	Label Claim	7mg	Reference to Finished product specifications	As per Innovators Specification	Proposed Pack Size	10s-As per SRO,14s-As per SRO,20s-As per SRO,30s-As per SRO,40s-As per SRO,50s-As per SRO	Shelf Life (Unit)	2 Year(s)store below 30C in a dry place and protect from sunlight	For generic drugs (me-too Status)	Excineur ER Capsule 7mg by M/s Kaizen Pharma	Pharmacotherapeutic Group of (API)	NMDA receptor antagonist. ATC Code; N06DX01	Name, address of Manufacturing site:	Self Manufacturing	Name & address of API manufacturer	Pellets Pharma Ltd.	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 form 6 issued dated 10-02-2023 specifying 04kg Memantine HCl 16% SR Pellets . Firm has submitted copy of goods declaration, commercial invoice, airway bill, packing list, form 3 and form 7 for procurement of API.	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Memantine HCl capsule ER by Amneal 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	NAMENDA XR 7mg capsule USFDA Approved. Discontinued**Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
Case Category	Routine (Dr. Farhad Ullah)																																				
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	(AYQ-6DQ-2RV1, 2024-07-23)																																				
Detail of Fee Submitted	75000.0, 225000.0 2024-05-10, 2024-06-24																																				
The proposed proprietary name / brand name	Memantine HCl SR Capsule 7mg																																				
Label Claim	7mg																																				
Reference to Finished product specifications	As per Innovators Specification																																				
Proposed Pack Size	10s-As per SRO,14s-As per SRO,20s-As per SRO,30s-As per SRO,40s-As per SRO,50s-As per SRO																																				
Shelf Life (Unit)	2 Year(s)store below 30C in a dry place and protect from sunlight																																				
For generic drugs (me-too Status)	Excineur ER Capsule 7mg by M/s Kaizen Pharma																																				
Pharmacotherapeutic Group of (API)	NMDA receptor antagonist. ATC Code; N06DX01																																				
Name, address of Manufacturing site:	Self Manufacturing																																				
Name & address of API manufacturer	Pellets Pharma Ltd.																																				
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 form 6 issued dated 10-02-2023 specifying 04kg Memantine HCl 16% SR Pellets . Firm has submitted copy of goods declaration, commercial invoice, airway bill, packing list, form 3 and form 7 for procurement of API.																																				
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Memantine HCl capsule ER by Amneal 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	NAMENDA XR 7mg capsule USFDA Approved. Discontinued**Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**																																				

	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 14-06-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 16-11-2022 specifying Capsule (General) Section.
	Evaluation Remarks	
	Shortcomings	Firm's response
	Submit copy of challan of differential fee submitted for applied product	Copy of challan of differential fee for applied product is submitted
	Standardize the label claim in terms of type of pellets along with submission of fee	Firm has standardize the label claim along with submission of fee Rs. 9400/- on deposit slip#9472907469. The revised label claim is: Each capsule contains: Memantine Hydrochloride 16% Sustained Release Pellets Equivalent to Memantine Hydrochloride.....7 mg
	Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	Firm has submitted copy of cGMP certificate of API manufacturer valid upto 22-03-2027
	Details of innovator/comparator product including country name of MAH, batch No#, manufacturing date and expiry date shall be submitted	Firm has submitted details of reference product. Reference product name: Memantine HCl Extended-Release Capsule 7mg Manufacturer country: United States Batch No.: 223901 Expiry date: 04-2024
	The application fulfils codal formalities and is submitted for consideration of Registration Board	
	Decision	
	Approved	
	Approved with following label claim;	
	Each capsule contains: Memantine Hydrochloride 16% Sustained Release Pellets Equivalent to Memantine Hydrochloride.....7 mg	
112	Case Category	Routine (Dr. Farhad Ullah)
	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	(7WE-NY2-PYEM, 2024-08-26)
	Detail of Fee Submitted	225000.0, 2024-06-26,
	The proposed proprietary name / brand name	Memantine HCl SR Capsule 28mg
	Label Claim	Memantine HCl 28mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10s-As per SRO,14s-As per SRO,20s-As per SRO,30s-As per SRO,40s-As per SRO,50s-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30C in a dry place and protect from sunlight
	For generic drugs (me-too Status)	Reyind SR 28mg Capsule by M/s Genetics Pharma
	Pharmacotherapeutic Group of (API)	NMDA receptor antagonist. ATC Code; N06DX01
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Pellets Pharma Ltd.

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 form 6 issued dated 10-02-2023 specifying 04kg Memantine HCl 16% SR Pellets . Firm has submitted copy of goods declaration, commercial invoice, airway bill, packing list, form 3 and form 7 for procurement of API.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Memantine HCl capsule ER by Amneal 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	Memantine Hydrochloride Extended Release capsule 28mg capsule by M/s Amneal Pharm USFDA Approved.
GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 14-06-2023.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 16-11-2022 specifying Capsule (General) Section.
Evaluation Remarks	
Shortcomings	Firm's response
Submit details of initial fee submitted for applied product in eApp online portal	Firm has submitted copy of initial fee challan#705327591 of Rs. 75000/ submitted for applied product
Standardize the label claim in terms of type of pellets along with submission of fee	Firm has standardize the label claim along with submission of fee Rs. 9400/- on deposit slip# 978027883422. The revised label claim is: Each capsule contains: Memantine Hydrochloride 16% Sustained Release Pellets Equivalent to Memantine Hydrochloride.....28mg
Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	Firm has submitted copy of cGMP certificate of API manufacturer valid upto 22-03-2027
Details of innovator/comparator product including country name of MAH shall be submitted	No response submitted
Clarification is required, as the expiry date on the reference product pack is stated as 04/2020, whereas CDP testing was reportedly performed in December 2023.	Platinum pharmaceuticals Pvt. Ltd purchased two reference samples from Amneal Pharma one for development and subsequently for pharmaceutical equivalence and CDP studies. The second reference sample was valid during analysis having details country name: India, B#22304 and expiry date 06-2024, and its picture is attached herewith as evidence. Furthermore, during dossier submission process, an expired reference sample picture was mistakenly attached with CDP report. Hope this will suffice the clarification. Country name India was not available on submitted pack picture.
Decision	
Approved	
Approved with following label claim;	

	Each capsule contains: Memantine Hydrochloride 16% Sustained Release Pellets Equivalent to Memantine Hydrochloride.....28mg	
113	Case Category	Contract Manufacturing (Dr. Farhad Ullah)
	Name, address of Applicant.	Welwink Pharmaceuticals G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751)
	Application Form Dy. No / Tracking ID & date of submission	(DJX-HRG-JWDV, 2024-08-20)
	Detail of Fee Submitted	75000.0, 2024-06-24,
	The proposed proprietary name / brand name	Nefcon 1mg/ml Eye Drops
	Label Claim	Each mL Contains: Nepafenac 1mg (0.1%) (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)	Neplo Ophthalmic Solution Alza Pharmaceuticals 081620
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Winbrains Research Laboratories-Plot No.69/1 Block B, Phase I-II, Industrial Estate, Hattar Pakistan-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Nefcon 1mg/ml eye drops in 336th RB meeting
	Evaluation Remarks	
114	The firm initially selected "No" but later on replied in response to a query that their contract manufacturing product has been approved in 336th meeting of the Registration Board and submitted undertaking, module I, extract of minutes and fee Rs. 9400/- on deposit slip#98723887756. The application fulfills codal formalities	
	Decision	
	Approved	
	Case Category	Export Facilitation (Dr. Farhad Ullah)
	Name, address of Applicant.	The Schazoo Pharmaceutical Laboratories (Pvt.) Ltd. Kalalwala Stop, 20 Km Lahore-Jaranwala Road, District Sheikhpura (000019)
	Application Form Dy. No / Tracking ID & date of submission	(62L-2H7-TRYE, 2026-01-28)
	Detail of Fee Submitted	38700, 2025-12-30,
	The proposed proprietary name / brand name	Xulta Eye Drops
	Label Claim	Each mL contains: Latanoprostene Bunod.....0.24mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5ml-As per SRO
	Shelf Life (Unit)	2 Year(s)Unopened bottle should be stored refrigerated at 2° to 8°C
	For generic drugs (me-too Status)	Latapren (Reg # 124158) ; M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan
	Pharmacotherapeutic Group of (API)	Prostaglandin analogs
	Name, address of Manufacturing site:	Self Manufacturing

	Name & address of API manufacturer	Everlight Chemical Industrial Corporation 12, Industrial Third Rd., Kuanyin District, Taoyuan City, Taiwan
	Detail of stability batches of drug product	3 batches having batch size of 3L (557 Bottles) each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of final clearance certificate dated 27-05-2025 specifying 0.0030kg Latanoprostene Bunod
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Vyzulta Eye Drops by M/s Bausch & Lomb Incorporated, 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
	The status in reference regulatory authorities	VYZULTA (latanoprostene bunod ophthalmic solution) 0.024%, for topical ophthalmic use; USFDA Approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 15-05-2025.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 19-09-2021 specifying Ophthalmic and Nasal Drops.
	Evaluation Remarks	
	Shortcomings	Firm's Response
	Copies of drug substance specification and analytical procedure used for testing of drug substance by drug product manufacturer is required	Submitted
	Stability study data of applied product at 6th month time point is required	Submitted
	Decision	
	Approved	
115	Case Category	Routine (Dr. Farhad Ullah)
	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	(WUR-8UR-VLRX, 2024-07-24)
	Detail of Fee Submitted	75000.0, 225000.0 2024-05-10, 2024-06-24
	The proposed proprietary name / brand name	Memantine HCl SR Capsule 14mg
	Label Claim	14mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10s-As per SRO,14s-As per SRO,20s-As per SRO,30s-As per SRO,40s-As per SRO,50s-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30C in a dry place and protect from sunlight
	For generic drugs (me-too Status)	Excineur ER Capsule 14mg by M/s Kaizen Pharma
	Pharmacotherapeutic Group of (API)	NMDA receptor antagonist. ATC Code; N06DX01
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Pellets Pharma Ltd.
	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 form 6 issued dated 10-02-2023 specifying 04kg Memantine HCl 16% SR Pellets . Firm has submitted copy of goods declaration, commercial invoice, airway bill, packing list, form 3 and form 7 for procurement of API.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Memantine HCl capsule ER by Amneal 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	Memantine Hydrochloride Extended Release capsule 14mg capsule by M/s Amneal Pharm USFDA Approved.
GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 14-06-2023.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 16-11-2022 specifying Capsule (General) Section.
Evaluation Remarks	
Shortcomings	Firm's response
Standardize the label claim in terms of type of pellets along with submission of fee	Firm has standardize the label claim along with submission of fee Rs. 9400/- on deposit slip#93146429215. The revised label claim is: Each capsule contains: Memantine Hydrochloride 16% Sustained Release Pellets Equivalent to Memantine Hydrochloride.....14 mg
Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	Firm has submitted copy of cGMP certificate of API manufacturer valid upto 22-03-2027
Details of innovator/comparator product including country name of MAH, batch No#, manufacturing date and expiry date shall be submitted	Firm has submitted details of reference product. Reference product name: Memantine HCl Extended-Release Capsule 14mg Manufacturer country: United States Batch No.: 223902 Expiry date: 05-2024
Justify the presence of the firm name in the report filename "Kaizen Report (Individual Chromatogram).isr" mentioned in chromatograms for 14mg strength capsule submitted in the CDP studies.	Platinum pharmaceuticals is the toll manufacturer for Kaizen pharmaceuticals Pvt. Ltd for different products as well as testing conducted in Platinum Pharmaceuticals QC Lab. During reporting of CDP, the analyst mistakenly imported "kaizen report format namely "Kaizen Report (Individual Chromatogram).isr" for printing chromatograms. The discrepancy was limited solely to the report header/template format and did not affect chromatographic acquisition, raw data integrity, instrument performance, processing parameters, calculations or analytical results. All system suitability requirements and validated method acceptance criteria were fulfilled; therefore, the generated analytical data remains scientifically valid, reliable and acceptable.
The application fulfils codal formalities and is submitted for consideration of Registration Board	
Decision	

	Rejected	
	Registration Board decided to reject the instant application for submitting same chromatograms in CDP studies as submitted by another firm for its approved product.	
116	Case Category	Routine (Dr. Farhad Ullah)
	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	(RZ8-S2N-5B76, 2024-08-26)
	Detail of Fee Submitted	225000.0, 2024-06-26,
	The proposed proprietary name / brand name	Memantine HCl SR Capsule 21mg
	Label Claim	Memantine HCl 21mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10s-As per SRO,14s-As per SRO,20s-As per SRO,30s-As per SRO,40s-As per SRO,50s-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30C in a dry place and protect from sunlight
	For generic drugs (me-too Status)	Excineur ER Capsule 21mg by M/s Kaizen Pharma
	Pharmacotherapeutic Group of (API)	NMDA receptor antagonist. ATC Code; N06DX01
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Pellets Pharma Ltd.
	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 form 6 issued dated 10-02-2023 specifying 04kg Memantine HCl 16% SR Pellets . Firm has submitted copy of goods declaration, commercial invoice, airway bill, packing list, form 3 and form 7 for procurement of API.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Memantine HCl capsule ER by Amneal 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	Memantine Hydrochloride Extended Release capsule 21mg capsule by M/s Amneal Pharm USFDA Approved.
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 14-06-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 16-11-2022 specifying Capsule (General) Section.
	Evaluation Remarks	
	Shortcomings	Firm's response
	Submit details of initial fee submitted for applied product in eApp online portal	Firm has submitted copy of initial fee challan#132707373299 of Rs. 75000/ submitted for applied product
	Standardize the label claim in terms of type of pellets along with submission of fee	Firm has standardize the label claim along with submission of fee Rs. 9400/- on deposit slip#1495665311. The revised label claim is: Each capsule contains: Memantine

	Hydrochloride 16% Sustained Release Pellets Equivalent to Memantine Hydrochloride.....21mg
Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	Firm has submitted copy of cGMP certificate of API manufacturer valid upto 22-03-2027
Details of innovator/comparator product including country name of MAH, batch No#, manufacturing date and expiry date shall be submitted	Firm has submitted details of reference product. Reference product name: Memantine HCl Extended-Release Capsule 21mg Manufacturer country: United states Batch No.: 223901 Expiry date: 04-2024
Justify the presence of the firm name in the report filename "Kaizen Report (Individual Chromatogram).isr" mentioned in chromatograms for 21mg strength capsule submitted in the CDP studies (only in acidic media).	Platinum pharmaceuticals is the toll manufacturer for Kaizen pharmaceuticals Pvt. Ltd for different products as well as testing conducted in Platinum Pharmaceuticals QC Lab. During reporting of CDP, the analyst mistakenly imported "kaizen report format namely "Kaizen Report (Individual Chromatogram).isr" for printing chromatograms. The discrepancy was limited solely to the report header/template format and did not affect chromatographic acquisition, raw data integrity, instrument performance, processing parameters, calculations or analytical results. All system suitability requirements and validated method acceptance criteria were fulfilled; therefore, the generated analytical data remains scientifically valid, reliable and acceptable.
The application fulfils codal formalities and is submitted for consideration of Registration Board	
Decision	
Rejected	
Registration Board decided to reject the instant application for submitting same chromatograms in CDP studies as submitted by another firm for its approved product.	
117	Case Category
	Routine (Dr. Farhad Ullah)
Name, address of Applicant.	fozan pharmaceuticals Industries (Pvt) Ltd 36-A hayatabad Industrial estate, Peshawar (000567)
Application Form Dy. No / Tracking ID & date of submission	(QQW-R1J-E922, 2024-11-18)
Detail of Fee Submitted	37000.0, 2024-11-08,
The proposed proprietary name / brand name	Thilcho
Label Claim	Each Capsule Contains: Thiocolchicoside 4mg (Innovator Spec's)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	as per SRO-As per SRO
Shelf Life (Unit)	2 Year(s)Store below 30°C.
For generic drugs (me-too Status)	Thicoid 4mg capsules Manufactured by Albert Pharma (pvt) Limited
Pharmacotherapeutic Group of (API)	Centrally Acting Myorelaxant
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	M/S: Alkalioids Private Ltd. 834(P), Medchai Shamirpet Road, Medchai Mandal, Medchai,

		Malkajgiri District
	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 loan letter of API (indicating Thiocolchicoside 03kg) from M/s Seraph pharmaceuticals. Firm has submitted copy of clearance certificate dated 06-09-2023 specifying 02kg Thiocolchicoside in name of M/s Seraph Pharmaceuticals
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Thilcho 4mg capsule by Sanofi Aventis
	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	Miorel 4mg capsule, ANSM France Approved
	GMP status of the firm	Not submitted
	Evidence of approval of manufacturing facility	Not submitted
	Evaluation Remarks	
	Shortcomings	
	Valid copy of DML or application submitted for renewal of DML in licensing division shall be provided Copy of cGMP certificate or GMP inspection report conducted within last three years and evidence of required manufacturing facility from licensing division shall be submitted Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required Justification is required for using a different assay method for the API by the drug product manufacturer than that used by the drug substance manufacturer, particularly with respect to mobile phase composition and ration of mobile phase in gradient method. Clarification is required, as the batch number of API mentioned in COA provided by drug product manufacturer differs from the batch number provided in COA by API manufacturer. Analytical record including chromatograms for submitted PE and CDP studies for drug product is required Submit complete details of the innovator/comparator product used in PE and CDP studies, including batch number, manufacturing date, expiry date, and marketing authorization holder. Further, clarify the discrepancy in the stated MAH, which is mentioned as Sanofi Aventis Limited at one place and Albert Pharmaceutical at another. Stability study data of applied product at 6th month time point shall be submitted Clarification is required, as the API lender has imported only 02kg of API, whereas approval was granted for loan of 03kg. Intimation of API loan submitted to DRAP is required. Submit the list of technical staff of the R&D and Quality Control departments, along with copies of their appointment letters, from January 2024 till date.	
	Firm's Response	
	Due to Recent shifts in Market Dynamics (Higher API Prices from many Supplier) and an internal portfolio reassessment, we want to withdraw our product.	
	Decision	
	Rejected	
	Registration Board acceded the request of the firm and decided to reject the instant application	
118	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	S.J & G. Fazul Ellahie (pvt) limited. E-46, S.I.T.E., Karachi (000083)
	Application Form Dy. No / Tracking ID & date of submission	(QX9-QAN-VBNG, 2024-10-21)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-23, 2024-10-15
	The proposed proprietary name / brand name	Thiolax 8mg Capsules
	Label Claim	Each capsule contains: Thiocolchicoside.....8mg
	Reference to Finished product specifications	Manufacturer Specification
	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)	Cholchisid 8mg Capsule by M/s Novartana Pharmaceuticals
Pharmacotherapeutic Group of (API)	Muscle Relaxant
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	M/S: Sarv BioLabs Pvt. Limited
Detail of stability batches of drug product	3 batches having batch size of 500 capsule each
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate dated 19-01-2023 specifying 10kg Thiocolchicoside.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Muscoril 8mg capsule by M/s Sanofi
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 II till 6th months
The status in reference regulatory authorities	MuscoRil 8mg Capsule by AIFA Approved
GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 27-11-2025.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 20-09-2021 specifying Capsule (General) Section.
Evaluation Remarks	
Shortcomings	Firm's Response
Submit evidence of applied formulation in RRA along with weblink since the submitted evidence could not be verified	Firm has submitted weblink of AIFA. However, the applied product could not be verified
Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	Firm has submitted copy of cGmp certificate of API manufacturer valid upto 15-10-2024
Stability study data of API as per Zone IV conditions till claimed shelf life, shall be submitted	Stability study data of one batch of API as at real time conditions per Zone IV is submitted
Justification is required for performing the assay of the applied product by UV spectrophotometry method instead of HPLC.	The analytical method for testing of Thiolax 8 mg Capsule has been developed using UV-Visible Spectrophotometry based on scientific rationale, product similarity, method suitability, and regulatory compliance considerations. The UV spectrophotometric method was selected because the company already employs a validated UV method for its commercial product, Thiolax 4mg Capsule. Both products contain the same active pharmaceutical ingredient (API) and have similar formulation characteristics, differing only in strength; therefore, the same analytical principle is scientifically applicable as the UV absorption characteristics of the API remain unchanged. The method was developed in-house following evaluation of the physicochemical properties and UV absorbance profile of the API and has been successfully validated in accordance with applicable ICH guidelines for specificity, accuracy, precision, linearity, range, and robustness. Validation results confirmed that the method is reliable, reproducible, and suitable for its intended purpose. Accordingly, the use of this validated in-house UV spectrophotometric method for Thiolax 8 mg Capsule is scientifically

justified and appropriate for routine quality control testing.

Decision

Deferred

Deferred for submission of following;

1. Evidence of approval of applied formulation in Reference Regulatory Authority along with weblink
2. Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required
3. Stability study data of three batches of API at real time conditions as per Zone IV till claimed shelf life
4. Scientific justification for performing the assay of the applied product by UV spectrophotometry method instead of HPLC or otherwise revise your specifications and analytical method as per HPLC method along with submission of applicable fee

119	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	Dr. Raza Pharma 44-C Hayatabad Industrial Estate Peshawar (000387)
	Application Form Dy. No / Tracking ID & date of submission	(XB9-X71-3AU9, 2024-07-16)
	Detail of Fee Submitted	30000.0, 2024-07-09,
	The proposed proprietary name / brand name	Iroraz
	Label Claim	Each 5ml contains: Iron (III) hydroxide polymaltose complex equivalent to elemental Iron.....50 mg (Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	60,90.120 ml-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C.
	For generic drugs (me-too Status)	Bisleri Syrup by Sami Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Chemiworld Pvt Limited,97-J Hayatabad industrial estate peshawar KPK Pakistan
	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	Maltofer Syrup by M/s Vifor Pharma Pty Ltd (TGA Approved)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	

Evaluation Remarks

Shortcomings

Your application has been evaluated and found incomplete in respect of following deficiencies / shortcomings. Copy of cGMP certificate or GMP inspection report conducted within last three years is required Evidence of required manufacturing facility from licensing division is required Valid copy of cGMP certificate or DML of API manufacturer issued by relevant regulatory authority of

country of origin is required Copies of drug substance specification and analytical procedure used for testing of drug substance duly signed by both drug substance manufacturer and drug product manufacturer is required Pictorial evidence of innovator's product/comparator's product including details of name of MAH, batch number, manufacturing date and expiry date against which PE & CDP studies has been submitted is required Clarification is required, as the applied product is a syrup dosage form, whereas CDP studies have been conducted. Detailed analytical procedure duly signed by applicant for applied product shall be submitted Protocols for analytical method validation/verification studies shall be submitted Stability summary sheets for applied product at both accelerated and real time conditions contains same storage conditions of $40^{\circ}\text{C} \pm 2^{\circ}\text{C}/75\% \pm 5\% \text{ RH}$, clarification is required Loan letter, loan agreement and intimation of API loan submitted to DRAP is required Stability study data including raw data sheets and COA for applied product is required Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required

Firm's Response

Due to ongoing higher prices of API, and market fluctuations, we want to withdraw our product.

Decision

Rejected

Registration Board acceded the request of the firm and decided to reject the instant application

120	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Schazoo Zaka (Pvt) Ltd 20 Km Lahore-Jaranwala Road Distt: Sheikhpura (000636)
	Application Form Dy. No / Tracking ID & date of submission	(GG4-A69-BW2T, 2024-09-26)
	Detail of Fee Submitted	30000.0, 2023-05-03,
	The proposed proprietary name / brand name	Rovidin Tablets
	Label Claim	Each film coated tablet contains: Rosuvastatin as Calcium.....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10s-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 degree Centigrade
	For generic drugs (me-too Status)	Rovista tablets
	Pharmaceutical Group of (API)	Antihypertensive
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Changzhou Pharma, No. 518 East Laodong Road, Chanzhou, Jiansu Province
	Detail of stability batches of drug product	03 Batches : 6000 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 01-04-2022 for 0.6kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP performed against the comparator's product i.e. Rovista Tablet by M/s Getz Pharma.
	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_A.
	The status in reference regulatory authorities	Registered by FDA CRESTOR TABLETS
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	GMP certificate issue don 05-05-2026 is submitted.	
	Decision	

	Approved	
121	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Elite Pharma (Pvt) Ltd 9.5km Sheikupura Road (000455)
	Application Form Dy. No / Tracking ID & date of submission	(TNP-JQ8-U6UM, 2024-12-10)
	Detail of Fee Submitted	30000.0, 30000.0 2023-06-21, 2023-06-21
	The proposed proprietary name / brand name	Elicurium
	Label Claim	Each mL contains: Atracurium Besylate USP.....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5 Ampoule/pack (5ml)-As per SRO
	Shelf Life (Unit)	2 Year(s)2°C - 8°C
	For generic drugs (me-too Status)	ZAFA Pharmaceutical Laboratories (Pvt) Ltd
	Pharmaceutical Group of (API)	Non-depolarization muscle relaxant
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Lianyungang Guike 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)	06 months accelerated at 25±2°C/ 60±5% and 36 real time stability studies at 5±3°C of 03 batches.
	The status in reference regulatory authorities	MHRA-UK
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 06-10-2022 is submitted.
	Evidence of approval of manufacturing facility	Liquid Injectable Section (Revised and regularized) is approved.
Evaluation Remarks		
1. As per submitted COA from drug product manufacturer for drug substance, the tests for content estimation of cis-cis, cis-trans and trans-trans isomers have not been performed.		
2. . AMV studies for drug substance as per USP and the system suitability testing should be as per table 2 of USP monograph for drug substance. Procurement documents including clearance certificate for impurity standards as per table 2 as well.		
3. Reference standards/working standards for impurities as per table 2 of USP monograph of drug substance not submitted		
4. As per submitted COA of drug substance from drug product manufacturer, the limit of water content is 20% which is not according to USP (5%).		
5. As per submitted PE studies for drug product, the tests for content estimation of cis-cis, cis-trans and trans-trans isomers have not been performed.		
6. Bacterial endotoxin and TMC test have not been performed at drug substance level neither by drug substance manufacturer nor by drug product manufacturer.		
7. No chromatograms have been submitted other than acquired on 06-10-2022		
8. procurement documents have not been submitted.		

9. Audit trail report/system log not submitted.
10. AS per submitted stability summary sheets, the firm has mentioned Montelukast in the row of assay content for all the 06 summary sheets. Only name and batch numbers in the header have been changed.
11. The firm has submitted 36 months real time at 5±3°C and results at initial time points for all the 03 batches is different and 3 to 36 months' time point the results are identical, only batch numbers are changed).
12. The firm has submitted 36 months accelerated at 25±2°C/ 60±5% (results at initial time points for all the 03 batches is different and 3 to 36 months' time point the results are identical, only batch numbers are changed)
13. The chromatograms have been acquired on 06-10-2022, the chromatograms have been acquired on 8:00am, 8:22am, 8:52am which are inconsistent with the run time of 50mins.

Decision

Rejected

The Board after due deliberations, observed the discrepancies in the submitted stability data and decided to reject the case.

122	Case Category	Export Facilitation (Farooq Aslam)
	Name, address of Applicant.	Ferozsons Laboratories Limited PO Ferozsons, Amargarh (000038)
	Application Form Dy. No / Tracking ID & date of submission	(5GR-X52-DJ7P, 2025-10-14)
	Detail of Fee Submitted	38700, 2025-10-06,
	The proposed proprietary name / brand name	Aurora EZ Tablets 10mg/10mg
	Label Claim	Each film coated bilayer tablet contains: Rosuvastatin as calcium.....10mg Ezetimibe.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's (1x10's)-As per SRO,14's (1x14's)-As per SRO,20's (2x10's)-As per SRO,28's (2x14's)-As per SRO,30's (3x10's)-As per SRO,5's (1x5's)-As per SRO,7's (1x7's)-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store above 30°C
	For generic drugs (me-too Status)	Brand Name: Rovista EZ Tablets, Manufacturer: M/s Getz Pharma Pvt-Limited-Karachi
	Pharmacotherapeutic Group of (API)	Lipid modifying agents
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Enaltec Labs Private Limited,Synthimed Labs Private Limited
	Detail of stability batches of drug product	03 batches manufactured each having batch size i.e 1000 tablets 06 months acc and 06 months RT studies acc to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Rosuvastatin: Clearance certificate dated 08-07-2024 is submitted, Ezetimibe: Clearance certificate dated 05-11-2024 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies are conducted against Rovista EZ Tablets 10mg/10mg (Batch No: 020FH6, Exp. Date: 02/2026) of Getz Pharma Pvt Ltd-Karachi.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Rosuvastatin: 06 months acc and 48 months RT of 03 batches according to zone IV-B. Ezetimibe:

		06 months acc and 24 months RT of 03 batches according to zone IV-B.
	The status in reference regulatory authorities	Brand Name: Roszet Tablets Manufacturer: Althera Pharmaceuticals LLC-USFDA
	GMP status of the firm	GMP Certificate No. F.11-10/2024-DRAP-435 Dated: 26-11-2024, valid till 09-08-2027.
	Evidence of approval of manufacturing facility	Tablet Section (General) Approval granted by DRAP (Central Licensing Board) via tracking ID: XWU-WU3-4VZM dated: 01-08-2025.
	Evaluation Remarks	
	The application has been under export facilitation as per letter dated 30 April 2026.	
	Decision	
	Approved	
123	Case Category	Export Facilitation (Farooq Aslam)
	Name, address of Applicant.	Ferozsons Laboratories Limited PO Ferozsons, Amangarh (000038)
	Application Form Dy. No / Tracking ID & date of submission	(MB8-XR5-M6NH, 2025-10-14)
	Detail of Fee Submitted	38700, 2025-10-06,
	The proposed proprietary name / brand name	Aurora EZ Tablets 20mg/10mg
	Label Claim	Each film coated bilayer tablet contains: Rosuvastatin as calcium.....20mg Ezetimibe.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's (1x10's)-As per SRO,14's (1x14's)-As per SRO,20's (2x10's)-As per SRO,28's (2x14's)-As per SRO,30's (3x10's)-As per SRO,5's (1x5's)-As per SRO,7's (1x7's)-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store above 30°C
	For generic drugs (me-too Status)	Brand Name: Rovista EZ Tablets Manufacturer: M/s Getz Pharma Pvt-Limited-Karachi
	Pharmacotherapeutic Group of (API)	Lipid modifying agents
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Enaltec Labs Private Limited,Synthimed Labs Private Limited
	Detail of stability batches of drug product	03 batches manufactured each having batch size i.e 1000 tablets 06 months acc and 06 months RT studies acc to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Rosuvastatin: Clearance certificate dated 08-07-2024 is submitted, Ezetimibe: Clearance certificate dated 05-11-2024 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies are conducted against Rovista EZ Tablets 20mg/10mg (Batch No: 011FH7, Exp. Date: 02/2026) of Getz Pharma Pvt Ltd-Karachi.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Rosuvastatin: 06 months acc and 48 months RT of 03 batches according to zone IV-B. Ezetimibe: 06 months acc and 24 months RT of 03 batches according to zone IV-B.
	The status in reference regulatory authorities	Brand Name: Roszet Tablets , Manufacturer: Althera Pharmaceuticals LLC-USFDA

	GMP status of the firm	GMP Certificate No. F.11-10/2024-DRAP-435 Dated: 26-11-2024, valid till 09-08-2027.
	Evidence of approval of manufacturing facility	Tablet Section (General) Approval granted by DRAP (Central Licensing Board) via tracking ID: XWU-WU3-4VZM dated: 01-08-2025.
	Evaluation Remarks	
	The application has been under export facilitation as per letter dated 30 April 2026.	
	Decision	
	Approved	
124	Case Category	Export Facilitation (Farooq Aslam)
	Name, address of Applicant.	Ferozsons Laboratories Limited PO Ferozsons, Amangarh (000038)
	Application Form Dy. No / Tracking ID & date of submission	(X6Y-J32-RMZQ, 2025-10-14)
	Detail of Fee Submitted	38700, 2025-10-06,
	The proposed proprietary name / brand name	Aurora EZ Tablets 5mg/10mg
	Label Claim	Each film coated tablet contains: Rosuvastatin calcium eq. to Rosuvastatin....5mg Ezetimibe....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's (1x10's)-As per SRO,14's (1x14's)-As per SRO,20's (2x10's)-As per SRO,28's (2x14's)-As per SRO,30's (3x10's)-As per SRO,5's (1x5's)-As per SRO,7's (1x7's)-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 30°C
	For generic drugs (me-too Status)	Brand Name: Rovista EZ Tablets Manufacturer: M/s Getz Pharma Pvt-Limited-Karachi
	Pharmacotherapeutic Group of (API)	Lipid modifying agents
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Enaltec Labs Private Limited,Synthimed Labs Private Limited
	Detail of stability batches of drug product	03 batches manufactured each having batch size i.e 1000 tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate ,Drug Import License along with Goods Declaration, Invoice , Packing List, Form-03 & Form-07, AWB both for Rosuvastatin and Ezetimibe is/are attached in Module 03, Section 3.2.P, Sub-section 3.2.P.8.3
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP studies are conducted against Rovista EZ Tablets 5mg/10mg (Batch No: 006FH5, Exp. Date: 02/2026) of Getz Pharma Pvt Ltd-Karachi detail report is attached in Section 3.2.P, Sub- section 3.2.P.2
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data studies of 03 batches is performed by Drug substance manufacturer is/are attached at Module 03 Section 3.2.S.7
	The status in reference regulatory authorities	Brand Name: Roszet Tablets Manufacturer: Althera Pharmaceuticals LLC-USFDA
	GMP status of the firm	Complying cGMP as per Certificate No. F.11- 10/2024-DRAP-435 Dated: 26-11-2024, valid till 09-08-2027.

	Evidence of approval of manufacturing facility	Tablet Section (General) Approval granted by DRAP (Central Licensing Board) via tracking ID: XWU-WU3-4VZM dated: 01-08-2025.
	Evaluation Remarks	
	The application has been under export facilitation as per letter dated 30 April 2026.	
	Decision	
	Approved	
125	Case Category	Export Facilitation (Farooq Aslam)
	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	(WPS-376-MQNY, 2025-01-30)
	Detail of Fee Submitted	37000.0, 2024-11-22,
	The proposed proprietary name / brand name	Roswin-EZ Tablets 5mg + 10mg
	Label Claim	Each Bilayer film coated tablet contains: Rosuvastatin as calcium.....5 mg Ezetimibe.....10 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,15's-As per SRO,20's-As per SRO,25's-As per SRO,30's-As per SRO,35's-As per SRO,40's-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Rovista-EZ by Getz Pharma (073716)
	Pharmacotherapeutic Group of (API)	Lipid lowering agents/antihypertensive
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CTX Life science pvt LIMITED / Glenmark Life Sciences Limited
	Detail of stability batches of drug product	03 batches : 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)	Ezetimibe: Form 6 dated 05-07-2023 for 1.1kg material. Rosuvastatin: Clearance certificate dated 06-08-2022 for 10kg material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. RolipEze by M/s Hilton Pharma.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Ezetimibe: 06 months accelerated and 24 months real time stability data of 03 batches according to the conditions of zone IV-B. Rosuvastatin: 06 months accelerated and 24 months real time stability data of 03 batches according to the conditions of zone IV-B.
	The status in reference regulatory authorities	TGA Australia approved (uncoated)
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 2nd and 15th August, 2024.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been under export facilitation as per letter dated 30 April 2026.	
	Decision	

	Approved	
126	Case Category	Export Facilitation (Farooq Aslam)
	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	(HSU-J1V-X37L, 2025-01-30)
	Detail of Fee Submitted	37000.0, 2024-11-22,
	The proposed proprietary name / brand name	Roswin-EZ Tablets 10mg + 10mg
	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	10's-As per SRO,15's-As per SRO,20's-As per SRO,25's-As per SRO,30's-As per SRO,35's-As per SRO,40's-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Rovista-EZ by Getz Pharma (073718)
	Pharmacotherapeutic Group of (API)	Lipid lowering agents/antihypertensive
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CTX Life science pvt LIMITED / Glenmark Life Sciences Limited
	Detail of stability batches of drug product	03 batches : 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)	Ezetimibe: Form 6 dated 05-07-2023 for 1.1kg material. Rosuvastatin: Clearance certificate dated 06-08-2022 for 10kg material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. RolipEze by M/s Hilton Pharma.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Ezetimibe: 06 months accelerated and 24 months real time stability data of 03 batches according to the conditions of zone IV-B. Rosuvastatin: 06 months accelerated and 24 months real time stability data of 03 batches according to the conditions of zone IV-B.
	The status in reference regulatory authorities	The Netherlands approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 2nd and 15th August, 2024.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
Evaluation Remarks		
The application has been under export facilitation as per letter dated 30 April 2026.		
Decision		
Approved		
127	Case Category	Export Facilitation (Farooq Aslam)
	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	(XSG-PBV-A1GE, 2025-01-30)
	Detail of Fee Submitted	37000.0, 2024-11-22,
	The proposed proprietary name / brand name	Roswin-EZ Tablets 20mg + 10mg
	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	10's-As per SRO,15's-As per SRO,20's-As per SRO,25's-As per SRO,30's-As per SRO,35's-As per SRO,40's-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Rovista-EZ by Getz Pharma (073717)
	Pharmacotherapeutic Group of (API)	Lipid lowering agents/antihypertensive
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CTX Life science pvt LIMITED / Glenmark Life Sciences Limited
	Detail of stability batches of drug product	03 batches : 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)	Ezetimibe: Form 6 dated 05-07-2023 for 1.1kg material. Rosuvastatin: Clearance certificate dated 06-08-2022 for 10kg material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. RolipEze by M/s Hilton Pharma.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Ezetimibe: 06 months accelerated and 24 months real time stability data of 03 batches according to the conditions of zone IV-B. Rosuvastatin: 06 months accelerated and 24 months real time stability data of 03 batches according to the conditions of zone IV-B.
	The status in reference regulatory authorities	The Netherlands approved.
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 2nd and 15th August, 2024.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been under export facilitation as per letter dated 30 April 2026.	
128	Decision	
	Approved	
	Case Category	Export Facilitation (Farooq Aslam)
	Name, address of Applicant.	Getz Pharma (Pvt) Limited 29-30/27,Korangi Industrial Area karachi (000284)
	Application Form Dy. No / Tracking ID & date of submission	(5JW-EYD-LH9A, 2026-04-27)
	Detail of Fee Submitted	38700, 2026-02-09,
	The proposed proprietary name / brand name	Relumet Tablets 40mg
	Label Claim	Each film-coated tablet contains: Relugolix.....40mg
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,28's-De-Controlled,30's-De-Controlled,7's-De-Controlled
	Shelf Life (Unit)	24 Year(s)Do not store above 30°C. Protect from sunlight and moisture.
	For generic drugs (me-too Status)	RELUHIL Tablets 40mg by M/s Hilton Pharma (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Other hormone antagonists and related agents
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	-
	Detail of stability batches of drug product	02 batches : 5000 tablets 06 months accelerated and 06 months real time stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted Clearance Certificate, Form 6, GD, Airway Bill, Commercial Invoice.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence and CDP Study against the reference product Relumina Tablets 40mg marketed by M/s Takeda Pharmaceutical Company Limited, Japan (PMDA).
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability studies of Drug substance till 36month interval at both real time and accelerated conditions of 03 batches according to zone IV-B.
	The status in reference regulatory authorities	Relumina Tablets 40mg marketed by M/s Takeda Pharmaceutical Company Limited, Japan (PMDA)
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 14-10-2025.
	Evidence of approval of manufacturing facility	Tablet General section is approved.
	Evaluation Remarks	
	The application has been processed under export facility as per letter dated 30th April, 2026.	
	Decision	
	Deferred	
	as Bioequivalence studies are required for applied formulation as per DRAP's notification no. No-F-348-DRB-Addl-Dir (PER-t)/2025 dated 17-07-2025.	
129	Case Category	Export Facilitation (Farooq Aslam)
	Name, address of Applicant.	Getz Pharma (Pvt) Limited 29-30/27,Korangi Industrial Area karachi (000284)
	Application Form Dy. No / Tracking ID & date of submission	(4B9-8M1-T4G1, 2026-04-27)
	Detail of Fee Submitted	38700, 2026-02-09,
	The proposed proprietary name / brand name	Relumet Tablets 120mg
	Label Claim	Each film-coated tablets contains: Relugolix.....120mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's, 10's, 14's, 20's, 28's and 30's-As per SRO
	Shelf Life (Unit)	24 Year(s)Do not store above 30°C. Protect from sunlight and moisture.

	For generic drugs (me-too Status)	RELUHIL Tablets 120mg by M/s Hilton Pharma (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Other hormone antagonists and related agents
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	-
	Detail of stability batches of drug product	Firm has performed stability studies on two batches till 3 Months interval on Realtime and Accelerated conditions.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance Certificate, Airway Bill, GD, Form 6, Invoice have been submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical equivalence and CDP studies against the reference product Orgovyx Tablets 120mg by M/s Sumitomo Pharma America, Inc. (US-FDA)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability studies of Drug substance till 36month interval at both real time and accelerated conditions of 03 batches according to zone IV-B.
	The status in reference regulatory authorities	Orogovyx Tablets 120mg by M/s Sumitomo Pharma America, Inc. (US-FDA)
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 14-10-2025.
	Evidence of approval of manufacturing facility	Tablet General section is approved.
	Evaluation Remarks	
	The application has been processed under export facilitation as per letter dated 30th April 2026.	
	Decision	
	Deferred	
	as Bioequivalence studies are required for applied formulation as per DRAP's notification no. No-F-348-DRB-Addl-Dir (PER-t)/2025 dated 17-07-2025.	
130	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	(ASH-J3J-VMM2, 2024-12-02)
	Detail of Fee Submitted	37000.0, 2024-11-06,
	The proposed proprietary name / brand name	Nebix Plus 5/12.5mg Tablet
	Label Claim	Each film-coated tablet contains: Nebivolol as HCl 5mg Hydrochlorothiazide 12.5mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled,7's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Nebtec Plus Tablet 5/12.5mg manufactured by Pharmatec Pakistan (Pvt) Limited (Approved – 331st Meeting of Registration Board held on 31st Oct – 2nd Nov, 2023)
	Pharmacotherapeutic Group of (API)	Antihypertensive

	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Weiqida Pharmaceutical Co., Ltd., (Formerly: Suzhou Lixin Pharmaceutical Co., Ltd.), Shanghai Syndec Pharmaceutical Co. Ltd.,
	Detail of stability batches of drug product	03 batches: 4545 tablets 06 months accelerated and 6 months real time stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Nebivolol: AD attested invoice dated 12-03-2020 issued on 27-03-2020 for 3kg material. HCT: Clearance certificate dated 15-06-2022 for 100kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Nebilet plus tablet by M.s Berlin Chemie AG, Germany.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Nebivolol: 06 months accelerated and 36 months real time stability data of 03 batches according to zone IV_A. HCT: 06 months accelerated and 48 months real time stability data of 03 batches according to zone IV_B.
	The status in reference regulatory authorities	Nebilet Plus 5/12.5mg Film-coated Tablet manufactured by Berlin-Chemie AG, Germany and MAH is Menarini International Operations Luxembourg S.A, Luxembourg (HPRA Approved)
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 17-05-2023.
	Evidence of approval of manufacturing facility	Tablet General section is approved as per submitted GMP certificate.
	Evaluation Remarks	
	Manufacturer of Nebivolol DSL: New title: Weiqida Pharmaceutical Co., Ltd., Old title: Suzhou Lixin Pharmaceutical Co., Ltd.,)	
	Decision	
	Approved	
131	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	P.D.H Pharmaceuticals (Pvt) Ltd 19 Km Ferozepur Road Lahore (000459)
	Application Form Dy. No / Tracking ID & date of submission	(NHR-5R5-ST1R, 2024-10-28)
	Detail of Fee Submitted	37000.0, 2024-09-13,
	The proposed proprietary name / brand name	Nebvis tablet 5mg
	Label Claim	Each film coated tablet contains: Nebivolol as Hydrochloride.....5mg.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1*14's-De-Controlled
	Shelf Life (Unit)	2 Year(s)25°C ± 2°C
	For generic drugs (me-too Status)	Nebil btablets 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: N5-001, N5-002, N5-003 (Batch Size: 1000 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)	DHL receipt is submitted. The firm has not obtained Form 6 or clearance certificate.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. Byscard tablet by M/s Searle.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 60 months real time stability data of 03 batches according to the conditions of zone IV-A.
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 04-12-2023.
	Evidence of approval of manufacturing facility	GMP certificate issued on the basis of inspection conducted on 04-12-2023. Tablet General Section is approved as per submitted GMP certificate.
	Evaluation Remarks	
	The firm has developed the applied formulation as film coated tablet whereas it is approved as uncoated tablet in reference regulatory authorities. The firm has provided me-too reference (Byscard by M/s Searle).	
	The method for assessment of chiral purity of drug substance is submitted but performance has not been done by drug product manufacturer.	
	Decision	
132	Deferred	
	1. For evidence of approval of the applied formulation as film coated tablet in reference regulatory authorities as determined by Registration Board in its 275th meeting or otherwise the firm shall submit product development data for 03 batches for uncoated tablet.	
	2. Clarification for not performing the tests for chiral purity for drug substance.	
	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	P.D.H Pharmaceuticals (Pvt) Ltd 19 Km Ferozepur Road Lahore (000459)
	Application Form Dy. No / Tracking ID & date of submission	(162-7U5-USWG, 2024-12-05)
	Detail of Fee Submitted	37000.0, 2024-11-06,
	The proposed proprietary name / brand name	Nebvis tablet 10mg
	Label Claim	Each tablet contains: Nebivolol as Hydrochloride...10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14s-De-Controlled
	Shelf Life (Unit)	2 Year(s)25°C ± 2°C
	For generic drugs (me-too Status)	Byscard 10mg tablet
	Pharmacotherapeutic Group of (API)	Selective B1 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: 1000 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)	DHL receipt is submitted. The firm has not obtained Form 6 or clearance certificate.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. Byscard tablet by M/s Searle.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 60 months real time stability data of 03 batches according to the conditions of zone IV-A.
	The status in reference regulatory authorities	Bystolic 10mg tablet
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 04-12-2023.
	Evidence of approval of manufacturing facility	GMP certificate issued on the basis of inspection conducted on 04-12-2023. Tablet General Section is approved as per submitted GMP certificate.
	Evaluation Remarks	
	The firm has developed the applied formulation as film coated tablet whereas it is approved as uncoated tablet in reference regulatory authorities. The firm has provided me-too reference (Byscard by M/s Searle).	
	The method for assessment of chiral purity of drug substance is submitted but performance has not been done by drug product manufacturer.	
	Decision	
	Deferred	
133	1. For evidence of approval of the applied formulation as film coated tablet in reference regulatory authorities as determined by Registration Board in its 275th meeting or otherwise the firm shall submit product development data for 03 batches for uncoated tablet.	
	2. Clarification for not performing the tests for chiral purity for drug substance.	
	Case Category	Routine (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	(JTZ-Q2V-1WD7, 2025-05-15)
	Detail of Fee Submitted	75000.0, 2025-01-30,
	The proposed proprietary name / brand name	Auvita 45mg/105mg XR Tablet
	Label Claim	Each bilayer film coated tablet contains: Dextromethorphan HBr (immediate release).....45mg Bupropion HCl (extended release).....105mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	10's, 14's, 20's, 28-De-Controlled
	Shelf Life (Unit)	2 Year(s)Do not store over 30°C. Protect from direct sunlight, heat and moisture
	For generic drugs (me-too Status)	Dexsero XR 45mg/105mg Tablet (126606) by M/s Seraph
	Pharmacotherapeutic Group of (API)	Antitussive agent / Atypical antidepressants
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Divi's Laboratory Limited,Zhejiang Supor Pharmaceuticals Co., Ltd
	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)	Dextromethorphan: Form6 dated 01-09-2023 for 1kg material is submitted. Bupropion: unattested

		invoice for 2kg material, GD NO. KPAF-10409-2023 Date: 11-11-2023 and DHL receipt.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Auvelity tablet by M/s Axxome Therapeutics, Inc USA.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Dextromethorphan: 06 months accelerated and 60 months real time stability studies according to zone IV-A. Bupropion: 06 months accelerated and 60 months real time stability studies according to zone IV-B.
	The status in reference regulatory authorities	Auvelity 105mg/45mg Tablet by Axxome Therapeutics, Inc, USA
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 12-06-2023.
	Evidence of approval of manufacturing facility	Tablet General Section is approved
	Evaluation Remarks	
	Decision	
	Approved	
134	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	Jinnah Pharmaceuticals Pvt Ltd 13 Km Lahore Road Multan (000578)
	Application Form Dy. No / Tracking ID & date of submission	(3US-2E8-4Y5R, 2026-01-08)
	Detail of Fee Submitted	38700, 2025-12-12,
	The proposed proprietary name / brand name	Taldex 20mg Tablet
	Label Claim	Each film coated tablet contains: Tadalafil 20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2's, 4's, 6's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30%
	For generic drugs (me-too Status)	Fildil 20mg Tablet Highnoon Laboratories Ltd 127635
	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. Tadalafil 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 20 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	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	
135	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	Medisure Laboratories Pakistan Pvt Ltd A-115 S.I.T.E-II Super Highway Karachi (000503)
	Application Form Dy. No / Tracking ID & date of submission	(PB7-GMJ-2JEA, 2026-02-06)
	Detail of Fee Submitted	38700, 2026-01-20,
	The proposed proprietary name / brand name	Tadalafil 10mg Tablet
	Label Claim	Each film coated tablet contains: Tadalafil.....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO,4's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect from heat, moisture & sunlight.
	For generic drugs (me-too Status)	Tadalafil Tablet 10mg
	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	Stability data of batches T-001, T-002 & T-003 (Batch Size: 5000 tablets) 06 months accelerated and 09 months real time according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 07-11-2024 for 1.5kg material and unattested invoice are submitted. Clearance certificate is not submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been conducted against the comparator's product i.e. Tadalafil by Hilton pharma.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 60 months real time stability studies of 03 batches according to zone IV-B.
	The status in reference regulatory authorities	CIALIS (tadalafil) tablets
	GMP status of the firm	(Last GMP Inspection dated: 2nd December 2024)
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been processed on priority in compliance to decision of DRAP Authority regarding ED drugs.	
	Decision	
	Approved	
136	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	Medisure Laboratories Pakistan Pvt Ltd A-115 S.I.T.E-II Super Highway Karachi (000503)
	Application Form Dy. No / Tracking ID & date of submission	(LX5-GBS-43N7, 2026-02-06)

	Detail of Fee Submitted	38700, 2026-01-20,
	The proposed proprietary name / brand name	Tadalafil 20mg Tablet
	Label Claim	Each film coated tablet contains: Tadalafil.....20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO,4's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect from heat, moisture & sunlight.
	For generic drugs (me-too Status)	Tadalafil Tablet 20mg
	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	Stability data of batches T-001, T-002 & T-003 (Batch Size: 5000 tablets) 06 months accelerated and 09 months real time according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 07-11-2024 for 1.5kg material and unattested invoice are submitted. Clearance certificate is not submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been conducted against the comparator's product i.e. Tadalafil by Hilton pharma.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 60 months real time stability studies of 03 batches according to zone IV-B.
	The status in reference regulatory authorities	CIALIS (tadalafil) tablets
	GMP status of the firm	(Last GMP Inspection dated: 2nd December 2024)
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been processed on priority in compliance to decision of DRAP Authority regarding ED drugs.	
	Decision	
	Approved	
137	Case Category	Import (Farooq Aslam)
	Name, address of Applicant.	QASIM TRADERS Shop No.7 Medicine Centre Kutchi Gali No.1, Denso Hall, Marriot Road (645.)
	Application Form Dy. No / Tracking ID & date of submission	(UZ3-HLT-EX7R, 2026-01-14)
	Detail of Fee Submitted	300000.0, 2025-07-03,
	The proposed proprietary name / brand name	Sodium Chloride Infusion
	Label Claim	Each 100ml contains : Sodium chloride.....0.9g
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's -As per SRO
	Shelf Life (Unit)	3 Year(s)it should be packaged as marketing and stored in tight container
	For generic drugs (me-too Status)	B.Braun NS 0.9% ml infusion 1000ml -053853
	Pharmacotherapeutic Group of (API)	Fluid and electrolyte replensher

	Name, address of Manufacturing site:	Shandong Qidu Pharmaceutical Co., Ltd.-No. 17, Hongda road Linzi District Zibo City Shandong Province-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies'report against Viaflex by Baxter healthcare is submitted. (Batch No.:248418)
	Name, address of Marketing Authorization Holder:	Shandong Qidu Pharmaceutical Co., Ltd., No. 17, Hongda road Linzi District Zibo City Shandong Province, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	DML No Lu20160064 valid till 23-09-2030 including the small volume injection in its scope.
	Details of Authorization Letter :	CoPP: Copy of CoPP No. 20253009 dated 26-01-2025 is submitted. The applied product is available in free sale and, the facilities and operations conform to WHO-GMP as per submitted CoPP. LOA: LOA dated 14-07-2025 is submitted. DSL: DSL valid till 23-03-2029.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 36months real time (25°C ± 2°C/60% RH± 10% RH) stability data of 03 batches is submitted.
	The status in reference regulatory authorities	0.9% Sodium Chloride USP-USFDA
	Evaluation Remarks	
	The application has been processed on priority in compliance to the decision of DRAP Authority regarding imported drugs (220th meeting).	
	Decision	
	Approved	
	As per import policy for inspection of manufacturer abroad. The Board further decided that the firm shall submit legalized/apostille CoPP and LOA.	
138	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	May and Baker (Pvt.) Ltd 23-Ghour Block, Bahria Town, Lahore (000953)
	Application Form Dy. No / Tracking ID & date of submission	(6AD-LTW-S2PG, 2026-02-17)
	Detail of Fee Submitted	37000.0, 2024-09-27,
	The proposed proprietary name / brand name	bakzold 100mg/5ml
	Label Claim	Each reconstituted 5ml contains: Linezolid.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	15ml,30ml,60ml-As per SRO
	Shelf Life (Unit)	2 Year(s)below 24 degree
	For generic drugs (me-too Status)	Neozid by Searle
	Pharmacotherapeutic Group of (API)	antibiotics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vision Pharmaceuticals (Pvt.) Ltd Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad-Pakistan
	Detail of stability batches of drug product	T01,T 02, T03 (Batch size: 1000 bottles)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Not applicable as product is locally purchased for trial from vision Pharmaceuticals

139	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies against Neozid by Searle
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 36 months real time stability data of 03 batches acc to zone IV-A.
	The status in reference regulatory authorities	MHRA Approved
	GMP status of the firm	New license issued on 29-04-2022.
	Evidence of approval of manufacturing facility	Sachet General Section is approved
	Evaluation Remarks	
	The firm has stated that they are having manual system of HPLC software and hence audit trail report cannot be submitted.	
	Decision	
	Rejected	
	The Board rejected the case since the firm could not provide audit trail report/system log.	
	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Welcome Pakistan Trading Pharma (Pvt) Ltd Chakri Interchange, Gangawala (000987)
	Application Form Dy. No / Tracking ID & date of submission	(MJA-7YQ-SNMG, 2024-06-27)
	Detail of Fee Submitted	75000.0, 2024-06-21,
	The proposed proprietary name / brand name	Flutas 50mcg NASAL DROPS
	Label Claim	Each actuation Contains: Fluticasone Propionate (USP).....50mcg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25c
	For generic drugs (me-too Status)	Flexosone Nasal Spray by Schazoo Laboratories
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Name, address of Manufacturing site:	Winbrains Research Laboratories-Plot No. 69/1, Phase I-II, Industrial Area, Hattar.-
	Name & address of API manufacturer	Vamsi Labs Ltd
	Detail of stability batches of drug product	03 batches : 250 bottles (120 actuation fo reach bottle) 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)	Unattested invoice dated 12-11-2021 for 25grams of material Form 6 dated dated 22-11-2021 for 25g of material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the comparator's product ie Ticovate nasal spray by M/s Saffron.
	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	..
	Evidence of approval of manufacturing facility	Eye/Ear/Nasal Drop (General) Section is approved.
	Evaluation Remarks	
	The firm has not submitted: 1. Latest inspection report valid within the last 03 years of DP manufacturer. 2. Valid GMP of drug substance manufacturer.	
	Decision	

	Approved	
	Subject to submission of latest GMP inspection report valid within the last 03 years and valid GMP/DML of drug substance manufacturer.	
140	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Welcome Pakistan Trading Pharma (Pvt) Ltd Chakri Interchange, Gangawala (000987)
	Application Form Dy. No / Tracking ID & date of submission	(EZ9-2TL-7WDU, 2024-06-27)
	Detail of Fee Submitted	75000.0, 2024-06-21,
	The proposed proprietary name / brand name	METSON 50MCG NASAL DROPS
	Label Claim	Each actuation Contains: Mometasone Furoate Monohydrate eq.to Mometasone furoate 50mcg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25c
	For generic drugs (me-too Status)	Hivate Nasal Spray By Saffron Pharma
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Name, address of Manufacturing site:	Winbrains Research Laboratories-Plot No. 69/1, Phase I-II, Industrial Area, Hattar.-
	Name & address of API manufacturer	Aarti Industries Ltd.,
	Detail of stability batches of drug product	03 batches : 250 packs (120 actuations)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Copy of airway bill, unattested invoice No. APP/240123 dated 05-04-2023 and copy of GD NO. IPAF-1928-08062023 Date: 08-06-2023 (Winbrains).
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against comparator's product i.e. Columela nasal spray by M/s Rotex Pharma.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 36 months real time 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 12-10-2022 (Winbrains)
	Evidence of approval of manufacturing facility	Eye/Ear/Nasal Drop (General) is approved.
141	Evaluation Remarks	
	The firm has submitted Copy of airway bill, unattested invoice No. APP/240123 dated 05-04-2023 and copy of GD NO. IPAF-1928-08062023 Date: 08-06-2023 for 10g of material. The firm has not submitted: 1. Latest inspection report valid within the last 03 years of DP manufacturer.	
	Decision	
	Approved	
141	Subject to submission of latest GMP inspection report valid within the last 03 years.	
	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Wallace Pharma Evolutions Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (000951)
	Application Form Dy. No / Tracking ID & date of submission	(8E6-WPD-X79H, 2024-06-27)

	Detail of Fee Submitted	75000.0, 2024-06-23,
	The proposed proprietary name / brand name	Metson 50mcg Nasal Spray
	Label Claim	Each actuation Contains: Mometasone Furoate Monohydrate eq.to Mometasone furoate 50mcg
	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)	Hivate Nasal Spray by Saffron Pharma
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Name, address of Manufacturing site:	Winbrains Research Laboratories-Plot No. 69/1, Phase I-II, Industrial Estate, Hattar, KPK.-
	Name & address of API manufacturer	Aarti Industries Ltd.,
	Detail of stability batches of drug product	03 batches : 250 packs (120 actuations)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Copy of airway bill, unattested invoice No. APP/240123 dated 05-04-2023 and copy of GD NO. IPAF-1928-08062023 Date: 08-06-2023 (Winbrains).
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against comparator's product i.e. Columela nasal spray by M/s Rotex Pharma.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 36 months real time stability data according to zone IV-A.
	The status in reference regulatory authorities	UK MHRA
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 12-10-2022 (Winbrains)
	Evidence of approval of manufacturing facility	Eye/Ear/Nasal Drop (General) is approved.
	Evaluation Remarks	
	The firm has submitted Copy of airway bill, unattested invoice No. APP/240123 dated 05-04-2023 and copy of GD NO. IPAF-1928-08062023 Date: 08-06-2023 for 10g of material. Form 6 is not submitted.	
	Decision	
	Approved	
	Subject to submission of latest GMP inspection report valid within the last 03 years.	
142	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Wallace Pharma Evolutions Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (000951)
	Application Form Dy. No / Tracking ID & date of submission	(QE3-HP9-JXQ8, 2024-06-27)
	Detail of Fee Submitted	75000.0, 2024-06-22,
	The proposed proprietary name / brand name	Flutas 50mcg Nasal Drops
	Label Claim	Each Spray Contains: Fluticasone Propionate (USP).....50mcg
	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)	Flexosone Nasal Spray Schazoo Laboratories
	Pharmacotherapeutic Group of (API)	Corticosteroid

	Name, address of Manufacturing site:	Winbrains Research Laboratories-Plot No. 69/1, Phase I-II, Industrial Estate, Hattar, KPK.-
	Name & address of API manufacturer	Vamsi Labs Ltd
	Detail of stability batches of drug product	03 batches : 250 bottles (120 actuation fo reach bottle) 06 months real time and 06 months accelerated stability data accordng to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Unattested invoice dated 12-11-2021 for 25grams of material Form 6 dated dated 22-11-2021 for 25g of material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the comparator's product ie Ticovate nasal spray by M/s Saffron.
	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 12-10-2022 (Winbrains)
	Evidence of approval of manufacturing facility	Eye/Ear/Nasal Drop (General) Section is approved.
	Evaluation Remarks	
	GMP of DS manufacturer GMP of DP manufacturer.	
	Decision	
	Approved	
	Subject to submission of latest GMP inspection report valid within the last 03 years and valid GMP/DML of drug substance manufacturer.	
143	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Stanley Pharmaceuticals (Pvt) Ltd , Plot No.84-B,Industrial Estate,Jamrud Road,Peshawar (000434)
	Application Form Dy. No / Tracking ID & date of submission	(9NE-TVA-6ZNT, 2024-08-19)
	Detail of Fee Submitted	30000.0, 2024-08-13,
	The proposed proprietary name / brand name	ARB 50mg Tablet
	Label Claim	Each film coated tablet contains: Losartan potassium.....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's, 20's, 30's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30C at cool and dry place
	For generic drugs (me-too Status)	Eziday Tablet by Werick Pharma
	Pharmacotherapeutic Group of (API)	Angiotensin II Receptor Antagonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Smruthi Organics Limited
	Detail of stability batches of drug product	03 batches : 1500 tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 04-08-2023 for 2kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been submitted against Noktan tablet by Novartis.

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months acc and 24 months RT stability data according to zone IV-A.
	The status in reference regulatory authorities	COZAAR® 50MG TABLET by Merck Sharp & Dohme Corp, a subsidiary of Merck&Co., Inc White house station, NJ 08889, USA
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 28-08-2024. DML renewal letter issued on 02-10-2025 is submitted,
	Evidence of approval of manufacturing facility	Tablet General section is approved.
	Evaluation Remarks	
	Decision	
	Approved	
144	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	(2VE-NS4-URAU, 2024-12-20)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-28, 2024-11-21
	The proposed proprietary name / brand name	Cyzap10mg Tablets
	Label Claim	Each film coated tablet contains; Cyclobenzaprine HCl.....10mg
	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)	Comforta Tablets(Genome Pharmaceuticals
	Pharmacotherapeutic Group of (API)	centrally acting skeletal muscle relaxant used for short-term relief of muscle spasms
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	03 batches : 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 08-11-2022 is submitted issued to M/s Vision Pharmaceuticals.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product ie Comforta tablet by M/ Genome.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 72 months real time stability data of 03 batches according to zone IV-A.
	The status in reference regulatory authorities	Cyclobenzaprine Hydrochloride(USFDA Approved)
	GMP status of the firm	NEW DML was issued w.e.f. 17-01-2024.
	Evidence of approval of manufacturing facility	Tablet General Sections I and II are approved
	Evaluation Remarks	
	Shortcomings were communicated to the firm and the firm has submitted letter No. 67A-AR2-NV4H dated 03-June, 2025 APPROVAL OF CHANGE IN MANUFACTURING SITE OF ALREADY REGISTERED DRUG PRODUCT from M/s Seraph to self manufacturing facility. The firm has requested for withdrawal of application.	

	Decision	
	Rejected	
	The Board acceded the request of the firm and decided to reject the case.	
145	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	(5D1-BA3-564G, 2024-12-20)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-28, 2024-11-05
	The proposed proprietary name / brand name	Minoxisol 5%Solution w/v
	Label Claim	Each ml contains: Minoxidil.....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Hair Max PLUS5% solution w/v by M/s Elko
	Pharmacotherapeutic Group of (API)	Direct- and Indirect-Acting Vasodilators
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Sonia Organics private limited
	Detail of stability batches of drug product	03 batches : 1L each (60mL each unit) 06 months accelerated and 6 months real time stability data according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan agreement with M/s Caliph Pharmaceuticals for 500grams of material is submitted. Clearance certificate dated 29-01-2024 issued to m/s Caliph Pharmaceuticals.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been submitted against the comparator's product i.e Hair Max plus Solution by M/s Elko organization.
	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 the conditions of zone IV A.
	The status in reference regulatory authorities	Theroxidil Solution 5% USFDA Approved
	GMP status of the firm	NEW License issued w.e.f.. 17-01-2024 is submitted.
	Evidence of approval of manufacturing facility	Cream/Ointment/Gel/Lotion (General/Steroidal) section is approved.
	Evaluation Remarks	
	Verification of loan letter.	
	Decision	
	Approved	
	subject to verification of loan letter.	
146	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	(1YB-Y3S-NUH2, 2024-10-30)

	Detail of Fee Submitted	30000.0, 7000.0 2024-08-28, 2024-10-08
	The proposed proprietary name / brand name	Bisolol 2.5 mg Tablets
	Label Claim	Each film coated tablets contains: Bisoprolol Fumarate.....2.5mg
	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)	Concor 2.5mg Tablet, Manufacturer: Martin Dow Marker Ltd.
	Pharmacotherapeutic Group of (API)	Cadiosselective Beta blocking agent
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	03 batches : 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provision of loan intimation dated 5th April 2026 is submitted from M/s Biomark.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product ie concor tablet by m/s MartinDow Marker.
	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 the conditions of zone IV A.
	The status in reference regulatory authorities	Zentobiso Tablets 2.5mg, Company: Niche Generics Limited (MHRA Approved)
	GMP status of the firm	NEW License issued w.e.f.. 17-01-2024 is submitted.
	Evidence of approval of manufacturing facility	Tablet General Section I & II are approved.
	Evaluation Remarks	
	verification of loan letter is required.	
	Decision	
	Approved	
	subject to verification of loan letter.	
147	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	(9XJ-668-6UVY, 2024-10-30)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-28, 2024-10-08
	The proposed proprietary name / brand name	BISOLOL 5MG TABLETS
	Label Claim	Each film coated tablets contains: Bisoprolol Fumarate.....5mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Concor 5mg Tablet, Manufacturer: Martin Dow Marker Ltd.
	Pharmacotherapeutic Group of (API)	Cadiosselective Beta blocking agent

	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	03 batches : 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	.Provision of loan intimation dated 5th April 2026 is submitted from M/s Biomark.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product ie concor tablet by m/s MartinDOW Marker.
	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 the conditions of zone IV A.
	The status in reference regulatory authorities	Bisoprolol Fumarate 5mg Tablet, Company: Novitium Pharma, (NDA): 215563, (USFDA Approved)
	GMP status of the firm	NEW License issued w.e.f.. 17-01-2024 is submitted.
	Evidence of approval of manufacturing facility	Tablet General Section I & II are approved.
	Evaluation Remarks	
	Verification of loan letter is required.	
	Decision	
	Approved	
	subject to verification of loan letter.	
148	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	(URY-R4X-YXNA, 2024-10-30)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-28, 2024-10-08
	The proposed proprietary name / brand name	Bisolol 10 mg Tablets
	Label Claim	Each film coated tablets contains: Bisoprolol Fumarate.....10mg
	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)	Concor 10mg Tablet, Manufacturer: Martin Dow Marker Ltd.
	Pharmacotherapeutic Group of (API)	Cadioselective Beta blocking agent
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	03 batches : 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provision of loan intimation dated 5th April 2026 is submitted from M/s Biomark.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product ie concor tablet by m/s MartinDOW Marker.
	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 the

		conditions of zone IV A.
	The status in reference regulatory authorities	Bisoprolol Fumarate 10mg Tablet, Company: Novitium Pharma, (NDA): 215563, (USFDA Approved)
	GMP status of the firm	NEW License issued w.e.f.. 17-01-2024 is submitted.
	Evidence of approval of manufacturing facility	Tablet General Section I & II are approved.
	Evaluation Remarks	
	Verification of loan letter is required.	
	Decision	
	Approved	
	subject to verification of loan letter.	
149	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	(HU3-UXA-T1AZ, 2024-10-24)
	Detail of Fee Submitted	75000.0, 2024-07-12,
	The proposed proprietary name / brand name	Azilmed Plus 40/25mg tablet
	Label Claim	Each film coated tablet contains: Azilsartan medoxomil (As potassium salt)..... 40mg Chlorthalidone.....25mg
	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)	Available
	Pharmacotherapeutic Group of (API)	Antihypertensive
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Ami Lifesciences Pvt. Ltd.,Trichem Life Sciences Limited
	Detail of stability batches of drug product	03 batches:1000 tablets 06 months accelerated and 24 months real time stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Azilsartan: AD attested invoice dated 12-01-2018 for 1kg material is submitted. Chlorthalidone: Form 6 dated 20-05-2019 for 200grams of material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been submitted against Edarbyclor tablet by M/s Takeda Pharmaceuticals.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Azilsartan: 06 months accelerated (25oC/60%RH) and 60 months real time (2-8oC) Chlorthalidone: 06 months accelerate and 60 months real time 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 23-01-2023

	Evidence of approval of manufacturing facility	Tablet General Section is approved
	Evaluation Remarks	
	The firm was asked for clarification regarding, the sampling time point for Azilsartan which is 30minutes and for Chlorthalidone it is 15 minutes as per reference product's literature while the firm has selected 30 minutes sampling time point for both drug substances.	
	The firm has submitted that a new trial batch was manufactured after receiving the query regarding the sampling time point for dissolution. The firm has submitted the results of dissolution testing at 0 month time point according to revised sampling timepoint.	
	Batch number: T04 Batch size: 1000 tablets Mfg date: 05/2026 Testing dated: 08-05-2026	
	The firm has stated that the the sampling timepoint of 30 mins for Chrothalidone was selected inadvertently by referring USP general chapter.	
	Decision	
	Approved	
150	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	(Q2W-BD9-AYR4, 2024-09-13)
	Detail of Fee Submitted	75000.0, 2024-07-12,
	The proposed proprietary name / brand name	Azilmed Plus 40/12.5mg tablet
	Label Claim	Each film coated tablet contains: Azilsartan medoxomil (As potassium salt)..... 40mg Chlorthalidone.....12.5mg
	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)	Available
	Pharmacotherapeutic Group of (API)	Antihypertensive
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Ami Lifesciences Pvt. Ltd.,Trichem Life Sciences Limited
	Detail of stability batches of drug product	03 batches:1000 tablets 06 months accelerated and 24 months real time stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Azilsartan: AD attested invoice dated 12-01-2018 for 1kg material is submitted. Chlorthalidone: Form 6 dated 20-05-2019 for 200grams of material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been submitted against Edarbyclor tablet by M/s Takeda Pharmaceuticals.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Azilsartan: 06 months accelerated (25oC/60%RH) and 60 months real time (2-8oC) Chlorthalidone: 06 months accelerate and 60 months real time 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 23-01-2023

	Evidence of approval of manufacturing facility	Tablet General Section is approved
	Evaluation Remarks	
	The firm was asked for clarification regarding, the sampling time point for Azilsartan which is 30minutes and for Chlorthalidone it is 15 minutes as per reference product's literature while the firm has selected 30 minutes sampling time point for both drug substances.	
	The firm has submitted that a new trial batch was manufactured after receiving the query regarding the sampling time point for dissolution. The firm has submitted the results of dissolution testing at 0 month time poitn according to revised sampling timepoint.	
	Batch number: TF04 Batch size: 1000 tablets Mfg date: 05/2026 Testing dated: 08-05-2026	
	The firm has stated that the the sampling timepoint of 30 mins for Chrothalidone was selected inadvertently by referring USP general chapter. The firm further clarified that Chlorthalidone has sufficient solubility for the proposed strength with reported solubility of 20mg/100mL eq to 180mg/900mL therefore the compliance at 15-mins time point was scientifically expected and has now been confirmed.	
	Decision	
	Approved	
151	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi (000333)
	Application Form Dy. No / Tracking ID & date of submission	(4E5-3WZ-5ZTH, 2024-10-18)
	Detail of Fee Submitted	75000.0, 2024-10-11,
	The proposed proprietary name / brand name	XELL-EZ 40mg/10mg Tablets
	Label Claim	Each film coated tablet contains: Rosuvastatin as calcum.....40mg Ezetimibe.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	2 Year(s)store in a cool and dry place below 30
	For generic drugs (me-too Status)	Zuvaroz-E 40/10mg Tablet by M/s Daneen
	Pharmacotherapeutic Group of (API)	Lipid modifying agents.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Glenmark Lifesciences Ltd
	Detail of stability batches of drug product	03 batches (batch size: 825 tablets)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Rosuvastatin: Clerance certificate dated 05-07-2024 for 03 kg of material. Ezetimibe: Form 6 dated 22-12-2023 for 330 grams material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Zympass 40/10 by M/s Sanofi Aventis Ireland Limited.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Ezetimibe: 06 months accelerated and 24 months real time stability data of 03 batches is submitted according to zone IV-B.
	The status in reference regulatory authorities	ZYMPASS 40mg/10mg Tablets Sanofi Aventis Ireland
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 16-02-224 is submitted.
	Evidence of approval of manufacturing facility	Tablet General section is approved.
	Evaluation Remarks	
	The applied product is approved in different reference regulatory authorities as film coated bilayer tablet but HPRA Ireland has approved film coated tablet as a single core in strengths of 40/10mg,	

`data=eyJpZCI6bnVsbCwic2tpcCI6MCwidGFrZSI6MTAsInF1ZXJ5Ijoic3V2ZXplbiIsIm9yZGVyIjo`

Approved

Approved

Evaluation Remarks	
1	1. The first sentence is a good start, but it is a bit long and could be split into two sentences for better readability.
2	2. The second sentence is well-written and provides a clear example of the concept.
3	3. The third sentence is a bit repetitive and could be rephrased to avoid redundancy.
4	4. The fourth sentence is a good conclusion, but it could be strengthened by adding more evidence or examples.
5	5. The fifth sentence is a good start, but it is a bit long and could be split into two sentences for better readability.
6	6. The sixth sentence is well-written and provides a clear example of the concept.
7	7. The seventh sentence is a bit repetitive and could be rephrased to avoid redundancy.
8	8. The eighth sentence is a good conclusion, but it could be strengthened by adding more evidence or examples.
9	9. The ninth sentence is a good start, but it is a bit long and could be split into two sentences for better readability.
10	10. The tenth sentence is well-written and provides a clear example of the concept.
11	11. The eleventh sentence is a bit repetitive and could be rephrased to avoid redundancy.
12	12. The twelfth sentence is a good conclusion, but it could be strengthened by adding more evidence or examples.
13	13. The thirteenth sentence is a good start, but it is a bit long and could be split into two sentences for better readability.
14	14. The fourteenth sentence is well-written and provides a clear example of the concept.
15	15. The fifteenth sentence is a bit repetitive and could be rephrased to avoid redundancy.
16	16. The sixteenth sentence is a good conclusion, but it could be strengthened by adding more evidence or examples.
17	17. The seventeenth sentence is a good start, but it is a bit long and could be split into two sentences for better readability.
18	18. The eighteenth sentence is well-written and provides a clear example of the concept.
19	19. The nineteenth sentence is a bit repetitive and could be rephrased to avoid redundancy.
20	20. The twentieth sentence is a good conclusion, but it could be strengthened by adding more evidence or examples.

<https://assets.hpra.ie/products/Human/18202/33562aa6-f524-4cee-a5c9-329de6e3d3ba.pdf>

	https://www.medicines.ie/medicines/suvezen-40-mg-10-mg-film-coated-tablets-34831/license-info https://www.hpra.ie/find-a-medicine/for-human-use/authorised-medicines? data=eyJpZCI6bnVsbCwic2tpcCI6MCwidGFrZSI6MTAsInF1ZXJ5Ijoic3V2ZXplbiIsIm9yZGVyIjoi		
	Decision		
	Approved		
153	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	(P13-4Z2-3NLQ, 2024-12-04)	
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-13, 2024-10-23	
	The proposed proprietary name / brand name	Acitin 25mg Capsules	
	Label Claim	Each capsule contains: Acitretin.....25mg	
	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)	Acetin 25mg capsules, Manufacturer: Genome pharmaceuticals (Pvt) Limited	
	Pharmacotherapeutic Group of (API)	Retinoid/systemic antipsoriatic agent	
	Name, address of Manufacturing site:	Self Manufacturing	
	Name & address of API manufacturer		
	Detail of stability batches of drug product	03 batches : 1500 cap each 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 23-08-2023 for 5kg material issued to m/S Valor Pharma. Loan agreement is submitted.	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. Acetin cap 25mg by M/s Genome.	
	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-A.	
	The status in reference regulatory authorities	Acitretin 25mg capsules, Company: Barr Labs Inc, (NDA): 091455, USFDA Approved	
	GMP status of the firm	NEW DML was issued w.e.f. 17-01-2024.	
	Evidence of approval of manufacturing facility	Capsule Section is approved.	
	Evaluation Remarks		
	Verification of loan letter is required. Valid GMP/DML of drug substance manufacturer is not submitted.		
	Decision		
	Approved		
	subject to verification of loan letter and submission of valid GMP/DML of drug substance manufacturer.		
	154	Case Category	Any Other (Farooq Aslam)
		Name, address of Applicant.	Bio-Labs(Pvt) Ltd Plot 145, Industrial Triangle, Kahuta Road (000296)

Decision

153

Routine (Farooq Aslam)

Name, address of Applicant.

Application Form Dy. No / Tracking ID & date of submission

Detail of Fee Submitted

The proposed proprietary name / brand name

Label Claim

Reference to Finished product specifications

Proposed Pack Size

Shelf Life (Unit)

For generic drugs (me-too Status)

Pharmacotherapeutic Group of (API)

Name, address of Manufacturing site:

Name & address of API manufacturer

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

GMP status of the firm

Evidence of approval of manufacturing facility

Evaluation Remarks

Decision

subject to verification of loan letter and submission of valid GMP/DML of drug substance manufacturer.

Any Other (Farooq Aslam)

Name, address of Applicant.

Application Form Dy. No / Tracking ID & date of submission	(S3E-Z8Z-MZUIJ, 2025-01-21)
Detail of Fee Submitted	75000.0, 2025-01-13,
The proposed proprietary name / brand name	Dalafil 5mg Tablet
Label Claim	Each film-coated tablet contains : Tadalafil 5mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	10's & 30's-As per SRO
Shelf Life (Unit)	2 Year(s)store below 30°C
For generic drugs (me-too Status)	Not available
Pharmacotherapeutic Group of (API)	Phosphodiesterase (PDE) inhibitors. ATC code: G04BE08.
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Centurey Pharmaceuticals limited
Detail of stability batches of drug product	03 batches having batch size of 1500 Tablets each.
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted documents of DHL. However, no clearance certificate is submitted by the firm.
Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and PE are performed against the innovator product i.e. CIALIS 5MG tablet, Batch No: YT623, Mfg. date 12/23 and both reference and applied formulation have shown similar release pattern and values of F2 are in acceptable ranges.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of 3 batches of drug substance as per Zone IV-B is submitted. Accelerated 06 months and real time for 60 months.
The status in reference regulatory authorities	CIALIS 2.5 mg, 5mg, 10mg & 20mg film-coated tablets, MHRA approved.
GMP status of the firm	Firm has submitted copy of GMP Certificate No. No. F.3-19/2019-Addl. Dir. (QA<-I)-77 dated 28-12-2023 issued on the basis of inspection conducted on 09-10-2023.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-12/98-Lic (Vol-II) dated 24-03-2007 mentioning Tablet (General) section.
Evaluation Remarks	
Evaluation by PEC; 1. Justification shall be submitted regarding release of more than 70% in all the three mediums of the CDP studies with respect to the solubility of the drug substance. Firm has submitted that the product "Dalafil 5mg Tablet" is developed as per USP specification. There are two tests described in the USP for the dissolution of Tadalafil Tablet with different dissolution profile requirement, i.e. USP Test 1 Medium: 0.5% sodium dodecyl sulfate; 1000 mL Apparatus 2:50 rpm, use suitable sinkers if necessary Times: 10 and 30 minutes. Tolerance: NLT 40% (Q) of the labeled amount of tadalafil is dissolved in 10 min and NLT 80% (Q) of the labeled amount of tadalafil is dissolved in 30 min. USP Test 2: Medium: 0.5% sodium dodecyl sulfate; 1000 mL. Apparatus 2: 50 rpm, use suitable sinkers if necessary Times: 15minutes. Tolerance: NLT 80% (Q) of the labeled amount of tadalafil is dissolved in 15 minutes. According to USP test 1, the product has to be designed and developed in a manner that the dissolution of tablet is controlled to less than 40% in first 10 minutes and tablet has to release more than 80% (Q) in the next 20 minutes. While according to USP test 2, the product should be developed in a way that the tablet should release more than 80% (Q) in 15 minutes, i.e. immediate release is required. As the firm has developed the product in accordance with USP test 2", therefore the qualitative formulation of tablet was same as	

innovator's product. however quantitatively disintegrant ""Croscarmellose Sodium" also called super disintegrant"" was used in maximum allowable limit to enhance the dissolution of product. In addition to disintegrant, surfactant "Sodium Lauryl Sulphate"" was also used in the formulation, which has enhanced the dissolution profile of the product. Moreover, surfactant was added to the dissolution medium to enhance the dissolution profile. Firm was asked about the release of the applied formulation in all the mediums of CDP. Wherein, they responded the question in general dissolution. 2. Pictorial evidence of the reference product against which CDP and PE studies are performed with visible details of batch number, manufacturing date and name of the manufacturer shall be submitted. Firm has submitted a picture wherein B. No. D735814, Expiry date 05-2026 manufactured by Eli Lilly & company. 3. Document for procurement of API (Import) with approval from DRAP shall be submitted. Firm has submitted copy of DHL. They didn't provide any clearance certificate. 4. Copies of Executed BMRs along with blank production document shall be submitted. Submitted.

The case was deferred in 345th meeting, The firm has requested for withdrawal of the applicaiton.

Decision

Rejected

The Board acceded the request of the firm and rejected the case.

155	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	(ZJD-JAQ-TPRW, 2025-01-21)
	Detail of Fee Submitted	75000.0, 2025-01-13,
	The proposed proprietary name / brand name	Dalafil 20mg Tablet
	Label Claim	Each film-coated tablet contains ; Tadalafil 20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's & 30's-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30°C
	For generic drugs (me-too Status)	Not available
	Pharmacotherapeutic Group of (API)	Phosphodiesterase (PDE) inhibitors. ATC code: G04BE08.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Centurey Pharmaceuticals limited
	Detail of stability batches of drug product	03 batches having batch size of 1500 Tablets each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted documents of DHL with Air waybill No. 7157313157. However, no clearance certificate is submitted by the firm.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and PE are performed against the innovator product i.e. CIALIS 5MG tablet, Batch No: MK456, Mfg. date 01/24 and both reference and applied formulation have shown similar release pattern and values of F2 are in acceptable ranges.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of 3 batches of drug substance as per Zone IV-B is submitted. Accelerated 06 months and real time for 60 months.
	The status in reference regulatory authorities	CIALIS 2.5 mg, 5mg, 10mg & 20mg film-coated tablets, MHRA approved.

GMP status of the firm	Firm has submitted copy of GMP Certificate No. No. F.3-19/2019-Addl. Dir. (QA<-I)-77 dated 28-12-2023 issued on the basis of inspection conducted on 09-10-2023.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-12/98-Lic (Vol-II) dated 24-03-2007 mentioning Tablet (General) section.

Evaluation Remarks

Evaluation by PEC; 1. Justification shall be submitted regarding release of more than 70% in all the three mediums of the CDP studies with respect to the solubility of the drug substance. Firm has submitted that the product "Dalafil 5mg Tablet" is developed as per USP specification. There are two tests described in the USP for the dissolution of Tadalafil Tablet with different dissolution profile requirement, i.e. USP Test 1 Medium: 0.5% sodium dodecyl sulfate; 1000 mL Apparatus 2: 50 rpm, use suitable sinkers if necessary Times: 10 and 30 minutes. Tolerance: NLT 40% (Q) of the labeled amount of tadalafil is dissolved in 10 min and NLT 80% (Q) of the labeled amount of tadalafil is dissolved in 30 min. USP Test 2: Medium: 0.5% sodium dodecyl sulfate; 1000 mL. Apparatus 2: 50 rpm, use suitable sinkers if necessary Times: 15 minutes. Tolerance: NLT 80% (Q) of the labeled amount of tadalafil is dissolved in 15 minutes. According to USP test 1, the product has to be designed and developed in a manner that the dissolution of tablet is controlled to less than 40% in first 10 minutes and tablet has to release more than 80% (Q) in the next 20 minutes. While according to USP test 2, the product should be developed in a way that the tablet should release more than 80% (Q) in 15 minutes, i.e. immediate release is required. As the firm has developed the product in accordance with USP test 2", therefore the qualitative formulation of tablet was same as innovator's product. however quantitatively disintegrant ""Croscarmellose Sodium" also called super disintegrant"" was used in maximum allowable limit to enhance the dissolution of product. In addition to disintegrant, surfactant "Sodium Lauryl Sulphate"" was also used in the formulation, which has enhanced the dissolution profile of the product. Moreover, surfactant was added to the dissolution medium to enhance the dissolution profile. Firm was asked about the release of the applied formulation in all the mediums of CDP. Wherein, they responded the question in general dissolution. 2. Pictorial evidence of the reference product against which CDP and PE studies are performed with visible details of batch number, manufacturing date and name of the manufacturer shall be submitted. Firm has submitted a picture wherein B. No. D675505, Expiry date 02-2026 manufactured by Eli Lilly & company. 3. Document for procurement of API (Import) with approval from DRAP shall be submitted. Firm has submitted copy of DHL. They didn't provide any clearance certificate. 4. Copies of Executed BMRs along with blank production document shall be submitted. Submitted.

The case was deferred in 345th meeting, The firm has requested for withdrawal of the application.

Decision

Rejected

The Board acceded the request of the firm and rejected the case.

156	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	(DJ6-EG3-TUM1, 2024-11-13)
	Detail of Fee Submitted	75000.0, 2024-11-05,
	The proposed proprietary name / brand name	Eslicar 600mg Tablet
	Label Claim	Each tablet contains: Eslicarbazepine acetate.....600mg
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	10's, 30's, As per S-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)	could not be confirmed
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Ami Lifesciences Private Limited.
	Detail of stability batches of drug product	03 batches (Batch size: 1000 tables) 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)	AD attested invoice vide dy. No. 0777 dated 11-03-2020 for 10 Kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e Apitom Tablets.
	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	APTiom 600mg tablets; Sunovion Pharmaceuticals Inc. Marlborough, MA 01752 USA.; FDA Approved
	GMP status of the firm	GMP certificate issued on the basis on inspection conducted on 14-12-2023.
	Evidence of approval of manufacturing facility	Tablet General Section is approved
	Evaluation Remarks	
	The case was considered in 357th meeting and the case was deferred for submission of audit trail report. The firm was asked to submit audit trail report for submitted stability studies for drug product. In reply the firm had stated that:	
	“The firm has Waters HPLC system with Empower 2 software this system is currently not 21CFR compliance. As regards the use of a CFR-compliant system, it is submitted that at the time of testing of the submitted product, the batch under evaluation was a trial / development batch. Due to over-occupancy of the available 21 CFR-compliant HPLC systems, the stability testing of this trial batch was performed on a GxP-compliant HPLC system. However, we assure that upon registration of the product and initiation of commercial-scale manufacturing, all testing including routine QC and stability studies will be performed exclusively on 21 CFR Part 11–compliant HPLC systems to ensure enhanced data integrity, audit-trail compliance, and secure electronic data management.”	
	Then the case was presented before the Board in 358th meeting and the Board rejected the cases on the basis of unavailability of analytical record for CDP and AMV studies for drug product and audit trail report/system log. The firm submitted the required data after the meeting vide application ID No. N8M-PUW-7GRD dated May 14th, 2026, 6:39 pm.	
	Submitted for consideration by the Board.	
	Decision	
	Approved	
157	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	(MTR-XE5-VTZX, 2024-11-14)
	Detail of Fee Submitted	75000.0, 2024-11-05,

	The proposed proprietary name / brand name	Eslicar 400mg Tablet
	Label Claim	Each tablet contains: Eslicarbazepine acetate.....400mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 30's, As per -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)	could not be confirmed
	Pharmacotherapeutic Group of (API)	Anti-epileptic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Ami Lifesciences Private Limited.
	Detail of stability batches of drug product	03 batches (Batch size: 1000 tables) 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)	AD attested invoice vide dy. No. 0777 dated 11-03-2020 for 10 Kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e Apitom Tablets.
	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	APTOM 400mg tablets; Sunovion Pharmaceuticals Inc. Marlborough, MA 01752 USA.; FDA Approved
	GMP status of the firm	GMP certificate issued on the basis on inspection conducted on 14-12-2023.
	Evidence of approval of manufacturing facility	Tablet General Section is approved
	Evaluation Remarks	
	The case was considered in 357th meeting and the case was deferred for submission of audit trail report. The firm was asked to submit audit trail report for submitted stability studies for drug product. In reply the firm had stated that:	
	“The firm has Waters HPLC system with Empower 2 software this system is currently not 21CFR compliance. As regards the use of a CFR-compliant system, it is submitted that at the time of testing of the submitted product, the batch under evaluation was a trial / development batch. Due to over-occupancy of the available 21 CFR-compliant HPLC systems, the stability testing of this trial batch was performed on a GxP-compliant HPLC system.However, we assure that upon registration of the product and initiation of commercial-scale manufacturing, all testing including routine QC and stability studies will be performed exclusively on 21 CFR Part 11–compliant HPLC systems to ensure enhanced data integrity, audit-trail compliance, and secure electronic data management.”	
	Then the case was presented before the Board in 358th meeting and the Board rejected the cases on the basis of unavailability of analytical record for CDP and AMV studies for drug product and audit trail report/system log. The firm submitted the required data after the meeting vide application ID No. N8M-PUW-7GRD dated May 14th, 2026, 6:39 pm.	
	Submitted for consideration by the Board.	
	Decision	
	Approved	
158	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	(B7J-W18-2B8Q, 2024-11-13)
Detail of Fee Submitted	75000.0, 2024-11-05,
The proposed proprietary name / brand name	Eslicar 800mg Tablet
Label Claim	Each tablet contains: Eslicarbazepine acetate.....800mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	10's, 30's, As per S-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)	could not be confirmed
Pharmacotherapeutic Group of (API)	Anti-epileptic
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Ami Lifesciences Private Limited.
Detail of stability batches of drug product	03 batches (Batch size: 1000 tables) 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)	AD attested invoice vide dy. No. 0777 dated 11-03-2020 for 10 Kg material is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference roduct i.e Apitom Tablets.
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	APTOM 800mg tablets; Sunovion Pharmaceuticals Inc. Marlborough, MA 01752 USA.; FDA Approved
GMP status of the firm	GMP certificate issued on the basis on inspection conducted on 14-12-2023.
Evidence of approval of manufacturing facility	Tablet General Section is approved
Evaluation Remarks	
The case was considered in 357th meeting and the case was deferred for submission of audit trail report. The firm was asked to submit audit trail report for submitted stability studies for drug product. In reply the firm had stated that:	
“The firm has Waters HPLC system with Empower 2 software this system is currently not 21CFR compliance. As regards the use of a CFR-compliant system, it is submitted that at the time of testing of the submitted product, the batch under evaluation was a trial / development batch. Due to over-occupancy of the available 21 CFR-compliant HPLC systems, the stability testing of this trial batch was performed on a GxP-compliant HPLC system.However, we assure that upon registration of the product and initiation of commercial-scale manufacturing, all testing including routine QC and stability studies will be performed exclusively on 21 CFR Part 11–compliant HPLC systems to ensure enhanced data integrity, audit-trail compliance, and secure electronic data management.”	
Then the case was presented before the Board in 358th meeting and the Board rejected the cases on the basis of unavailability of analytical record for CDP and AMV studies for drug product and audit trail report/system log. The firm submitted the required data after the meeting vide application ID No. N8M-PUW-7GRD dated May 14th, 2026, 6:39 pm.	
Submitted for consideration by the Board.	
Decision	
Approved	
159	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	(T8L-AH3-Y3GZ, 2024-11-13)
Detail of Fee Submitted	75000.0, 2024-11-05,
The proposed proprietary name / brand name	Eslicar 200mg Tablet
Label Claim	Each tablet contains: Eslicarbazepine acetate.....200mg
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 below 30OC at a dry place, protect from light and heat.
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	Ami Lifesciences Private Limited.
Detail of stability batches of drug product	03 batches (Batch size: 1000 tables) 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)	AD attested invoice vide dy. No. 0777 dated 11- 03-2020 for 10 Kg material is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e Apitom Tablets.
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	APTOM 200mg tablets; Sunovion Pharmaceuticals Inc. Marlborough, MA 01752 USA.; FDA Approved
GMP status of the firm	GMP certificate issued on the basis on inspection conducted on 14-12-2023.
Evidence of approval of manufacturing facility	Tablet General Section is approved
Evaluation Remarks	
The case was considered in 357th meeting and the case was deferred for submission of audit trail report. The firm was asked to submit audit trail report for submitted stability studies for drug product. In reply the firm had stated that:	
“The firm has Waters HPLC system with Empower 2 software this system is currently not 21CFR compliance. As regards the use of a CFR-compliant system, it is submitted that at the time of testing of the submitted product, the batch under evaluation was a trial / development batch. Due to over-occupancy of the available 21 CFR-compliant HPLC systems, the stability testing of this trial batch was performed on a GxP-compliant HPLC system.However, we assure that upon registration of the product and initiation of commercial-scale manufacturing, all testing including routine QC and stability studies will be performed exclusively on 21 CFR Part 11–compliant HPLC systems to ensure enhanced data integrity, audit-trail compliance, and secure electronic data management.”	
Then the case was presented before the Board in 358th meeting and the Board rejected the cases on the basis of unavailability of analytical record for CDP and AMV studies for drug product and audit trail report/system log. The firm submitted the required data after the meeting vide application ID No. N8M-PUW-7GRD dated May 14th, 2026, 6:39 pm.	
Submitted for consideration by the Board.	

	Decision	
	Approved	
160	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)	6mg strength is registered.
	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.		
The case was considered in 357th meeting and the case was deferred for submission of audit trail report. The firm was asked to submit audit trail report for submitted stability studies for drug product. In reply the firm had stated that:		
“The firm has Waters HPLC system with Empower 2 software this system is currently not 21CFR compliance. As regards the use of a CFR-compliant system, it is submitted that at the time of testing of the submitted product, the batch under evaluation was a trial / development batch. Due to over-occupancy of the available 21 CFR-compliant HPLC systems, the stability testing of this trial batch was performed on a GxP-compliant HPLC system.However, we assure that upon registration of the		

product and initiation of commercial-scale manufacturing, all testing including routine QC and stability studies will be performed exclusively on 21 CFR Part 11–compliant HPLC systems to ensure enhanced data integrity, audit-trail compliance, and secure electronic data management.”

Then the case was presented before the Board in 358th meeting and the Board rejected the cases on the basis of unavailability of audit trail report/system log. The firm submitted the required data after the meeting vide application ID No. N8M-PUW-7GRD dated May 14th, 2026, 6:39 pm.

Submitted for consideration by the Board.

Decision

Approved

Subject to submission of applicable fee for revision of specification for LOD as per innovator.

161	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)	6mg strength is registered.
	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.

The case was considered in 357th meeting and the case was deferred for submission of audit trail report. The firm was asked to submit audit trail report for submitted stability studies for drug product. In reply the firm had stated that:

“The firm has Waters HPLC system with Empower 2 software this system is currently not 21CFR compliance. As regards the use of a CFR-compliant system, it is submitted that at the time of testing of the submitted product, the batch under evaluation was a trial / development batch. Due to over-occupancy of the available 21 CFR-compliant HPLC systems, the stability testing of this trial batch was performed on a GxP-compliant HPLC system. However, we assure that upon registration of the product and initiation of commercial-scale manufacturing, all testing including routine QC and stability studies will be performed exclusively on 21 CFR Part 11-compliant HPLC systems to ensure enhanced data integrity, audit-trail compliance, and secure electronic data management.”

Then the case was presented before the Board in 358th meeting and the Board rejected the cases on the basis of unavailability of audit trail report/system log. The firm submitted the required data after the meeting vide application ID No. N8M-PUW-7GRD dated May 14th, 2026, 6:39 pm.

Submitted for consideration by the Board.

Decision

Approved

Subject to submission of applicable fee for revision of specification for LOD as per innovator.

162	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)	6mg strength is registered.
	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.	
	The case was considered in 357th meeting and the case was deferred for submission of audit trail report. The firm was asked to submit audit trail report for submitted stability studies for drug product. In reply the firm had stated that:	
	“The firm has Waters HPLC system with Empower 2 software this system is currently not 21CFR compliance. As regards the use of a CFR-compliant system, it is submitted that at the time of testing of the submitted product, the batch under evaluation was a trial / development batch. Due to over-occupancy of the available 21 CFR-compliant HPLC systems, the stability testing of this trial batch was performed on a GxP-compliant HPLC system. However, we assure that upon registration of the product and initiation of commercial-scale manufacturing, all testing including routine QC and stability studies will be performed exclusively on 21 CFR Part 11-compliant HPLC systems to ensure enhanced data integrity, audit-trail compliance, and secure electronic data management.”	
	Then the case was presented before the Board in 358th meeting and the Board rejected the cases on the basis of unavailability of audit trail report/system log. The firm submitted the required data after the meeting vide application ID No. N8M-PUW-7GRD dated May 14th, 2026, 6:39 pm.	
	Submitted for consideration by the Board.	
	Decision	
	Approved	
	Subject to submission of applicable fee for revision of specification for LOD as per innovator.	
163	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)	...
	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	
	This strength was approved in 347th meeting and is registered already approved (128073). The has been confirmed by the firm: "we have already approved and registered product for Deflazacort 6mg tablet and it was mistakenly re-applied. we apologize of this inconvenience."	
164	Decision	
	Rejected	
	The Board rejected the case since the registration of the applied strength has already been granted to the applicant.	
	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. The firm shall submit applicable fee for correction of specifications for LOD from 0.1% to 1% for DS.	
	The case was considered in 357th meeting and the case was deferred for submission of audit trail report. The firm was asked to submit audit trail report for submitted stability studies for drug product. In reply the firm had stated that:	
	“The firm has Waters HPLC system with Empower 2 software this system is currently not 21CFR compliance. As regards the use of a CFR-compliant system, it is submitted that at the time of testing of the submitted product, the batch under evaluation was a trial / development batch. Due to over-occupancy of the available 21 CFR-compliant HPLC systems, the stability testing of this trial batch was performed on a GxP-compliant HPLC system. However, we assure that upon registration of the product and initiation of commercial-scale manufacturing, all testing including routine QC and stability studies will be performed exclusively on 21 CFR Part 11–compliant HPLC systems to ensure enhanced data integrity, audit-trail compliance, and secure electronic data management.”	
	Then the case was presented before the Board in 358th meeting and the Board rejected the cases on the basis of unavailability of audit trail report/system log. The firm submitted the required data after the meeting vide application ID No. N8M-PUW-7GRD dated May 14th, 2026, 6:39 pm.	
	Submitted for consideration by the Board.	
	Decision	
	Approved	
	Subject to submission of applicable fee for revision of specification for LOD as per innovator.	
165	Case Category	Export Facilitation (Farooq Aslam)
	Name, address of Applicant.	Highnoon Laboratories Ltd 17.5 KM, Multan Road, (000155)
	Application Form Dy. No / Tracking ID & date of submission	(PX9-HM6-SG1Z, 2025-11-11)
	Detail of Fee Submitted	38700, 2025-09-24,
	The proposed proprietary name / brand name	Finovia 10mg Tablet
	Label Claim	Each Film Coated Tablet contains: Finerenone.....10 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's-As per SRO, 1x7's-As per SRO, 2x10's-As per SRO, 2x7's-As per SRO, 3x10's-As per SRO
	Shelf Life (Unit)	2 Year(s) Do not Store above 30°C
	For generic drugs (me-too Status)	Fynone Tablet 10mg (129225)
	Pharmacotherapeutic Group of (API)	Diuretics, aldosterone antagonists (ATC Code: C03DA05)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Xier Kangtai pharmaceuticals Co., LTD
	Detail of stability batches of drug product	RDP0053-08 RDP0053-11 RDP0053-12 (Batch size: 3571)

	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 21-03-2024 for 1kg material is submitted,
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative Dissolution Profile and Pharmaceuticla equivalence studies for Finovia 10mg Tablet & Kerendia® 10 mg Tablets (reference product) by M/s Bayer AG Germany.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 24 months real time stability data according to zone IV-B.
	The status in reference regulatory authorities	EMA Kerendia 10 mg film-coated tablets
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 12-06-2025.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been processed under exports facilitation as per letter No.F.1-6/2019-PR-II (EFD)/Pt dated 03-03-2025. Test for R-enantiomer has been performed at drug substance level. The firm has stated that they will perform the testing at commercial manufacturing stage.	
	Decision	
	Approved	
166	Case Category	Export Facilitation (Farooq Aslam)
	Name, address of Applicant.	Highnoon Laboratories Ltd 17.5 KM, Multan Road, (000155)
	Application Form Dy. No / Tracking ID & date of submission	(YE9-VLD-M67E, 2025-11-11)
	Detail of Fee Submitted	38700, 2025-09-24,
	The proposed proprietary name / brand name	Finovia 20mg Tablet
	Label Claim	Each Film Coated Tablet contains: Finerenone.....20 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's-As per SRO,1x7's-As per SRO,2x10's-As per SRO,2x7's-As per SRO,3x10's-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not Store above 30°C
	For generic drugs (me-too Status)	Fynone Tablet 20mg Reg # 129226
	Pharmacotherapeutic Group of (API)	Diuretics, Aldosterone Antagonists ATC C03DA05
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Xier Kangtai pharmacueticals Co.,LTD
	Detail of stability batches of drug product	RDP0059-04 RDP0059-07 RDP0059-08 (Batch size: 3571)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 21-03-2024 for 1kg material is submitted,
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative Dissolution Profile and Pharmacetucial equivalence studies for Finovia 20mg Tablet & Kerendia® 20 mg Tablets (reference product) by M/s Bayer AG Germany.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 24 months real time stability data according to zone IV-B.
	The status in reference regulatory authorities	EMA Kerendia 20 mg film-coated tablets
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 12-06-2025.

	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been processed under exports facilitation as per letter No.F.1-6/2019-PR-II (EFD)/Pt dated 03-03-2025. Test for R-enantiomer has been performed at drug substance level. The firm has stated that they will perform the testing at commercial manufacturing stage.	
	Decision	
	Approved	
167	Case Category	New Section (Farooq Aslam)
	Name, address of Applicant.	Hamaz Pharmaceuticals (Pvt) Ltd. 13-KM Bosan Road, Lutfabad (000427)
	Application Form Dy. No / Tracking ID & date of submission	(RJH-TLS-JGWD, 2026-04-09)
	Detail of Fee Submitted	75000, 2026-01-28,
	The proposed proprietary name / brand name	Xanpo Capsule 125mg/30mg
	Label Claim	Each Capsule contains: Xanomeline tartrate IR pellets equivalent to Xanomeline.....125mg Trospium chloride IR pellets equivalent to Trospium Chloride.....30mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3 x 10's capsule-As per SRO
	Shelf Life (Unit)	2 Year(s)Store 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)	N/A
	Pharmacotherapeutic Group of (API)	Xanomeline Tartrate: Xanomeline is a muscarinic agonist used in conjunction with trospium, a muscarinic antagonist, to treat schizoph. Trospium cHLORIDE is an antimuscarinic agent used to treat the symptoms of overactive bladder (OAB).renia.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	SHANDONG RISEN-SUN PHARMACEUTICAL CO., LTD.,VIYASH LIFE SCIENCES PRIVATE LIMITED
	Detail of stability batches of drug product	XTH-001, XTH-002, XTH-003 Each of 1000 capsules 06 months real time and 06 moth accelerated according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Xanomeline Tartrate: Form 6 dated 24-03-2025 is submitted for 2.15kg material. Trospium chloride: Form 6 dated 24-03-2025 for 400 grams of material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Cobenfy Capsule 125mg/30mg (USFDA)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Xanomeline tartrate: 06 months accelerated and 18 months real time stability data of 03 batches according to zone IV-A. Trospium chloride: 06 months accelerated and 24 months real time stability data of 03 batches according to zone IV-A.
	The status in reference regulatory authorities	US FDA

	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 07-04-2025.
	Evidence of approval of manufacturing facility	Second Capsule General Section is approved as new section.
	Evaluation Remarks	
	The process of IR pellet manufacturing will be carried out in the same section using spheronizer. The case was deferred in 358th meeting for submission of Risk Management Plan (RMP).	
	The firm has submitted intimation letter for appointment of PV Officer vide R&I dated 16-04-2026 and RMP doc No. RMP/XPC/008. The submitted RMP is derived from Risk Assessment and Risk Mitigation Review by USFDA. Following are the details of contents of RMP:	
	Part I containing product's overview.	
	Part II, Safety Specification which is divided into following modules: Module S1: Epidemiology of the indication and target population (description is provided for the prevalence Schizophrenia globally and in Pakistan) Module SII: Non Clinical part of the safety specification Module SIII: Clinical trials exposure Module SIV: Population not studied in clinical trials Module SV: Post-authorization experience Module SVI: Additional requirement for safety specification in Pakistan Module SVII: Identified and potential risks Module SVIII: Summary of the safety concerns	
	Part III containing the details of Pharmacovigilance Plan (Including post-authorization safety studies).	
	Part IV: Plan for port authorization efficacy studies	
	Part V: Risk minimization measure (including evaluation of the effectiveness of risk minimization measures)	
	Part VI: Summary of risk management plan	
	Part VII: Annexes	
	Decision	
	Approved	
168	Case Category	New Section (Farooq Aslam)
	Name, address of Applicant.	Hamaz Pharmaceuticals (Pvt) Ltd. 13-KM Bosan Road, Lutfabad (000427)
	Application Form Dy. No / Tracking ID & date of submission	(XTS-LP7-T8J1, 2026-04-09)
	Detail of Fee Submitted	75000, 2026-01-28,
	The proposed proprietary name / brand name	Xanpo 100mg/20mg Capsule
	Label Claim	Each Capsule contains: Xanomeline tartrate IR pellets equivalent to Xanomeline.....100mg Trospium chloride IR pellets equivalent to Trospium Chloride.....20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3 x 10's capsule-As per SRO
	Shelf Life (Unit)	2 Year(s)Store 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)	N/A
	Pharmacotherapeutic Group of (API)	Xanomeline Tartrate: Xanomeline is a muscarinic agonist used in conjunction with trospium, a muscarinic antagonist, to treat schizophrenia. Trospium Chloride: Trospium Chloride is an antimuscarinic agent used to treat the symptoms of overactive bladder (OAB).
	Name, address of Manufacturing site:	Self Manufacturing

Name & address of API manufacturer	SHANDONG RISEN-SUN PHARMACEUTICAL CO., LTD.,VIYASH LIFE SCIENCES PRIVATE LIMITED
Detail of stability batches of drug product	XTM-001, XTM-002, XTM-003 each of 1200 Capsules 06 months real time and 06 moth accelerated according to zone IV-A.
Documents for the procurement of API with approval from DRAP (in case of Import)	Xanomeline Tartrate: Form 6 dated 24-03-2025 is submitted for 2.15kg material. Trospium chloride: Form 6 dated 24-03-2025 for 400 grams of material is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Cobenfy Capsule 100mg/20mg.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Xanomeline tartrate: 06 months accelerated and 18 months real time stability data of 03 batches according to zone IV-A. Trospium chloride: 06 months accelerated and 24 months real time stability data of 03 batches according to zone IV- A.
The status in reference regulatory authorities	US FDA
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 07-04-2025.
Evidence of approval of manufacturing facility	Second Capsule General Section is approved as new section.
Evaluation Remarks	
The process of IR pellet manufacturing will be carried out in the same section using spheronizer. The case was deferred in 358th meeting for submission of Risk Management Plan (RMP).	
The firm has submitted intimation letter for appointment of PV Officer vide R&I dated 16-04-2026 and RMP doc No. RMP/XPC/008. The submitted RMP is derived from Risk Assessment and Risk Mitigation Review by USFDA. Following are the details of contents of RMP:	
Part I containing product’s overview.	
Part II, Safety Specification which is divided into following modules: Module S1: Epidemiology of the indication and target population (description is provided for the prevalence Schizophrenia globally and in Pakistan) Module SII: Non Clinical part of the safety specification Module SIII: Clinical trials exposure Module SIV: Population not studied in clinical trials Module SV: Post- authorization experience Module SVI: Additional requirement for safety specification in Pakistan Module SVII: Identified and potential risks Module SVIII: Summary of the safety concerns	
Part III containing the details of Pharmacovigilance Plan (Including post-authorization safety studies).	
Part IV: Plan for port authorization efficacy studies	
Part V: Risk minimization measure (including evaluation of the effectiveness of risk minimization measures)	
Part VI: Summary of risk management plan	
Part VII: Annexes	
Decision	
Approved	
Case Category	New Section (Farooq Aslam)
Name, address of Applicant.	Hamaz Pharmaceuticals (Pvt) Ltd. 13-KM Bosan Road, Lutfabad (000427)
Application Form Dy. No / Tracking ID & date of submission	(37S-BHM-6U4A, 2026-04-09)
Detail of Fee Submitted	75000, 2026-01-28,

The proposed proprietary name / brand name	Xanpo 50mg/20mg Capsule
Label Claim	Each Capsule Contains: Xanomeline tartrate IR pellets equivalent to Xanomeline.....50mg Trospium chloride IR pellets equivalent to Trospium Chloride.....20mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	3 x 10's capsule-As per SRO
Shelf Life (Unit)	2 Year(s)Store 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)	N/A
Pharmacotherapeutic Group of (API)	Xanomeline Tartrate: Xanomeline is a muscarinic agonist used in conjunction with trospium, a muscarinic antagonist, to treat schizophrenia. Trospium Chloride is an antimuscarinic agent used to treat the symptoms of overactive bladder (OAB).
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	SHANDONG RISEN-SUN PHARMACEUTICAL CO., LTD.,VIYASH LIFE SCIENCES PRIVATE LIMITED
Detail of stability batches of drug product	XTL-001, XTL-002, XTL-003 each of 1200 Capsules 06 months real time and 06 moth accelerated according to zone IV-A.
Documents for the procurement of API with approval from DRAP (in case of Import)	Xanomeline Tartrate: Form 6 dated 24-03-2025 is submitted for 2.15kg material. Trospium chloride: Form 6 dated 24-03-2025 for 400 grams of material is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Cobenfy 50mg/20mg Capsules
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Xanomeline tartrate: 06 months accelerated and 18 months real time stability data of 03 batches according to zone IV-A. Trospium chloride: 06 months accelerated and 24 months real time stability data of 03 batches according to zone IV-A.
The status in reference regulatory authorities	US FDA
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 07-04-2025.
Evidence of approval of manufacturing facility	Second Capsule General Section is approved as new section.
Evaluation Remarks	
The process of IR pellet manufacturing will be carried out in the same section using spheronizer. The case was deferred in 358th meeting for submission of Risk Management Plan (RMP).	
The firm has submitted intimation letter for appointment of PV Officer vide R&I dated 16-04-2026 and RMP doc No. RMP/XPC/008. The submitted RMP is derived from Risk Assessment and Risk Mitigation Review by USFDA. Following are the details of contents of RMP:	
Part I containing product's overview.	
Part II, Safety Specification which is divided into following modules: Module S1: Epidemiology of the indication and target population (description is provided for the prevalence Schizophrenia globally and in Pakistan) Module SII: Non Clinical part of the safety specification Module SIII: Clinical trials exposure Module SIV: Population not studied in clinical trials Module SV: Post-	

	authorization experience Module SVI: Additional requirement for safety specification in Pakistan Module SVII: Identified and potential risks Module SVIII: Summary of the safety concerns Part III containing the details of Pharmacovigilance Plan (Including post-authorization safety studies). Part IV: Plan for port authorization efficacy studies Part V: Risk minimization measure (including evaluation of the effectiveness of risk minimization measures) Part VI: Summary of risk management plan Part VII: Annexes	
	Decision	
	Approved	
	170	Case Category
		Routine (Farooq Aslam)
		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
		(HN8-8YS-HYPJ, 2024-01-23)
		Detail of Fee Submitted
		30000.0, 2023-11-22,
		The proposed proprietary name / brand name
		Docsol 10mg/5ml Injection
		Label Claim
		Each ml contains:Doxorubicin HCl 2mg
		Reference to Finished product specifications
		United States Pharmacopeia
		Proposed Pack Size
		1 vial-As per SRO
		Shelf Life (Unit)
		2 Year(s)2°C - 8°C
		For generic drugs (me-too Status)
		Robol 10mg/5mL by Helix pharma
		Pharmacotherapeutic Group of (API)
		Anti-cancer
		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)
		Form 6 dated 03-10-2022 is submitted (50 grams). Goods declaration with igm dated 29-09-2022 is submitted.
		Pharmaceutical Equivalence and Comparative Dissolution Profile
		.
		Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)
		.
		The status in reference regulatory authorities
		MHRA approved
		GMP status of the firm
		Pharmasol: GMP certificate issued on the basis of inspection conducted on 22-08-2022
		Evidence of approval of manufacturing facility
		Liquid injection section (anti-cancer) human
	Evaluation Remarks	
	Observations	Response
	Tabulated results for PE studies have been submitted against reference listed drug product while pack of Robo injection is provided, please clarify and provide complete analytical record of P.E studies.	Formulation comparison against RLD is performed qualitatively and mentioned in the Table No. 5 (Page no. 7 of 14) whereas the quantitatively comparison is performed against the sample available in the Pakistan market i.e. Robol Injection 10mg/5ml and results are reported in Table No 6 (Page no. 8 of 14). Reference Documents attached: • 3.2.P.2

	Pharmaceutical Development. • The analytical data of PE studies
Finished product: Assay results of accelerated stability studies are well out of specifications at 3rd and 6 th month time points, please clarify since the shelf life of 2 years is granted on the basis of stability study data of 6 months (including real time and accelerated).	Doxorubicin HCl Injection is thermal sensitive and should be stored in a refrigerator (Doxorubicin Hydrochloride Injection, USP Monograph; Packaging and Storage). Docsol injection 10mg/5ml at accelerated conditions was placed to check impact of the accelerated conditions on the product. The product was tested after 1M, 2M, 3M and 6M timepoints. The purpose of the accelerated condition was to check the impact of storage condition on product and collect data for transportation. The results show that the product should be transferred on a controlled temperature during shipping. However, long-term stability was conducted at 2-8°C. The shelf life will be based on the longterm stability study. Long term stability studies at 2-8°C for 6 months have been submitted at the time of the dossier submission. The long term stability is ongoing for 24 months.
RSD values have not been calculated for assay values in linearity parameter of analytical method validation studies, please clarify	The linearity of an analytical procedure is its ability to elicit test results that are directly, or by a well-defined mathematical transformation, proportional to the concentration of analyte in samples within a given range. The correlation coefficient, y-intercept, slope of the regression line, and residual sum of squares should be submitted. (USP: VALIDATION OF COMPENDIAL PROCEDURES) In Docsol 10mg/5ml Injection analytical method validation studies; results are expressed as the coefficient of determination (r^2) i.e; is square of correlation between x and y variables. linear correlation, and the equation of the regression line
The case was deferred in 348th meeting held on 1-2nd July, 2025. Significant change was observed in accelerated stability studies as well as out of specs results were also observed at 6th month time point. The Board decided to defer the case for submission of stability studies on a single batch stored outside the storage condition of finished drug product for a period shorter than 03 months with more frequent testing. The storage conditions for drug product are 2-8oC for Rt and 25oC&60%RH are for accelerated stability studies.	
The firm has imported 10grams of material and submitted form 6 dated 22-10-2025, unattested invoice No. DZD-PAP-251013, copy of GD No. LPAF-7041-30102025 Date: 30-10-2025, Fedex receipt.	
The firm has manufactured another Batch No. E133 with a batch size of 750mL on 14-11-2025 and has submitted stability studies at 2-8oC for RT and 25oC&60%RH for accelerated with a frequency of 0, 1week, 2 week, 3week, 4 week, 1.5month, 2 month and 2.5 month time point.	
At accelerated condition, significant change has been observed again as well as assay value at 2.5month time point is 89.90% and the specs are 90-115%.	
At real time stability condition, the results are well within the limits. The assay at 2.5month time point is 98.70%.	
Submitted for consideration by the Board.	
Decision	
Rejected	

171	The Board observed that:	
	1. The submitted stability data of the applied formulation did not adequately demonstrate the stability of the applied formulation under the accelerated stability conditions compromising the potency, safety and quality throughout the claimed shelf life of the applied product. 2. The instability of the formulation raises the concerns regarding the therapeutic consistency and patient safety. 3. The critical nature of anticancer medicines where reliable efficacy and safety are paramount, the absence of robust stability evidence is unacceptable. The Board taking into account the intended use of the applied formulation in the treatment of life-threatening conditions in cancer patients, decided to reject the case.	
171	Case Category	Routine (Farooq Aslam)
	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	(Z4H-SJP-LVJ8, 2024-01-23)
	Detail of Fee Submitted	30000.0, 2023-11-22,
	The proposed proprietary name / brand name	Docsol 50mg/25ml Injection
	Label Claim	Each ml contains:Doxorubicin HCl.....2mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 vial-As per SRO
	Shelf Life (Unit)	2 Year(s)2°C-8°C
	For generic drugs (me-too Status)	Robol injection 50mg/25mL by Helix pharma
	Pharmacotherapeutic Group of (API)	Anti-cancer
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	DZD (Heze) Pharmaceutical Co., Ltd.,
	Detail of stability batches of drug product	.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 03-10-2022 is submitted (50 grams). Goods declaration with igm dated 29-09-2022 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	.
	The status in reference regulatory authorities	MHRA approved
	GMP status of the firm	Pharmasol: GMP certificate issued on the basis of inspection conducted on 22-08-2022
	Evidence of approval of manufacturing facility	Liquid injection section (anti-cancer) human
	Evaluation Remarks	
	Observations	Response
	Stability data of 02 batches is submitted. Provide data of third batch of finished product.	Submitted.
	Finished product: Assay results of accelerated stability studies are well out of specifications at 6th month time points, please clarify since the shelf life of 2 years is granted on the basis of stability study data of 6 months (including real time and accelerated).	Doxorubicin HCl Injection is thermal sensitive and should be stored in a refrigerator (Doxorubicin Hydrochloride Injection, USP Monograph; Packaging and Storage). Docsol injection 50mg/25ml at accelerated conditions was placed to check impact of the accelerated

	conditions on the product. The product was tested after 1M, 2M, 3M and 6M timepoints. The purpose of the accelerated condition was to check the impact of storage condition on product and collect data for transportation. The results show that the product should be transferred on a controlled temperature during shipping. However, long-term stability was conducted at 2-8°C. The shelf life will be based on the long-term stability study. Long term stability studies at 2-8°C for 6 months have been submitted at the time of the dossier submission. The long term stability is ongoing for 24 months.
RSD values have not been calculated for assay values in linearity parameter of analytical method validation studies, please clarify.	The linearity of an analytical procedure is its ability to elicit test results that are directly, or by a welldefined mathematical transformation, proportional to the concentration of analyte in samples within a given range. The correlation coefficient, y-intercept, slope of the regression line, and residual sum of squares should be submitted. (USP: <1225>VALIDATION OF COMPENDIAL PROCEDURES) In Docsol 50mg/25ml Injection analytical method validation studies; results are expressed as the coefficient of determination (r^2) i.e; is square of correlation between x and y variables. linear correlation, and the equation of the regression line
Tabulated results for PE studies have been submitted against reference listed drug product while pack of Robo injection is provided, please clarify and provide complete analytical record of P.E studies.	Formulation comparison against RLD is performed qualitatively and mentioned in the Table No. 5 (Page no. 7 of 14) whereas the quantitatively comparison is performed against the sample available in the Pakistan market i.e. Robol Injection 50mg/25ml and results are reported in Table No 6 (Page no. 8 of 14). Reference Documents attached: ☐ 3.2.P.2 Pharmaceutical Development. ☐ The analytical data of PE studies
The case was deferred in 348th meeting held on 1-2nd July, 2025. Significant change was observed in accelerated stability studies as well as out of specs results were also observed at 6th month time point. The Board decided to defer the case for submission of stability studies on a single batch stored outside the storage condition of finished drug product for a period shorter than 03 months with more frequent testing. The storage conditions for drug product are 2-8oC for Rt and 25oC&60%RH are for accelerated stability studies.	
The firm has imported 10grams of material and submitted form 6 dated 22-10-2025, unattested invoice No. DZD-PAP-251013, copy of GD No. LPAF-7041-30102025 Date: 30-10-2025, Fedex receipt.	
The firm has manufactured another Batch No. E134 with a batch size of 2L on 14-11-2025 and has submitted stability studies at 2-8oC for RT and 25oC&60%RH for accelerated with a frequency of 0, 1 week, 2 week, 3week, 4 week, 1.5month, 2 month and 2.5 month time point.	
At accelerated condition, significant change has been observed again at 2.5month time point and the assay value is 91.30% and the specs are 90-115%	
At real time stability condition, the results are well within the limits. The assay at 2.5month time point is 99.20%.	
Submitted for consideration by the Board.	
Decision	

Rejected

The Board observed that:

1. The submitted stability data of the applied formulation did not adequately demonstrate the stability of the applied formulation under the accelerated stability conditions compromising the potency, safety and quality throughout the claimed shelf life of the applied product.
2. The instability of the formulation raises the concerns regarding the therapeutic consistency and patient safety.
3. The critical nature of anticancer medicines where reliable efficacy and safety are paramount, the absence of robust stability evidence is unacceptable.

The Board taking into account the intended use of the applied formulation in the treatment of life-threatening conditions in cancer patients, decided to reject the case.

172	Case Category	Export Facilitation (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	(E6J-GMP-MVAW, 2026-01-08)
	Detail of Fee Submitted	75000, 2025-12-09,
	The proposed proprietary name / brand name	Dopti Tablet 20mg
	Label Claim	Each film-coated tablet contains: Avatrombopag as maleate.....20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Avatrombopag 20 mg Tablet are packed in Alu/Alu blister which is further De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in a cool dry place stored at room temperature below 30°C
	For generic drugs (me-too Status)	New molecule
	Pharmacotherapeutic Group of (API)	Thrombopoietin
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	GANSU HAOTIAN PHARMACEUTICAL CO., LTD
	Detail of stability batches of drug product	Stability data conducted on 3 batches(233 DS01, 233 DS02, 233 DS03) (3 Month Accelerated 40C + 2C and 75% RH + 5% and 3 Month Long Term 30C + 2C and 75% RH + 5%)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 14-05-2025 for 0.6grams of material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP have been conducted against Doptelet Tablet manufactured by Kawashima Plant, Eisai Co., Japan
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Long Term:24 Months, Accelerated_6 Months. according to zone IV-A. HT200221006AVA, HT200221012AVA, HT200221020AVA
	The status in reference regulatory authorities	USFDA Approved detailed provided in Module 1 Section 1.5.9
	GMP status of the firm	The certificate is valid till 14/10/2028
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
Evaluation Remarks		

The application has been processed on priority under exports facilitation as per letter No.F.1-6/2019-PR-II (EFD)/Pt dated 03-03-2025. As per submitted copy of GD, Form 6, invoice the material imported in 600grams whereas 0.6grams quantity is mentioned on invoice, however 600grams is mentioned with the name of APi of clearance certificate.

Various shortcomings were communicated to the firm including provision of RMP plan and related documents. The firm has provided EMA reference for RMP and the same RMP has been adopted by the firm.

The firm has submitted intimation email sent to PV centre (pv@dra.gov.pk) as an evidence for appointment of PV Officer dated May 25th, 2026.

Part I containing product's overview.

Part II, Safety Specification which is divided into following modules: Module S1: Epidemiology of the indication and target population (description is provided for the prevalence Schizophrenia globally and in Pakistan) Module SII: Non Clinical part of the safety specification Module SIII: Clinical trials exposure Module SIV: Population not studied in clinical trials Module SV: Post-authorization experience Module SVI: Additional requirement for safety specification in Pakistan Module SVII: Identified and potential risks Module SVIII: Summary of the safety concerns

Part III containing the details of Pharmacovigilance Plan (Including post-authorization safety studies).

Part IV: Plan for port authorization efficacy studies

Part V: Risk minimization measure (including evaluation of the effectiveness of risk minimization measures)

Part VI: Summary of risk management plan

Part VII: Annexes

Decision

Approved

173	Case Category	Export Facilitation (Farooq Aslam)
	Name, address of Applicant.	Searle Pakistan Limited C-14, Manghopir Road, SITE, Karachi (000012)
	Application Form Dy. No / Tracking ID & date of submission	(A99-VVT-3BLX, 2026-01-13)
	Detail of Fee Submitted	300000.0, 2025-01-16,
	The proposed proprietary name / brand name	Orlisafe 120mg Capsules
	Label Claim	Each capsule contains: Orlistat as 50% W/W IR pellets.....120 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per DPC-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 degree C.
	For generic drugs (me-too Status)	Abnil Capsules 120mg by AGP Pharma
	Pharmacotherapeutic Group of (API)	Peripherally acting anti-obesity products/Lipase Inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Murli Krishna Pharma Pvt. Ltd
	Detail of stability batches of drug product	03 batches : 2500 capsule each 12 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 20-01-2023 for 3kg material is submitted. Copy of GD No. KPAF-779-2023 Date: 27-01-2023
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the innovator's product i.e. Xenical Capsule marketed by M/s MartinDow Limited.

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	36 months real time stability data of 03 batches according to zone IV-B. Accelerated stability data of pellets has not been submitted due to low melting point of Orlistat.
	The status in reference regulatory authorities	Orlistat 120mg Capsules by Crescent Pharma Limited, UK) (MHRA Approved)
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 06-03-2024.
	Evidence of approval of manufacturing facility	Capsule General Section is approved.
	Evaluation Remarks	
	The application is marked under export facilitation vide letter dated 12 August 2025.	
	Decision	
	Approved	
174	Case Category	Export Facilitation (Farooq Aslam)
	Name, address of Applicant.	Atco Laboratories Limited B-18 SITE KARACHI (000188)
	Application Form Dy. No / Tracking ID & date of submission	(4MA-D8Y-367P, 2025-03-06)
	Detail of Fee Submitted	37000.0, 2025-01-14,
	The proposed proprietary name / brand name	RENOFIN TABLET
	Label Claim	Each film coated tablet contains: Finerenone.....20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,28's-De-Controlled,30's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Don't store & transport above 30degree centigrade
	For generic drugs (me-too Status)	FIRIALTA Tablet byBayer Pakistan (Pvt.) Ltd. (formerly Medipharma (Pvt) Ltd).
	Pharmacotherapeutic Group of (API)	Diuretics, aldosterone antagonists (ATC Code: C03DA05)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Henan Jin Huaitang Biological Engineering Co.,Ltd
	Detail of stability batches of drug product	03 batches : 1500 batches 06 months accelerated and 06 months real time stability data is submitted according to zone IV-B.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 for 2kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been submitted against the reference product i.e. Kerendia by M/s Bayer AG Germany.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 24 months real time stability data according to zone IV-A.
	The status in reference regulatory authorities	KERENDIA 20mg Tablets by Bayer HealthCare Pharmaceuticals Inc. Whippany, NJ 07981 Manufactured in Germany.
	GMP status of the firm	Submitted.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	

	The application is processed under exports facilitation as per letter No.F.1-6/2019-PR-II (EFD)/Pt dated 03-03-2025. The test for R-enantiomer has not been performed by drug product manufacturer.	
	Decision	
	Approved	
175	Case Category	Export Facilitation (Farooq Aslam)
	Name, address of Applicant.	Atco Laboratories Limited B-18 SITE KARACHI (000188)
	Application Form Dy. No / Tracking ID & date of submission	(AN8-HB9-TPX1, 2025-05-06)
	Detail of Fee Submitted	37000.0, 2025-01-14,
	The proposed proprietary name / brand name	RENOFIN TABLET
	Label Claim	Each film coated tablet contains: Finerenone.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,28's-De-Controlled,30's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Don't store & transport above 30degree centigrade
	For generic drugs (me-too Status)	FIRIALTA Tablet byBayer Pakistan (Pvt.) Ltd. (formerly Medipharm (Pvt) Ltd).
	Pharmacotherapeutic Group of (API)	Diuretics, aldosterone antagonists (ATC Code: C03DA05)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Henan Jin Huaitang Biological Engineering Co.,Ltd
	Detail of stability batches of drug product	03 batches : 1500 batches 06 months accelerated and 06 months real time stability data is submitted according to zone IV-B.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 for 2kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been submitted against the reference product i.e. Kerendia by M/s Bayer AG Germany.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 24 months real time stability data according to zone IV-A.
	The status in reference regulatory authorities	KERENDIA 10mg Tablets by Bayer HealthCare Pharmaceuticals Inc. Whippany, NJ 07981 Manufactured in Germany.
	GMP status of the firm	Submitted.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application is processed under exports facilitation as per letter No.F.1-6/2019-PR-II (EFD)/Pt dated 03-03-2025. The test for R-enantiomer has not been performed by drug product manufacturer. Covering and conclusion of real time stability of drug substance mentions the storage conditions of zone II whereas the conditions mentioned in summary sheets are as per zone IV-A, the firm was asked to submit clarification.	
	Covering and conclusion of real time stability of drug substance mentions the storage conditions of zone II whereas the conditions mentioned in summary sheets are as per zone IV-A, the firm was asked to submit clarification.	

Reply: We are hereby submitting updated Drug Substance Stability Documents with harmonized storage conditions (Zone-IVa at 30°C ±2°C & 65%±5% RH) mentioned in both covering/conclusion section and in the stability summary sheets.		
Decision		
Approved		
176	Case Category	Any Other (Farooq Aslam)
	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	(UJA-LD3-D36L, 2026-04-14)
	Detail of Fee Submitted	38700, 2025-11-11,
	The proposed proprietary name / brand name	Amdala 5mg Tablet
	Label Claim	Each Film Coated Tablet contains: Tadalafil....5mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's-De-Controlled, 1x4's-De-Controlled
	Shelf Life (Unit)	24 Year(s)Below 25°C
	For generic drugs (me-too Status)	Tadalafil 5mg Tablets, Reg.No. 131450, Scotmann Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Phosphodiesterase inhibitor
	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	Stability studies of 3 trial batches TT-002, TT-003 and TT-003 is provided (batch size: 5000 tablets)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 29-04-2025 for 5kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CPD in-comparison with comparator product i.e. Fildil Tablet by M/s Highnoon.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies of 3 batches TD/21/028, TD/21/029 and TD/21/030 is provided (06 months acc and 24 months RT according to zone IV-B).
	The status in reference regulatory authorities	US-FDA approval status of CIALIS (tadalafil) tablets, manufactured by Lilly USA, LLC , Indianapolis, IN 46285, USA is provided
	GMP status of the firm	Valid GMP certificate No. F.3-4/2018-Addl. Dir. (QA<-FO)-84 Validity: 26-09-2027 is provided
	Evidence of approval of manufacturing facility	Tablet General Section is approved
Evaluation Remarks		
The application has been processed on priority as per decision of DRAP Authority regarding ED drugs.		
Decision		
Approved		
177	Case Category	Any Other (Farooq Aslam)
	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	(WEA-DD1-NS4G, 2026-04-14)
	Detail of Fee Submitted	38700, 2025-10-02,
	The proposed proprietary name / brand name	Amdala 20mg Tablet
	Label Claim	Each Film Coated Tablet contains: Tadalafil....20mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's-As per SRO, 1x4's-As per SRO
	Shelf Life (Unit)	24 Year(s)Below 25°C
	For generic drugs (me-too Status)	Tafil Tablet 20mg, Reg. No. 130679, Getz Pharma Pvt. Ltd
	Pharmacotherapeutic Group of (API)	Phosphodiesterase inhibitor
	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	Stability studies of 3 trail batches TT-007, TT-008 and TT-009 is provided (batch size: 5000 tablets)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 29-04-2025 for 5kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CPD in-comparison with comparator product i.e. Fildil Tablet by M/s Highnoon.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies of 3 batches TD/21/028, TD/21/029 and TD/21/030 is provided (06 months acc and 24 months RT according to zone IV-B).
	The status in reference regulatory authorities	US-FDA approval status of CIALIS (tadalafil) tablets, manufactured by Lilly USA, LLC , Indianapolis, IN 46285, USA is provided
	GMP status of the firm	Valid GMP certificate No. F.3-4/2018-Addl. Dir. (QA<-FO)-84 Validity: 26-09-2027 is provided
	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.	
178	Decision	
	Approved	
	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	May and Baker (Pvt.) Ltd 23-Ghourri Block, Bahria Town, Lahore (000953)
	Application Form Dy. No / Tracking ID & date of submission	(NA8-N5Q-1E2E, 2025-11-07)
	Detail of Fee Submitted	37000.0, 2024-09-19,
	The proposed proprietary name / brand name	Oramep 40mg capsule
	Label Claim	Each capsule Contains: Omeprazole as enteric coated pellets 40mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	7, 14, 28, 50, 100-As per SRO

Shelf Life (Unit)	2 Year(s)below 24 degree
For generic drugs (me-too Status)	Available
Pharmacotherapeutic Group of (API)	PPI
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Vision Pharmaceuticals (Pvt.) Ltd Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad-Pakistan
Detail of stability batches of drug product	
Documents for the procurement of API with approval from DRAP (in case of Import)	Invoice No. 232402300 dated 23-02-2024 for 1kg material from M/s Vision Pharma is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Risek cap y M/s Getz Pharma.
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-A.
The status in reference regulatory authorities	USFDA Approved
GMP status of the firm	New License
Evidence of approval of manufacturing facility	Capsule General Section is approved.
Evaluation Remarks	
Analytical record for Pe and AMV studies for drug product has not been submitted.	
05 chromatograms for CDP studies have been submitted.	
The firm does not have the audit trail report/system log. the firm has stated that their HPLC system in manual therefore, the audit trail report is not available.	
Decision	
Rejected	
The Board rejected the case since the firm could not provide audit trail report/system log, chromatograms for CDP, PE and AMV studies for drug product.	
179	Case Category
	Any Other (Farooq Aslam)
	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
	(N9N-AJJ-2RLP, 2026-01-08)
	Detail of Fee Submitted
	38700, 2025-12-02,
	The proposed proprietary name / brand name
	TENIGRA 10 MG TABLET
	Label Claim
	Each Film Coated Tablet Contains: Tadalafil 2.5 mg
	Reference to Finished product specifications
	United States Pharmacopeia
	Proposed Pack Size
	1 ×10'S-As per SRO,1 ×4'S-As per SRO,2 ×10'S-As per SRO,2 ×4'S-As per SRO,2×7'S-As per SRO,3 ×10'S-As per SRO,4 ×7'S-As per SRO
	Shelf Life (Unit)
	2 Year(s) Store below 30°C in a dry place, protect from light.
	For generic drugs (me-too Status)
	Fildil (Highnoon laboratories ltd)
	Pharmacotherapeutic Group of (API)
	(PDE5 INHIBITORS)
	Name, address of Manufacturing site:
	Self Manufacturing
	Name & address of API manufacturer
	Rakshit pharmaceutical limited

	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)	Form 6 dated 10-03-2025 for 0.21kg material is submitted along with airway bill No. 960-00362891.
	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 studies of 03 batches according to zone IV-B is submitted.
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 13-11-2024.
	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	
180	Case Category	Any Other (Farooq Aslam)
	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	(SN9-H7P-Y145, 2026-02-03)
	Detail of Fee Submitted	38700, 2025-12-02,
	The proposed proprietary name / brand name	TENIGRA 10 MG TABLET
	Label Claim	Each Film Coated Tablet Contains ; Tadalafil 10 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 × 10's-As per SRO,1 × 4's-As per SRO,2 × 10's-As per SRO,2 × 4's-As per SRO,2 × 7's -As per SRO,3 × 10's-As per SRO,4 × 7's -As per SRO
	Shelf Life (Unit)	2 Year(s) Store below 30°C in a dry place, protect from light.
	For generic drugs (me-too Status)	Fildil (Highnoon laboratories ltd)
	Pharmacotherapeutic Group of (API)	(PDE5 INHIBITORS)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rakshit pharmaceutical limited
	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)	Form 6 dated 10-03-2025 for 0.21kg material is submitted along with airway bill No. 960-00362891.
	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 studies of 03 batches according to zone IV-B is submitted.
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	Valid (attached)
	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	
181	Approved	
	Case Category	Any Other (Farooq Aslam)
	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	(P51-GTE-3HWG, 2026-01-08)
	Detail of Fee Submitted	38700, 2025-12-02,
	The proposed proprietary name / brand name	TENIGRA 20 MG TABLET
	Label Claim	Each Film Coated Tablet Contains ; Tadalafil 20 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 × 10's-As per SRO,1 × 4's-As per SRO,2 × 10's-As per SRO,2 × 4's-As per SRO,2 × 7's -As per SRO,3 × 10's-As per SRO,4 × 7's -As per SRO
	Shelf Life (Unit)	2 Year(s) Store below 30°C in a dry place, protect from light.
	For generic drugs (me-too Status)	Fildil (Highnoon laboratories ltd)
	Pharmacotherapeutic Group of (API)	(PDE5 INHIBITORS)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rakshit pharmaceutical limited
	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)	Form 6 dated 10-03-2025 for 0.21kg material is submitted along with airway bill No. 960-00362891.
	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 studies of 03 batches according to zone IV-B is submitted.
	The status in reference regulatory authorities	MHRA
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 13-11-2024.
	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	
182	Case Category	Any Other (Farooq Aslam)
	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	(YUT-G3J-WQDZ, 2026-01-08)

	Detail of Fee Submitted	38700, 2025-12-02,
	The proposed proprietary name / brand name	TENIGRA 5 MG TABLET
	Label Claim	Each film Coated Tablet Contains; Tadalafil 5 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 × 10's-As per SRO, 1 × 4's-As per SRO, 2 × 10's-As per SRO, 2 × 4's-As per SRO, 2 × 7's -As per SRO, 3 × 10's-As per SRO, 4 × 7's -As per SRO
	Shelf Life (Unit)	2 Year(s) Store below 30°C in a dry place, protect from light.
	For generic drugs (me-too Status)	Fildil (Highnoon laboratories ltd)
	Pharmacotherapeutic Group of (API)	(PDE5 INHIBITORS)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rakshit pharmaceutical limited
	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)	Form 6 dated 10-03-2025 for 0.21kg material is submitted along with airway bill No. 960-00362891.
	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 studies of 03 batches according to zone IV-B is submitted.
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 13-11-2024.
	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	
183	Case Category	Routine (Hafiz M. Ali Tayyab)
	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	(8HA-N8D-S5SR, 2024-10-22)
	Detail of Fee Submitted	75000.0, 2024-09-18,
	The proposed proprietary name / brand name	Rinvok Oral Solution
	Label Claim	Each ml contains: Upadacitinib Hemihydrate Eq. to Upadacitinib.....1mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	60ml, 100ml. 120ml/A-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C, protect from light and heat
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Jiangxi LongLife Bio-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	RINVOQ LQ ORAL SOLUTION;AbbVie Inc., North Chicago, IL 60064, USA, FDA Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has informed that they have Waters HPLC system with Empower 2 software. The system is currently not 21CFR compliance. The firm has informed that they have Waters HPLC system with Empower 2 software. The system is currently not 21CFR compliance. The case was initially deferred for submission on audit trail report/system log. The applied product was considered in 358th meeting. The firm was asked to submit audit trail report for submitted stability studies for drug product. In reply the firm had stated that: "The firm has Waters HPLC system with Empower 2 software this system is currently not 21CFR compliance. As regards the use of a CFR-compliant system, it is submitted that at the time of testing of the submitted product, the batch under evaluation was a trial / development batch. Due to over-occupancy of the available 21 CFR-compliant HPLC systems, the stability testing of this trial batch was performed on a GxP-compliant HPLC system. However, we assure that upon registration of the product and initiation of commercial-scale manufacturing, all testing including routine QC and stability studies will be performed exclusively on 21 CFR Part 11-compliant HPLC systems to ensure enhanced data integrity, audit-trail compliance, and secure electronic data management." The Board rejected the cases on the basis of unavailability of audit trail report/system log. The firm submit the required data after the meeting vide application ID No. N8M-PUW-7GRD dated May 14th, 2026, 6:39 pm as well as the required data is submitted through instant application. Submitted for consideration by the Board.	
	Decision	
	Approved	
184	Case Category	Routine (Hafiz M. Ali Tayyab)
	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	(AB6-5Y6-248N, 2024-08-27)
	Detail of Fee Submitted	75000.0, 2024-07-11,
	The proposed proprietary name / brand name	Rinvok 30mg Tablet
	Label Claim	Each film coated prolonged release tablet contains: Upadacitinib Hemihydrate eq. to Upadacitinib.....30mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 30's, 100's, A-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30C, protect from light and heat
	For generic drugs (me-too Status)	Unijak of Ms Kaizen Pharma
	Pharmacotherapeutic Group of (API)	JAK inhibitor

	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Jiangxi LongLife Bio-Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	3 batches of 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	NOt submitted, the commercial invoice already submitted does not state the name of manufacturer/
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP data submitted against Rinvoq 30mg tablets
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted from Chiral quest (DMF holder)
	The status in reference regulatory authorities	RINVOQ 30 mg prolonged-release tablets; AbbVie Ltd, UK
	GMP status of the firm	GMP certificate based on inspection conducted on 14-12-2023
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	The firm has informed that they have Waters HPLC system with Empower 2 software. The system is currently not 21CFR compliance. The firm has informed that they have Waters HPLC system with Empower 2 software. The system is currently not 21CFR compliance. The firm has informed that they have Waters HPLC system with Empower 2 software. The system is currently not 21CFR compliance. The case was initially deferred for submission on audit trail report/system log. The applied product was considered in 358th meeting. The firm was asked to submit audit trail report for submitted stability studies for drug product. In reply the firm had stated that: “The firm has Waters HPLC system with Empower 2 software this system is currently not 21CFR compliance. As regards the use of a CFR-compliant system, it is submitted that at the time of testing of the submitted product, the batch under evaluation was a trial / development batch. Due to over-occupancy of the available 21 CFR-compliant HPLC systems, the stability testing of this trial batch was performed on a GxP-compliant HPLC system. However, we assure that upon registration of the product and initiation of commercial-scale manufacturing, all testing including routine QC and stability studies will be performed exclusively on 21 CFR Part 11–compliant HPLC systems to ensure enhanced data integrity, audit-trail compliance, and secure electronic data management.” The Board rejected the cases on the basis of unavailability of audit trail report/system log. The firm submit the required data after the meeting vide application ID No. N8M-PUW-7GRD dated May 14th, 2026, 6:39 pm as well as the required data is submitted through instant application. Submitted for consideration by the Board.	
	Decision	
	Approved	
185	Case Category	Routine (Hafiz M. Ali Tayyab)
	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	(WPW-B8A-363E, 2024-08-12)
	Detail of Fee Submitted	75000.0, 2024-07-11,
	The proposed proprietary name / brand name	Rinvok 7.5mg Tablet
	Label Claim	Each film coated prolonged release tablet contains: Upadacitinib Hemihydrate eq. to Upadacitinib..... 7.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 30's, 100's, A-As per SRO

	Shelf Life (Unit)	2 Year(s)Store below 30C, protect from light and heat
	For generic drugs (me-too Status)	Unijak of Ms Kaizen Pharma
	Pharmacotherapeutic Group of (API)	JAK inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Jiangxi LongLife Bio-Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	3 batches of 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Not submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP submitted against Rinvoq 7.5mg tablets
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	submitted
	The status in reference regulatory authorities	RINVOQ 7.5 mg tablets, AbbVie Ltd, JAPAN, PMDA Approved
	GMP status of the firm	GMP certificate submitted based on evaluation conducted on 14-12-2023
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	The firm has informed that they have Waters HPLC system with Empower 2 software. The system is currently not 21CFR compliance. The firm has informed that they have Waters HPLC system with Empower 2 software. The system is currently not 21CFR compliance. The firm has informed that they have Waters HPLC system with Empower 2 software. The system is currently not 21CFR compliance. The case was initially deferred for submission on audit trail report/system log. The applied product was considered in 358th meeting. The firm was asked to submit audit trail report for submitted stability studies for drug product. In reply the firm had stated that: "The firm has Waters HPLC system with Empower 2 software this system is currently not 21CFR compliance. As regards the use of a CFR-compliant system, it is submitted that at the time of testing of the submitted product, the batch under evaluation was a trial / development batch. Due to over-occupancy of the available 21 CFR-compliant HPLC systems, the stability testing of this trial batch was performed on a GxP-compliant HPLC system. However, we assure that upon registration of the product and initiation of commercial-scale manufacturing, all testing including routine QC and stability studies will be performed exclusively on 21 CFR Part 11-compliant HPLC systems to ensure enhanced data integrity, audit-trail compliance, and secure electronic data management." The Board rejected the cases on the basis of unavailability of audit trail report/system log. The firm submit the required data after the meeting vide application ID No. N8M-PUW-7GRD dated May 14th, 2026, 6:39 pm as well as the required data is submitted through instant application. Submitted for consideration by the Board.	
	Decision	
	Approved	
186	Case Category	Routine (Hafiz M. Ali Tayyab)
	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	(3UL-Y8N-G7JN, 2024-08-29)
	Detail of Fee Submitted	75000.0, 2024-07-11,
	The proposed proprietary name / brand name	Rinvok 45mg Tablet
	Label Claim	Each film coated prolonged release tablet contains: Upadacitinib Hemihydrate eq. to

		Upadacitinib 45mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 30's, 100's, A-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30C, protect from light and heat
	For generic drugs (me-too Status)	Unijak of Ms Kaizen Pharma
	Pharmacotherapeutic Group of (API)	JAK inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Jiangxi LongLife Bio-Pharmaceutical Co., Ltd.
	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)	Form-3 submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP data submitted against Rinvoq 45mg tablets (Batch No: M269K9)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per zone IV-A conditions
	The status in reference regulatory authorities	AbbVie Ltd, AbbVie House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire, SL6 4UB, UK, EMA Approved
	GMP status of the firm	GMP certificate based on evaluation conducted on 14-12-2023
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	The firm has informed that they have Waters HPLC system with Empower 2 software. The system is currently not 21CFR compliance. The firm has informed that they have Waters HPLC system with Empower 2 software. The system is currently not 21CFR compliance. The firm has informed that they have Waters HPLC system with Empower 2 software. The system is currently not 21CFR compliance. The case was initially deferred for submission on audit trail report/system log. The applied product was considered in 358th meeting. The firm was asked to submit audit trail report for submitted stability studies for drug product. In reply the firm had stated that: "The firm has Waters HPLC system with Empower 2 software this system is currently not 21CFR compliance. As regards the use of a CFR-compliant system, it is submitted that at the time of testing of the submitted product, the batch under evaluation was a trial / development batch. Due to over-occupancy of the available 21 CFR-compliant HPLC systems, the stability testing of this trial batch was performed on a GxP-compliant HPLC system. However, we assure that upon registration of the product and initiation of commercial-scale manufacturing, all testing including routine QC and stability studies will be performed exclusively on 21 CFR Part 11-compliant HPLC systems to ensure enhanced data integrity, audit-trail compliance, and secure electronic data management." The Board rejected the cases on the basis of unavailability of audit trail report/system log. The firm submit the required data after the meeting vide application ID No. N8M-PUW-7GRD dated May 14th, 2026, 6:39 pm as well as the required data is submitted through instant application. Submitted for consideration by the Board.	
	Decision	
	Approved	
187	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	Dr. Raza Pharma 44-C Hayatabad Industrial Estate Peshawar (000387)
	Application Form Dy. No / Tracking ID & date of submission	(ZQR-GSR-QAPR, 2024-11-12)
	Detail of Fee Submitted	37000.0, 2024-09-13,

	The proposed proprietary name / brand name	Glubirol
	Label Claim	Each Tablet Contains: Paracetamol.....450mg Orphenadrine Citrate.....35mg (Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C.
	For generic drugs (me-too Status)	Nuberol Tablet (Searle Pakistan Ltd)
	Pharmacotherapeutic Group of (API)	Analgesic/Antiallergic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CITI Pharma Pvt Ltd,Harika Drugs Private Limited
	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	iNOVA Pharmaceuticals (Australia TGA Approved)
	GMP status of the firm	-
	Evidence of approval of manufacturing facility	-
	Evaluation Remarks	
	Instant application was evaluated and shortcomings were conveyed to the firm in response to which firm has submitted that "Due to ongoing higher prices of API, and market fluctuations, we want to withdraw our product".	
	Decision	
	Rejected	
	Rejected As Withdrawn.	
188	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	Dr. Raza Pharma 44-C Hayatabad Industrial Estate Peshawar (000387)
	Application Form Dy. No / Tracking ID & date of submission	(NRH-JMY-PNQX, 2024-11-13)
	Detail of Fee Submitted	37000.0, 2024-10-07,
	The proposed proprietary name / brand name	TEMFLEX
	Label Claim	Each Film Coated Tablet Contains: Tramadol HCL.....37.5mg Paracetamol.....325mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10 tablets-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C.
	For generic drugs (me-too Status)	Pantra Plus by Getz Pharma
	Pharmacotherapeutic Group of (API)	Analgesic/Antiallergic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CITI Pharma Pvt Ltd,Lucent drugs Pvt Ltd Factory: Sy No 10, Gaddapotharam

		Village, Jinnaram Mandal Sangarddy District, Telangana State,
	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
	GMP status of the firm	-
	Evidence of approval of manufacturing facility	-
	Evaluation Remarks	
	The instant application was evaluated and shortcomings were conveyed to the firm in response to which firm has submitted that "Due to ongoing higher prices of API, and market fluctuations, we want to withdraw our product".	
	Decision	
	Rejected	
	Rejected as withdrawn.	
189	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	Cell Health Sciences, Plot No 217, Industrial Triangle, Kahuta Road, Islamabad (000711)
	Application Form Dy. No / Tracking ID & date of submission	(ZAP-JET-PEE3, 2024-06-03)
	Detail of Fee Submitted	75000.0, 2024-05-29,
	The proposed proprietary name / brand name	Trela 50mg Tablet
	Label Claim	Each Film Coated tablet contains Trelagliptin Succinate Equivalent to Trelagliptin 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x4's, 1 X 10's, 2x7-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a cool & Dry place below 30
	For generic drugs (me-too Status)	Trelaget 50mg Tablet of M/s Getz Pharma
	Pharmacotherapeutic Group of (API)	Antidiabetic Agent
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	Name & address of API manufacturer	Anhui Haikang Pharmaceutical Co., Ltd. Add: No. 21 Huancheng West Road Anqing Anhui 246000 China
	Detail of stability batches of drug product	Data Already Approved as Informed by firm
	Documents for the procurement of API with approval from DRAP (in case of Import)	Data Already Approved as Informed by firm
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Data Already Approved as Informed by firm
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data Already Approved as Informed by firm
	The status in reference regulatory authorities	Zafatek Tablets 50 mg of M/s Takeda Pharmaceutical Company Limited (PMDA

		Approved)
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Firm has submitted following declaration: We hereby declare that we will adopt the same source of drug substance, drug product formulation, specifications and container closure as already approved by the Registration Board for the same formulation at the same manufacturing site. In case of any post-registration variation by the contract manufacturer, same shall be immediately applied by the applicant/registration holder for requisite approval by Registration Board as per "Post Registration Variation Guideline for Pharmaceutical and Biological Products", available on DRAP's official website. Trelamit 50mg Tablet (Trelagliptin as Trelagliptin succinate 50mg) is approved in 353rd meeting of Registration Board as per copy of minutes attached by firm.	
	Decision	
	Approved	
	Applicant shall submit fee for change of title of firm from M/s. Siam to M/s. Cell Health Sciences along with CLB letter for change in title of firm before issuance of Registration Letter.	
190	Case Category	Routine (Haleema Sharif)
	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	(Y5N-HNQ-3NE1, 2024-10-31)
	Detail of Fee Submitted	30000.0, 7000.0 2024-09-02, 2024-10-25
	The proposed proprietary name / brand name	PROVAS NIGHT
	Label Claim	Each film coated tablet contains: Paracetamol.....500mg Diphenhydramine HCl 25mg
	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)	Panadol Night
	Pharmacotherapeutic Group of (API)	Analgesic/Antiallergic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Stability data for 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)	Submitted
	The status in reference regulatory authorities	Panadol Night MHRA
	GMP status of the firm	Submitted in Dossier
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Decision	
	Approved	
191	Case Category	Routine (Haleema Sharif)

	Name, address of Applicant.	Werrick Pharmaceuticals Plot No. 216 - 217, I-10/3, Industrial Area Islambad (000340)
	Application Form Dy. No / Tracking ID & date of submission	(L45-X3X-55TB, 2024-10-30)
	Detail of Fee Submitted	30000.0, 7000.0 2024-06-04, 2024-09-05
	The proposed proprietary name / brand name	Flueze Multi Symptom Severe Cold Sachets
	Label Claim	Each sachet contains:- Paracetamol.....500mg, Dextromethorphan HBr.....20mg, Phenylephrine HCl.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled, 20's-De-Controlled
	Shelf Life (Unit)	2 Year(s) Store Below 30°C
	For generic drugs (me-too Status)	Colynol Multi Symptom Severe Cold Sachets (It has different formulation))
	Pharmacotherapeutic Group of (API)	Analgesic/Antipyretic/Antiallergic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	N/A
	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	Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Dailymed, Theraflu Multi Symptom Severe Cold Sachets
	GMP status of the firm	Submitted in Dossier
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Submitted Me TOO product has different composition.	
	Decision	
	Deferred	
	Registration Board Deferred the case for submission of the following:	
	1. A Risk Management Plan (RMP) for the proposed new molecule.	
	2. Differential fee of PKR 38,000/- for new molecule approval, as applicable fee for new molecule at the time of application submission was 75000/-	
192	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	Werrick Pharmaceuticals Plot No. 216 - 217, I-10/3, Industrial Area Islambad (000340)
	Application Form Dy. No / Tracking ID & date of submission	(M1W-MGB-AHUZ, 2024-10-09)
	Detail of Fee Submitted	75000.0, 2024-09-05,
	The proposed proprietary name / brand name	Flueze Vapour Release Plus Decongestant Sachets
	Label Claim	Each sachet contains: Paracetamol.....600mg,

		Phenylephrine HCl.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Coldene-P 600/10mg Sachet (Reg No. 131260)
	Pharmacotherapeutic Group of (API)	Analgesic/Antipyretic/Antiallergic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	N/A
	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	-
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Approved in MHRA PL 00240/0585
	GMP status of the firm	Submitted in dossier
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Decision	
	Approved	
193	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	Swiss Pharmaceuticals Pvt. Ltd. A/159, S.I.T.E.-II, Super Highway (000438)
	Application Form Dy. No / Tracking ID & date of submission	(XS9-1QD-ARPA, 2024-07-23)
	Detail of Fee Submitted	30000.0, 2024-05-30,
	The proposed proprietary name / brand name	DESOTIN 0.5mg/ml Syrup
	Label Claim	Each ml contains: Desloratadine.....0.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	120ml-As per SRO,30ml-As per SRO,60ml-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Neo-Antial Syrup 0.5mg/ml by M/s Sami Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Antiallergic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	N/A
	Detail of stability batches of drug product	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)	Submitted but not complete
	The status in reference regulatory authorities	Clarinox Syrup 0.5mg/ml by Merck Sharp & Dohme Corp US FDA

	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Queries	Response
	COA of reference standard in drug product part is of year 2012	Mistakenly incorrect CoA of working standard was incorporated in the dossier. The Certificate of analysis of working standard used in studies is hereby attached.
	Audit trail report of 21 CFR compliant system	The stability data pertains to studies conducted in 2023, during which the HPLC systems in use were not compliant with 21 CFR requirements. Following the subsequent notification by DRAP, all HPLC systems have been upgraded to ensure full 21 CFR compliance. At present, all ongoing and future stability studies are being performed using fully compliant HPLC systems.
	Decision	
	Rejected	
	Registration Board rejected the product due to non-availability of audit trail report of 21 CFR compliant system.	
194	Case Category	Routine (Haleema Sharif)
	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	(XPD-Y8X-7PVZ, 2024-12-17)
	Detail of Fee Submitted	37000.0, 2024-12-16,
	The proposed proprietary name / brand name	Levomark 50mg Tablet
	Label Claim	Each uncoated tablet contains levosulpiride 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2*10s-As per SRO
	Shelf Life (Unit)	2 Year(s)15° to 30°C
	For generic drugs (me-too Status)	Sulvoric 50mg Tablet by M/s High-Q (Reg#070485)
	Pharmacotherapeutic Group of (API)	Antipsychotic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	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	Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	levosupliride tablet AIFA Italy Approved
	GMP status of the firm	Inside Dossier
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Decision	

	Approved	
195	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	Cell Health Sciences , Plot No 217, Industrial Triangle, Kahuta Road, Islamabad (000711)
	Application Form Dy. No / Tracking ID & date of submission	(VJR-4D4-XQ12, 2024-06-03)
	Detail of Fee Submitted	75000.0, 2024-05-29,
	The proposed proprietary name / brand name	Pzole 40mg/ml Oral Suspension
	Label Claim	Each ml of oral suspension contains: Posaconazole.....40mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x60ml, 1x90ml, 1x10-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a cool & Dry place below 30
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Antifungal
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Posaconazole 40mg/ml oral suspension of M/s Thornton & Ross Ltd. (trading as STADA)Linthwaite,Huddersfield,HD7 5QH, UK (USFDA Approved)
	Detail of previous approval	
	Evaluation Remarks	
	Firm has submitted following undertaking: We hereby declare that we will adopt the same source of drug substance, drug product formulation,specifications and container closure as already approved by the Registration Board for the same formulationat the same manufacturing site.In case of any post-registration variation by the contract manufacturer, same shall be immediately appliedby the applicant/registration holder for requisite approval by Registration Board as per "Post RegistrationVariation Guideline for Pharmaceutical and Biological Products", available on DRAP's official website. Noxamit 40mg/ml oral suspension(Posaconazole 40mg/ml) of M/s. Wimits already approved in 353rd meeting as per copy of minutes shared by firm.	
	Decision	
	Approved	
	Applicant shall submit fee for change of title of firm from M/s. Siam to M/s. Cell Health Sciences along with CLB letter for change in title of firm before issuance of Registration Letter.	
196	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	Winlet Pharmaceuticals (Pvt) Ltd. 30-Km, Lahore Sargodha Raod, Sargodha (000874)
	Application Form Dy. No / Tracking ID & date of submission	(RQZ-RUW-P3WT, 2024-07-22)
	Detail of Fee Submitted	30000.0, 2024-04-02,
	The proposed proprietary name / brand name	cruz 120 tablet
	Label Claim	120mg per tablet
	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)	StarCox by M/s Getz
	Pharmacotherapeutic Group of (API)	NSAID

	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	kopalle pharma chemiclas pvt ltd D-133,130,127,121,Road no.13, phase III Industrial development area jeedimetla hyderabad-500055
	Detail of stability batches of drug product	Submitted for six months
	Documents for the procurement of API with approval from DRAP (in case of Import)	Submitted but name is different from dossier
	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	Arcoxia 120mg tablet of MSD, MHRA
	GMP status of the firm	GMP certificate submitted in dossier
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	1. DML of drug substance manufacturer is not valid/Expired. 2. GMP certificate of Drug substance manaufcaturer is not valid. 3. Address of API/Drug substance manufacturer is not same on Dossier and Clearance certificate.	
	Decision	
	Deferred	
197	Deferred for submission of the following:	
	1. Valid DML and GMP certificate of drug substance manufacturer issued by concerned regulatory authority of country of origin.	
	2. Clarification for difference in address of manufacturer between clearance certificate and dossier.	
	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	Cell Health Sciences , Plot No 217, Industrial Triangle, Kahuta Road, Islamabad (000711)
	Application Form Dy. No / Tracking ID & date of submission	(267-1BR-D2WA, 2024-06-03)
	Detail of Fee Submitted	75000.0, 2024-05-29,
	The proposed proprietary name / brand name	Trela 100mg Tablet
	Label Claim	Each Film Coated tablet contains Trelagliptin Succinate Equivalent to Trelagliptin 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x4's, 1 X 10's, 2x7-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a cool & Dry place below 30
	For generic drugs (me-too Status)	Trelaget 100mg Tablet of M/s Getz Pharma
	Pharmacotherapeutic Group of (API)	Antidiabetic Agent
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Zafatek Tablets 100 mg of M/s Takeda Pharmaceutical Company Limited (PMDA Approved)
	Detail of previous approval	
	Evaluation Remarks	

Firm has submitted following: Registration Board in its 324th meeting decided to consider cross-referred approved products on Form 5-F in contract manufacturing. This decision was notified vide F.No.1-2/2022-DMC dated 13th June, 2023, In 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer. Therefore, you are advised to inform regarding status of your application. In case your cross-referenced product has already been approved by the Registration Board on Form-5 F or in PRVC on Form 5F, please provide the following and your application will be considered accordingly: 1. Module 1, 2. extract of the minutes of the relevant meeting of Registration Board and 3. undertaking to adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification

Decision

Approved

Applicant shall submit fee for change of title of firm from **M/s. Siam** to **M/s. Cell Health Sciences** along with CLB letter for change in title of firm before issuance of Registration Letter.

198	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	(29U-P27-W6LY, 2024-10-09)
	Detail of Fee Submitted	37000.0, 2024-09-24,
	The proposed proprietary name / brand name	Loraqad 10mg Tablet
	Label Claim	Each Tablet Contains: Loratadine 10mg
	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 heat, light and humidity
	For generic drugs (me-too Status)	Antial 10mg Tablet
	Pharmacotherapeutic Group of (API)	Antiallergic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Morepen Laboratories Limited
	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	Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	FDA, MHRA, EMC & HPRA
	GMP status of the firm	Submitted in dossier
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Queries	Response
	Valid GMP certificate of drug substance manufacturer.	Submitted

Clarify regarding COA of reference standard which is more than 10 years old	Mistakenly incorrect CoA of working standard was incorporated in the dossier. The Certificate of analysis of working standard used in studies is hereby attached. In response to your query regarding the Certificate of Analysis (COA) of the reference standard being more than 10 years old, we hereby clarify that, for the drug substance, the reference standard initially established by the manufacturer is utilized for validation of the analytical testing methods and qualification of the API during the development stage. Subsequently, the qualified primary reference standard is used by the drug substance manufacturer to prepare and standardize the analytical working standard for routine analysis and further testing purposes. Therefore, the original COA of the primary reference standard may be older than 10 years; however, it remains traceable and scientifically justified as part of the established analytical standardization procedure.
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Decision

Deferred

Registration Board deferred the case for the following:

1. Scientific justification/traceability for usage of 10 years old reference standard along with evidence of purchase of it.

199	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	Saffron Pharmaceuticals 19-Km Sheikhpura Road (000616)
	Application Form Dy. No / Tracking ID & date of submission	(QZ6-NJL-8TX2, 2024-12-31)
	Detail of Fee Submitted	37000.0, 2024-12-17,
	The proposed proprietary name / brand name	Aknif 0.005% w/w Cream
	Label Claim	Aknif 0.005% w/w Cream Each Gram Contains: Trifarotene 0.05 mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	5g & 10g-As per SRO
	Shelf Life (Unit)	24 Year(s) Do not store above 30°C.
	For generic drugs (me-too Status)	Aklief (Not verifiable)
	Pharmacotherapeutic Group of (API)	Retinoic acid receptor (RAR) agonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Kehui Pharmaceutical Co., Ltd.
	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)	Clearance certificate 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	ANSM (France) https://agence-prd.ansm.sante.fr/php/ecodex/extrait.php?specid=63631908

	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Decision	
	Deferred	
	Deferred the case for submission of the following:	
	Either evidence of Me Too of applied product OR RMP (Risk Management plan) along with differential fee for new molecule which was applicable at the time of submission of application.	
200	Case Category	New Section (Incharge Evaluation Cell)
	Name, address of Applicant.	STARWAYS PHARMACEUTICALS Plot No. (Private Land), Near China Glassware, Nowshera Economic Zone, Risalpur, Nowshera, K.P.K, Pakistan (000999)
	Application Form Dy. No / Tracking ID & date of submission	(EX1-QNJ-VDW8, 2026-02-03)
	Detail of Fee Submitted	38700, 2026-01-21,
	The proposed proprietary name / brand name	Azmyc 200mg/5ml Dry Suspension
	Label Claim	Each 5ml Reconstituted Suspension Contains: Azithromycin as Dihydrate.....200mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's (15ml)-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at cool and Dry place below 30 C
	For generic drugs (me-too Status)	Azomax 200mg/5ml Dry Suspension
	Pharmacotheapeutic Group of (API)	Macrolide Antibiotics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Citi Pharma Limited
	Detail of stability batches of drug product	Data for 03 batches at long term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	API from Citi Pharma
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Azomax Batch Number H4448
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data for 03 batches at long term and accelerated conditions
	The status in reference regulatory authorities	FDA Approved
	GMP status of the firm	Approval of Additional section 01.08.2025
	Evidence of approval of manufacturing facility	DML dated 02.12.2024; Approval of Additional section 01.08.2025
	Evaluation Remarks	
	The application fulfils codal formalities.	
	Decision	
	Approved	
	Approved subject to provision of API Invoice from Citi Pharma	
201	Case Category	Routine (Incharge Evaluation Cell)
	Name, address of Applicant.	Helix Pharma (Pvt)., Ltd. Hakimsons House, A-56, S.I.T.E, Manghopir Road, Karachi-75700

		(000030)
	Application Form Dy. No / Tracking ID & date of submission	(ZWE-RJX-QU7R, 2024-08-15)
	Detail of Fee Submitted	75000.0, 2024-07-10,
	The proposed proprietary name / brand name	FINEREN Tablets 20mg
	Label Claim	Each Tablet Contains: Finerenone 20mg (Innovator Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	24 Month(s)Store below 30C
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	C03DA05; aldosterone antagonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Gansu Hanju Pharmaceutical Co Ltd. -China
	Detail of stability batches of drug product	Three batches of 2000 tablets at 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	Performed; Kerendia Tablet 20 mg
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Kerendia Tablets approved by FDA for Bayer HealthCare Pharmaceuticals Inc.
	GMP status of the firm	GMP certificate 25.08.2022
	Evidence of approval of manufacturing facility	DML 000030
	Evaluation Remarks	
	GMP/License of Drug Substance manufacturer	
	Decision	
	Approved	
202	Case Category	Routine (Incharge Evaluation Cell)
	Name, address of Applicant.	Helix Pharma (Pvt)., Ltd. Hakimsons House, A-56, S.I.T.E, Manghopir Road, Karachi-75700 (000030)
	Application Form Dy. No / Tracking ID & date of submission	(Y7A-6L1-D62W, 2024-07-31)
	Detail of Fee Submitted	75000.0, 2024-07-10,
	The proposed proprietary name / brand name	FINEREN Tablets 10mg
	Label Claim	Each Tablet Contains: Finerenone 10mg (Innovator Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30C
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	C03DA05; aldosterone antagonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Gansu Hanju Pharmaceutical Co Ltd. -China

	Detail of stability batches of drug product	Three batches of 2000 tablets at 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	Performed; Kerendia Tablet 20 mg
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Kerendia Tablets approved by FDA for Bayer HealthCare Pharmaceuticals Inc.
	GMP status of the firm	GMP certificate 25.08.2022
	Evidence of approval of manufacturing facility	DML 000030
	Evaluation Remarks	
	GMP/License of Drug Substance manufacturer	
	Decision	
	Approved	
203	Case Category	Routine (Incharge Evaluation Cell)
	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	(LDX-26P-BV5H, 2024-11-27)
	Detail of Fee Submitted	300000.0, 2024-10-24,
	The proposed proprietary name / brand name	Tamzel 0.4mg Capsule
	Label Claim	Each capsule contains: Tamsulosin Hydrochloride....0.4mg (as modified release pellets)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's 5's 7's 10's 14'-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30o C
	For generic drugs (me-too Status)	Tamsolin 0.4mg Capsule
	Pharmacotherapeutic Group of (API)	G04CA02; alpha-adrenoreceptor antagonists
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	FDA Approved Flomax Capsule
	GMP status of the firm	GMP certificate dated 10.01.2024
	Evidence of approval of manufacturing facility	DML 000504 dated 05.10.2022
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	

	Approved	
204	Case Category	Routine (Incharge Evaluation Cell)
	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	(SPM-GB9-QN85, 2024-11-22)
	Detail of Fee Submitted	75000.0, 2024-09-23,
	The proposed proprietary name / brand name	Pirfon 534mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Pirfenidone.....534mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's 5's 7's 10's 14'-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30o C
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	L04AX05; other immunosuppressants
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Three batches of 2500 tablets at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long-term and accelerated conditions
	The status in reference regulatory authorities	HPRA Approved Pirfenidone APS 534mg Film Coated Tablet
	GMP status of the firm	GMP Certificate dated 10.01.2024
	Evidence of approval of manufacturing facility	DML No. 000504 dated 05.10.2022; Tablet General
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
205	Case Category	Routine (Incharge Evaluation Cell)
	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	(J4A-7R3-ADSB, 2024-11-22)
	Detail of Fee Submitted	37000.0, 2024-09-23,
	The proposed proprietary name / brand name	Pirfon 801mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Pirfenidone.....801mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's 5's 7's 10's 14'-De-Controlled

	Shelf Life (Unit)	2 Year(s)Store below 30o C
	For generic drugs (me-too Status)	Mac-Fenid Tablet manufactured by Macter International Limited
	Pharmacotherapeutic Group of (API)	L04AX05; other immunosuppressants
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Three batches of 2500 tablets at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long-term and accelerated conditions
	The status in reference regulatory authorities	FDA Approved Esbriet Tablet
	GMP status of the firm	GMP Certificate dated 10.01.2024
	Evidence of approval of manufacturing facility	DML No. 000504 dated 05.10.2022; Tablet General
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
206	Case Category	Routine (Incharge Evaluation Cell)
	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	(7LH-UBE-EZX4, 2024-11-22)
	Detail of Fee Submitted	37000.0, 2024-09-23,
	The proposed proprietary name / brand name	Pirfon 267mg Tablet
	Label Claim	Each film coated tablet contains: Pirfenidone....267mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's 5's 7's 10's 14'-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30o C
	For generic drugs (me-too Status)	Mac-Fenid Tablet manufactured by Macter International Limited
	Pharmacotherapeutic Group of (API)	L04AX05; other immunosuppressants
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Three batches of 2500 tablets at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long-term and accelerated conditions

	The status in reference regulatory authorities	FDA Approved Esbriet Tablet
	GMP status of the firm	GMP Certificate dated 10.01.2024
	Evidence of approval of manufacturing facility	DML No. 000504 dated 05.10.2022; Tablet General
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
207	Case Category	Export Facilitation (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	(RUN-2W7-AV12, 2025-11-18)
	Detail of Fee Submitted	38700, 2025-10-20,
	The proposed proprietary name / brand name	Aprovio
	Label Claim	Each film-coated tablet contains: Aprocitentan.....12.5mg (Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's, 10's, 14's, 20's, 28's, 30's, 50's and 100's- De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below at 30°C
	For generic drugs (me-too Status)	Aprocent 12.5mg
	Pharmacotherapeutic Group of (API)	Anti-Hypertension
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	GANSU HAOTIN PHARMACEUTICAL CO; LTD
	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)	COMMERCIAL INVOICE, CLEARANCE CERTIFICATE, LICENSE TO IMPORT, BATCH CERTIFICATE, DML, GMP
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted pharmaceutical equivalence of our product against the product Aprocent by Solaris Pharma Submitted CDP results of our product against the product Aprocent by Solaris Pharma Pakistan,
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted stability study data of 3 batches of Aprocitentan at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C + 65%RH ± 5% for 24 months.
	The status in reference regulatory authorities	MHRA APPROVED
	GMP status of the firm	DML 000105 dated 12.07.2024
	Evidence of approval of manufacturing facility	DML 000105 dated 12.07.2024
	Evaluation Remarks	
	The application fulfills codal formalities.	

	Decision	
	Approved	
208	Case Category	Export Facilitation (Incharge Evaluation Cell)
	Name, address of Applicant.	Maxitech Pharma (Pvt) Ltd. E-178, S.I.T.E., Super Highway Phase-II, Karachi (000851)
	Application Form Dy. No / Tracking ID & date of submission	(9BQ-9PD-ZWZP, 2026-05-11)
	Detail of Fee Submitted	38700, 2026-04-28,
	The proposed proprietary name / brand name	Ritfulo 50mg Capsule
	Label Claim	Each capsule contains ritlecitinib tosylate equivalent to 50 mg ritlecitinib.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's-As per SRO,2x7's-As per SRO,4x7's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at temperatures not more than 30 degree Celsius
	For generic drugs (me-too Status)	Ritanib 50mg Capsule by Crystolite Pharmaceuticals
	Pharmacotherapeutic Group of (API)	L04; Immunosuppressants, Janus-associated kinase (JAK) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Real time: 0,3,6, (Months) and Accelerated : 0,3,6 (Months)
	Documents for the procurement of API with approval from DRAP (in case of Import)	All documents for procurement of an API has been attached.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed against Ritanib by Crystollite Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Litfulo 50mg Hard Capsules by Pfizer Limited
	GMP status of the firm	Certificate No: [86/2024-DRAP (K)]
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfils codal formalities.	
	Decision	
	Approved	
209	Case Category	Routine (Incharge Evaluation Cell)
	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	(1A4-T2B-RV7Q, 2024-11-27)
	Detail of Fee Submitted	30000.0, 7000.0 2024-09-12, 2024-11-21
	The proposed proprietary name / brand name	Peridam 4+5mg Tablet
	Label Claim	Each tablet contains: Perindopril tert-butylamine.....4mg (equivalent to 3.34 mg

		perindopril) Amlodipine.....5mg (as amlodipine besylate)
	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 30o C
	For generic drugs (me-too Status)	Rilerb Tablet of Martin Dow
	Pharmacotherapeutic Group of (API)	calcium channel blocker and ACE inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	HPRA Approved Perindopril/Amlodipine Krka Tablet
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
210	Case Category	Export Facilitation (Incharge Evaluation Cell)
	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	(U82-LT6-GD63, 2024-11-27)
	Detail of Fee Submitted	30000.0, 7000.0 2024-09-12, 2024-11-21
	The proposed proprietary name / brand name	Peridam 4+10mg Tablet
	Label Claim	Each tablet contains: Perindopril tert-butylamine.....4mg (equivalent to 3.34 mg perindopril) Amlodipine.....10mg (as amlodipine besilate)
	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 30o C
	For generic drugs (me-too Status)	Rilerb Tablet of Martin Dow
	Pharmacotherapeutic Group of (API)	calcium channel blocker and ACE inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	HPRA Approved Perindopril/Amlodipine Krka Tablet
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
211	Case Category	Export Facilitation (Incharge Evaluation Cell)
	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	(ZJ3-SAY-SNSR, 2024-11-27)
	Detail of Fee Submitted	30000.0, 7000.0 2024-09-12, 2024-11-21
	The proposed proprietary name / brand name	Peridam 8+5mg Tablet
	Label Claim	Each tablet contains: Perindopril tert-butylamine.....8mg (equivalent to 6.68 mg perindopril) Amlodipine.....5mg (as amlodipine besilate)
	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 30o C
	For generic drugs (me-too Status)	Rilerb Tablet of Martin Dow
	Pharmacotherapeutic Group of (API)	calcium channel blocker and ACE inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	HPRA Approved Perindopril/Amlodipine Krka Tablet
	GMP status of the firm	calcium channel blocker and ACE inhibitor
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
212	Case Category	Export Facilitation (Incharge Evaluation Cell)

	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	(2SH-S26-YPLU, 2024-11-27)
	Detail of Fee Submitted	30000.0, 7000.0 2024-09-12, 2024-11-21
	The proposed proprietary name / brand name	Peridam 8+10mg Tablet
	Label Claim	Each tablet contains: Perindopril tert-butylamine.....8mg (equivalent to 6.68 mg perindopril) Amlodipine.....10mg (as amlodipine besylate)
	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 30o C
	For generic drugs (me-too Status)	Rilerb Tablet of Martin Dow
	Pharmacotherapeutic Group of (API)	calcium channel blocker and ACE inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	HPRA Approved Perindopril/Amlodipine Krka Tablet
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
213	Case Category	Export Facilitation (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	(V24-2JB-V2VW, 2025-04-09)
	Detail of Fee Submitted	37000.0, 2025-03-28,
	The proposed proprietary name / brand name	Roxadon
	Label Claim	Each film coated tablet contains: Roxadustat.....100mg (Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's, 10's, 14's, 12'-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 degree celsius
	For generic drugs (me-too Status)	Roxaget tablet 100mg Getz pharma
	Pharmacotherapeutic Group of (API)	B03XA05; Antianemic preparations

	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	shandong kehui pharmaceutical Ltd.
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	FDA Approved
	GMP status of the firm	DML 000105; Renewal applied vide U56-LEZ-B86B
	Evidence of approval of manufacturing facility	DML 000105; Renewal applied vide U56-LEZ-B86B
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
214	Case Category	Export Facilitation (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	(DWB-TY7-4T4U, 2025-04-09)
	Detail of Fee Submitted	37000.0, 2025-03-28,
	The proposed proprietary name / brand name	Roxadon
	Label Claim	Each film coated tablet contains: Roxadustat.....20mg (Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's, 10's, 14's, 12'-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 degree celsius
	For generic drugs (me-too Status)	Roxaget tablet 20mg
	Pharmacotherapeutic Group of (API)	B03XA05; Antianemic preparations
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	shandong kehui pharmaceutical Ltd.
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	FDA Approved
	GMP status of the firm	DML 000105; Renewal applied vide U56-LEZ-B86B
	Evidence of approval of manufacturing facility	DML 000105; Renewal applied vide U56-LEZ-B86B

	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
215	Case Category	Export Facilitation (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	(DU2-LSB-QE2L, 2025-04-09)
	Detail of Fee Submitted	37000.0, 2025-03-28,
	The proposed proprietary name / brand name	Roxadon
	Label Claim	Each film coated tablet contains: Roxadustat.....50mg (Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's, 10's, 14's, 12'-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 degree celsius
	For generic drugs (me-too Status)	Roxaget tablet 50mg
	Pharmacotherapeutic Group of (API)	B03XA05; Antianemic preparations
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	shandong kehui pharmaceutical Ltd.
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	FDA Approved
	GMP status of the firm	DML 000105; Renewal applied vide U56-LEZ-B86B
	Evidence of approval of manufacturing facility	DML 000105; Renewal applied vide U56-LEZ-B86B
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
216	Case Category	Export Facilitation (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	(VEV-BJD-M28A, 2025-07-03)
	Detail of Fee Submitted	75000.0, 2025-03-25,
	The proposed proprietary name / brand name	Mirolgal ODT 2.5mg Tablets
	Label Claim	Each Tablet contains Mirogabalin as besylate 2.5mg (Innovator's Specification).
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	As per DPC-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	Gabapentinoids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	• Shandong Chenghuishuangda Pharmaceutical Co., Ltd. No.9al,Tianheng Road, Gaoqing City Shandong, China.
	Detail of stability batches of drug product	PDS-354-24,PDS-355-24,PDS-356-24 .Applied with 3months
	Documents for the procurement of API with approval from DRAP (in case of Import)	K-2068146205392
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Enclosed in Module-III
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	24 Months
	The status in reference regulatory authorities	Tarlige OD Tablet 2.5mg PMDA
	GMP status of the firm	Valid till 15 Jan 2027
	Evidence of approval of manufacturing facility	DML No.000028
	Evaluation Remarks	
	Under export facilitation as per letter dated 30 April 2026.	
	Decision	
	Approved	
217	Case Category	Export Facilitation (Incharge Evaluation Cell)
	Name, address of Applicant.	shrooq pharmaceuticals pvt ltd 21km feorzpur road lahore (000577)
	Application Form Dy. No / Tracking ID & date of submission	(HMA-VS5-LWRL, 2025-09-26)
	Detail of Fee Submitted	37000.0, 2025-05-13,
	The proposed proprietary name / brand name	Remetrom Tablet 100mg
	Label Claim	Each Film Coated Tablet contains: Resmetirom.....100mg (In-house Specifications)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1x30's-De-Controlled
	Shelf Life (Unit)	2 YearStore at temperature below 25oC
	For generic drugs (me-too Status)	Resmit Tablet 100mg by Nabiqasim Industries (Pvt) Ltd.
	Pharmacotherapeutic Group of (API)	Partial agonist of the thyroid hormone receptor-beta (THR-β), Liver Therapy
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	SHANDONG CHENGHUISHUANGDA PHARMACEUTICAL CO.,LTD ADDRESS: ECONOMIC DEVELOPMENT ZONE, PINGYUAN COUNTY, DEZHOU, SHANDONG, CHINA Telephone ? +86-531-58897029 / +86-531-58897070 Email? lily.yue@chsdpharma.com / market@chsdpharma.com URL: http://chsdpharma.com

	Detail of stability batches of drug product	The detailed stability study data of three stability batches of Resmetirom Tablet 100mg are T-001, T-002, T-003 having manufacturing / expiry date 01-2025 / 01-2027 and batch size of 1000 Tablet are submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	The Form 6 (License to import drug for test analysis) from DRAP along with form 3, form 7 and AWB for the procurement of API Resmetirom from the SHANDONG CHENGHUISHUANGDA PHARMACEUTICAL CO., LTD are submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The Pharmaceutical Equivalence (Comparative Assay Profile) Report and Comparative Dissolution Profile report performed between developed product "Resmetirom Tablet 100mg" Batch # T-001 and Reference Product "LuciRes Tablet 100mg" Batch # RSC240901 and detailed report attached in Module 3 section 3.2.P.2.2.1
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	The stability study data of following batches of API 230601, 230602, 230603, performed at Accelerated Stability Conditions 40oC + 2oC / RH 75% + 5% & Real time Stability Conditions 30oC + 2oC / RH 75% + 5% from API manufacturer are submitted
	The status in reference regulatory authorities	Rezdiffra Tablet 100mg USFDA Approved
	GMP status of the firm	GMP certificate issued based upon evaluation conducted on 01-12-2023 and valid for three years from date of inspection
	Evidence of approval of manufacturing facility	Tablet Section General
	Evaluation Remarks	
	Under export facilitation	
	Decision	
	Approved	
218	Case Category	Export Facilitation (Incharge Evaluation Cell)
	Name, address of Applicant.	shrooq pharmaceuticals pvt ltd 21km feorzpur road lahore (000577)
	Application Form Dy. No / Tracking ID & date of submission	(T4X-JP2-EH1B, 2025-09-26)
	Detail of Fee Submitted	37000.0, 2025-05-13,
	The proposed proprietary name / brand name	Remetrom Tablet 60mg
	Label Claim	Each Film Coated Tablet contains: Resmetirom.....60mg (In-house Specifications)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1x30's-De-Controlled
	Shelf Life (Unit)	2 YearStore at temperature below 25oC
	For generic drugs (me-too Status)	Resmit Tablet 60mg by Nabiqasim Industries (Pvt) Ltd.
	Pharmacotherapeutic Group of (API)	Partial agonist of the thyroid hormone receptor-beta (THR-β), Liver Therapy
	Name, address of Manufacturing site:	Self Manufacturing

	Name & address of API manufacturer	SHANDONG CHENGHUIHUANGDA PHARMACEUTICAL CO.,LTD ADDRESS: ECONOMIC DEVELOPMENT ZONE, PINGYUAN COUNTY, DEZHOU, SHANDONG, CHINA Telephone ? +86-531-58897029 / +86-531-58897070 Email? lily.yue@chsdpharma.com / market@chsdpharma.com URL: http://chsdpharma.com
	Detail of stability batches of drug product	The detailed stability study data of three stability batches of Resmetirom Tablet 60mg are T-001, T-002, T-003 having manufacturing / expiry date 01-2025 / 01-2027 and batch size of 1000 tablets are submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	The Form 6 (License to import drug for test analysis) from DRAP along with form 3, form 7 and AWB for the procurement of API Resmetirom from the SHANDONG CHENGHUIHUANGDA PHARMACEUTICAL CO., LTD are submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The Pharmaceutical Equivalence (Comparative Assay Profile) Report and Comparative Dissolution profile report performed between developed product "Resmetirom Tablet 60mg" Batch # T-001 and Reference Product "LuciRes Tablet 60mg" Batch # RSA240901 and detailed report attached in Module 3 section 3.2.P.2.2.1
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	The stability study data of following batches of API 230601, 230602, 230603, performed at Accelerated Stability Conditions 40oC + 2oC / RH 75% + 5% & Real time Stability Conditions 30oC + 2oC / RH 75% + 5% from API manufacturer are submitted
	The status in reference regulatory authorities	Rezdiffra Tablet 60mg USFDA Approved
	GMP status of the firm	GMP certificate issued based upon evaluation conducted on 01-12-2023 and valid for three years from date of inspection
	Evidence of approval of manufacturing facility	Tablet Section General
	Evaluation Remarks	
	Under export facilitation	
219	Decision	
	Approved	
	Case Category	Export Facilitation (Incharge Evaluation Cell)
	Name, address of Applicant.	shrooq pharmaceuticals pvt ltd 21km feorzpur road lahore (000577)
	Application Form Dy. No / Tracking ID & date of submission	(LXY-W79-N8AY, 2026-04-01)
	Detail of Fee Submitted	37000.0, 2025-05-13,
	The proposed proprietary name / brand name	Remetrom Tablet 80mg
	Label Claim	Each Film Coated tablet Contains: Reametirom.....80mg (In-house Specifications)
	Reference to Finished product specifications	Manufacturer Specification

	Proposed Pack Size	1x30's-De-Controlled
	Shelf Life (Unit)	2 YearStore at temperature below 25oC
	For generic drugs (me-too Status)	Resmit Tablet 80mg by Nabiqasim Industries (Pvt) Ltd.
	Pharmacotherapeutic Group of (API)	Partial agonist of the thyroid hormone receptor-beta (THR-β), Liver Therapy
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	SHANDONG CHENGHUISHUANGDA PHARMACEUTICAL CO.,LTD ADDRESS: ECONOMIC DEVELOPMENT ZONE, PINGYUAN COUNTY, DEZHOU, SHANDONG, CHINA Telephone ? +86-531-58897029 / +86-531-58897070 Email? lily.yue@chsdpharma.com / market@chsdpharma.com URL: http://chsdpharma.com
	Detail of stability batches of drug product	The detailed stability study data of three stability batches of Resmetirom Tablet 80mg are T-001, T-002, T-003 having manufacturing / expiry date 01-2025 / 01-2027 and batch size of 1000 tablets are submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	The Form 6 (License to import drug for test analysis) from DRAP along with form 3, form 7 and AWB for the procurement of API Resmetirom from the SHANDONG CHENGHUISHUANGDA PHARMACEUTICAL CO., LTD are submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The Pharmaceutical Equivalence (Comparative Assay Profile)Report and Comparative Dissolution profile report performed between developed product “Resmetirom Tablet 80mg” Batch # T-001 and Reference Product “LuciRes Tablet 80mg” Batch # RSB240901 and detailed report attached in Module 3 section 3.2.P.2.2.1
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	The stability study data of following batches of API 230601, 230602, 230603, performed at Accelerated Stability Conditions 40oC + 2oC / RH 75% + 5% & Real time Stability Conditions 30oC + 2oC / RH 75% + 5% from API manufacturer are submitted
	The status in reference regulatory authorities	Rezdiffra Tablet 80mg USFDA Approved
	GMP status of the firm	GMP certificate issued based upon evaluation conducted on 01-12-2023 and valid for three years from date of inspection
	Evidence of approval of manufacturing facility	Tablet Section General
220	Evaluation Remarks	
	Under export facilitation	
	Decision	
	Approved	
	Case Category	Routine (Incharge Evaluation Cell)
	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	(7ZP-Y32-68HE, 2024-12-02)
	Detail of Fee Submitted	75000.0, 2024-10-24,
	The proposed proprietary name / brand name	Sotag 200mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Sotagliflozin.....200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's 5's 7's 10's 14'-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30o C
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	dual SGLT1/2 inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	FDA Approved Inpefa Tablet
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
221	Case Category	Routine (Incharge Evaluation Cell)
	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	(X4J-3N3-JEEY, 2024-12-05)
	Detail of Fee Submitted	75000.0, 2024-10-24,
	The proposed proprietary name / brand name	Sotag 400mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Sotagliflozin.....400mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's 5's 7's 10's 14'-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30o C
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	dual SGLT1/2 inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Three batches at 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	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	FDA Approved Inpefa Tablet
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
222	Case Category	Export Facilitation (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	(7AL-JRZ-UY51, 2025-10-06)
	Detail of Fee Submitted	75000.0, 2025-04-11,
	The proposed proprietary name / brand name	Mirogal OD Tablet 15mg
	Label Claim	Each Tablet contains Mirogabalin as besylate 1 5mg (Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per DPC-As per SRO
	Shelf Life (Unit)	2 YearBelow 30
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	Gabapentinoids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Chenghuishuangda Pharmaceutical Co., Ltd. No.9al,Tianheng Road, Gaoqing City Shandong, China.
	Detail of stability batches of drug product	PDS-345-24, PDS-346-24, PDS-347-24
	Documents for the procurement of API with approval from DRAP (in case of Import)	K-2068146205392
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability till 24 months
	The status in reference regulatory authorities	Tarlige OD Tablet 15mg PMDA
	GMP status of the firm	Valid till 2027
	Evidence of approval of manufacturing facility	DML NO 000028
	Evaluation Remarks	
	Under export facilitation	
	Decision	
	Approved	
223	Case Category	Export Facilitation (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	(8DA-42Y-PJ8L, 2025-10-06)
	Detail of Fee Submitted	75000.0, 2025-04-11,
	The proposed proprietary name / brand name	Mirogal OD Tablet 10mg
	Label Claim	Each Tablet contains Mirogabalin as besylate 10mg (Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per DPC-As per SRO
	Shelf Life (Unit)	2 YearBelow 30
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	Gabapentinoids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Chenghuishuangda Pharmaceutical Co., Ltd. No.9al,Tianheng Road, Gaoqing City Shandong, China.
	Detail of stability batches of drug product	PDS-348-24, PDS-349-24, PDS-350-24
	Documents for the procurement of API with approval from DRAP (in case of Import)	K-2068146205392
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability till 24 months
	The status in reference regulatory authorities	Tarlige OD Tablet 10mg PMDA
	GMP status of the firm	Valid till 2027
	Evidence of approval of manufacturing facility	DML NO 000028
	Evaluation Remarks	
	Under export facilitation	
	Decision	
	Approved	
224	Case Category	Export Facilitation (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	(ZDB-2UA-WD1S, 2025-10-07)
	Detail of Fee Submitted	75000.0, 2025-04-11,
	The proposed proprietary name / brand name	Mirogal OD Tablet 5mg
	Label Claim	Each Tablet contains Mirogabalin as besylate 5mg (Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per DPC-As per SRO
	Shelf Life (Unit)	2 YearBelow 30
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	Gabapentinoids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Chenghuishuangda Pharmaceutical Co., Ltd. No.9al,Tianheng Road, Gaoqing City

		Shandong, China.
	Detail of stability batches of drug product	PDS-351-24, PDS-352-24, PDS-353-24
	Documents for the procurement of API with approval from DRAP (in case of Import)	K-2068146205392
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability till 24 months
	The status in reference regulatory authorities	Tarlige OD Tablet 5mg PMDA
	GMP status of the firm	Valid till 2027
	Evidence of approval of manufacturing facility	DML NO 000028
	Evaluation Remarks	
	Under export facilitation	
	Decision	
	Approved	
225	Case Category	Export Facilitation (Incharge Evaluation Cell)
	Name, address of Applicant.	AGP Limited B-23-C, S.I.T.E., Karachi (000348)
	Application Form Dy. No / Tracking ID & date of submission	(8SU-DGE-UXX8, 2025-11-05)
	Detail of Fee Submitted	38700, 2025-09-16,
	The proposed proprietary name / brand name	Remirom Tablet 100mg
	Label Claim	Each film coated tablet contains Resmetirom.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 x 7's, 1 x 10's, 2 x 7's, 2 x 10's, 4 x 7's, 3 x 10's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30° C
	For generic drugs (me-too Status)	Resmirom Tablet 100mg, Getz Pharma
	Pharmacotherapeutic Group of (API)	Thyroid hormone receptor (THR)-beta agonists.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Chenghuishuangda Pharmaceutical Co.,Ltd
	Detail of stability batches of drug product	3 months accelerated & 3 months long term stability studies ongoing (at zone IV-B)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 (License to import Raw material for Trial Production) issued by DRAP
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP has been conducted against Resmirom Tablet 100mg by Getz Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	6 months accelerated & 24 months long term stability studies at zone IV-A
	The status in reference regulatory authorities	USFDA Approved. Rezdiffra 100mg Tablet by Madrigal Pharmaceuticals, Eu.Ltd.
	GMP status of the firm	GMP certificate valid till 14.10. 2028, Attached in module1.
	Evidence of approval of manufacturing facility	DML & GMP certificates attached in 1.3.4 & 1.3.5 of Module 01

	Evaluation Remarks	
	Under export facilitation	
	Decision	
	Approved	
226	Case Category	Export Facilitation (Incharge Evaluation Cell)
	Name, address of Applicant.	AGP Limited B-23-C, S.I.T.E., Karachi (000348)
	Application Form Dy. No / Tracking ID & date of submission	(B25-G39-BELQ, 2025-11-05)
	Detail of Fee Submitted	38700, 2025-09-16,
	The proposed proprietary name / brand name	Remirom Tablet 80mg
	Label Claim	Each Film Coated Tablet Contains: Resmetirom.....80mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 x 7's, 1 x 10's, 2 x 7's, 2 x 10's, 4 x 7's, 3 x 10's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30° C
	For generic drugs (me-too Status)	Resmirom Tablet 80mg, Getz Pharma
	Pharmacotherapeutic Group of (API)	Thyroid hormone receptor (THR)-beta agonists.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Chenghuishuangda Pharmaceutical Co.,Ltd
	Detail of stability batches of drug product	3 months accelerated & 3 months long term stability studies ongoing (at zone IV-B)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 (License to import Raw material for Trial Production) issued by DRAP
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP has been conducted against Resmirom Tablet 80mg by Getz Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	6 months accelerated & 24 months long term stability studies at zone IV-A
	The status in reference regulatory authorities	USFDA Approved. Rezdiffra 80mg Tablet by Madrigal Pharmaceuticals, Eu.Ltd.
	GMP status of the firm	GMP certificate valid till 14.10. 2028, Attached in module1.
	Evidence of approval of manufacturing facility	DML & GMP certificates attached in 1.3.4 & 1.3.5 of Module 01
	Evaluation Remarks	
	Under export facilitation	
	Decision	
	Approved	
227	Case Category	Export Facilitation (Incharge Evaluation Cell)
	Name, address of Applicant.	AGP Limited B-23-C, S.I.T.E., Karachi (000348)
	Application Form Dy. No / Tracking ID & date of submission	(4AE-7H6-3NL2, 2025-11-05)
	Detail of Fee Submitted	38700, 2025-09-16,

	The proposed proprietary name / brand name	Remirom Tablet 60mg
	Label Claim	Each film coated tablet contains: Resmetirom..... 60mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 x 7's, 1 x 10's, 2 x 7's, 2 x 10's, 4 x 7's, 3 x 10's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30° C
	For generic drugs (me-too Status)	Resmirom Tablet 60mg, Getz Pharma
	Pharmacotherapeutic Group of (API)	Thyroid hormone receptor (THR)-beta agonists.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Chenghuishuangda Pharmaceutical Co.,Ltd
	Detail of stability batches of drug product	3 months accelerated & 3 months long term stability studies and ongoing (at zone IV-B)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 (License to import Raw material for Trial Production) issued by DRAP
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP has been conducted against Resmirom Tablet 60mg by Getz Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	6 months accelerated & 24 months long term stability studies at zone IV-A
	The status in reference regulatory authorities	USFDA Approved. Rezdiffra 60mg Tablet by Madrigal Pharmaceuticals, Eu.Ltd.
	GMP status of the firm	GMP certificate valid till 14.10. 2028, Attached in module1.
	Evidence of approval of manufacturing facility	DML & GMP certificates attached in 1.3.4 & 1.3.5 of Module 01
	Evaluation Remarks	
	Under export facilitation	
	Decision	
	Approved	
228	Case Category	New Section (Incharge Evaluation Cell)
	Name, address of Applicant.	STARWAYS PHARMACEUTICALS Plot No. (Private Land), Near China Glassware, Nowshera Economic Zone, Risalpur, Nowshera, K.P.K, Pakistan (000999)
	Application Form Dy. No / Tracking ID & date of submission	(EV8-LRQ-YGA7, 2026-02-06)
	Detail of Fee Submitted	38700, 2025-12-16,
	The proposed proprietary name / brand name	SW Linz 100mg/5ml Suspension
	Label Claim	Each 5ml of reconstituted suspension contains: Linezolid.....100mg (Innovator's Specs.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C in a cool and dry place.
	For generic drugs (me-too Status)	Ecasil Oral Suspension BY Sami Pharmaceuticals (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Antibiotic

	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Optimus Drugs Private Limited Plot No. 6P, 2nd Floor, Signature Towers, Kothaguda, Kondapur, Hyderabad – 500084, Telangana, India
	Detail of stability batches of drug product	2000 bottles of each batch.
	Documents for the procurement of API with approval from DRAP (in case of Import)	API on loan from Obsons pharma
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies are according to zone IV A.
	The status in reference regulatory authorities	USFDA approved
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Attached.
	Evaluation Remarks	
	Decision	
	Approved	
	Subject to verification of API loan from Obsons Pharma	
229	Case Category	New Section (Incharge Evaluation Cell)
	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	(GR4-96R-A7NR, 2026-05-11)
	Detail of Fee Submitted	38700, 2026-04-15,
	The proposed proprietary name / brand name	Nagodine Surgical Scrub Solution
	Label Claim	Each ml of cutaneous solution contains: Iodinated Povidone 75 mg/ml (7.5% w/v). This yields approx. 8 mg/ml (0.8% w/v) of available iodine.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50 ml, 60 ml, 70 ml, 100 ml, 200 ml, 300 ml, 400 ml, 450 ml, 500 ml, 1000 ml, 4.5 L, 5 L-As per SRO
	Shelf Life (Unit)	2 Year(s)20C-25C
	For generic drugs (me-too Status)	Pyodine by Brookes Pharma
	Pharmacotherapeutic Group of (API)	Antiseptics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	03 batches : 50 bottles each 50mL 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)	Loan letter for 1kg of material along with memorandum of understanding for loan dated 04-08-2025 is submitted. Clearance certificate dated 24-07-2024 issued to M/s Kohinoor Industries is submitted. Stability batches were manufactured in September, 2025.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted against Pyodine by M/s brookes.

	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-A.
	The status in reference regulatory authorities	Health Products Regulatory Authority (HPRA)
	GMP status of the firm	External preparation (Liquid) General Section is approved on 18-03-2026.
	Evidence of approval of manufacturing facility	External preparation (Liquid) General Section is approved.
	Evaluation Remarks	
	Loan letter for 1kg of material along with memorandum of understanding for loan dated 04-08-2025 is submitted. Clearance certificate dated 24-07-2024 issued to M/s Kohinoor Industries is submitted. Stability batches were manufactured in September, 2025.	
	Decision	
	Deferred	
	The Board decided to refer the case to DRAP Authority for decision regarding the borrowing of drug substance after DRAP's notification No.14-1/2022-PEC dated 01.08.2025.	
230	Case Category	New Section (Incharge Evaluation Cell)
	Name, address of Applicant.	STARWAYS PHARMACEUTICALS Plot No. (Private Land), Near China Glassware, Nowshera Economic Zone, Risalpur, Nowshera, K.P.K, Pakistan (000999)
	Application Form Dy. No / Tracking ID & date of submission	(P12-L5L-QG1Q, 2026-02-03)
	Detail of Fee Submitted	38700, 2025-12-16,
	The proposed proprietary name / brand name	Monmax 4mg Sachet
	Label Claim	Each Sachet contains: Montelukast Sodium eq. to Montelukast 4 mg (USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s) Store below 30°C in a cool and dry place.
	For generic drugs (me-too Status)	Montiget 4mg sachet BY Getz Pharma (Pvt.) Limited.
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonists
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Pure and Cure Healthcare Private Limited. (Akums Lifesciences Limited.) Akums Lifesciences Limite Village Chachrauli, Derabassi, District Sahibzada Ajit Singh Nagar, Punjab India (India)
	Detail of stability batches of drug product	1500 sachet each batch.
	Documents for the procurement of API with approval from DRAP (in case of Import)	API on loan from Obsons
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies are according to zone IV A.
	The status in reference regulatory authorities	MHRA Approved.
	GMP status of the firm	New DML

	Evidence of approval of manufacturing facility	Attached.
	Evaluation Remarks	
	API on loan from Obsons	
	Decision	
	Approved	
231	Case Category	Export Facilitation (Incharge Evaluation Cell)
	Name, address of Applicant.	AGP Limited B-23-C, S.I.T.E., Karachi (000348)
	Application Form Dy. No / Tracking ID & date of submission	(MWX-P5R-453L, 2025-10-31)
	Detail of Fee Submitted	38700, 2025-09-16,
	The proposed proprietary name / brand name	Lyrica CR Tablet 165mg
	Label Claim	Each extended-release film coated tablet contain: Pregabalin.....165mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's (1 x 7's), 10's (1 x 10's), 14's, (1 x 14's, 2-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30° C
	For generic drugs (me-too Status)	Gablin CR Tablet 165mg by CCL Pharmaceutical (Pvt.)Ltd.
	Pharmacotherapeutic Group of (API)	Gabapentanoid
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Not Applicable
	Detail of stability batches of drug product	6 months accelerated & 3months long term stability studies and ongoing (at zone IV-B)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 (License to import Raw material for Trial Production) issued by DRAP
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP has been conducted against Gablin CR Tablet 165mg
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	6 months accelerated & 24 months long term stability studies at zone IV-B
	The status in reference regulatory authorities	Lyrica CR Tablet 165mg by Upjohn US 2 LLC.
	GMP status of the firm	GMP certificate valid till 26 Sep 2028, Attached in module1.
	Evidence of approval of manufacturing facility	DML & GMP certificates attached in 1.3.4 & 1.3.5 of Module 01
	Evaluation Remarks	
	Under exports facilitation	
	Decision	
	Approved	
232	Case Category	Export Facilitation (Incharge Evaluation Cell)
	Name, address of Applicant.	AGP Limited B-23-C, S.I.T.E., Karachi (000348)
	Application Form Dy. No / Tracking ID & date of submission	(QPZ-WYH-VW9J, 2025-10-31)
	Detail of Fee Submitted	38700, 2025-09-16,
	The proposed proprietary name / brand name	Lyrica CR Tablet 330mg

	Label Claim	Each extended-release film coated tablet contain: Pregabalin.....330mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's (1 x 7's), 10's (1 x 10's), 14's, (1 x 14's, 2-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30° C
	For generic drugs (me-too Status)	Gablin CR Tablet 330mg by CCL Pharmaceutical (Pvt.)Ltd.
	Pharmacotherapeutic Group of (API)	Gabapentanoid
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Not Applicable
	Detail of stability batches of drug product	3 months accelerated & 3 months long term stability studies and ongoing (at zone IV-B)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 (License to import Raw material for Trial Production) issued by DRAP
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP has been conducted against Gablin CR Tablet 330mg
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	6 months accelerated & 24 months long term stability studies at zone IV-B
	The status in reference regulatory authorities	Lyrica CR Tablet 330mg by Upjohn US 2 LLC.
	GMP status of the firm	GMP certificate valid till 26 Sep 2028, Attached in module1.
	Evidence of approval of manufacturing facility	DML No. 000348 dated 06.02.2025
	Evaluation Remarks	
	Under exports facilitation	
	Decision	
	Approved	
233	Case Category	Export Facilitation (Incharge Evaluation Cell)
	Name, address of Applicant.	AGP Limited B-23-C, S.I.T.E., Karachi (000348)
	Application Form Dy. No / Tracking ID & date of submission	(H6N-ZA3-SULE, 2025-10-31)
	Detail of Fee Submitted	38700, 2025-09-16,
	The proposed proprietary name / brand name	Lyrica CR Tablet 82.5mg
	Label Claim	Each extended-release film coated tablet contain: Pregabalin.....82.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's (1 x 7's), 10's (1 x 10's), 14's, (1 x 14's, 2-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30° C
	For generic drugs (me-too Status)	Gablin CR Tablet 82.5mg by CCL Pharmaceutical (Pvt.)Ltd.
	Pharmacotherapeutic Group of (API)	Gabapentanoid
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Not Applicable
	Detail of stability batches of drug product	6 months accelerated & 3months long term stability studies and ongoing (at zone IV-B)
	Documents for the procurement of API with approval from DRAP	Form 6 (License to import Raw material for Trial Production) issued by DRAP

	(in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP has been conducted against Gablin CR Tablet 82.5mg
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	6 months accelerated & 24 months long term stability studies at zone IV-B
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	GMP certificate valid till 26 Sep 2028, Attached in module1.
	Evidence of approval of manufacturing facility	DML & GMP certificates attached in 1.3.4 & 1.3.5 of Module 01
	Evaluation Remarks	
	Under exports facilitation	
	Decision	
	Approved	
234	Case Category	Export Facilitation (Incharge Evaluation Cell)
	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	(LRA-B5S-BRXE, 2026-03-06)
	Detail of Fee Submitted	38700, 2025-12-18,
	The proposed proprietary name / brand name	Prucalo 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	5's, 7's , 10's, 14's, 20's, 28's, 30's, 56's, 84's, 100's and 122's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 C
	For generic drugs (me-too Status)	Prucalax Tablet by Kaizen Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Serotonin 5-HT4 receptor agonists
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Loncom Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	Stability data of 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	License to import drug issue on date 10/12/2025 is attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and CDP against the drug product Resolor Tablet is attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 3 batches
	The status in reference regulatory authorities	Resolor tablet approved by EMA
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	General Tablet (Section approval is attached)
	Evaluation Remarks	
	Under export facilitation	
	Decision	
	Approved	
235	Case Category	Export Facilitation (Incharge Evaluation Cell)

	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	(69N-1Z4-QNL2, 2026-04-07)
	Detail of Fee Submitted	38700, 2025-12-18,
	The proposed proprietary name / brand name	Prucalo 1mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Prucalopride (as succinate) 1mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5's, 7's , 10's, 14's, 20's, 28's, 30's, 56's, 84's, 100's and 122's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 C
	For generic drugs (me-too Status)	Prucalax Tablet by Kaizen Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Serotonin 5-HT4 receptor agonists
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Loncom Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	Stability data of 3 batches at Zone IV A conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	License to import drug issue on date 10/12/2025 is attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and CDP against the drug product Resolor Tablet is attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 3 batches at Zone IV conditions
	The status in reference regulatory authorities	Resolor tablet approved by EMA
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	General Tablet (Section approval is attached)
	Evaluation Remarks	
	Under export facilitation	
	Decision	
	Approved	
236	Case Category	Export Facilitation (Incharge Evaluation Cell)
	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	(W7Q-HBE-1SVT, 2026-02-03)
	Detail of Fee Submitted	38700, 2025-10-01,
	The proposed proprietary name / brand name	Mirolin 15mg Tablet
	Label Claim	Each film coated tablet contains: Mirogabalin besylate equivalent to Mirogabalin.....15mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's , 10's, 14's, 20's, 28's, 30's, 56's, 84's, 100's and 122's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 C
	For generic drugs (me-too Status)	Miro Tablet by Nabi Qasim Industries
	Pharmacotherapeutic Group of (API)	Gabapentinoids

	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Gansu Haotian PharmaTech Co., Ltd.
	Detail of stability batches of drug product	Stability data of 3 batches attached in section 3.2.P.8.3
	Documents for the procurement of API with approval from DRAP (in case of Import)	DRAP cleared invoice dated 29/10/2025 along with the import documents is attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence against the innovator product Tarlige is attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 3 batches is attached in section 3.2.S.7.3
	The status in reference regulatory authorities	Tarlige Tablet approved by PMDA Japan
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	General Tablet (Section approval is attached)
	Evaluation Remarks	
	Under export facilitation	
	Decision	
	Approved	
237	Case Category	Export Facilitation (Incharge Evaluation Cell)
	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	(JMR-AAX-M567, 2026-02-03)
	Detail of Fee Submitted	38700, 2025-10-01,
	The proposed proprietary name / brand name	Mirolin 10mg Tablet
	Label Claim	Each film coated Tablet Contains: Mirogabalin besylate equivalent to Mirogabalin 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's , 10's, 14's, 20's, 28's, 30's, 56's, 84's, 100's and 122's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30 C
	For generic drugs (me-too Status)	Miro Tablet by Nabi Qasim Industries
	Pharmacotherapeutic Group of (API)	Gabapentinoids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Gansu Haotian PharmaTech Co., Ltd.
	Detail of stability batches of drug product	Stability data of 3 batches attached in section 3.2.P.8.3
	Documents for the procurement of API with approval from DRAP (in case of Import)	DRAP cleared invoice dated 29/10/2025 along with the import documents is attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence against the innovator product Tarlige is attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 3 batches is attached in section 3.2.S.7.3
	The status in reference regulatory authorities	Tarlige Tablet approved by PMDA Japan
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	General Tablet (Section approval is attached)
	Evaluation Remarks	

	Under export facilitation	
	Decision	
	Approved	
238	Case Category	Export Facilitation (Incharge Evaluation Cell)
	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	(HER-T9R-GH4J, 2026-02-03)
	Detail of Fee Submitted	38700, 2025-10-01,
	The proposed proprietary name / brand name	Mirolin 5mg Tablet
	Label Claim	Each film coated tablet contains: Mirogabalin besylate equivalent to Mirogabalin 5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's , 10's, 14's, 20's, 28's, 30's, 56's, 84's, 100's and 122's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30 C
	For generic drugs (me-too Status)	Miro Tablet by Nabi Qasim Industries
	Pharmaceutical Group of (API)	Gabapentinoids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Gansu Haotian PharmaTech Co., Ltd.
	Detail of stability batches of drug product	Stability data of 3 batches attached in section 3.2.P.8.3
	Documents for the procurement of API with approval from DRAP (in case of Import)	DRAP cleared invoice dated 29/10/2025 along with the import documents is attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence against the innovator product Tarlige is attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 3 batches is attached in section 3.2.S.7.3
	The status in reference regulatory authorities	Tarlige Tablet approved by PMDA Japan
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	General Tablet (Section approval is attached)
	Evaluation Remarks	
	Under export facilitation	
	Decision	
	Approved	
239	Case Category	Export Facilitation (Incharge Evaluation Cell)
	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	(8NN-EY5-N8MD, 2026-02-03)
	Detail of Fee Submitted	38700, 2025-10-01,
	The proposed proprietary name / brand name	Mirolin 2.5mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Mirogabalin Besylate equivalent to Mirogabalin.... 2.5mg
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	7's , 10's, 14's, 20's, 28's, 30's, 56's, 84's, 100's and 122's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30 C
	For generic drugs (me-too Status)	Miro Tablet by Nabi Qasim Industries
	Pharmacotherapeutic Group of (API)	Gabapentinoids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Gansu Haotian PharmaTech Co., Ltd.
	Detail of stability batches of drug product	Stability data of 3 batches attached in section 3.2.P.8.3
	Documents for the procurement of API with approval from DRAP (in case of Import)	DRAP cleared invoice dated 29/10/2025 along with the import documents is attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence against the innovator product Tarlige is attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 3 batches is attached in section 3.2.S.7.3
	The status in reference regulatory authorities	Tarlige Tablet approved by PMDA Japan
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	General Tablet (Section approval is attached)
	Evaluation Remarks	
	Under export facilitation	
	Decision	
	Approved	
240	Case Category	Routine (Iqra Aftab)
	Name, address of Applicant.	Biogen Life Sciences 8-KM, Chak Beli Road, Rawat, (000911)
	Application Form Dy. No / Tracking ID & date of submission	(VV7-B5U-8N8G, 2024-12-31)
	Detail of Fee Submitted	37000.0, 2024-12-19,
	The proposed proprietary name / brand name	Voricam 200mg Tablet
	Label Claim	Each film coated tablet contains: Voriconazole.....200mg
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	10's, 20's, 30's & 1-As per SRO
	Shelf Life (Unit)	3 Year(s)Room Condition
	For generic drugs (me-too Status)	Brand Name Voricon 200mg tablet Manufacturer Name Genome Pharmaceuticals
	Pharmacotherapeutic Group of (API)	.Attached
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. Maithili Life Sciences Private Limited Plot.No.2, APIIC Industrial Estate, Gajulamandyam Village, Renigunta Mandal, Chittoor District, Pincode-517520 Andhra Pradesh, India.
	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	Approved by: USFDA approved. Brand Name: Vfend 200mg Tablets
	GMP status of the firm	Attached
	Evidence of approval of manufacturing facility	.Attached
	Evaluation Remarks	
	Applicant has stated HPLC systems are not 21 CFR compliant	
	Decision	
	Rejected	
	Rejected, as the applicant stated that their HPLC system is not 21 CFR compliant and did not submit the required audit trail.	
241	Case Category	Routine (Iqra Aftab)
	Name, address of Applicant.	shrooq pharmaceuticals pvt ltd 21km feorzpur road lahore (000577)
	Application Form Dy. No / Tracking ID & date of submission	(82S-A4N-DGY1, 2024-08-29)
	Detail of Fee Submitted	30000.0, 9400 2024-07-25, 2026-05-11
	The proposed proprietary name / brand name	Cozil Dry Suspension
	Label Claim	Each 5ml reconstituted suspension contains: Fluconazole 50mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1×35ml-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30°C
	For generic drugs (me-too Status)	ATCO Laboratories
	Pharmacotherapeutic Group of (API)	Triazole antifungal agent
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Endoc Liesciences pvt Ltd.
	Detail of stability batches of drug product	T-002, T-003, T-004 Batch Size 150 bottles
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate attached dated: 21 March 2022.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Fonaz Dry powder Suspension 50mg/5ml PX008J
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data is as per Zone IV a condition.
	The status in reference regulatory authorities	MHRA
	GMP status of the firm	GMP certificate with validity 01-12-2026
	Evidence of approval of manufacturing facility	GMP certificate attached mentioning section for oral liquid.
	Evaluation Remarks	
	Decision	
	Approved	
242	Case Category	Routine (Iqra Aftab)
	Name, address of Applicant.	Jenner Pharmceuticals Pvt. Ltd Plot No. 03, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhupura (000823)

	Application Form Dy. No / Tracking ID & date of submission	(78Z-WH1-27RJ, 2024-07-10)
	Detail of Fee Submitted	30000.0, 2024-05-30,
	The proposed proprietary name / brand name	Vorijen Tablets 200mg
	Label Claim	Each Film Coated Tablet Contains: Voriconazole 200mg
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	10 s-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30C
	For generic drugs (me-too Status)	Vorif Tablets 200mg 069765
	Pharmacotherapeutic Group of (API)	Antimycotics for systemic use, triazole derivatives
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Hema Pharmaceuticals Pvt. Ltd. Plot No.6201/A&B, Opp: EWAC Alloys, Ltd. GIDC Estate, Ankleshwar- 393002 Dist. Bharuch, Gujarat, India
	Detail of stability batches of drug product	3 Batches with batch size 800 tablets DOM 11-2023 attached.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 13-October 2023 of M/s Dyson. Loan letter on M/s Dyson letter head attached. Loan agreement not attached.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference Product :Ferozsans Laboratories , Batch No: 240233 Pakistan
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study as per zone IVa attached.
	The status in reference regulatory authorities	MHRA/ Vfend 200mg film-coated tablets https://products.mhra.gov.uk/product/?product=VFEND%20200%20MG%20FILM-COATED%20TABLETS
	GMP status of the firm	GMP for export attached.
	Evidence of approval of manufacturing facility	Renewal of DML attached dated:August 2015 Tablet section available.
	Evaluation Remarks	
	Decision	
	Approved	
	Approved with JP Specs. Registration letter will be issued after loan verification and valid GMP certificate for local manufacturing.	
243	Case Category	Routine (Iqra Aftab)
	Name, address of Applicant.	CRYSTOLITE PHARMACEUTICALS Plot # 1 & 2, street S-2, National Industrial Zone Rawat, Islamabad (000778)
	Application Form Dy. No / Tracking ID & date of submission	(N36-ZT2-PLPJ, 2024-08-26)
	Detail of Fee Submitted	30000.0, 2024-08-16,
	The proposed proprietary name / brand name	Sitazole 2% craem
	Label Claim	Each gram contains: Sertaconazole nitrate 20mg
	Reference to Finished product specifications	As per Innovators Specification

Proposed Pack Size	2g,5g,10g,15g,30g -As per SRO
Shelf Life (Unit)	2 Year(s)Store below 30 degree
For generic drugs (me-too Status)	sertazole 2% craem by hudson pharma
Pharmacotherapeutic Group of (API)	antifungal medication of the imidazole class.
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	optimus drugs private limited
Detail of stability batches of drug product	007T24 DOM 04-24 008T24 DOM 04-24 009T24 DOM 04-24
Documents for the procurement of API with approval from DRAP (in case of Import)	CLEARANCE CERTIFICATE (Date of issue: 27-Nov-2023)
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies with Sertazole Cream by M/s Hudson Pharma.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of API as per zone IV a condition has been attached.
The status in reference regulatory authorities	ertaczo 2% cream by usfda approved
GMP status of the firm	Valid GMP certificate is attached.
Evidence of approval of manufacturing facility	GMP certificate mentions relevant section.
Evaluation Remarks	
Innovator product contains polyethylene glycol palmitostearate and the applied product contains propylene glycol palmitostearate, as per master formulation and BMR, now applicant states that they have used propylene glycol palmitostearate as per innovator. Method is not properly developed. The base line is unstable in chromatograms. The retention time of API at 0 month is 11 mins and at 6 months is 6 mins. Sequence audit trail is required for verification of chromatograms. All tests are same as per EU, Difference is that.•Limits of Assay as per In House is 98.5% to 101% and in EU its 99.0 to 101%. •In identification tests UV Visible test is mentioned along with FTIR in Inhouse Specs. •Related Substances are performed as per Inhouse Specs in which detector condition is same in both specs i.e. 220nm only difference in Flow rate and Mobile Phase composition. Names of all impurities are same in EU and Inhouse Specs.	
Decision	
Deferred	
The Registration Board deferred the case for submission of the following documents:	
• Revised master formulation in accordance with the innovator product.	
• Proper method development along with complete validation studies.	
• Adoption of EU specs. for Drug substance.	
Case Category	Contract Manufacturing (Iqra Aftab)
Name, address of Applicant.	McOlson Research Laboratories Pvt. Ltd Plot No. 02, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhpura Pakistan (000664)
Application Form Dy. No / Tracking ID & date of submission	(UNL-APX-Z53L, 2024-09-23)
Detail of Fee Submitted	75000.0, 18000.0 2024-06-27, 2024-09-13
The proposed proprietary name / brand name	Oltine 0.1 % Eye Drops
Label Claim	Each ml Contains: Olopatadine as Hydrochloride (USP).....1mg (1%) (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 30C

	For generic drugs (me-too Status)	Opat Ophthalmic Solution Alza Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Winbrains Research Laboratories-Plot No. 69/1, Phase I-II, Industrial Estate, Hattar, Haripur, KPK-
	The status in reference regulatory authorities	https://www.accessdata.fda.gov/drugsatfda_docs/la
	Detail of previous approval	
	Evaluation Remarks	
	Following shortcomings were communicated to the applicant: Provide the valid DML and GMP certificates for both the drug substance and drug product manufacturers. Submit the contract agreement. Provide stability data of the API till claimed shelf life. Specify which innovator/reference drug product the applied drug product is qualitatively similar to. For average volume or minimum fill, state the limits in volume units rather than percentages. Submit drug substance import documents, such as the clearance certificate or DRAP-attested invoice. Clearly mention the retest date or expiry date of the drug substance. Include the test for water loss as part of the specifications. Include assay of preservative at both release and shelf-life specification. Add particulate matter testing to the specifications. Include drop size and viscosity tests in the specifications and ensure they are performed. Two different stability summary data sheets (T-01 and T-001) with different batch sizes have been submitted, clarify. Submit in-use stability study data. Clarify the standards of different concentrations in the zero-time (initial) analysis. Identification by UV has not been performed for the drug product. The injection volume specified in USP is 30 µL, whereas 20 µL has been used for both API and DP testing, justify. The stated storage condition is 4–25°C, while the stability study conditions differ, justify. A peak has been observed at RT 0.5 in the attached chromatogram (305), justify. Verify the attached chromatograms using the audit trail and provide supporting snapshots. Provide the test method of the API as used by the drug product manufacturer. Applicant has stated "This Product of Winbrains (Olopatadine) is approved in 352 Meeting". But fee for pre-registration variation is required and inclusion of following tests in DP, if missing. Include the test for water loss, assay of preservative at both release and shelf-life specification, add particulate matter testing, drop size and viscosity tests in the specifications and in-use stability studies.	
	Decision	
	Approved	
	Firm shall submit requisite pre-registration variation fee as per the latest SRO and declaration as per contract policy notification F.No. 1-2/2022-DMC dated:13,June,2023.The following tests to be made part of DP specifications: water loss, assay of preservative at both release and shelf-life specification, add particulate matter testing, drop size and viscosity tests in the specifications and in-use stability studies.	
245	Case Category	Contract Manufacturing (Iqra Aftab)
	Name, address of Applicant.	McOlson Research Laboratories Pvt. Ltd Plot No. 02, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhpura Pakistan (000664)
	Application Form Dy. No / Tracking ID & date of submission	(9ZM-2ND-XBZ3, 2024-09-19)
	Detail of Fee Submitted	75000.0, 2024-06-27,
	The proposed proprietary name / brand name	Oltine 0.2% EyeDrops
	Label Claim	Each ml Contains: Olopatadine as Hydrochloride 2mg
	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 30C

	For generic drugs (me-too Status)	Optidine Eye Drops (Hudson Pharma)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Winbrains Research Laboratories-Plot No. 69/1, Phase I-II, Industrial Estate, Hattar, Haripur, KPK-
	The status in reference regulatory authorities	https://www.accessdata.fda.gov/drugsatfda_docs/la
	Detail of previous approval	
	Evaluation Remarks	
	Following shortcomings were communicated to the applicant: Provide valid DML and GMP certificates for both the drug substance and drug product manufacturers. Submit the contract agreement. Provide stability data of the API till claimed shelf life. Specify which innovator/reference drug product the applied drug product is qualitatively similar to. For average volume or minimum fill, state the limits in volume units rather than percentages. Submit drug substance import documents, such as the clearance certificate or DRAP-attested invoice. Clearly mention the retest date or expiry date of the drug substance. Include the test for water loss as part of the specifications. Include assay of preservative at both release and shelf-life specification. Add particulate matter testing to the specifications. Include drop size and viscosity tests in the specifications and ensure they are performed. Submit in-use stability study data. Clarify the standards of different concentrations in the zero-time (initial) analysis. Identification by UV has not been performed for the drug product. The injection volume specified in USP is 30 µL, whereas 20 µL has been used for both API and DP testing, justify. The stated storage condition is 4–25°C, while the stability study conditions differ, justify. A peak has been observed at RT 0.5 in the attached chromatogram (304), justify. Verify the attached chromatograms using the audit trail and provide supporting snapshots. Provide the test method of the API as used by the drug product manufacturer. Verify the attached chromatograms from attached audit trails and highlight. Applicant has stated "This Product of Winbrains (Olopatadine) is approved in 352 Meeting". But fee for pre-registration variation and commitment is required with inclusion of following tests in DP, test for water loss, assay of preservative at both release and shelf-life specification, add particulate matter testing, drop size and viscosity tests in the specifications and in-use stability studies, if missing in specifications of M/s Winbrains.	
	Decision	
	Approved	
	Firm shall submit requisite pre-registration variation fee as per the latest SRO and declaration as per contract policy notification F.No. 1-2/2022-DMC dated:13,June,2023.The following tests to be made part of DP specifications: water loss, assay of preservative at both release and shelf-life specification, add particulate matter testing, drop size and viscosity tests in the specifications and in-use stability studies.	
246	Case Category	New Section (Iqra Aftab)
	Name, address of Applicant.	Medwell Pharmaceuticals 1 km, terbella road, lawrencepur, faqirabad Attock (000699)
	Application Form Dy. No / Tracking ID & date of submission	(2UR-RJP-YJH8, 2026-03-19)
	Detail of Fee Submitted	38700, 2026-02-23,
	The proposed proprietary name / brand name	Azojin 250mg Capsule
	Label Claim	Each Capsule Contains: - Azithromycin Dihydrate Eq to Azithromycin 250mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30 degree Celsius
	For generic drugs (me-too Status)	Zetro 250mg Capsule Getz Pharma (Pvt) Limited Reg 045375
	Pharmacotherapeutic Group of (API)	Antibiotic

	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Ningxia Taiyicin Biotech Co., Ltd. Pacific Road No.1, Nuanquan Economic Zone, Helan County, Yinchuan, Ningxia, China
	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 APPROVED
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	Attached
	Evaluation Remarks	
	Exactly the Same Retention Time i.e. 11.449, 11.455 and 11.458 for all the sample chromatograms for 0 month, 3 months and 6 months analysis. The application was evaluated on 28 April 2026, and the applicant was requested to submit the following documents: Valid DML /GMP certificate of API manufacturer. Section 1.5.2 is missing. Complete characterization studies 3.2.S.3. COA of API by DP is of Tranexamic acid. COA of API is not readable. 3.2.S.5 REFERENCE STANDARD Applied product is qualitatively similar to which product. Identification test by FTIR to be performed. DT test to be made part of specs. System suitability not performed for dissolution. System suitability The test is not valid unless: in the chromatogram obtained with solution (2), the symmetry factor of the peak due to azithromycin is between 0.8 and 2.0; in the chromatogram obtained with solution (3), the resolution between the peaks due to impurity A and azithromycin is at least 1.5. Injection volume not mentioned in test method of dissolution and assay. System suitability not part of specs. The test is not valid unless, in the chromatogram obtained with solution (3), the resolution between the peaks due to impurity A and azithromycin is at least 1.5. Submit batch analysis 3.2.P.5.4. 3.2.P.6 Reference Standards or Materials DS specs are of USP and DP is of BP. Justify in the light of reference guidelines. DS verification studies by DP manufacturer. Commercial invoice is not readable. QTY of API taken as loan from M/s Winthrox. Original loan agreement to be attached. 3. Documents for the procurement of API with approval from DRAP (in case of import). M/S City Pharmaceuticals Locally Purchased. Clarification is required. Initiation letter is not within 15 days. At serial number 484 11-07-2025 in digital data logger the humidity is 44 %RH instead of 65%. Justify. At serial number 1541 01-08-2025 in digital data logger the humidity is 98.2 %RH instead of 65%. Justify. At serial number 1624, humidity is again out. 41.7%RH. The dissolution chromatograms are not clear no chromatographic conditions are visible on the chromatograms. Peak is also merged with other peaks.. Raw data sheet is also not clear. Dissolution of each unit should be provided separately with % release. Submit system suitability of dissolution as per BP. Attach audit trail of dissolution and assay. Sample information not appearing in both dissolution and assay chromatograms. Same RT for all the chromatograms 11.449, 11.455, 11.458	
	Decision	
	Rejected	
	The Registration Board rejected the application due to concerns regarding the authenticity of the submitted stability data, as the sample chromatograms exhibited identical retention times at 0 month, 3 months and 6 months stability intervals.	
247	Case Category	Contract Manufacturing (Iqra Aftab)
	Name, address of Applicant.	Wnsfeild Pharmaceuticals Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK (000610)
	Application Form Dy. No / Tracking ID & date of submission	(558-54A-WQ39, 2024-09-19)

	Detail of Fee Submitted	75000.0, 2024-06-24,
	The proposed proprietary name / brand name	OLP 0.1% Eye Drops
	Label Claim	Each ml Contains: Olopatadine as Hydrochloride 1mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C.
	For generic drugs (me-too Status)	Opat Ophthalmic 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.-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	
	Evaluation Remarks	
	The following deficiencies were communicated to the applicant: Provide the valid DML and GMP certificates for both the drug substance and drug product manufacturers. Submit the contract agreement. Provide stability data of the API till claimed shelf life. Specify which innovator/reference drug product the applied drug product is qualitatively similar to. For average volume or minimum fill, state the limits in volume units rather than percentages. Submit drug substance import documents, such as the clearance certificate or DRAP-attested invoice. Clearly mention the retest date or expiry date of the drug substance. Include the test for water loss as part of the specifications. Include assay of preservative at both release and shelf-life specification. Add particulate matter testing to the specifications. Include drop size and viscosity tests in the specifications and ensure they are performed. Two different stability summary data sheets (T-01 and T-001) with different batch sizes have been submitted, clarify. Submit in-use stability study data. Clarify the standards of different concentrations in the zero-time (initial) analysis. Identification by UV has not been performed for the drug product. The injection volume specified in USP is 30 µL, whereas 20 µL has been used for both API and DP testing, justify. The stated storage condition is 4–25°C, while the stability study conditions differ, justify. A peak has been observed at RT 0.5 in the attached chromatogram (305), justify. Verify the attached chromatograms using the audit trail and provide supporting snapshots. Provide the test method of the API as used by the drug product manufacturer. Now, the applicant has stated their product is already approved in M-352 meeting of RB. Pre-registration variation for change is status of data already approved and commitment as per contract manufacturing notification is required.	
	Decision	
	Approved	
	Firm shall submit requisite pre-registration variation fee as per the latest SRO and declaration as per contract policy notification F.No. 1-2/2022-DMC dated:13,June,2023.The following tests to be made part of DP specifications: water loss, assay of preservative at both release and shelf-life specification, add particulate matter testing, drop size and viscosity tests in the specifications and in-use stability studies.	
248	Case Category	New Section (Iqra Aftab)
	Name, address of Applicant.	Medwell Pharmaceuticals 1 km, terbella road, lawrencepur, faqirabad Attock (000699)
	Application Form Dy. No / Tracking ID & date of submission	(3JN-BZ4-4Z6Y, 2026-02-20)
	Detail of Fee Submitted	38700, 2026-01-30,
	The proposed proprietary name / brand name	Diclowl SR 100mg Capsules

Label Claim	Each sustained release Capsules Contains: - Diclofenac Sodium(as Diclofenac Sodium SR Pellets 32%)... 100mg (BP Specification)
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	10 s,30 s May bee-As per SRO
Shelf Life (Unit)	2 YearBelow 30 Degree Celsius
For generic drugs (me-too Status)	Phlogin 100mg Capsules Brookes Pharmaceuticals, Karachi,Reg#009129
Pharmacotherapeutic Group of (API)	Non-steroidal anti-inflammatory Drug.(NSAID)
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Vision Pharmaceuticals (Pvt.) Ltd. Plot No. 22-23, Industrial Triangle, Kahuta road Islamabad-Pakistan
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)	Attach
The status in reference regulatory authorities	Approved by HPRA Glenwood GmbH Pharmazeutische Germany Diclofenac sodium 100mg Modified Release capsule
GMP status of the firm	Valid
Evidence of approval of manufacturing facility	Valid

Evaluation Remarks

Query	Response	Evaluation
The entire DS part and even product development part mentions enteric coated pellet whereas, you have applied sustain release capsules.	The reference to "Sustained-Release Capsule" in certain sections of the dossier was a typographical/clerical error and does not reflect the actual dosage form of the product.We confirm that the formulation, manufacturing process, specifications, and all supporting data submitted correspond to an Enteric-Coated Pellet Capsule. The relevant sections have been corrected accordingly in the revised dossier.	Attached Module 1 and Module 2 are still of Sustain release in response.

Decision

Rejected

Rejected due to inconsistency between the applied formulation i.e. sustained release capsules and the submitted Module 3 data i.e. delayed release capsules.

249	Case Category	New Section (Iqra Aftab)
	Name, address of Applicant.	Medwell Pharmaceuticals 1 km, terbella road, lawrencepur, faqirabad Attock (000699)
	Application Form Dy. No / Tracking ID & date of submission	(SL7-TB4-SHLM, 2026-03-17)

	Detail of Fee Submitted	38700, 2026-01-30,
	The proposed proprietary name / brand name	Doxycel 100mg Capsule
	Label Claim	Labeling Claims Each Capsules Contains: - Doxycycline 100mg (BP Specification)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10 s,20s-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 degree Celsius
	For generic drugs (me-too Status)	Vibradoxin 100mg Capsules Plantinium Pharmaceuticals,
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	SHANDONG GUOBANG PHARMACEUTICAL CO., LTD. Address: No. 06335, Lingang Road, Green Chemical Industrial Park, Binhai Economic Development Zone, Weifang City, Shandong Province, P. R.
	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	Approved By USFDA
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	Attached
	Evaluation Remarks	
	The 6 months standard chromatograms show a print date of September, whereas the acquisition date is of December. It has also been observed that the standard peak areas for the 3 month and 6-month analyses are nearly identical, with only change in one digit.	
	Decision	
	Rejected	
	The Registration Board rejected the instant application due to serious concerns regarding the authenticity of the submitted stability data.	
250	Case Category	Routine (Iqra Aftab)
	Name, address of Applicant.	Horizon Healthcare (pvt.) ltd. 35-A Small Industrial Estate - Taxila (000856)
	Application Form Dy. No / Tracking ID & date of submission	(T24-RZS-95YT, 2025-10-06)
	Detail of Fee Submitted	75000.0, 2025-08-13,
	The proposed proprietary name / brand name	Perbo Ophthalmic Solution 3ml (100%)
	Label Claim	Each 3mL Multi-Dose Container Contains: Perfluorohexyloctane.....3ml (100%)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1×3ml -As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 30°C until opened
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	semifluorinated alkane

	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Kehui Pharmaceutical Co., Ltd., No. 9A1, Tianheng Road, Changjia Town, Gaoqing County, Zibo City, Shandong Province.,
	Detail of stability batches of drug product	POS-001, POS-002 Each of 500 Packs
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is attached. Commercial invoice attached without ADC attestation.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed with MIEBO Ophthalmic Solution 100%
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Conducted at Zone IV-a stability conditions.
	The status in reference regulatory authorities	MIEBO™, (USFDA Approved
	GMP status of the firm	w.e.f 16-08-2022 applied for renewal 21-12-2023
	Evidence of approval of manufacturing facility	DML# 000856
	Evaluation Remarks	
	Decision	
	Deferred	
	Deferred for the submission of the submission of the following documents:	
	i. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation.	
	ii. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07	
	iii. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.	
251	Case Category	New License (Iqra Aftab)
	Name, address of Applicant.	Well Go Pharmaceuticals (Pvt) Ltd 5-km, Raiwind Manga Road Lahore (001004)
	Application Form Dy. No / Tracking ID & date of submission	(6AU-2HR-174H, 2026-04-15)
	Detail of Fee Submitted	38700, 2026-04-03,
	The proposed proprietary name / brand name	Zedronil 4mg/5ml Infusion
	Label Claim	Each 5ml Contains: Zoledronic Acid(as Monohydrate)...4mg (As per Innovators Specifications.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5ml x 1s-As per SRO
	Shelf Life (Unit)	2 Year(s)Store Below 30 degree Celsius
	For generic drugs (me-too Status)	Zoleron 4mg Infusion M/s Genix pharmaceuticals Reg 081456
	Pharmacotherapeutic Group of (API)	Inhibitor of osteoclast-mediated bone resorption
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Synnat Pharma Private Limited, Plot No.60A, Jawaharlal Nehru Pharma City, Parawada Mandal, Anakapalli District-531019, Andhra Pradesh, India
	Detail of stability batches of drug product	Attached

	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan from M/s Biogen
	Pharmaceutical Equivalence and Comparative Dissolution Profile	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	.
	The status in reference regulatory authorities	MHRA Approved
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	Attached
	Evaluation Remarks	
	"It was observed that the chromatograms of M/s GMP Pharma (Pvt.) Ltd. and M/s Well Go are identical." Other Shortcomings Fee challan mention 4mg/100ml. Fee challan for 4mg/5ml is required. Evidence of SVP section. Reference/ innovator product "Zometa® (zoledronic acid for injection) For Intravenous Infusion "Each vial contains 4.264 mg zoledronic acid monohydrate, corresponding to 4 mg zoledronic acid on an anhydrous basis, 220 mg of mannitol, applied product contains only 5mg mannitol Mannitol, USP, is bulking agent applicant has mentioned Isotonic. Submit evidence of reference regulatory authority in which it is used as isotonicity agent(with 5mg strength) instead of bulking. Batch type (commercial or otherwise)used for manufacturing, as the batch size mentioned on COA is 0.05 kg not provided. Details for Reference Standards or Materials under 3.2.S.5 and 3.2.P.6 is missing.File is not readable. Audit trail is missing. The manufacturing of batches is 20-08-2025 whereas, analysis date is 14-08-2025.Submitting new BMR with change of date is not justifiable. Supporting data of dilution studies like chromatograms with 100 mL of sterile 0.9% Sodium Chloride, USP, or 5% Dextrose Injection, USP is missing. Chromatograms of M/s GMP pharma are attached.	
	Decision	
	Rejected	
	The Registration Board rejected the application due to concerns regarding the authenticity of the submitted stability data, as chromatograms attached in the query response of M/s Well Go Pharmaceuticals were found to be of M/s GMP Pharma (Pvt.) Ltd.	
252	Case Category	Import (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	MS Enterprises P42/2, Opp Municipal Degree College, Jaranwala Road Faisalabad (063310168118843D)
	Application Form Dy. No / Tracking ID & date of submission	(7Y8-3L6-HB6Y, 2025-06-25)
	Detail of Fee Submitted	300000.0, 2025-06-23,
	The proposed proprietary name / brand name	Alcofan 6%
	Label Claim	Each 1 ml contains: Ketoprofen 60mg
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	50ml Vial-De-Controlled
	Shelf Life (Unit)	2 YearStore at Temperature not exceeding 30°C used after opening for 28 days when stored at temperature not exceeding 30°C
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Eva Pharma for Pharmaceuticals and Medical Applian-176 El Sadat st. from Elmansouriya Canal - Kafr El Gabal -El Giza.-Egypt

	Name, address of Marketing Authorization Holder:	Eva Pharma for Pharmaceuticals and Medical Applian, 176 El Sadat st. from Elmansouriya Canal - Kafr El Gabal -El Giza., Egypt
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
	Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy	
253	Case Category	Routine (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Muller & Phipps Pakistan (Pvt) Ltd. Uzma Court Main Clifton Road Karachi (264)
	Application Form Dy. No / Tracking ID & date of submission	(UPV-YA5-5VAS, 2025-07-29)
	Detail of Fee Submitted	300000.0, 2025-05-09,
	The proposed proprietary name / brand name	SmofKabiven Peripheral, Emulsion for infusion
	Label Claim	Do not store above 25°C. Do not freeze. Store in overpouch.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4 X 1206 mL-As per SRO, 4 X 1448 mL-As per SRO, 4 X 1904 mL -As per SRO
	Shelf Life (Unit)	18 Month(s) Do not store above 30°C
	For generic drugs (me-too Status)	None
	Pharmacotherapeutic Group of (API)	1. Cargill S.L.U. C/Marie Curie, 6 Spain-08760 Martorell (Barcelona) 2. Merck KGaA Frankfurter Strasse 250 Germany
	Name, address of Manufacturing site:	M/s. Fresenius Kabi AB-Fresenius Kabi AB, Ragsgatan 7, Uppsala 751 74, Sweden-Sweden
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference standards have been attached
	Name, address of Marketing Authorization Holder:	M/s. Muller & Phipps Pakistan Private Limited, Uzma Court, Main Clifton Road Karachi. Godown: Plot No. 208/1, Sector 23 Korangi Industrial Area Karachi, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	It complies with the principles and guidelines of GMP laid down in Directive (EU) 2017/1572, Commission Delegated Regulation (EU) 2017/1569.
	Details of Authorization Letter :	Active substance along with the site and the manufacturing operation
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Documents attached including the stability summary, post approval stability
	The status in reference regulatory authorities	Approved in Sweden UK Switzerland Germany
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	

	Decision	
	Deferred	
	In compliance with the decision taken by the RB, please submit following information/ documents for further processing of your application(s):	
	i. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation. ii. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07 iii. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.	
254	Case Category	Import (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Muller & Phipps Pakistan (Pvt) Ltd. Uzma Court Main Clifton Road Karachi (264)
	Application Form Dy. No / Tracking ID & date of submission	(744-6SQ-HZMW, 2025-07-29)
	Detail of Fee Submitted	300000.0, 2025-05-09,
	The proposed proprietary name / brand name	SmofKabiven, emulsion for infusion
	Label Claim	Do not store above 25 °C. Don't freeze.
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1970 ml-As per SRO,2463 ml-As per SRO,986 ml-As per SRO
	Shelf Life (Unit)	24 MonthDo not store above 25°C
	For generic drugs (me-too Status)	None
	Pharmacotherapeutic Group of (API)	1. Evonik Rexim (Nanning) Pharmaceutical Co., Ltd. China. 2. Evonik Rexim (Nanning) Pharmaceutical Co., Ltd. Japan
	Name, address of Manufacturing site:	M/s. Fresenius Kabi AB-Fresenius Kabi AB, Ragsgatan 7, Uppsala 751 74, Sweden-Sweden
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference standards have been attached
	Name, address of Marketing Authorization Holder:	M/s. Muller & Phipps Pakistan Private Limited, Uzma Court, Main Clifton Road Karachi. Godown: Plot No. 208/1, Sector 23 Korangi Industrial Area Karachi, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	it complies with the principles and guidelines of GMP laid down in Directive (EU) 2017/1572, Commission Delegated Regulation (EU) 2017/1569.
	Details of Authorization Letter :	Active substance along with the site and the manufacturing operation
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Documents attached including the stability summary, post approval stability
	The status in reference regulatory authorities	Approved in Sweden UK Normay
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
	Decision	

Deferred

In compliance with the decision taken by the RB, please submit following information/ documents for further processing of your application(s):

- i. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation.
- ii. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07
- iii. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.

255	Case Category	Routine (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Titlis Pharma (Private) Limited 528-A Sundar Industrial Estate, Lahore (05-352-0066-035681D)
	Application Form Dy. No / Tracking ID & date of submission	(EUP-61S-531X, 2024-11-27)
	Detail of Fee Submitted	300000.0, 2024-11-15,
	The proposed proprietary name / brand name	Ketocleen
	Label Claim	Each medicated plaster contains 30 mg of Ketoprofen.
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	5's, 7's & 10's-De-Controlled
	Shelf Life (Unit)	3 YearStore at room temperature (1 ~ 30 °C)
	For generic drugs (me-too Status)	KefenTech Plaster
	Pharmaceutical Group of (API)	
	Name, address of Manufacturing site:	Sin Sin Pharmaceutical Co., Ltd-9, Sojeongsandandong-ro, Sojeong-myeon, Sejong-si, Republic of Korea-South Korea
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	Sin Sin Pharmaceutical Co., Ltd., 9, Sojeongsandandong-ro, Sojeong-myeon, Sejong-si, Republic of Korea, South Korea
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Mohrus Pap (PMDA Approved)
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
	Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy	
256	Case Category	Export Facilitation (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Hoechst Pakistan Limited Plot 23, Sector 22, Korangi Industrial Area, (000007)
	Application Form Dy. No / Tracking ID & date of submission	(Z11-GE5-6V82, 2026-01-28)

	Detail of Fee Submitted	38700, 2026-01-05,
	The proposed proprietary name / brand name	Avibac 2g/0.5g Injection
	Label Claim	Each Vial Contains: Ceftazidime Pentahydrate eq. to Ceftazidime 2g Avibactam Sodium Eq. to Avibactam 0.5g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO,10's-As per SRO,5's-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 30°C. Protect from light
	For generic drugs (me-too Status)	Zavicefta 2g/0.5g Marketed by Lucky core Industries Limited (Formerly Pfizer Laboratories Ltd) (Reg. No. 106848)
	Pharmacotherapeutic Group of (API)	Cephalosporins / Beta lactamase Inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	N/A
	Detail of stability batches of drug product	Batch # NPD041, NPD042, NPD043, Accelerated Stability Studies = 40 ± 2 °C & RH 75 ± 5 % & Real Time Stability Studies = 30 ± 2 °C & RH 65 ± 5 %. Data submitted for 3 months with commitment to complete the studies till the assigned shelf life.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Drug import license attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Zavicefta Injection 2g/0.5g by Pfizer Pakistan Limited
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 3 batches (2001GJ85JB, 2002GJ85JB & 2003GJ85JB) submitted both accelerated (6M) and real time (36M)
	The status in reference regulatory authorities	Zavicefta 2 g/0.5 g by MHRA UK
	GMP status of the firm	GMP Certified. valid up to: 18-Sep-2026
	Evidence of approval of manufacturing facility	Injectables (Dry Powder) Cephalosporins
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
257	Case Category	Export Facilitation (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Hoechst Pakistan Limited Plot 23, Sector 22, Korangi Industrial Area, (000007)
	Application Form Dy. No / Tracking ID & date of submission	(YGU-RNN-PX8T, 2025-10-03)
	Detail of Fee Submitted	75000.0, 2025-08-06,
	The proposed proprietary name / brand name	APROVECST TABLETS 300mg+5mg (Irbesartan + Amlodipine)
	Label Claim	Each Film-coated tablet contains: Irbesartan.....300mg + Amlodipine Besylate eq. to Amlodipine.....5mg
	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,30's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 C

	For generic drugs (me-too Status)	Not applicable
	Pharmacotherapeutic Group of (API)	Antihypertensive
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	N/A
	Detail of stability batches of drug product	Batch # NPD009, NPD010, NPD011, Accelerated Stability Studies = $40 \pm 2^{\circ}\text{C}$ & RH $75 \pm 5\%$ & Real Time Stability Studies = $30 \pm 2^{\circ}\text{C}$ & RH $65 \pm 5\%$ for 6 months.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 7 & Invoice documents attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP for the quality test are submitted against the innovator drug Aprovasc Tablet by M/s Sanofi.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Irbesartan: Stability data of 3 batches (L0102320230301M, L0102320230401M & L0102320230402M) submitted both accelerated (6M) and real time (24M) Amlodipine: Stability data of 3 batches (AAMB-II21002, AAMB-II21003 & AAMB-II21004) submitted both accelerated (6M) and real time (36M)
	The status in reference regulatory authorities	APREXEVO 300mg/5mg by M/s Sanofi, France
	GMP status of the firm	GMP Certified. valid up to: 18-Sep-2026
	Evidence of approval of manufacturing facility	Tablet Section approved
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Deferred	
	In compliance with the decision taken by the RB, please submit following information/ documents for further processing of your application(s):	
	i. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation.	
	ii. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07	
	iii. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.	
258	Case Category	Export Facilitation (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Hoechst Pakistan Limited Plot 23, Sector 22, Korangi Industrial Area, (000007)
	Application Form Dy. No / Tracking ID & date of submission	(XTP-YLH-SJNY, 2025-10-03)
	Detail of Fee Submitted	75000.0, 2025-08-06,
	The proposed proprietary name / brand name	Aprovecst Tablets 300mg+10mg
	Label Claim	Each Film-coated tablet contains: Irbesartan.....300mg + Amlodipine Besylate eq. to Amlodipine.....10mg
	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, 30's-As per SRO

Shelf Life (Unit)	2 YearStore below 30°C. Protect from light
For generic drugs (me-too Status)	Not Applicable
Pharmacotherapeutic Group of (API)	Antihypertensive
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	N/A
Detail of stability batches of drug product	Batch # NPD012, NPD013, NPD014, Accelerated Stability Studies = 40 ± 2 °C & RH 75 ± 5 % & Real Time Stability Studies = 30 ± 2 °C & RH 65 ± 5 % for 6 months
Documents for the procurement of API with approval from DRAP (in case of Import)	Form 7 & Invoice documents attached
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP for the quality test are submitted against the innovator drug Aprovasc Tablet by M/s Sanofi.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Irbesartan: Stability data of 3 batches (L0102320230301M, L0102320230401M & L0102320230402M) submitted both accelerated (6M) and real time (24M) Amlodipine: Stability data of 3 batches (AAMB-II21002, AAMB-II21003 & AAMB-II21004) submitted both accelerated (6M) and real time (36M)
The status in reference regulatory authorities	APREXEVO 300mg/10mg by M/s Sanofi, France
GMP status of the firm	GMP Certified. valid up to: 18-Sep-2026
Evidence of approval of manufacturing facility	Liquid Injectable (SVP) Section approved
Evaluation Remarks	
the application is complete as per codal formalities for consideration by the Registration Board	
Decision	
Deferred	
In compliance with the decision taken by the RB, please submit following information/ documents for further processing of your application(s):	
i. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation.	
ii. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07	
iii. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.	
259	Case Category
	Export Facilitation (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.
	Hoechst Pakistan Limited Plot 23, Sector 22, Korangi Industrial Area, (000007)
	Application Form Dy. No / Tracking ID & date of submission
	(W7M-AT5-3U9G, 2025-10-03)
	Detail of Fee Submitted
	37000.0, 2025-05-13,
	The proposed proprietary name / brand name
	Perasul 2g Injection IV/IM
	Label Claim
	Each vial contains: Cefoperazone Sodium eq. to Cefoperazone 1g + Sulbactam sodium eq. to Sulbactam 1g
	Reference to Finished product specifications
	As per Innovators Specification
	Proposed Pack Size
	1's-De-Controlled

	Shelf Life (Unit)	2 YearStore between 15°C to 30°C
	For generic drugs (me-too Status)	2SUM 2g Injection by SAMI Pharmaceuticals, Manufactured by Healthtek (Pvt) Ltd (Reg. No. 047003)
	Pharmacotherapeutic Group of (API)	Cefoperazon Sodium - (Third-generation cephalosporins); Sulbactam Sodium - (Beta-lactamase inhibitors)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Batch # NPD007, NPD008, NPD009, Accelerated Stability Studies = 40 ± 2 °C & RH 75 ± 5 % & Real Time Stability Studies = 30 ± 2 °C & RH 65 ± 5 %. Data submitted for 3 months with commitment to complete the studies till the assigned shelf life.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 7, Invoice, Airwaybill and Goods Declaration documents attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence for the quality test is submitted for Perasul 2g Injection against the comparator drug 2SUM 2g Injection by SAMI Pharmaceuticals (Manufactured by Healthtek (Pvt.) Ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 3 batches (9001HKS1NG, 9002HKS1NG & 900311101NG) submitted both accelerated (6M) and real time (24M)
	The status in reference regulatory authorities	Sulperazon Injection approved by AIFA, Italy
	GMP status of the firm	GMP Certified. valid up to: 18-Sep-2026
	Evidence of approval of manufacturing facility	Dry Powder Injectable (Cephalosporin) Section approved
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
260	Decision	
	Approved	
	Case Category	Export Facilitation (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Hoechst Pakistan Limited Plot 23, Sector 22, Korangi Industrial Area, (000007)
	Application Form Dy. No / Tracking ID & date of submission	(SNB-DU4-VTM3, 2025-09-30)
	Detail of Fee Submitted	75000.0, 2025-08-06,
	The proposed proprietary name / brand name	APROVECST TABLETS 150mg+10mg (Irbesartan + Amlodipine)
	Label Claim	Each Film-coated tablet contains: Irbesartan.....150mg + Amlodipine Besylate eq. to Amlodipine.....10mg
	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,30's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 C
	For generic drugs (me-too Status)	Not applicable
	Pharmacotherapeutic Group of (API)	Antihypertensive

Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	N/A
Detail of stability batches of drug product	Batch # NPD004, NPD005, NPD006, Accelerated Stability Studies = $40 \pm 2^{\circ}\text{C}$ & RH $75 \pm 5\%$ & Real Time Stability Studies = $30 \pm 2^{\circ}\text{C}$ & RH $65 \pm 5\%$ for 6 months.
Documents for the procurement of API with approval from DRAP (in case of Import)	Form 7 & Invoice documents attached
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP for the quality test are submitted against the innovator drug Aprovasc Tablet by M/s Sanofi.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Irbesartan: Stability data of 3 batches (L0102320230301M, L0102320230401M & L0102320230402M) submitted both accelerated (6M) and real time (24M) Amlodipine: Stability data of 3 batches (AAMB-II21002, AAMB-II21003 & AAMB-II21004) submitted both accelerated (6M) and real time (36M)
The status in reference regulatory authorities	APREXEVO 150mg/10mg by M/s Sanofi, France
GMP status of the firm	GMP Certified. valid up to: 18-Sep-2026
Evidence of approval of manufacturing facility	Tablet Section approved
Evaluation Remarks	
the application is complete as per codal formalities for consideration by the Registration Board	
Decision	
Deferred	
In compliance with the decision taken by the RB, please submit following information/ documents for further processing of your application(s):	
i. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation.	
ii. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07	
iii. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.	
261	Case Category
	Export Facilitation (Muhammad Sarfraz Nawaz)
	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
	(GGD-W6H-3458, 2025-03-11)
	Detail of Fee Submitted
	300000.0, 2024-08-08,
	The proposed proprietary name / brand name
	Dexopal Capsule 30mg
	Label Claim
	Each enteric coated capsule contains: Dexlansoprazole 22.5% (Dual Delayed Release Pellets) Equivalent to Dexlansoprazole ... 30mg (FP: As per Innovator's Specifications)
	Reference to Finished product specifications
	As per Innovators Specification
	Proposed Pack Size
	2 x 15's-De-Controlled
	Shelf Life (Unit)
	2 YearBelow 30°C
	For generic drugs (me-too Status)
	Dexxo Capsule 30mg

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Integrin Healthcare Pvt.Ltd
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	DEXILANT (Delayed Release Capsule) Mfg:Takeda Pharmaceuticals America, Inc
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
262	Case Category	Export Facilitation (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Hoechst Pakistan Limited Plot 23, Sector 22, Korangi Industrial Area, (000007)
	Application Form Dy. No / Tracking ID & date of submission	(EVE-1JA-3YWM, 2025-10-30)
	Detail of Fee Submitted	75000.0, 2025-08-06,
	The proposed proprietary name / brand name	Aprovecst Tablets 150mg+5mg
	Label Claim	Each Film-coated Tablet Contains: Irbesartan.....150mg + Amlodipine Besylate eq. to Amlodipine 5mg
	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,30's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C. Protect from light
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	Antihypertensive
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	N/A
	Detail of stability batches of drug product	Batch # NPD003, NPD006, NPD007, Accelerated Stability Studies = 40 ± 2 °C & RH 75 ± 5 % & Real Time Stability Studies = 30 ± 2 °C & RH 65 ± 5 % for 6 months
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 7 & Invoice documents attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP for the quality test are submitted against the innovator drug Aprovasc Tablet by M/s Sanofi.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Irbesartan: Stability data of 3 batches (L0102320230301M, L0102320230401M & L0102320230402M) submitted both accelerated (6M) and real time (24M) Amlodipine: Stability

		data of 3 batches (AAMB-II21002, AAMB-II21003 & AAMB-II21004) submitted both accelerated (6M) and real time (36M)
	The status in reference regulatory authorities	APREXEVO 150mg/5mg by M/s Sanofi, France
	GMP status of the firm	GMP Certified. valid up to: 18-Sep-2026
	Evidence of approval of manufacturing facility	Liquid Injectable (SVP) Section approved
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Deferred	
	In compliance with the decision taken by the RB, please submit following information/ documents for further processing of your application(s):	
	i. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation.	
	ii. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07	
	iii. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.	
263	Case Category	Export Facilitation (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Hoechst Pakistan Limited Plot 23, Sector 22, Korangi Industrial Area, (000007)
	Application Form Dy. No / Tracking ID & date of submission	(81H-AGP-T7QD, 2025-10-06)
	Detail of Fee Submitted	37000.0, 2025-05-13,
	The proposed proprietary name / brand name	Perasul 1g Injection IV/IM
	Label Claim	Each vial contains: Cefoperazone Sodium eq. to Cefoperazone 500mg + Sulbactam sodium eq. to Sulbactam 500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	2 YearStore between 15°C to 30°C
	For generic drugs (me-too Status)	2SUM 1g Injection by SAMI Pharmaceuticals, Manufactured by Healthtek (Pvt) Ltd (Reg. No. 047002)
	Pharmacotherapeutic Group of (API)	Cefoperazon Sodium - (Third-generation cephalosporins); Sulbactam Sodium - (Beta-lactamase inhibitors)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Batch # NPD004, NPD005, NPD006, Accelerated Stability Studies = 40 ± 2 °C & RH 75 ± 5 % & Real Time Stability Studies = 30 ± 2 °C & RH 65 ± 5 %. Data submitted for 3 months with commitment to complete the studies till the assigned shelf life.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 7, Invoice, Airwaybill and Goods Declaration documents attached

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence for the quality test is submitted for Perasul 1g Injection against the comparator drug 2SUM 1g Injection by SAMI Pharmaceuticals (Manufactured by Healthtek (Pvt.) Ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 3 batches (9001HKS1NG, 9002HKS1NG & 900311101NG) submitted both accelerated (6M) and real time (24M)
	The status in reference regulatory authorities	Sulperazon Injection approved by PMDA Japan
	GMP status of the firm	GMP Certified. valid up to: 18-Sep-2026
	Evidence of approval of manufacturing facility	Dry Powder Injectable (Cephalosporin) Section approved
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
264	Case Category	Export Facilitation (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Hoechst Pakistan Limited Plot 23, Sector 22, Korangi Industrial Area, (000007)
	Application Form Dy. No / Tracking ID & date of submission	(7UQ-666-6MUW, 2026-02-12)
	Detail of Fee Submitted	38700, 2025-10-20,
	The proposed proprietary name / brand name	Finova 10mg Tablets
	Label Claim	Each Film coated tablet contains: Finerenone.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's-As per SRO, 2x10's-As per SRO, 2x7's-As per SRO, 3x10's-As per SRO, 4x7's-As per SRO
	Shelf Life (Unit)	2 YearDo not store above room temperature 25°C.
	For generic drugs (me-too Status)	Fenhil 10mg by Hilton Pharma Pvt. Ltd (Reg No. 120319)
	Pharmacotherapeutic Group of (API)	Mineralocorticoid receptor (MR) antagonists
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	N/A
	Detail of stability batches of drug product	Batch # NPD033, NPD034, NPD035, Accelerated Stability Studies = 40 ± 2 °C & RH 75 ± 5 % & Real Time Stability Studies = 30 ± 2 °C & RH 65 ± 5 %. Data submitted for 3 months with commitment to complete the studies till the assigned shelf life.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Drug import license attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP: Finova tablet against the comparator drug Fenhil tablet by Hilton Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 3 batches (HF200202, HF200212 & HF200220) submitted both accelerated (6M) and real time (24M)
	The status in reference regulatory authorities	Kerendia Tablet approved by US FDA
	GMP status of the firm	GMP Certified. valid up to: 18-Sep-2026

	Evidence of approval of manufacturing facility	Tablet Section approved
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
265	Case Category	Export Facilitation (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Hoechst Pakistan Limited Plot 23, Sector 22, Korangi Industrial Area, (000007)
	Application Form Dy. No / Tracking ID & date of submission	(6M5-8XA-SW15, 2025-10-02)
	Detail of Fee Submitted	37000.0, 2025-05-13,
	The proposed proprietary name / brand name	Perasul 0.5g Injection IV/IM
	Label Claim	Each vial contains: Cefoperazone Sodium eq. to Cefoperazone 250mg; Sulbactam sodium eq. to Sulbactam 250mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	2 YearStore between 15°C to 30°C
	For generic drugs (me-too Status)	2SUM 500mg Injection Manufactured by Healthtek (Pvt) Ltd (Reg. No. 079941)
	Pharmacotherapeutic Group of (API)	Cefoperazon Sodium - (Third-generation cephalosporins); Sulbactam Sodium - (Beta-lactamase inhibitors)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Batch # NPD001, NPD002, NPD003, Accelerated Stability Studies = 40 ± 2 °C & RH 75 ± 5 % & Real Time Stability Studies = 30 ± 2 °C & RH 65 ± 5 %. Data submitted for 3 months with commitment to complete the studies till the assigned shelf life.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 7, Invoice, Airwaybill and Goods Declaration documents attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence for the quality test is submitted for Perasul 0.5g Injection against the comparator drug 2SUM 500mg Injection by SAMI Pharmaceuticals (Manufactured by Healthtek (Pvt.) Ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 3 batches (9001HKS1NG, 9002HKS1NG & 900311101NG) submitted both accelerated (6M) and real time (24M)
	The status in reference regulatory authorities	Sulperazon Injection approved by PMDA Japan
	GMP status of the firm	GMP Certified. valid up to: 18-Sep-2026
	Evidence of approval of manufacturing facility	Dry Powder Injectable (Cephalosporin) Section approved
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	

266	Case Category	Export Facilitation (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Hoechst Pakistan Limited Plot 23, Sector 22, Korangi Industrial Area, (000007)
	Application Form Dy. No / Tracking ID & date of submission	(46S-RJ3-T9E7, 2026-02-12)
	Detail of Fee Submitted	38700, 2025-10-20,
	The proposed proprietary name / brand name	Finova 20mg Tablets
	Label Claim	Each Film coated tablet contains: Finerenone.....20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's-As per SRO,2x10's-As per SRO,2x7's-As per SRO,3x10's-As per SRO,4x7's-As per SRO
	Shelf Life (Unit)	2 YearDo not store above room temperature 25°C.
	For generic drugs (me-too Status)	Fenhil 20mg by Hilton Pharma Pvt. Ltd (Reg No. 120320)
	Pharmacotherapeutic Group of (API)	Mineralocorticoid receptor (MR) antagonists
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	N/A
	Detail of stability batches of drug product	Batch # NPD036, NPD037, NPD038, Accelerated Stability Studies = 40 ± 2 °C & RH 75 ± 5 % & Real Time Stability Studies = 30 ± 2 °C & RH 65 ± 5 %. Data submitted for 3 months with commitment to complete the studies till the assigned shelf life.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Drug import license attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP: Finova tablet against the comparator drug Fenhil tablet by Hilton Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 3 batches (HF200202, HF200212 & HF200220) submitted both accelerated (6M) and real time (24M)
	The status in reference regulatory authorities	Kerendia Tablet approved by US FDA
	GMP status of the firm	GMP Certified. valid up to: 18-Sep-2026
	Evidence of approval of manufacturing facility	Tablet Section approved
267	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
267	Case Category	Export Facilitation (Muhammad Sarfraz Nawaz)
	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	(1WT-B7N-DBGQ, 2026-03-11)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-08, 2025-07-30
	The proposed proprietary name / brand name	Relief Plus Sachet
	Label Claim	Each sachet contains: Omeprazole 40mg Sodium bicarbonate 1680mg (FP: As per Innovator's Specifications)

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Teph Insta 40mg/1680mg (Omeprazole/Sodium Bicarbonate)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Metrochem Private Limited
	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	Zegerid (Salix Pharmaceuticals, U.S.A., Inc)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
268	Case Category	Export Facilitation (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Hoechst Pakistan Limited Plot 23, Sector 22, Korangi Industrial Area, (000007)
	Application Form Dy. No / Tracking ID & date of submission	(RJA-W2D-UPHG, 2025-06-20)
	Detail of Fee Submitted	93000.0, 2025-04-30,
	The proposed proprietary name / brand name	Ticasure 90mg Tablet
	Label Claim	Each film coated tablet contains: Ticagrelor 90mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10's, 14's, 20's, 28-As per SRO
	Shelf Life (Unit)	2 YearStore at or below 30°C in dry and dark place
	For generic drugs (me-too Status)	Hitica 90mg Tablet by Highnoon
	Pharmacotherapeutic Group of (API)	Platelet aggregation inhibitors excluding heparin (B01AC24)
	Name, address of Manufacturing site:	Highnoon Laboratories Limited-17.5 Km Multan Road, Lahore-
	Name & address of API manufacturer	N/A
	Detail of stability batches of drug product	Batches used are 1) 202552, 211607 & 221694. Accelerated Stability at 40° ± 2°C, 75 ± 5% and Long-term stability at 30° ± 2° C, 65 ± 5% (Reports attached in 3.2.P.8)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Inoive No. CV120199 Dated 11 Aug 2020 & Invoice No. NT121168 Dated 5 Jan 2022 (Invoices are attached in 1.6.5)

	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP is performed against Innovator brand BRILINTA 90mg Tablet and results are compliant. (Attached in 3.2.P.2.2.1)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated Stability at 40° ± 2°C, 75 ± 5% and Long-term stability at 30° ± 2° C, 65 ± 5% (Reports attached in 3.2.S.7)
	The status in reference regulatory authorities	Brilique 90 mg film coated tablets approved by Health Canada
	GMP status of the firm	GMP attached valid till 18 Sep 2028 (Attached in 1.4.3)
	Evidence of approval of manufacturing facility	DML attached along with Renewal acknowledgment copy (Attached in 1.3.4)
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
269	Case Category	Routine (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	punjnad pharma PVT LTD 35-km shamy bhattian multan road lahore (053520066059717D)
	Application Form Dy. No / Tracking ID & date of submission	(HUW-QXU-3H1A, 2025-03-12)
	Detail of Fee Submitted	300000.0, 2025-02-26,
	The proposed proprietary name / brand name	FIPROES DOG SPOT-ON SOLUTION
	Label Claim	Fiproes Dog Spot-on Solution is used in dogs; in the treatment and control of flea (Ctenocephalides sp.), ticks (Rhipicephalus sp. Dermacentor sp., Ixodes sp.), biting lice (Trichodectes canis); for the control of allergic dermatitides (FAD); to prevent the development of eggs, larvae and pupa of fleas. Multiple applications on a monthly basis are advised to eliminate mites properly. Fiproes Dog Spot-on Solution is effective for 2 months on mature, larvae or pupa forms of flea and flea eggs and 1 month against ticks depending on the infestation intensity. Newly arrived fleas are killed within 24 hours.
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	1.34 ML-De-Controlled
	Shelf Life (Unit)	3 YearSTORE BELOW 25 DEGREE CENTIGRADE
	For generic drugs (me-too Status)	NOT AVAILABLE
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	TEKNOVET ILAC SAN. VE TIC. A.S.-C.O.S.B. GHAZI USMAN PASA MAHALLESİ 18. SOKAK NO:3 59500 CERKEZKOY TEKIRGAD-Turkey
	Name, address of Marketing Authorization Holder:	PUNJNAD PHARMA (PVT)LTD, 35-KM, MULTAN ROAD, SHAMKEY BHATTIAN LAHORE, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
	Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy	
270	Case Category	Export Facilitation (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Haleon Pakistan Limited Petaro Road, Jamshoro (000010)
	Application Form Dy. No / Tracking ID & date of submission	(E67-1LJ-E67E, 2025-12-18)
	Detail of Fee Submitted	38700.0, 2025-08-08,
	The proposed proprietary name / brand name	Panadol Migraine
	Label Claim	Each caplet contains:
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	20's-De-Controlled, 24's-De-Controlled
	Shelf Life (Unit)	2 Yearstore below 30°C
	For generic drugs (me-too Status)	N/A
	Pharmaceutical Group of (API)	ATC Code: N02B E51 Paracetamol Combinations
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Lianyungang Kangle Pharmaceutical Co., Ltd. No. 2, Huanan Road, Ganyu Economic Development Zone, Lianyungang, NOVACYL1 Usine de St-Fons Rue Prosper Monnet F- 69190 St-FONS, FRANCE DUNS N°: 38-366-1402 GPS Coordinates of site entrance: N 45.706824° E 4.848589°, Siegfried PharmaChemikalien Minden GmbH Karlstraße 15–39, 42–44 32423 Minden, THE ANDHRA SUGARS LIMITED, Venkatarayapuram, West Godavari District, Tanuku - 534 215, ANDHRA PRADESH
	Detail of stability batches of drug product	AV5P, AV5R, AV5S
	Documents for the procurement of API with approval from DRAP (in case of Import)	DRAP NOCs are provided in Module 3 with 6-point stability data
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE & CDP performed and provide in Module 3
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability of each API is conducted at zone IV condition
	The status in reference regulatory authorities	Panadol Migraine Caplet Manufactured by GSK Consumer Health care USA approved by USFDA
	GMP status of the firm	GMP certificate is valid till 05 March 2027
	Evidence of approval of manufacturing facility	Drug Manufacturing License is provided in Module 1
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Deferred	

	In compliance with the decision taken by the RB, please submit following information/ documents for further processing of your application(s): i. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation. ii. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07 iii. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.	
271	Case Category	Routine (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	u.m.enterprises plot no.12 sector 15 korangi industrial area-74900 (313)
	Application Form Dy. No / Tracking ID & date of submission	(NSW-H8Z-H64B, 2025-04-30)
	Detail of Fee Submitted	300000.0, 2025-04-21,
	The proposed proprietary name / brand name	Bovicef LA
	Label Claim	Each 1mL contains: 75m g of cefquinome sulfate
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	36 MonthStore in a well-closed container and below 25°C.
	For generic drugs (me-too Status)	Cobactan® LC (Intervet Germany)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Manufacturer: QILU ANIMAL HEALTH PRODUCTS CO., LTD-No. 10688 Wenliang Road, Dongjia Town, Licheng District, Jinan, Shandong, China Zip code: 250100-China
	Name, address of Marketing Authorization Holder:	U.M. Enterprises, Plot No: 12, Sector 15, Korangi Industrial Area, Karachi 74900 (Pakistan), Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	Firm shall submit fee for standardization of formulation as per RRA i.e. 75 mg/mL Cefquinome (as cefquinome sulfate) .	
	Decision	
	Approved	
	Subject to submission of legalized CoPP and LoA.	
272	Case Category	Routine (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	punjad pharma PVT LTD 35-km shamy bhattian multan road lahore (053520066059717D)
	Application Form Dy. No / Tracking ID & date of submission	(RST-4D2-NDTY, 2025-05-17)
	Detail of Fee Submitted	300000.0, 2025-05-14,

	The proposed proprietary name / brand name	Imicarp Injectable Solution
	Label Claim	Each ml contains: 120 mg of imidocarb dipropionate equivalent to 85 mg of imidocarb
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	10 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)store below 25 degree centigrade.
	For generic drugs (me-too Status)	Imizol Injection
	Pharmacotherapeutic Group of (API)	Antiprotozoal
	Name, address of Manufacturing site:	TEKNOVET İlaç San. ve Tic. A.Ş.-Ç.O.S.B. Gazi Osman Paşa Mahallesi 18. Sokak No: 3 59500 Çerkezköy / Tekirdağ -Turkey
	Name, address of Marketing Authorization Holder:	PUNJNAD PHARMA (PVT) LIMITED, 35-KM, MULTAN ROAD, SHAMKEY BHATTIAN LAHORE, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
273	Decision	
	Approved	
	Subject to submission of legalized CoPP and LoA.	
	Case Category	Routine (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	u.m.enterprises plot no.12 sector 15 korangi industrial area-74900 (313)
	Application Form Dy. No / Tracking ID & date of submission	(VX9-QBB-1XXW, 2025-04-30)
	Detail of Fee Submitted	300000.0, 2025-04-21,
	The proposed proprietary name / brand name	Umezol
	Label Claim	Each 100mL contains: 8.5 g of imidocarb
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	100 ml-De-Controlled
	Shelf Life (Unit)	18 MonthSealed and protected from light, and store below 25 °C.
	For generic drugs (me-too Status)	Imizol (UK)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Manufacturer: QILU ANIMAL HEALTH PRODUCTS CO., LTD-No. 10688 Wenliang Road, Dongjia Town, Licheng District, Jinan, Shandong, China Zip code: 250100-China
	Name, address of Marketing Authorization Holder:	U.M. Enterprises, Plot No: 12, Sector 15, Korangi Industrial Area, Karachi 74900 (Pakistan), Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	

	the application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
	Subject to submission of legalized CoPP and LoA.	
274	Case Category	Routine (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	u.m.enterprises plot no.12 sector 15 korangi industrial area-74900 (313)
	Application Form Dy. No / Tracking ID & date of submission	(YXT-VL9-YR78, 2025-04-30)
	Detail of Fee Submitted	300000.0, 2025-04-21,
	The proposed proprietary name / brand name	Bovicef LA
	Label Claim	Each 1mL contains: 75m g of cefquinome sulfate
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	36 MonthStore in a well-closed container and below 25°C.
	For generic drugs (me-too Status)	Cobactan® LC (Intervet Germany)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	QILU ANIMAL HEALTH PRODUCTS CO., LTD.-No. 10688 Wenliang Road, Dongjia Tow n, Licheng District, Jinan, Shandong, China Zip code: 250100-China
	Name, address of Marketing Authorization Holder:	U.M. Enterprises, Plot No: 12, Sector 15, Korangi Industrial Area, Karachi 74900 (Pakistan), Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
	Subject to submission of legalized CoPP and LoA.	
275	Case Category	Routine (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Brand Station 69 Wocland Villas Lahore Near Raiwind Road (05-352-0065-042264D)
	Application Form Dy. No / Tracking ID & date of submission	(SMU-GTU-S9S2, 2025-05-28)
	Detail of Fee Submitted	300000.0, 2025-05-26,
	The proposed proprietary name / brand name	Chlor-TC
	Label Claim	Contain per 1000g: Chlortetracycline HCl.....200g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 Kg-De-Controlled
	Shelf Life (Unit)	36 Year(s)Store in shade and dry place, temperature below 25°C.

	For generic drugs (me-too Status)	Tetra Shell 20% Water Soluble Powder, Mfg: Inshal Pharmaceutical Industries, Address: Islamabad
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	M/s Inner Mongolia Huatian Pharmaceutical Co., Ltd-Economic Development & Experiment Zone Economical Transformation of Resource Dependent City, ChiFeng, Inner Mongolia, P.R. China-China
	Name, address of Marketing Authorization Holder:	M/s Brand Station, 69 Wocland Villas, Near Raiwind Road, Near Valenica Town, Opposite Alfatah Store, Lahore, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
	Subject to submission of legalized CoPP and LoA.	
276	Case Category	Routine (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Brand Station 69 Wocland Villas Lahore Near Raiwind Road (05-352-0065-042264D)
	Application Form Dy. No / Tracking ID & date of submission	(D1Q-U78-B9VS, 2025-05-28)
	Detail of Fee Submitted	300000.0, 2025-05-26,
	The proposed proprietary name / brand name	Tylo F-Bs
	Label Claim	Contain per 1000g: Fosfomycin Calcium.....200g Tylosin Tartrate.....100g Fructose+Electrolytes.....100g
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1 Kg-De-Controlled
	Shelf Life (Unit)	36 MonthStore in shade and dry place, temperature below 25°C.
	For generic drugs (me-too Status)	Ty Fos Water Soluble Powder, Mfg: Inshal Pharmaceutical Industries, Address: Islamabad
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Inner Mongolia Huatian Pharmaceutical Co., Ltd-Economic Development & Experiment Zone Economical Transformation of Resource Dependent City, ChiFeng, Inner Mongolia, P.R. China-China
	Name, address of Marketing Authorization Holder:	M/s Brand Station, 69 Wocland Villas, Near Raiwind Road, Near Valenica Town, Opposite Alfatah Store, Lahore, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	generic is not confirmed	
	Decision	
	Deferred	
	For generic or me-too.	
277	Case Category	Routine (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Brand Station 69 Wocland Villas Lahore Near Raiwind Road (05-352-0065-042264D)
	Application Form Dy. No / Tracking ID & date of submission	(QNX-3XT-2EP5, 2024-04-02)
	Detail of Fee Submitted	300000.0, 9000.0 2024-03-12, 2025-07-06
	The proposed proprietary name / brand name	Bio Tylodox Plus (Oral Soluble Powder)
	Label Claim	Tylosin tartrate.....100g Doxycyclin HCl.....200g Streptomycin Sulphate.....40g Bromohexine HCl.....5g Excipient q.s 1000g
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	Aluminum coated PE -De-Controlled
	Shelf Life (Unit)	3 YearStore in dry, cool place. Stay away from direct sunlight. FOR VETERINARY USE ONLY.
	For generic drugs (me-too Status)	DS- Majidox Powder by M/s Majestic Pharma Dy No.9885 30.03.2021
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s THIENQUAN JOINT STOCK COMPANY-Lot 17F2-F8, road 5, Tra Noc 1 Industrial zone, Binh Thuy District, Can Tho city, Vietnam-Vietnam
	Name, address of Marketing Authorization Holder:	M/s BRAND STATION, 69 Wocland villas lahore, near Raiwind road, Lahore, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	generic is not confirmed	
	Decision	
	Deferred	
	For generic or me-too.	
278	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	S.J & G. Fazul Ellahie (pvt) limited. E-46, S.I.T.E., Karachi (000083)
	Application Form Dy. No / Tracking ID & date of submission	(QT6-3VG-49P8, 2024-08-05)
	Detail of Fee Submitted	30000.0, 2024-06-14,
	The proposed proprietary name / brand name	Onzon

	Label Claim	Each 4ml contains: Ondansetron HCl eq. to Ondansetron.....8mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)As per zone-IVA
	For generic drugs (me-too Status)	Dansetron by Danas Pharmaceuticals
	Pharmacotherapeutic Group of (API)	5HT3 receptor antagonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s CTX Lifesciences
	Detail of stability batches of drug product	3 batches 175 ampoules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form-6, AWB and packing list submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE data submitted against Zofran injection
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per zone IV-A conditions
	The status in reference regulatory authorities	FDA-Approved Drug
	GMP status of the firm	GMP certificate based on evaluation conducted on 29-05-2023
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Decision	
	Approved	
279	Case Category	Export Facilitation (Najia Saleem)
	Name, address of Applicant.	Ferozsons Laboratories Limited PO Ferozsons, Amangarh (000038)
	Application Form Dy. No / Tracking ID & date of submission	(PSQ-6PW-Y6UD, 2025-12-05)
	Detail of Fee Submitted	75000, 2025-11-24,
	The proposed proprietary name / brand name	Upanib XR Tablets 30mg
	Label Claim	Each extended release tablet contains: Upadacitinib hemihydrate equivalent to Upadacitinib....30mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's (1x10's)-As per SRO,14's (1x14's)-As per SRO,20's (2x10's)-As per SRO,28's (2x14's)-As per SRO,30's (3x10's)-As per SRO,5's (1x5's)-As per SRO,7's (1x7's)-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store above 30°C
	For generic drugs (me-too Status)	Invonib 30mg Tablets of Ms The Schazoo Pharmaceutical Laboratories
	Pharmacotherapeutic Group of (API)	Janus kinase (JAK) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Chenghui Shuangda Pharmaceutical Co.,Ltd
	Detail of stability batches of drug product	03 batches manufactured each having batch size i.e. 1000 tablets
	Documents for the procurement of API with approval from DRAP	Form-06 (issued dated 21-10-2024, specifies 0.3kg import of (Upadacitinib Hemihydrate),

	(in case of Import)	Clearance certificate, Invoice, Packing List, Form-03 ,Form-07 & GD are attached in Module 03, Section 3.2.P, Sub-section 3.2.P.8.3
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP studies are conducted against Rinvoq Tablets 30mg (Batch No: 1303650, Exp. Date: 05/2027) of Abbvie Deutschland GmbH & Co. KG detail report is attached in Section 3.2.P, Sub-section 3.2.P.2
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data studies of 03 batches is performed by Drug substance manufacturer attached at Module 03 Section 3.2.S.7
	The status in reference regulatory authorities	Brand Name: Rinvoq extended-release Tablets 30mg Manufactured by: AbbVie Inc., North Chicago, IL 60064-USFDA
	GMP status of the firm	Complying cGMP as per Certificate No. F.11-10/2024-DRAP-435 Dated: 26-11-2024, valid till 09-08-2027
	Evidence of approval of manufacturing facility	Tablet Section (General) Approval granted by DRAP (Central Licensing Board) via tracking ID: XWU-WU3-4VZM dated: 01-08-2025.
	Evaluation Remarks	
	Decision	
	Approved	
280	Case Category	Export Facilitation (Najia Saleem)
	Name, address of Applicant.	Atco Laboratories Limited B-18 SITE KARACHI (000188)
	Application Form Dy. No / Tracking ID & date of submission	(G3P-79A-RRND, 2026-01-30)
	Detail of Fee Submitted	38700, 2026-01-08,
	The proposed proprietary name / brand name	UPAVECT Tablet
	Label Claim	Each extended-release tablet contains: Upadacitinib hemihydrate equivalent to Upadacitinib 15mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 strip x 10 Tablets-De-Controlled, 2 strips x 10 Tablets-De-Controlled, 3 strips x 10 Tablets-De-Controlled
	Shelf Life (Unit)	24 Month(s) Do not store and transport above 30 degree centigrade.
	For generic drugs (me-too Status)	Upacin ER Tablet manufactured by Dyson Research Laboratories.
	Pharmacotherapeutic Group of (API)	Upadacitinib Hemihydrate, "Immunosuppressants, Janus-associated kinase (JAK) 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 of 2500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form-6, GD and commercial invoice is attached.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence Report and Comparative Dissolution Profile are attached in Module 03.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months Accelerated Stability Data of Upadacitinib and 24 months Long-Term Stability Data of Upadacitinib is submitted.
	The status in reference regulatory authorities	RINVOQ 15 mg Prolonged-Release Tablets manufactured by: AbbVie Ltd, Address: AbbVie House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire, SL6 4UB, UK.
	GMP status of the firm	GMP Status is attached in Module 01.
	Evidence of approval of manufacturing facility	Manufacturing Facility Evidence is provided.
	Evaluation Remarks	
	Decision	
	Approved	
281	Case Category	Export Facilitation (Najia Saleem)
	Name, address of Applicant.	Ferozsons Laboratories Limited PO Ferozsons, Amargarh (000038)
	Application Form Dy. No / Tracking ID & date of submission	(E4Z-SPQ-UQTR, 2026-01-06)
	Detail of Fee Submitted	75000, 2025-11-27,
	The proposed proprietary name / brand name	Upanib XR Tablets 45mg
	Label Claim	Each extended release tablet contains: Upadacitinib hemihydrate equivalent to Upadacitinib.....45mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's (1x10's)-As per SRO,14's (1x14's)-As per SRO,20's (2x10's)-As per SRO,28's (2x14's)-As per SRO,30's (3x10's)-As per SRO,5's (1x5's)-As per SRO,7's (1x7's)-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store above 30°C
	For generic drugs (me-too Status)	Invonib 45mg Tablets of Ms The Schazoo Pharmaceutical Laboratories
	Pharmacotherapeutic Group of (API)	Janus kinase (JAK) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Chenghui Shuangda Pharmaceutical Co.,Ltd
	Detail of stability batches of drug product	03 batches manufactured each having batch size i.e 1000 tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form-06 (issued dated 21-10-2024, specifies 0.3kg import of (Upadacitinib Hemihydrate), Clearance certificate, Invoice, Packing List, Form-03 ,Form-07 & GD are attached in Module 03, Section 3.2.P, Sub-section 3.2.P.8.3
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP studies are conducted against Rinvoq Tablets 45mg (Batch No: 1289688, Exp. Date: 06/2026) of Abbvie Deutschland GmbH & Co. KG detail report is attached in Section 3.2.P, Sub-section 3.2.P.2
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data studies of 03 batches is performed by Drug substance manufacturer attached at

		Module 03 Section 3.2.S.7
	The status in reference regulatory authorities	Brand Name: Rinvoq extended-release Tablets 45mg Manufactured by: AbbVie Inc., North Chicago, IL 60064-USFDA
	GMP status of the firm	Complying cGMP as per Certificate No. F.11- 10/2024-DRAP-435 Dated: 26-11-2024, valid till 09-08-2027
	Evidence of approval of manufacturing facility	Tablet Section (General) Approval granted by DRAP (Central Licensing Board) via tracking ID: XWU-WU3-4VZM dated: 01-08-2025.
	Evaluation Remarks	
	Decision	
	Approved	
282	Case Category	Export Facilitation (Najia Saleem)
	Name, address of Applicant.	Ferozsons Laboratories Limited PO Ferozsons, Amangarh (000038)
	Application Form Dy. No / Tracking ID & date of submission	(3JN-WWM-LNMX, 2025-11-12)
	Detail of Fee Submitted	38700, 2025-10-31,
	The proposed proprietary name / brand name	Upanib XR Tablets 15mg
	Label Claim	Each extended release tablet contains: Upadacitinib hemihydrate equivalent to Upadacitinib.....15mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's (1x10's)-As per SRO,14's (1x14's)-As per SRO,20's (2x10's)-As per SRO,28's (2x14's)-As per SRO,30's (3x10's)-As per SRO,5's (1x5's)-As per SRO,7's (1x7's)-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store above 30°C
	For generic drugs (me-too Status)	Brand Name: Upaget XR Tablets 15mg Manufactured by: Getz Pharma Private Limited- Karachi
	Pharmacotherapeutic Group of (API)	Janus kinase (JAK) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Chenghui Shuangda Pharmaceutical Co.,Ltd
	Detail of stability batches of drug product	03 batches manufactured each having batch size i.e. 1000 tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form-06 (issued dated 21-10-2024, specifies 0.3kg import of (Upadacitinib Hemihydrate), Clearance certificate, Invoice, Packing List, Form-03 ,Form-07 & GD are attached in Module 03, Section 3.2.P, Sub-section 3.2.P.8.3
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP studies are conducted against Upaget XR Tablets 15mg (Batch No: F36001, Exp. Date: 08/2026) of Getz Pharma Private Limited- Karachi detail report is attached in Section 3.2.P, Sub-section 3.2.P.2
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data studies of 03 batches is performed by Drug substance manufacturer attached at Module 03 Section 3.2.S.7

	The status in reference regulatory authorities	Brand Name: Rinvoq extended-release Tablets 15mg Manufactured by: AbbVie Inc., North Chicago, IL 60064-USFDA
	GMP status of the firm	Complying cGMP as per Certificate No. F.11- 10/2024-DRAP-435 Dated: 26-11-2024, valid till 09-08-2027
	Evidence of approval of manufacturing facility	Tablet Section (General) Approval granted by DRAP (Central Licensing Board) via tracking ID: XWU-WU3-4VZM dated: 01-08-2025.
	Evaluation Remarks	
	Decision	
	Approved	
283	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	OPTIMUS LABORATORIES (PVT.) LTD. 259 F1 Block Wapda Town (001010)
	Application Form Dy. No / Tracking ID & date of submission	(66M-RT4-WJ43, 2026-04-01)
	Detail of Fee Submitted	38700, 2025-12-16,
	The proposed proprietary name / brand name	OPTIBREX-D Ophthalmic Ointment
	Label Claim	Each gram of Ointment Contains: Dexamethasone....1.0mg Tobramycin..... 3.0mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5ml-As per SRO
	Shelf Life (Unit)	2 Year(s)Store Below 25°C
	For generic drugs (me-too Status)	Orcydex Eye Ointment by JAENS PHARMACEUTICAL INDUSTRIES PVT LTD
	Pharmacotherapeutic Group of (API)	Aminoglycoside Antibiotic/corticosteroid
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches of 600 tubes
	Documents for the procurement of API with approval from DRAP (in case of Import)	Borrowing of Tobramycin from Ms Hansel and Dexamethasone from Ms Winthrox may be verified accordingly.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Orcydex Eye Ointment by JAENS PHARMACEUTICAL INDUSTRIES PVT LTD
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per zone IV-A conditions
	The status in reference regulatory authorities	USFDA
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	Section Approval Letter Attached
	Evaluation Remarks	
	API loan may be verified before issuance of registration letter.	
	Decision	
	Approved	
	subject to verification of loan.	
284	Case Category	New License (Najia Saleem)

	Name, address of Applicant.	OPTIMUS LABORATORIES (PVT.) LTD. 259 F1 Block Wapda Town (001010)
	Application Form Dy. No / Tracking ID & date of submission	(9HW-RNY-5U5T, 2026-04-01)
	Detail of Fee Submitted	38700, 2025-12-15,
	The proposed proprietary name / brand name	OPTIBREX 0.3% Ophthalmic Solution
	Label Claim	Each ml of Solution Contains: Tobramycin 3mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10 ml-As per SRO, 5 ml-As per SRO
	Shelf Life (Unit)	2 Year(s) Store Below 25°C
	For generic drugs (me-too Status)	Optibrex 0.3% ophthalmic Solution by Winthrox Laboratories (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Aminoglycoside Antibiotic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Livzon group Fuzhou Fuxing Pharmaceutical CO.LTD.
	Detail of stability batches of drug product	3 batches of 600 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Import)	API Loan from Ms Hansel Pharma may be verified accordingly
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Optibrex 0.3% ophthalmic Solution by Winthrox Laboratories (Pvt.) Ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Tobrex 0.3% ophthalmic solution by Sandoz USFDA Approved
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	Section Approval Letter submitted
	Evaluation Remarks	
	API loan may be verified before issuance of registration letter.	
	Decision	
	Approved	
	subject to verification of loan letter.	
285	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	ELKO ORGANIZATION (PRIVATE) LIMITED PLOT NO. 27 & 28, SECTOR-12B, NORTH KARACHI INDUSTRIAL AREA, KARACHI (000245)
	Application Form Dy. No / Tracking ID & date of submission	(VSE-GYL-DYLH, 2025-03-11)
	Detail of Fee Submitted	37000.0, 2025-02-21,
	The proposed proprietary name / brand name	T-Dine Oral Powder
	Label Claim	Each gm contains : Amantadine HCl.....100MG
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 KG -De-Controlled, 2.5 KG -De-Controlled, 250MG -De-Controlled, 500MG-De-Controlled
	Shelf Life (Unit)	2 Year(s) 20 -25 °C

	For generic drugs (me-too Status)	Amentavetz Oral Powder , Vetz Pharmaceutical
	Pharmacotherapeutic Group of (API)	Antiviral
	Name, address of Manufacturing site:	--
	GMP status of the firm	03-06-2024; Based on above stated observation and keeping in view the attitude of the management towards continues improvements their current level of compliance is rated Good.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Targeted species: Poultry	
	Decision	
	Rejected	
	since the Sub-committee on Veterinary Drugs recommended restricting the use of Amantadine formulations to non-food-producing animals only while the firm has mentioned target species poultry.	
286	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Archard Pharmaceuticals Pvt Ltd Plot No 27-28/B Small Industrial Estate Bhimber AJK (000991)
	Application Form Dy. No / Tracking ID & date of submission	(4RQ-P6T-Q4AL, 2024-05-27)
	Detail of Fee Submitted	30000.0, 2024-05-16,
	The proposed proprietary name / brand name	AR AVIL Liquid Inj.
	Label Claim	Each ml contains (As Per Innovator Spec.) Pheniramine Maleate BP 25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	PHENRASYM LIQUID INJECTION (023433) SYMANS Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Antihistamine
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML granted w.e.f. 17-01-2024
	Evidence of approval of manufacturing facility	Liquid injectable (General) Vet approval submitted
	Evaluation Remarks	
	Decision	
	Approved	
287	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Archard Pharmaceuticals Pvt Ltd Plot No 27-28/B Small Industrial Estate Bhimber AJK (000991)
	Application Form Dy. No / Tracking ID & date of submission	(77D-P56-PZZJ, 2024-05-22)
	Detail of Fee Submitted	30000.0, 2024-05-16,
	The proposed proprietary name / brand name	AR ENRO 20% Liquid Inj.

	Label Claim	Each ml contains (As Per Innovator Spec.) Enrofloxacin 200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	ENRAS-20 INJECTION (057071) ZAKFAS PHARMA
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML granted w.e.f. 17-01-2024
	Evidence of approval of manufacturing facility	Liquid Injectable (General) vet approval submitted
	Evaluation Remarks	
	Decision	
	Approved	
288	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(P8U-QNN-U763, 2024-10-26)
	Detail of Fee Submitted	37000.0, 2024-10-22,
	The proposed proprietary name / brand name	OTC FORTE INJECTION (10ML)
	Label Claim	Each ml contains: -Oxytetracycline HCL 300mgFlunixin meglumin 20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	113647 TETRIN-FM INJECTION M/S. UNIVET PHARMACEUTICALS, RAWALPINDI.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Initially, the firm has claimed USP specifications for FPP. However, the official monograph of FPP does not exist in the latest USP. Firm has now revised specifications to as per innovator's specifications. Firm shall submit fee for pre-approval correction in FPP specifications.	
	Decision	
	Approved	
	with as per innovators specifications. The firm shall submit fee for pre-approval correction in FPP specifications before issuance of registration letter.	
289	Case Category	Routine (Najia Saleem)
	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	(3NX-H3S-97QA, 2024-07-02)

	Detail of Fee Submitted	30000.0, 2024-06-26,
	The proposed proprietary name / brand name	Solina 10mg Tablet
	Label Claim	Each film coated tablet contains: Solifenacin Succinate.....10mg BP Specification
	Reference to Finished product specifications	British Pharmacopeia
	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)	Solfy Tablet 10mg, M/s Sami Pharmaceutical (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Antimuscarinic agent
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhejiang Guobang Pharmaceutical Co., Ltd., No. 6, Weiwu Road, Hangzhou Gulf Shangyu Economic and Technological Development Zone, Zhejiang, P.R. China
	Detail of stability batches of drug product	3 batches of 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form-3, Form-6, Form-7 commercial invoice, packing list submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP against Vesicare tablets of Ms Astellas Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	submitted as per zone IV-B conditions
	The status in reference regulatory authorities	Vesicare Tablet, Astellas Pharma, USFDA Approved.
	GMP status of the firm	GMP certificate base on evaluation conducted on 28-03-2024
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	This is to declare that the Free of Cost (FOC) sample (Solifenacin Succinate) of our applied product SOLINA tablets 10mg was imported in August 2023 by our company prior to the implementation and mandatory applicability of the issued Notification dated 14th October, 2025, with captioned subject "Mandatory Sourcing requirement for Active pharmaceutical Ingredients Imported for Product Development" (Notification attached).We have imported FOC sample (Solifenacin Succinate), the said regulatory requirements were not mandatory /applicable; therefore, the shipment was processed under the prevailing regulatory practice and procedure applicable on August 2023.We further confirm that the FOC sample was obtained directly from the manufacturer M/s. Zhejiang Guobang pharmaceutical Co., Ltd, China and complete traceability of the shipment is available in our records. In support of this declaration, the following documentary evidences is being provided for your ready reference and verification:Form 06InvoicePacking ListForm 07Form 03	
	Decision	
	Approved	
290	Case Category	Routine (Najia Saleem)
	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	(XYA-V7Q-RR14, 2024-08-09)
	Detail of Fee Submitted	30000.0, 2024-06-26,
	The proposed proprietary name / brand name	Solina 5mg Tablet

	Label Claim	Each film coated tablet contains: Solifenacin Succinate.....5mg BP Specification
	Reference to Finished product specifications	British Pharmacopeia
	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)	Solfy Tablet 5mg, M/s Sami Pharmaceutical (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	antimuscarinic agent
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhejiang Guobang Pharmaceutical Co., Ltd., No. 6, Weiwu Road, Hangzhou Gulf Shangyu Economic and Technological Development Zone, Zhejiang, P.R. China
	Detail of stability batches of drug product	3 batches of 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form-3, Form-6, Form-7, commercial invoice, packing list submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP against Vesicare tablets of Ms Astellas Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per zone IV-B
	The status in reference regulatory authorities	Vesicare Tablet, Astellas Pharma, USFDA Approved.
	GMP status of the firm	GMP certificate based on evaluation conducted on 28-03-2024
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	This is to declare that the Free of Cost (FOC) sample (Solifenacin Succinate) of our applied product SOLINA tablets 10mg was imported in August 2023 by our company prior to the implementation and mandatory applicability of the issued Notification dated 14th October, 2025, with captioned subject "Mandatory Sourcing requirement for Active pharmaceutical Ingredients Imported for Product Development" (Notification attached).We have imported FOC sample (Solifenacin Succinate), the said regulatory requirements were not mandatory /applicable; therefore, the shipment was processed under the prevailing regulatory practice and procedure applicable on August 2023.We further confirm that the FOC sample was obtained directly from the manufacturer M/s. Zhejiang Guobang pharmaceutical Co., Ltd, China and complete traceability of the shipment is available in our records. In support of this declaration, the following documentary evidence is being provided for your ready reference and verification: Form 06, Invoice, Packing List, Form 07, and Form 03	
	Decision	
	Approved	
291	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(YQ5-WX4-Y9W3, 2024-07-14)
	Detail of Fee Submitted	30000.0, 2024-07-11,
	The proposed proprietary name / brand name	CAL FASFO ORAL POWDER
	Label Claim	Each 100gm contains: - Fosfomycin Calcium..... .25%

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm-De-Controlled,10Kg -De-Controlled,1Kg-De-Controlled,250gm-De-Controlled,25Kg-De-Controlled,500gm-De-Controlled,5Kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	LEADS PHARMACEUTICALS (PVT.)LTD. ,ISLAMABAD (FOSMIUM POWDER REG. # 118659)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	The firm has demanded following pack sizes: 100gm,250gm,500gm,1 Kg,5Kg,10Kg & 25 Kg	
	Decision	
	Approved	
	with pack sizes up to 1Kg.	
292	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	AMSEZA PHARMA Plot # 12, 01km Bangreel Road, T-Chowk, Rawat, Islamabad (001007)
	Application Form Dy. No / Tracking ID & date of submission	(LP1-1JG-8NVM, 2025-05-19)
	Detail of Fee Submitted	37000.0, 2025-05-15,
	The proposed proprietary name / brand name	AM FLOXICOL 10 Oral solution
	Label Claim	Each 100 ml Contains: Enrofloxacin 10gm Colistin Sulphate 50MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	20ml,50ml,100ml,250 -De-Controlled
	Shelf Life (Unit)	2 Year(s)Room temperature
	For generic drugs (me-too Status)	ENROTEN Oral Liquid (Reg No 079141) Kailgon Agro Karachi
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	New License granted w.e.f. 28-03-2025
	Evidence of approval of manufacturing facility	Oral liquid (General) veterinary submitted
	Evaluation Remarks	
	The firm has revised formulation in line with reference product 099310 "EFLIN-GA 10% ORAL LIQUID of M/S. VETEC LABORATORIES, RAWALPINDI along with submission of fee Rs. 38700/- vide challan No. 14792439002 Moreover, the firm has demanded the following pack sizes: I x20ml, I x50ml, I x100ml, I x250ml, I x500ml, I x1L, I x2.5L, I x5L	
	Decision	
	Approved	
	with pack sizes up to 1L.	
293	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)

	Application Form Dy. No / Tracking ID & date of submission	(RTE-79R-BZ8D, 2026-02-03)
	Detail of Fee Submitted	38700, 2026-01-30,
	The proposed proprietary name / brand name	Amoxibak LA Injection
	Label Claim	Each 100ml Contains, Amoxicillin as trihydrate.....15%w/v (B.P Vet Specification)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	50 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat, light and moisture.
	For generic drugs (me-too Status)	Almox 15% LA Injection (Star laboratoroies PVT LTD.)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
294	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(JJB-RUU-12JA, 2026-02-03)
	Detail of Fee Submitted	38700, 2026-01-30,
	The proposed proprietary name / brand name	Amoxibak LA Injection
	Label Claim	Each 100ml Contains, Amoxicillin as Trihydrate.....15%w/v (B.P Vet Specification)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat, light and moisture.
	For generic drugs (me-too Status)	Almox 15% LA Injection (Star laboratoroies PVT LTD.)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
295	Case Category	New License (Sabahat Zehra)

	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(5JG-WPQ-GPUG, 2026-02-04)
	Detail of Fee Submitted	38700, 2026-02-03,
	The proposed proprietary name / brand name	Amoxi-C Injection
	Label Claim	Each ml contains, Amoxicillin as Trihydrate.....100mg Colistin Sulphate.....250,000 (As per Innovators Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat, light and moisture.
	For generic drugs (me-too Status)	colimoxin injection reg. no.034576 (Selmore Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
296	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(ULJ-63Z-2Y2P, 2026-02-04)
	Detail of Fee Submitted	38700, 2026-02-03,
	The proposed proprietary name / brand name	Amoxi-C Injection
	Label Claim	Each ml contains, Amoxicillin as Trihydrate.....100 mg Colistin Sulphate.....250,000 IU (As per Innovators Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Colimoxin injection reg no.034576 (Selmore Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	

	Decision	
	Approved	
297	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(UJM-SYU-TYV9, 2026-02-04)
	Detail of Fee Submitted	38700, 2026-02-03,
	The proposed proprietary name / brand name	Penbak 5 Dry Powder Injection
	Label Claim	Each vial contains, Benzyl Pencilline.....500,000 IU Procaine Pencilline.....1,500,000 IU Streptomycin Sulphate.....5gm (As per Innovators Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	05 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat, light and moisture.
	For generic drugs (me-too Status)	Penbiotic Injection reg no.022148 (Nawan Laboratories)
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
298	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(SA7-TXJ-YRBY, 2026-02-03)
	Detail of Fee Submitted	38700, 2026-01-30,
	The proposed proprietary name / brand name	Gen-Mox Forte Injection
	Label Claim	Each ml Contains, Amoxicillin trihydrate (BP) eq. to amoxicillin.....150 mg Gentamycin Sulphate (BP) eq. to Gentamicin.....40 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat, light and moisture.
	For generic drugs (me-too Status)	Amoxygent forte IM Injection reg no.097945 (Selmore Pharmaceuticals Lahore)
	Pharmacotherapeutic Group of (API)	Antibiotics

	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
299	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(VXS-L7N-W44W, 2026-02-04)
	Detail of Fee Submitted	38700, 2026-02-03,
	The proposed proprietary name / brand name	Amox-T Powder
	Label Claim	Each 100gm contains, Amoxicillin as trihydrate.....50gm eq. to amoxicillin 43.48gm (BP Vet specification)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1 kg-De-Controlled,10 kg-De-Controlled,100 gm-De-Controlled,2.5 kg-De-Controlled,25 kg-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Amox 50 powder reg no. 120612 Tarobina
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
300	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(56T-WBB-GU4M, 2026-02-03)
	Detail of Fee Submitted	38700, 2026-01-30,
	The proposed proprietary name / brand name	Coli-Pro Powder
	Label Claim	Each 100g contains: Colistin Sulphate-----6MIU Procaine Pencilline-----1.2gm Zinc Bacitracin-----5.2gm Streptomycin Sulphate-----3.6gm (As per Innovators Specification)
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	1 kg-De-Controlled,100 gm-De-Controlled,2.5 kg-De-Controlled,25 kg-De-Controlled,250 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Pro-C Plus Powder reg no.082792 leads pharma
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Formulation contains four antibiotics.	
	Decision	
	Deferred	
	Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and for submission of valid international reference in support of their product.	
301	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(7X3-WHQ-RYWQ, 2026-02-20)
	Detail of Fee Submitted	38700, 2026-02-12,
	The proposed proprietary name / brand name	Tylonor-C Oral Solution
	Label Claim	Each 100 ml Contains, Norfloxacin.....10% Colistin Sulphate.....250MIU Tylosin Tartrate.....5% (As per Innovators Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 litre-De-Controlled,100 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Tyloconor oral solution Reg no.130383 (Pivotal Pharmaceutical)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
302	Case Category	New License (Sabahat Zehra)

	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(82N-QV5-LG36, 2026-02-06)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	NeoPro ZS Powder
	Label Claim	Each 1000 gm contains, Procaine Pencilline----- -12gm Zinc Bacitracin-----52 gm Streptomycin Sulphate-----36 gm Neomycin Sulphate-----10 gm (As per Innovators Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	05 kg-De-Controlled,100 gm-De-Controlled,1000 gm-De-Controlled,2.5 kg-De-Controlled,25 kg- De-Controlled,250 gm-De-Controlled,500 gm- De-Controlled
	Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Probac-N (Selmore)
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	present
	Evaluation Remarks	
	Formulation contains four antibiotics.	
	Decision	
	Deferred	
	Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and for submission of valid international reference in support of their product.	
303	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(ZZA-87A-6SNT, 2026-02-03)
	Detail of Fee Submitted	38700, 2026-01-30,
	The proposed proprietary name / brand name	Probak ZS Powder
	Label Claim	Each 100 gm contains, Procaine Pencilline----- -1.2gm Zinc Bacitracin-----5.2gm Streptomycin Sulphate-----3.6gm (As per Innovators specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gm-De-Controlled,1000 gm-De- Controlled,2.5 kg-De-Controlled,25 kg-De- Controlled,250 gm-De-Controlled,5 kg-De- Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	probond plus (leads pharma)

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
304	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(USE-JZE-YW85, 2026-02-04)
	Detail of Fee Submitted	38700, 2026-02-03,
	The proposed proprietary name / brand name	SL-Amox Powder
	Label Claim	Each 100 gm contains, Amoxycilline as Trihydrate.....20gm Lincomycin (HCL).....8.8gm Spectinomycin HCL.....8.8 gm (As per Innovators specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 kg-De-Controlled,10 kg-De-Controlled,100 gm-De-Controlled,2.54 kg-De-Controlled,25 kg-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Tritin-LE Powder reg no.082795 (Leads Pharma
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
305	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(EQP-MBU-8Z1G, 2026-02-17)
	Detail of Fee Submitted	38700, 2026-02-12,
	The proposed proprietary name / brand name	Amoxitin-C Powder
	Label Claim	Each 100 gm contains, Amoxicillin as tryhydrate 20 gm Colistin Sulphate.....80MIU (As per Innovators specification)

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 kg-De-Controlled,10 kg-De-Controlled,100 gm-De-Controlled,2.5 kg-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Kolmox powder reg no. 115073 (mylab pvt ltd)
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
306	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(LQ8-HPA-G9RX, 2026-02-04)
	Detail of Fee Submitted	38700, 2026-02-03,
	The proposed proprietary name / brand name	Amox-C Maarson Powder
	Label Claim	Each 100 gm contains, Amoxicillin as trihydrate (B.P) 50gm Colistin Sulphate (B.P).....50MIU (As per Innovators Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 kg-De-Controlled,100 gm-De-Controlled,2.5 kg-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	AD Mox w/s Powder reg. no. 103837 (inshal pharmaceutical industries)
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
307	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)

	Application Form Dy. No / Tracking ID & date of submission	(RNX-Z7E-TGH7, 2026-02-04)
	Detail of Fee Submitted	38700, 2026-02-03,
	The proposed proprietary name / brand name	ASL-20 Powder
	Label Claim	Each kg contains, Amoxicilline Trihydrate....200g eq. to 173.92 gm amoxicilline base Lincoimycin (HCL).....88 gm Spectinomycin Sulphate.....88 gm Vitamin-E 50%.....30 gm (As per Innovators specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 kg-De-Controlled,10 kg-De-Controlled,100 gm-De-Controlled,2.5 kg-De-Controlled,25 kg-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Tritin-LE Powder reg no.082795 (Leads Pharma)
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
308	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(JV7-14R-D1W7, 2026-05-01)
	Detail of Fee Submitted	38700, 2026-04-30,
	The proposed proprietary name / brand name	Albirox Drench 25mg+40mg/ml
	Label Claim	Each ml contains:- Albendazole..... 25mg Ricobendazole.....40mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 250ml, 500ml, 1L or as per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)should be store below 30 celcius
	For generic drugs (me-too Status)	RICOBEN-S Suspension(Reg. # 062196) M/s INTERVAC (PVT)LTD
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP inspection is done and GMP issued accordingly.
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	

	Decision	
	Approved	
309	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(B3U-UY7-7BSR, 2026-05-01)
	Detail of Fee Submitted	38700, 2026-04-30,
	The proposed proprietary name / brand name	ALBAMIT-1500 BOLUS
	Label Claim	Each Bolus contains:- Albendazole..... 1500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5's, 10's, 50's, 100's, or As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s) should be store below 30 celcius
	For generic drugs (me-too Status)	VETY ALBEN BOLUS 1500 (Registration # 058856) M/s Leads Pharma (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP inspection is done and GMP issued accordingly.
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
310	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(275-M3P-8WWW, 2026-05-01)
	Detail of Fee Submitted	38700, 2026-04-30,
	The proposed proprietary name / brand name	Oxyfen Plus Bolus
	Label Claim	Each Bolus contains:- Oxiclozanide.....625mg Oxfendazole.....275mg Cobalt Sulphate.....30mg Sodium Selenite.....3mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 50's, 100's, 200's, 500's or as Per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s) should be store below 30 celcius
	For generic drugs (me-too Status)	Galied Bolus Registration No: 078222 INTERNATIONAL PHARMA LABS
	Pharmacotherapeutic Group of (API)	Anthelmintic & Minerals Supplement
	Name, address of Manufacturing site:	--

	GMP status of the firm	GMP inspection is done and GMP issued accordingly.
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
311	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(WTJ-9U7-QQN9, 2026-05-01)
	Detail of Fee Submitted	38700, 2026-04-30,
	The proposed proprietary name / brand name	Triclev Bolus 900mg+90mg
	Label Claim	Each Bolus contains:- Triclabendazole..... ...900mg Levamisole HCl.....90mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5's, 10's, 50's, 100's or 200's or as Per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)should be store below 30 celcius
	For generic drugs (me-too Status)	Trileva Bolus Registration # 106716 M/s Mediexcel Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Anthelmintics
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP inspection is done and GMP issued accordingly.
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
312	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(8JM-142-D6PD, 2026-05-01)
	Detail of Fee Submitted	38700, 2026-04-30,
	The proposed proprietary name / brand name	TriClabex 250mg BOLUS
	Label Claim	Each Bolus contains:- Triclabendazole..... 250mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5's, 10's, 50's, 100's, 200's or as Per SRO-De-Controlled
	Shelf Life (Unit)	2 Yearshould be store below 30 celcius

	For generic drugs (me-too Status)	Tribencare 250mg Bolus M/s Advacare Pharma USA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP inspection is done and GMP issued accordingly.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
313	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(81H-R77-8RYX, 2026-05-01)
	Detail of Fee Submitted	38700, 2026-04-30,
	The proposed proprietary name / brand name	Albatop-17 Drench
	Label Claim	Each ml contains:- Albendazole..... 170mg Cobalt Sulphate....1.67mg Sodium Selenite....0.50mg Zinc.....2.6mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 150ml, 250ml 500ml, 1L, 2.5L or As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)should be store below 30 celcius
	For generic drugs (me-too Status)	Albo 17% Liquid (Registration # 063785) M/s MALLARD PHARMACEUTICALS (PVT) LTD
	Pharmacotherapeutic Group of (API)	Anthelmintics
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP inspection is done and GMP issued accordingly.
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
314	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(U3J-QMP-TA9P, 2026-05-01)
	Detail of Fee Submitted	38700, 2026-04-30,
	The proposed proprietary name / brand name	OxiNiclos Drench 250g+10g/L

	Label Claim	Each Liter contains:- Niclosamide..... 250g Oxfendazole.....10g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 mL, 250 mL, 500 mL, 1 L, 10L, 5L or as per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)should be store below 30 celcius
	For generic drugs (me-too Status)	Niczole Drench Registration number: 063865 M/s Symas Pharmaceuticals (Pvt.) Ltd
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP inspection is done and GMP issued accordingly.
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
315	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	M/s. Xealth Pharma (Pvt) Ltd Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir (001021)
	Application Form Dy. No / Tracking ID & date of submission	(HAQ-NNB-2S6D, 2026-02-19)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	XEL FEN 25 ORAL LIQUID
	Label Claim	Each ml contains:- Florfenicol.....250 mg (as per innovators specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML, 150 ML, 250 ML, 500 ML, 1000 ML- De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Arch Fen 25 % Liquid (121910)
	Pharmacotherapeutic Group of (API)	Amphenicol Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
316	Case Category	New License (Sabahat Zehra)

	Name, address of Applicant.	M/s. Xealth Pharma (Pvt) Ltd Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir (001021)
	Application Form Dy. No / Tracking ID & date of submission	(3JY-VW8-EZS3, 2026-02-19)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	NOVA FEN 23 ORAL LIQUID
	Label Claim	Each 1000 ml contains:- Florfenicol.....230 gm Colistin Sulphate.....500MIU (as per innovators specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML, 150 ML, 250 ML, 500 ML, 1000 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Arch Rotin 23% Liquid (121912)
	Pharmacotherapeutic Group of (API)	Amphenicol Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
317	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Decent Pharma Plot No. 30, Street No. SS-3, RCCI, RAWAT (000766)
	Application Form Dy. No / Tracking ID & date of submission	(YUG-QTT-99W3, 2024-10-25)
	Detail of Fee Submitted	30000.0, 2024-06-27,
	The proposed proprietary name / brand name	RENYL Injection 100 ml
	Label Claim	Each ml Contains: Furosemide ... 50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100 ml-De-Controlled
	Shelf Life (Unit)	24 Year(s)Store Cool and Dry
	For generic drugs (me-too Status)	Frusicon Injection Reg No.049685 Mfg By: M/S Alina Combine Pharmaceutical
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	Decision	
	Approved	
318	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	M/s. Xealth Pharma (Pvt) Ltd Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir (001021)
	Application Form Dy. No / Tracking ID & date of submission	(SN5-VZB-HG2E, 2026-02-19)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	XEL FEN 23 ORAL LIQUID
	Label Claim	Each 100 ml contains:- Florfenicol.....23 gm (as per innovators specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML, 150 ML, 250 ML, 500 ML, 1000 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Arch Fen 23% Liquid Reg#121909
	Pharmacotherapeutic Group of (API)	Amphenicol Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
319	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(TAY-5Q5-V8U5, 2026-05-01)
	Detail of Fee Submitted	38700, 2026-04-30,
	The proposed proprietary name / brand name	Wim Tri-Leva Drench
	Label Claim	Each 100ml contains:- Triclabendazole.....5.0g Levamisole as HCl....3.75g Cobalt.....0.04g Selenium.....0.05g Copper.....0.21g Zinc.....0.055g
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	100 mL, 250 mL, 500 mL, 1 L or as per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)should be store below 30 celcius
	For generic drugs (me-too Status)	N.A
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP inspection is done and GMP issued accordingly.
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
320	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(ZUG-XQG-5LPX, 2026-05-01)
	Detail of Fee Submitted	38700, 2026-04-30,
	The proposed proprietary name / brand name	Fenraxowim Drench 50mg+50mg/ml
	Label Claim	Each ml contains:- Fenbendazole..... 50mg Rafoxanide.....50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 mL, 250 mL, 500 mL, 1 L or as per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)should be store below 30 celcius
	For generic drugs (me-too Status)	Fen Fox Oral Liquid Registration number: 062170 M/s Attabak Pharmaceutical Industries Address: 5-C Industrial Area I-10/3 Islamabad
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP inspection is done and GMP issued accordingly.
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
321	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Decent Pharma Plot No. 30, Street No. SS-3, RCCI, RAWAT (000766)
	Application Form Dy. No / Tracking ID & date of submission	(BUV-7Y7-MGTU, 2024-10-25)
	Detail of Fee Submitted	30000.0, 2024-06-27,

	The proposed proprietary name / brand name	Titan Injection 50 ml
	Label Claim	Each ml contains: Tylosin tartrate (USP) 100 mg Gentamicin as Sulfate (USP) 50 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50 ml-De-Controlled
	Shelf Life (Unit)	24 Year(s)Store Cool and Dry
	For generic drugs (me-too Status)	Tygent Injection Reg No.049636 Mfg By: M/S Selmore Pharmaceutical
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Approved
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
322	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Decent Pharma Plot No. 30, Street No. SS-3, RCCI, RAWAT (000766)
	Application Form Dy. No / Tracking ID & date of submission	(BVV-UD1-RJRU, 2024-10-25)
	Detail of Fee Submitted	30000.0, 2024-06-27,
	The proposed proprietary name / brand name	RENYL Injection 50 ml
	Label Claim	Each ml contains: Furosemide 50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50 ml-De-Controlled
	Shelf Life (Unit)	24 Year(s)Store Cool and Dry
	For generic drugs (me-too Status)	Frusicon Injection Reg No.049685 Mfg By: M/S Alina Combine Pharmaceutical
	Pharmacotherapeutic Group of (API)	Antibaceterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Approved
	Evidence of approval of manufacturing facility	
323	Evaluation Remarks	
	Decision	
	Approved	
	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	QADIR PHARMACEUTICALS FATEH GHAR SAHUWALA ROAD SIALKOT (000944)
	Application Form Dy. No / Tracking ID & date of submission	(6A2-A6Z-R3PP, 2024-08-19)

	Detail of Fee Submitted	30000.0, 2024-08-09,
	The proposed proprietary name / brand name	Esital 5mg
	Label Claim	Each film coated tablet contains escitalopram (as Oxalate) 5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2x7's=14's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Me-Too
	Pharmacotherapeutic Group of (API)	SSRI
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Smilax Laboratories Limited
	Detail of stability batches of drug product	TTR117, TTR118
	Documents for the procurement of API with approval from DRAP (in case of Import)	v
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Citanew 5mg B# 152424, Esital 5mg Tablets Batch # TTR017
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	SCOI/H019/14, SCOI/H020/14, SCOI/H021/14
	The status in reference regulatory authorities	EMC, FDA HPRA
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
324	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	QADIR PHARMACEUTICALS FATEH GHAR SAHUWALA ROAD SIALKOT (000944)
	Application Form Dy. No / Tracking ID & date of submission	(3DT-DD3-SPMR, 2024-08-21)
	Detail of Fee Submitted	30000.0, 2024-08-09,
	The proposed proprietary name / brand name	Esital 10mg
	Label Claim	Each film coated tablet contains Escitalopram (as Oxalate) 10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2x7's=14's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Me-Too
	Pharmacotherapeutic Group of (API)	SSRI
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Smilax Laboratories Limited
	Detail of stability batches of drug product	TTR111, TTR112, TTR113
	Documents for the procurement of API with approval from DRAP (in case of Import)	Computerized No: E-6578007555987

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Cipralext 10mg
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	SCOI/H019/14, SCOI/H020/14 , SCOI/H021/14
	The status in reference regulatory authorities	EMC, FDA HPRA
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
325	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	QADIR PHARMACEUTICALS FATEH GHAR SAHUWALA ROAD SIALKOT (000944)
	Application Form Dy. No / Tracking ID & date of submission	(9N1-WVE-PTEH, 2024-08-15)
	Detail of Fee Submitted	30000.0, 2024-08-09,
	The proposed proprietary name / brand name	Esital 20mg
	Label Claim	Each film coated tablet contains Escitalopram (as Oxalate) 20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2x7's=14's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Me-Too
	Pharmacotherapeutic Group of (API)	SSRI
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Smilax Laboratories Limited
	Detail of stability batches of drug product	TTR114, TTR115, TTR116
	Documents for the procurement of API with approval from DRAP (in case of Import)	Computerized No: E-6578007555987
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Citanew 20mg
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	SCOI/H019/14, SCOI/H020/14 , SCOI/H021/14
	The status in reference regulatory authorities	EMC, FDA HPRA
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
326	Case Category	Routine (Sabahat Zehra)

	Name, address of Applicant.	Danas Pharmaceuticals (Pvt) Ltd. 312-Industrial Triangle, Kahuta road, Islamabad. (000569)
	Application Form Dy. No / Tracking ID & date of submission	(3TY-DME-4848, 2024-10-29)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-29, 2024-09-26
	The proposed proprietary name / brand name	Metrodan
	Label Claim	Each 100ml Vial contains: Metronidazole.....500.0 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100ml(1x1's)-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30 degree
	For generic drugs (me-too Status)	Flagyl Injection 500mg/100ml (M/S Sanofi-Aventis Pakistan Limited, Karachi)
	Pharmacotherapeutic Group of (API)	Antiprotazoal
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Hubei Hongyuan Pharmaceutical Technology Co Ltd
	Detail of stability batches of drug product	On 3 batches TRD-MTD-001, TRD-MTD-002 , TRD-MTD-003
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Flagyl 500mg/100ml batch # AD056
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached
	The status in reference regulatory authorities	Metrozine Injection Vial (Proqualix Pty Ltd http://www.tga.gov.au/about/website-copyright.htm .)
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	The DML inspection of the firm is still pending however, the fee was submitted on time. Audit trail report/system log is not submitted.	
	Decision	
	Deferred	
	Deffered, for the submission of audit trail report/system log for submitted stability studies for drug product.	
327	Case Category	Export Facilitation (Saima Hussain)
	Name, address of Applicant.	Ferozsons Laboratories Limited PO Ferozsons, Amangarh (000038)
	Application Form Dy. No / Tracking ID & date of submission	(STP-R1B-QGRP, 2025-10-17)
	Detail of Fee Submitted	75000.0, 2025-09-01,
	The proposed proprietary name / brand name	Dapriya Tablets 1mg
	Label Claim	Each film coated tablet contains: Daprodustat.....1mg
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	10's (1x10's)-As per SRO,12's (1x12's)-As per SRO,14's (1x14's)-As per SRO,20's (2x10's)-As per SRO,28's (2x14's)-As per SRO,30's (3x10's)-As per SRO,5's (1x5's)-As per SRO,7's (1x7's)-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Hypoxia-inducible Factor Prolyl Hydroxylase Inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	NA
	Detail of stability batches of drug product	03 batches manufactured each having batch size i.e 1000 tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form-06 (issued dated 12-09-2024, specifies 0.1kg import of Daprodustat, Invoice ,Form-03 ,Form-07, GD are attached in Module 03, Section 3.2.P, Sub-section 3.2.P.8.3
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP studies are conducted against Duvroq Tablets 1mg (Batch No: 488X-B, Exp. Date: 04/2027) of Kyowa kirin Co., Ltd- Japan, detail report is attached in Section 3.2.P, Sub-section 3.2.P.2
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data studies of 03 batches is performed by Drug substance manufacturer attached at Module 03 Section 3.2.S.7
	The status in reference regulatory authorities	Brand Name: Duvroq Tablets (Product of GSK) Manufacturer: Kyowa kirin Co., Ltd Japan- PMDA & Brand Name: Jesduvroq Tablets Manufacturer: GlaxoSmithKline Durham, NC 27701-USFDA
	GMP status of the firm	Complying cGMP as per Certificate No. F.11-10/2024-DRAP-435 Dated: 26-11-2024, valid till 09-08-2027.
	Evidence of approval of manufacturing facility	Tablet Section (General) Approval granted by DRAP (Central Licensing Board) via tracking ID: XWU-WU3-4VZM dated: 01-08-2025.
Evaluation Remarks		
Decision		
Approved		
328	Case Category	Export Facilitation (Saima Hussain)
	Name, address of Applicant.	Ferozsons Laboratories Limited PO Ferozsons, Amangarh (000038)
	Application Form Dy. No / Tracking ID & date of submission	(QS6-Z3G-S26H, 2025-10-15)
	Detail of Fee Submitted	75000.0, 2025-09-01,
	The proposed proprietary name / brand name	Dapriwa Tablets 4mg
	Label Claim	Each film coated tablet contains: Daprodustat.....4mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's (1x10's)-As per SRO,12's (1x12's)-As per SRO,14's (1x14's)-As per SRO,20's (2x10's)-As per SRO,28's (2x14's)-As per SRO,30's (3x10's)-

		As per SRO,5's (1x5's)-As per SRO,7's (1x7's)-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Hypoxia-inducible Factor Prolyl Hydroxylase Inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	NA
	Detail of stability batches of drug product	03 batches manufactured each having batch size i.e 1000 tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form-06 (issued dated 12-09-2024, specifies 0.1kg import of Daprodustat), Invoice ,Form-03 ,Form-07, GD are attached in Module 03, Section 3.2.P, Sub-section 3.2.P.8.3
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP studies are conducted against Duvroq Tablets 4mg (Batch No: UB4E, Exp. Date: 11/2027) of Kyowa kirin Co., Ltd- Japan, detail report is attached in Section 3.2.P, Sub-section 3.2.P.2
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data studies of 03 batches is performed by Drug substance manufacturer attached at Module 03 Section 3.2.S.7
	The status in reference regulatory authorities	Brand Name: Duvroq Tablets (Product of GSK) Manufacturer: Kyowa kirin Co., Ltd Japan- PMDA & Brand Name: Jesduvroq Tablets Manufacturer: GlaxoSmithKline Durham, NC 27701-USFDA
	GMP status of the firm	Complying cGMP as per Certificate No. F.11-10/2024-DRAP-435 Dated: 26-11-2024, valid till 09-08-2027.
	Evidence of approval of manufacturing facility	Tablet Section (General) Approval granted by DRAP (Central Licensing Board) via tracking ID: XWU-WU3-4VZM dated: 01-08-2025.
	Evaluation Remarks	
	Decision	
	Approved	
329	Case Category	Export Facilitation (Saima Hussain)
	Name, address of Applicant.	Ferozsons Laboratories Limited PO Ferozsons, Amangarh (000038)
	Application Form Dy. No / Tracking ID & date of submission	(6QZ-MQZ-LWWB, 2025-10-15)
	Detail of Fee Submitted	75000.0, 2025-09-01,
	The proposed proprietary name / brand name	Dapriva Tablets 6mg
	Label Claim	Each film coated tablet contains: Daprodustat.....6mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's (1x10's)-As per SRO,12's (1x12's)-As per SRO,14's (1x14's)-As per SRO,20's (2x10's)-As per SRO,28's (2x14's)-As per SRO,30's (3x10's)-As per SRO,5's (1x5's)-As per SRO,7's (1x7's)-As per SRO

	Shelf Life (Unit)	2 YearDo not store above 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Hypoxia-inducible Factor Prolyl Hydroxylase Inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	NA
	Detail of stability batches of drug product	03 batches manufactured each having batch size i.e 1000 tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form-06 (issued dated 12-09-2024, specifies 0.1kg import of Daprodustat, Invoice ,Form-03 ,Form-07, GD are attached in Module 03, Section 3.2.P, Sub-section 3.2.P.8.3
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP studies are conducted against Duvroq Tablets 6mg (Batch No: U58N, Exp. Date: 02/2028) of Kyowa kirin Co., Ltd- Japan, detail report is attached in Section 3.2.P, Sub-section 3.2.P.2
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data studies of 03 batches is performed by Drug substance manufacturer attached at Module 03 Section 3.2.S.7
	The status in reference regulatory authorities	Brand Name: Duvroq Tablets (Product of GSK) Manufacturer: Kyowa kirin Co.,Ltd Japan-PMDA & Brand Name: Jesduvroq Tablets Manufacturer: GlaxoSmithKline Durham, NC 27701-USFDA
	GMP status of the firm	Complying cGMP as per Certificate No. F.11-10/2024-DRAP-435 Dated: 26-11-2024, valid till 09-08-2027.
	Evidence of approval of manufacturing facility	Tablet Section (General) Approval granted by DRAP (Central Licensing Board) via tracking ID: XWU-WU3-4VZM dated: 01-08-2025.
	Evaluation Remarks	
	Decision	
	Approved	
330	Case Category	Export Facilitation (Saima Hussain)
	Name, address of Applicant.	Atco Laboratories Limited B-18 SITE KARACHI (000188)
	Application Form Dy. No / Tracking ID & date of submission	(XXY-N75-RZ7Q, 2025-05-09)
	Detail of Fee Submitted	37000.0, 2025-01-31,
	The proposed proprietary name / brand name	Apexorin Tablet
	Label Claim	Each film coated tablet contains: Apixaban 2.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30's-Controlled
	Shelf Life (Unit)	2 YearDon't store & transport above 30degree centigrade
	For generic drugs (me-too Status)	Apixaget Tablet 2.5mg by Getz Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Jiangxi Synergy 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	ELIQUIS Tablets by BRISTOL MYERS SQUIBB USA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
331	Case Category	Export Facilitation (Saima Hussain)
	Name, address of Applicant.	Atco Laboratories Limited B-18 SITE KARACHI (000188)
	Application Form Dy. No / Tracking ID & date of submission	(WQ1-L7A-733G, 2025-05-09)
	Detail of Fee Submitted	37000.0, 2025-01-31,
	The proposed proprietary name / brand name	Apexorin Tablet
	Label Claim	Each film coated tablet contains: Apixaban 5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30's-Controlled
	Shelf Life (Unit)	2 YearDon't store & transport above 30degree centigrade
	For generic drugs (me-too Status)	Apixaget Tablet 5mg by Getz Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Jiangxi Synergy 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	ELIQUIS Tablets by BRISTOL MYERS SQUIBB USA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
332	Case Category	Export Facilitation (Saima Hussain)
	Name, address of Applicant.	Atco Laboratories Limited B-18 SITE KARACHI (000188)

	Application Form Dy. No / Tracking ID & date of submission	(H75-W2Q-YZ6P, 2025-10-07)
	Detail of Fee Submitted	37000.0, 2025-05-06,
	The proposed proprietary name / brand name	Bemavator Tablets
	Label Claim	Each film coated tablet contains: Bempedoic Acid 180mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10-De-Controlled
	Shelf Life (Unit)	2 YearDon't store & transport above 30degree centigrade
	For generic drugs (me-too Status)	Bempeget Tablet 180mg by Getz Pharma
	Pharmacotherapeutic Group of (API)	In House
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Enaltec Labs Private Limited
	Detail of stability batches of drug product	Stability study data of 03 batches having batch size of 3000 Tablets each. Accelerated 03 months and real time for 03 months
	Documents for the procurement of API with approval from DRAP (in case of Import)	Copy of clearance certificate dated 09/07/2024
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and PE studies are performed against Bemletol 180mg Tablet by Nabiqasim
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of 3 batches of drug substance is submitted. Accelerated 06 months and real time for 12 months
	The status in reference regulatory authorities	NEXLETOL Tablet by ESPERION THERAPS INC
	GMP status of the firm	Copy of GMP certificate Valid till October,2027
	Evidence of approval of manufacturing facility	CLB Section approval letter dated 23-01-2019
	Evaluation Remarks	
	Decision	
	Approved	
333	Case Category	Export Facilitation (Saima Hussain)
	Name, address of Applicant.	Ferozsans Laboratories Limited PO Ferozsans, Amangarh (000038)
	Application Form Dy. No / Tracking ID & date of submission	(W54-5V5-4U89, 2025-10-01)
	Detail of Fee Submitted	75000.0, 2025-09-01,
	The proposed proprietary name / brand name	Dapriya Tablets 2mg
	Label Claim	Each film coated tablet contains: Daprodustat.....2mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's (1x10's)-As per SRO,12's (1x12's)-As per SRO,14's (1x14's)-As per SRO,20's (2x10's)-As per SRO,28's (2x14's)-As per SRO,30's (3x10's)- As per SRO,5's (1x5's)-As per SRO,7's (1x7's)-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 30°C
	For generic drugs (me-too Status)	NA

	Pharmacotherapeutic Group of (API)	Hypoxia-inducible Factor Prolyl Hydroxylase Inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	NA
	Detail of stability batches of drug product	03 batches manufactured each having batch size i.e 1000 tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form-06 (issued dated 12-09-2024, specifies 0.1kg import of Daprodustat, Invoice ,Form-03 ,Form-07, GD are attached in Module 03, Section 3.2.P, Sub-section 3.2.P.8.3
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP studies are conducted against Duvroq Tablets 2mg (Batch No: N32S, Exp. Date: 11/2027) of Kyowa kirin Co., Ltd- Japan, detail report is attached in Section 3.2.P, Sub-section 3.2.P.2
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data studies of 03 batches is performed by Drug substance manufacturer attached at Module 03 Section 3.2.S.7
	The status in reference regulatory authorities	Brand Name: Duvroq Tablets (Product of GSK) Manufacturer: Kyowa kirin Co., Ltd Japan- PMDA & Brand Name: Jesduvroq Tablets Manufacturer: GlaxoSmithKline Durham, NC 27701-USFDA
	GMP status of the firm	Complying cGMP as per Certificate No. F.11-10/2024-DRAP-435 Dated: 26-11-2024, valid till 09-08-2027.
	Evidence of approval of manufacturing facility	Tablet Section (General) Approval granted by DRAP (Central Licensing Board) via tracking ID: XWU-WU3-4VZM dated: 01-08-2025.
	Evaluation Remarks	
	Decision	
	Approved	
334	Case Category	Export Facilitation (Saima Hussain)
	Name, address of Applicant.	Highnoon Laboratories Ltd 17.5 KM, Multan Road, (000155)
	Application Form Dy. No / Tracking ID & date of submission	(V7Q-3WQ-27ZR, 2025-11-12)
	Detail of Fee Submitted	38700, 2025-10-28,
	The proposed proprietary name / brand name	Bempecol 180mg Tablet
	Label Claim	Each Film coated Tablet contains: Bempedoic Acid 180mg
	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,21's-As per SRO,28's-As per SRO,30's-As per SRO,7's-As per SRO
	Shelf Life (Unit)	24 MonthDo not Store above 30°C. Protect from light and moisture
	For generic drugs (me-too Status)	The Searle Company Limited Bempics Tablet Reg # 120232
	Pharmacotherapeutic Group of (API)	Adenosine triphosphate citrate lyase (ACL) inhibitor ATC code: C10AX15

	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, Anakapalli District, Andhra Pradesh, 531021, India (IND).
	Detail of stability batches of drug product	RDP0066-01 RDP0066-02 RDP0066-03
	Documents for the procurement of API with approval from DRAP (in case of Import)	E-9035964687381
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Study was conducted for Comparative Dissolution Profile of Bempecol 180mg Tablet & Nexletol 180 mg film-coated tablets (reference product). Dissolution profile for both Bempecol 180mg Tablet & Nexletol 180 mg film-coated tablets (reference product) found to be satisfactory
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IV B
	The status in reference regulatory authorities	Nilemdo 180 mg film-coated tablets MHRA
	GMP status of the firm	Validity 18-12-2027
	Evidence of approval of manufacturing facility	Metrochem API Private Limited, Unit-IV, Plot No. 34B, 40B & 60B, J.N. Pharma City, Thanam Village, Parawada Mandal, Anakapalli District, Andhra Pradesh, 531021, India (IND).
	Evaluation Remarks	
	Decision	
	Approved	
335	Case Category	Export Facilitation (Saima Hussain)
	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	(D1G-QP4-45JH, 2025-07-15)
	Detail of Fee Submitted	75000.0, 2025-05-09,
	The proposed proprietary name / brand name	Hifstat Tablet 8mg
	Label Claim	Each film coated tablet contains: Daprodustat.....8mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,14's-As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO,5's-As per SRO,7's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	Hypoxia-inducible Factor Prolyl Hydroxylase Inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Not Applicable
	Detail of stability batches of drug product	Batch No: NPD-T-2702-S, Batch No: NPD-T-2714-S, Batch No: NPD-T-2715-S
	Documents for the procurement of API with approval from DRAP	Form 6 attached mentioning import of Daprodustat (0.6800kg) from M/S.Gansu Haotian

	(in case of Import)	Pharmatech Co Ltd
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence established with Innovator Product Duvroq 8mg Tablet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
	The status in reference regulatory authorities	Jesduvroq Tablets 8mg by US-FDA
	GMP status of the firm	GMP certificate valid till 15th August 2027
	Evidence of approval of manufacturing facility	Tablet (General)
	Evaluation Remarks	
	Decision	
	Approved	
336	Case Category	Export Facilitation (Saima Hussain)
	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	(H8M-AEL-3UVR, 2025-10-01)
	Detail of Fee Submitted	75000.0, 2025-06-19,
	The proposed proprietary name / brand name	Hifstat Tablet 2mg
	Label Claim	Each film coated tablet contains: Daprodustat.....2mg
	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,5's-As per SRO,7's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	Hypoxia-inducible Factor Prolyl Hydroxylase Inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Not Applicable
	Detail of stability batches of drug product	Batch No: NPD-T-2710-S, Batch No: NPD-T-2760-S, Batch No: NPD-T-2761-S
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 attached mentioning import of Daprodustat (0.6800kg) from M/S.Gansu Haotian Pharmatech Co Ltd
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence established with Innovator Product Duvroq 2mg Tablet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
	The status in reference regulatory authorities	Duvroq Tablets by PMDA-Japan
	GMP status of the firm	GMP certificate valid till 15th August 2027
	Evidence of approval of manufacturing facility	Tablet (General)
	Evaluation Remarks	
	Decision	
	Approved	
337	Case Category	Export Facilitation (Saima Hussain)

	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	(UXY-BVA-SRYU, 2025-10-01)
	Detail of Fee Submitted	75000.0, 2025-06-19,
	The proposed proprietary name / brand name	Hifstat Tablet 6mg
	Label Claim	Each film coated tablet contains: Daprodustat.....6mg
	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,5's-As per SRO,7's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	Hypoxia-inducible Factor Prolyl Hydroxylase Inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Not Applicable
	Detail of stability batches of drug product	Batch No: NPD-T-2705-S, Batch No: NPD-T-2768-S, Batch No: NPD-T-2769-S
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 attached mentioning import of Daprodustat (0.6800kg) from M/S.Gansu Haotian Pharmatech Co Ltd
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence established with Innovator Product Duvroq 6mg Tablet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
	The status in reference regulatory authorities	Duvroq Tablets by PMDA-Japan
	GMP status of the firm	GMP certificate valid till 15th August 2027
	Evidence of approval of manufacturing facility	Tablet (General)
	Evaluation Remarks	
	Decision	
	Approved	
338	Case Category	Export Facilitation (Saima Hussain)
	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	(YBW-31M-Q4M9, 2025-10-07)
	Detail of Fee Submitted	75000.0, 2025-06-19,
	The proposed proprietary name / brand name	Hifstat Tablet 4mg
	Label Claim	Each film coated tablet contains: Daprodustat.....4mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,14's-As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO,5's-As per SRO,7's-As per SRO

	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	Hypoxia-inducible Factor Prolyl Hydroxylase Inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Not Applicable
	Detail of stability batches of drug product	Batch No: NPD-T-2704-S, Batch No: NPD-T-2762-S, Batch No: NPD-T-2763-S
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 attached mentioning import of Daprodustat (0.6800kg) from M/S.Gansu Haotian Pharmatech Co Ltd
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence established with Innovator Product Duvroq 4mg Tablet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
	The status in reference regulatory authorities	Duvroq Tablets by PMDA-Japan
	GMP status of the firm	GMP certificate valid till 15th August 2027
	Evidence of approval of manufacturing facility	Tablet (General)
	Evaluation Remarks	
	Decision	
	Approved	
339	Case Category	Export Facilitation (Saima Hussain)
	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	(PNP-T8G-X5XG, 2025-07-15)
	Detail of Fee Submitted	75000.0, 2025-05-09,
	The proposed proprietary name / brand name	Hifstat Tablet 1mg
	Label Claim	Each film-coated tablet contains: Daprodustat.....1mg
	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,5's-As per SRO,7's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	Hypoxia-inducible Factor Prolyl Hydroxylase Inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Not Applicable
	Detail of stability batches of drug product	Batch No: NPD-T-2701-S, Batch No: NPD-T-2726-S, Batch No: NPD-T-2727-S
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 attached mentioning import of Daprodustat (0.6800kg) from M/S.Gansu Haotian Pharmatech Co Ltd
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence established with Innovator Product Duvroq 1mg Tablet

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
	The status in reference regulatory authorities	Duvroq Tablets by PMDA-Japan
	GMP status of the firm	GMP certificate valid till 15th August 2027
	Evidence of approval of manufacturing facility	Tablet (General)
	Evaluation Remarks	
	Decision	
	Approved	
340	Case Category	Contract Manufacturing (Saima Hussain)
	Name, address of Applicant.	Cell Health Sciences , Plot No 217, Industrial Triangle, Kahuta Road, Islamabad (000711)
	Application Form Dy. No / Tracking ID & date of submission	(AE7-267-VXUW, 2024-06-20)
	Detail of Fee Submitted	75000.0, 2024-05-31,
	The proposed proprietary name / brand name	Atex 4mg/ml Oral Solution
	Label Claim	Each ml of oral solution contains: Atomoxetine Hydrochloride eq. to Atomoxetine.....4mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x60ml, 1x90ml, 1x10-As per SRO
	Shelf Life (Unit)	2 YearStore in a cool & Dry place below 30
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Strattera 4mg/ml oral solution of M/s Patheon France 40 Boulevard de Champaret 38300 Bourgoin-Jallieu France. (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.12/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. Registration Board in its 350th meeting approved the product Atten 4mg/ml oral solution (Each ml of oral solution contains: Atomoxetine Hydrochloride eq. to Atomoxetine.....4mg) in the name of M/s. Wimits Pharmaceuticals.	
	Decision	
	Approved	
	Firm shall submit fee for pre-registration variation as per the latest fee SRO prior the issuance of Registration letter.	
341	Case Category	Export Facilitation (Saima Hussain)
	Name, address of Applicant.	OBS Pharma (Pvt) Ltd 108 Kotlakhpat Industrial Estate, Lahore 54760 Pakistan (000243)

	Application Form Dy. No / Tracking ID & date of submission	(MHV-J1R-H27S, 2026-03-31)
	Detail of Fee Submitted	38700, 2025-12-02,
	The proposed proprietary name / brand name	OBS-PILL Tablet
	Label Claim	Each tablet contains: Norgestrel.....0.075mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14's-As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO,56's-As per SRO,84's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C.
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Progestogens, contraception and hormone replacement therapy
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Qinhuangdao Zizhu Pharmaceutical Co., Ltd. No.10, Longhai Road, Economic and Technological Development Zone, Qinhuangdao, Hebei Province, China.
	Detail of stability batches of drug product	OBSRD06-003, OBSRD06-004, OBSRD06-005
	Documents for the procurement of API with approval from DRAP (in case of Import)	Final Clearance Certificate for Norgestrel has been issued against Computerized No. RO-466F48 on 04-06-2025.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence and comparative dissolution data has been submitted, demonstrating the results between the Opill 0.075mg Tablet (test product) and the Norgestrel 0.075mg Tablet (reference product)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	71001803001, 71001803002, 71001803003
	The status in reference regulatory authorities	Opill Tablet (USFDA Approved)
	GMP status of the firm	GMP certificate of Manufacturer (OBS Pharma Pvt Ltd) has been issued based on the evaluation conducted on 07-05-2024 and is valid for three years from the date of inspection.
	Evidence of approval of manufacturing facility	The Central Licensing Board has approved the renewal of the tablet (hormone) section in its 309th meeting held on 19th May, 2025
	Evaluation Remarks	
	Decision	
	Approved	
342	Case Category	Contract Manufacturing (Saima Hussain)
	Name, address of Applicant.	Welcome Pakistan Trading Pharma (Pvt) Ltd Chakri Interchange, Gangawala (000987)
	Application Form Dy. No / Tracking ID & date of submission	(E2U-VQ9-P5W6, 2024-08-29)
	Detail of Fee Submitted	75000.0, 2024-06-27,
	The proposed proprietary name / brand name	Tacrowin 0.03% Ointment
	Label Claim	Each gm Contains: Tacrolimus (as Monohydrate).....0.3mg (0.03%w/w) (Product complies Innovator's Specs)

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25c
	For generic drugs (me-too Status)	Aimus Ointment by Aims Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot NO. 122, Block-A, Phase-V, Industrial Estate, Hattar, KPK. -
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. Registration Board in its 353rd meeting approved the instant product in the name of M/s. Wnsfeild Pharmaceuticals (Contract acceptor)	
	Decision	
	Approved	
	Firm shall submit fee for pre-registration variation as per the latest fee SRO, prior the issuance of Registration letter.	
343	Case Category	Export Facilitation (Saima Hussain)
	Name, address of Applicant.	Highnoon Laboratories Ltd 17.5 KM, Multan Road, (000155)
	Application Form Dy. No / Tracking ID & date of submission	(22E-MRD-QRNB, 2026-02-03)
	Detail of Fee Submitted	38700, 2025-12-04,
	The proposed proprietary name / brand name	Bempac-EZ 180/10mg Tablets
	Label Claim	Each film coated tablet contains: - Bempedoic Acid 180 mg Ezetimibe 10mg
	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,30's-As per SRO
	Shelf Life (Unit)	2 YearDo not Store above 30°C. Protect from light and moisture.
	For generic drugs (me-too Status)	Horizon HealthCare (Pvt) Ltd Bempex-Z Tablets 180/10mg Reg # 121671
	Pharmacotherapeutic Group of (API)	Lipid modifying agents ATC code: C10BA10
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Metrochem API Private Limited, Synthimed Labs Private Limited
	Detail of stability batches of drug product	RDP0060-06 RDP0060-08 RDP0060-09
	Documents for the procurement of API with approval from DRAP (in case of Import)	E-9035964687381 E-7623864687293

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Study was conducted for Comparative Dissolution Profile of Bempedoic Acid/Ezetimibe 180mg/10mg Tablet and Nexlizet 180mg/10mg. Dissolution profile for both Bempedoic Acid/Ezetimibe 180mg/10mg Tablet and Nexlizet 180mg/10mg found to be satisfactory.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IV B
	The status in reference regulatory authorities	Nustendi 180mg/10mg film-coated tablets (EMA)
	GMP status of the firm	Copy of GMP certificate on basis of inspection dated 12.06.2024 is submitted.
	Evidence of approval of manufacturing facility	Renewal letter dated 17.11.2025 is submitted wherein Tablet General section is mentioned.
	Evaluation Remarks	
	Decision	
	Approved	
344	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	Magns Pharmaceuticals Plot # 7B Value Addition City Sahianwala Road Khurrianwala (000849)
	Application Form Dy. No / Tracking ID & date of submission	(H6N-D21-NEMY, 2024-05-07)
	Detail of Fee Submitted	30000.0, 2024-04-30,
	The proposed proprietary name / brand name	Magzidol Extra
	Label Claim	Each Tablet Contains: Paracetamol 500 mg Caffeine 65 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10 x10,s -As per SRO
	Shelf Life (Unit)	2 Yearstore below 30 oC
	For generic drugs (me-too Status)	Panadol Extra Tablet by GSK
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Aarti Industries Limited (For Caffeine). Unit – III Plot no. K – 17/18/19, MIDC, Tarapur,Tal. Palghar Dist. Thane – 401 506 Maharashtra India Phone: 91-2525-272524, 272528, 205131 Web site: www.aartig,PHARMAGEN LIMITED (For Paracetamol). Address: Manufacturing unit: Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore. Tel: +92 (042) 5935261-68 Fax:+92 (042) 5935269 UAN: 111-111-305 E-mail: pblbd@hotmail
	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	Panadol Extra by GSK Ireland HPRA

	GMP status of the firm			
	Evidence of approval of manufacturing facility			
	Evaluation Remarks			
	Decision			
	Approved			
	Firm shall submit fee for pre-registration variation as per the latest fee SRO, prior the issuance of Registration letter.			
345	Case Category	Contract Manufacturing (Saima Hussain)		
	Name, address of Applicant.	Bio-Next Pharmaceuticals plot no 50 street no S-10 RCCI Rawat (000910)		
	Application Form Dy. No / Tracking ID & date of submission	(ZDV-YDZ-8A1Q, 2024-06-20)		
	Detail of Fee Submitted	75000.0, 2021-10-14,		
	The proposed proprietary name / brand name	Fixen		
	Label Claim	Each capsule contains: Cefixime as trihydrate 400mg		
	Reference to Finished product specifications	Manufacturer Specification		
	Proposed Pack Size	5s & 10s-Controlled		
	Shelf Life (Unit)	2 YearStore below 30C		
	For generic drugs (me-too Status)	Cebosh Capsule Bosch Pharma		
	Pharmacotherapeutic Group of (API)			
	Name, address of Manufacturing site:	Bio-Labs (Pvt) Ltd.-145, Industrial Trangle, Kahuta Road-		
	Name & address of API manufacturer	Saakh Pharma Karachi		
	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		
	GMP status of the firm			
	Evidence of approval of manufacturing facility			
		Evaluation Remarks		
		sr.no.	Observations	Response of the Firm
		1.	Submit the revised drug product specification along with the requisite fee, in accordance with the Cefixime Capsules monograph approved by DRAP dated 22 March 2022, a copy of which is available on the official DRAP website.	Firm submitted revised specification in compliance Cefixime Capsule Monograph approved by DRAP, CDP report and Pharmaceutical Equivalence report.
		Decision		
		Approved		
		Firm shall submit fee for pre-registration variation as per the latest fee SRO prior the issuance of Registration letter.		

346	Case Category	Routine (Saima Hussain)
	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	(UTH-V9E-NYBD, 2024-08-26)
	Detail of Fee Submitted	30000.0, 2024-08-13,
	The proposed proprietary name / brand name	Vonop 10mg Tablets
	Label Claim	Each film coated tablet contains: Vonoprazan Fumarate (equivalent to vonoprazan).....10mg (Innovator Specifications)
	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)	Vonozan Tablets 10 mg, Manufacturer: Getz Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Voquezna 10mg Tablet, Company: Phathom, (NDA): 215151 (USFDA Approved)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Firm in their response informed that, the product was approved on contract manufacturing basis and then they had transferred the product from M/s Seraph Pharmaceuticals, Islamabad to their own facility M/s Solaris Life Sciences (Pvt.) Ltd. Now, they have got the approval of change in manufacturing site of already registered drug product. Therefore, they have to withdraw this application for registration.	
	Decision	
	Rejected	
	Registration Board rejected the application as withdrawn by the firm	
347	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	Genesis Pharmaceuticals Pvt. Ltd. 25-Sundar Industrial Estate, Raiwind Road Lahore (000793)
	Application Form Dy. No / Tracking ID & date of submission	(4ZX-6T7-E7L3, 2024-06-03)
	Detail of Fee Submitted	, ,
	The proposed proprietary name / brand name	Genedex 60mg Capsule

	Label Claim	Each Capsule contains: Dexlansoprazole Dual Delayed Release Pellets 22.5 % w/w Equivalent to Dexlansoprazole.....60mg (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 temperature 15 to 30 C away from sunlight
	For generic drugs (me-too Status)	Razodex 60mg Capsule Getz Pharma Reg. 000793
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	VISION PHARMACEUTICALS Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad-Pakistan
	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	Dexilant 60 mg CAPSULES by USFDA Approve
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm submitted Pharmaceutical Equivalence Report in which the results reported for the comparator product are exactly same across all quality test to those submitted by another firm in its registration dossier.	
	Decision	
	Rejected	
	The Registration Board decided to reject the instant application, considering that the firm had submitted Pharmaceutical Equivalence Report in which the results reported for the comparator product are exactly same across all quality test to those submitted by another firm in its registration dossier.	
348	Case Category	Routine (Saima Hussain)
	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	(YYH-R76-44S5, 2026-06-08)
	Detail of Fee Submitted	37000.0, 2025-07-04,
	The proposed proprietary name / brand name	Vonprate 10mg Tablet
	Label Claim	Each Tablet Contain: Vonoprazane as fumarate.....10 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x14's-As per SRO
	Shelf Life (Unit)	2 Year30°C
	For generic drugs (me-too Status)	VONOZAN 10MG TABLET by Getz Pharma

	Pharmacotherapeutic Group of (API)	Potassium-Competitive Acid Blocker
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Guangdong xianqiang pharmaceutical co., Ltd
	Detail of stability batches of drug product	3 Batches of Accelerated and long term Stability provided
	Documents for the procurement of API with approval from DRAP (in case of Import)	YES air bill invoice attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	attached comparative study perform with branded generic product
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 Batches provided
	The status in reference regulatory authorities	PMDA Japan Approved
	GMP status of the firm	03-june-2028
	Evidence of approval of manufacturing facility	DML attached
	Evaluation Remarks	
	Firm has submitted exactly same assay verification report of drug substance performed by drug product manufacturer, Pharmaceutical Equivalence data, Comparative dissolution Profile report and Chromatograms of stability data as submitted by another firm along with their registration application.	
	Decision	
	Rejected	
349	The Registration Board decided to reject the instant application, considering that the firm had submitted the exact same assay verification report of the drug substance performed by the drug product manufacturer, pharmaceutical equivalence data, comparative dissolution profile report, assay validation report of the drug product, and chromatograms of stability data that had been submitted by M/s. Dew-Max Pharmaceuticals (Pvt.) Ltd., Islamabad, along with its registration application.	
	Case Category	Routine (Saima Hussain)
	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	(2JQ-V5J-STR6, 2026-02-26)
	Detail of Fee Submitted	37000.0, 2025-07-04,
	The proposed proprietary name / brand name	Vonprate 20mg Tablet
	Label Claim	Each tablet Contain: Vonoprazane as fumarate.....20 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x14's-As per SRO
	Shelf Life (Unit)	2 Year30°C
	For generic drugs (me-too Status)	VONOZAN 20MG TABLET by Getz Pharma
	Pharmacotherapeutic Group of (API)	Potassium-Competitive Acid Blocker
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Guangdong xianqiang pharmaceutical co., Ltd
	Detail of stability batches of drug product	3 Batches of Accelerated and long term Stability provided
	Documents for the procurement of API with approval from DRAP (in case of Import)	YES air bill invoice attached

	Pharmaceutical Equivalence and Comparative Dissolution Profile	attached comparative study perform with branded generic product
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 Batches provided
	The status in reference regulatory authorities	PMDA Japan Approved
	GMP status of the firm	03-june-2028
	Evidence of approval of manufacturing facility	DML attached
	Evaluation Remarks	
	Firm has submitted exactly same assay verification report of drug substance performed by drug product manufacturer, Comparative dissolution Profile report and assay validation report of drug product as submitted by another firm along with their registration application.	
	Decision	
	Rejected	
	The Registration Board decided to reject the instant application, considering that the firm had submitted the exact same assay verification report of the drug substance performed by the drug product manufacturer, pharmaceutical equivalence data, comparative dissolution profile report and assay validation report of the drug product that had been submitted by M/s. Dew-Max Pharmaceuticals (Pvt.) Ltd., Islamabad, along with its registration application.	
350	Case Category	Routine (Saima Hussain)
	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	(X9R-P18-X6NQ, 2026-06-08)
	Detail of Fee Submitted	37000.0, 2025-03-06,
	The proposed proprietary name / brand name	Dewnop 10mg Tablet
	Label Claim	Each Film Coated Tablet Contain: Vonoprazan as fumarate 10mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3*10-As per SRO
	Shelf Life (Unit)	2 Year Ambient
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Guangdon Xianging Pharmaceuticals 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	

Firm has submitted exactly same assay verification report of drug substance performed by drug product manufacturer, Pharmaceutical Equivalence data, Comparative dissolution Profile report and Chromatograms of stability data as submitted by another firm along with their registration application.

Decision

Rejected

The Registration Board decided to reject the instant application, considering that the firm had submitted the exact same assay verification report of the drug substance performed by the drug product manufacturer, pharmaceutical equivalence data, comparative dissolution profile report, assay validation report of the drug product, and chromatograms of stability data that had been submitted by M/s. Mediate Pharmaceutical Pvt Ltd., Karachi, along with its registration application.

351	Case Category	Routine (Saima Hussain)
	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	(N2Y-SQB-1PZE, 2026-06-08)
	Detail of Fee Submitted	37000.0, 2025-03-06,
	The proposed proprietary name / brand name	Dewnop 20mg Tablet
	Label Claim	Each Film Coated Tablet Contain: Vonoprazan as fumarate 20mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14s-As per SRO
	Shelf Life (Unit)	2 Year Ambient
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Xianqiang Pharmaceutical Pvt. Ltd. No. 6, Industrial Avenue, Conghua Economic Development zone, Guangzhou city, Guangdong Province, 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	
	Firm has submitted exactly same assay verification report of drug substance performed by drug product manufacturer, Comparative dissolution Profile report and assay validation report of drug product as submitted by another firm along with their registration application.	
	Decision	
	Rejected	

	The Registration Board decided to reject the instant application, considering that the firm had submitted the exact same assay verification report of the drug substance performed by the drug product manufacturer, pharmaceutical equivalence data, comparative dissolution profile report and assay validation report of the drug product that had been submitted by M/s. Mediate Pharmaceutical Pvt Ltd., Karachi, along with its registration application.	
352	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	TRISON RESEARCH LABORATORIES PRIVATE LIMITED 27-A PUNJAB SMALL INDUSTRIAL ESTATE (000529)
	Application Form Dy. No / Tracking ID & date of submission	(9H7-6A7-G9YB, 2026-06-08)
	Detail of Fee Submitted	37000.0, 2025-02-12,
	The proposed proprietary name / brand name	PRANOZ 10MG TABLET
	Label Claim	Each Tablet Contains VONOPRAZAN AS FUMARATE 10MG
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	20s-As per SRO
	Shelf Life (Unit)	2 Year Ambient
	For generic drugs (me-too Status)	Manufacturer Name: Hilton Pharma Brand Name & Strength: : . Voniza 10 mg Tablet Composition: Each Tablet contains: Vonoprazane 10 mg Dosage Form: Oral solid dosa
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Guangdon Xianging Pharmaceuticals 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	Reference regulatory authority: PMDA Japan Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Firm has submitted exactly same assay verification report of drug substance performed by drug product manufacturer, Comparative dissolution Profile report, assay validation report and Chromatograms of stability data as submitted by another firm along with their registration application.	
	Decision	
	Rejected	
	Registration Board decided to reject the instant application, considering that the firm had submitted the exact same assay verification report of the drug substance performed by the drug product manufacturer, pharmaceutical equivalence data, comparative dissolution profile report, assay validation report of the drug product, and stability data (including	

	chromatograms and calculation sheets) that had been submitted by M/s. Dew-Max Pharmaceuticals Pvt. Ltd., Islamabad, along with its registration application.	
353	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	TRISON RESEARCH LABORATORIES PRIVATE LIMITED 27-A PUNJAB SMALL INDUSTRIAL ESTATE (000529)
	Application Form Dy. No / Tracking ID & date of submission	(7Z8-PV3-52GN, 2026-06-08)
	Detail of Fee Submitted	37000.0, 2025-02-12,
	The proposed proprietary name / brand name	PRANOZ 20MG TABLET
	Label Claim	EACH TABLET VONOPRAZAN AS FUMARATE 20MG
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14s-As per SRO
	Shelf Life (Unit)	2 YearAmbient
	For generic drugs (me-too Status)	Manufacturer Name: Hilton Pharma Brand Name & Strength: : . Voniza 20 mg Tablet Composition: Each Tablet contains: Vonoprazane 20 mg Dosage Form: Oral solid dosa
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Guangdon Xianging Pharmaceuticals 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	Reference regulatory authority: PMDA Japan Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
354	Evaluation Remarks	
	Firm has submitted exactly same assay verification report of drug substance performed by drug product manufacturer, Comparative dissolution Profile report, assay validation report and Chromatograms of stability data as submitted by another firm along with their registration application.	
	Decision	
354	Rejected	
	Registration Board decided to reject the instant application, considering that the firm had submitted the exact same assay verification report of the drug substance performed by the drug product manufacturer, comparative dissolution profile report, assay validation report of the drug product, and stability data (including chromatograms and calculation sheets) that had been submitted by M/s. Dew-Max Pharmaceuticals Pvt. Ltd., Islamabad, along with its registration application.	
354	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	Bloom Pharmaceuticals (Pvt) Ltd. Plot No. 30, Phase I & II, Industrial Estate, Hattar (000374)

	Application Form Dy. No / Tracking ID & date of submission	(Z4G-QEG-HLYX, 2026-06-08)
	Detail of Fee Submitted	38700, 2025-09-01,
	The proposed proprietary name / brand name	BLONOVO 10MG TABLET
	Label Claim	Each 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 Ambient
	For generic drugs (me-too Status)	Attached
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Guangdone Xianqiang Pharmaceuticals, Co LTD China
	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	
	Firm has submitted exactly same assay verification report of drug substance performed by drug product manufacturer, Comparative dissolution Profile report and assay validation report as submitted by another firm along with their registration application.	
355	Decision	
	Rejected	
	The Registration Board decided to reject the instant application, considering that the firm had submitted the exact same assay verification report of the drug substance performed by the drug product manufacturer, comparative dissolution profile report and assay validation report of the drug product that had been submitted by M/s. Mediate Pharmaceutical Pvt Ltd., Karachi, and M/s. Dew- max Pharmaceuticals (Pvt.) Ltd, Islamabad. along with their registration applications.	
	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	Bloom Pharmaceuticals (Pvt) Ltd. Plot No. 30, Phase I & II, Industrial Estate, Hattar (000374)
	Application Form Dy. No / Tracking ID & date of submission	(8HR-YS8-2RBJ, 2026-06-08)
	Detail of Fee Submitted	38700, 2025-09-01,
	The proposed proprietary name / brand name	BLONOVO 20MG TABLET
	Label Claim	Each Tablet Contain VONOPRAZAN 20MG
	Reference to Finished product specifications	As per Innovators Specification
	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	Guangdne Xianqiang Pharmaceuticals Co, LTD China
	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	
	Firm has submitted exactly same assay verification report of drug substance performed by drug product manufacturer, Comparative dissolution Profile report and assay validation report as submitted by another firm along with their registration application.	
	Decision	
	Rejected	
	The Registration Board decided to reject the instant application, considering that the firm had submitted the exact same assay verification report of the drug substance performed by the drug product manufacturer, comparative dissolution profile report and assay validation report of the drug product that had been submitted by M/s. Mediate Pharmaceutical Pvt Ltd., Karachi, and M/s. Dew- max Pharmaceuticals (Pvt.) Ltd, Islamabad. along with their registration applications.	
356	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	Zeta Pharmaceuticals 494-A Sundar Industrial Estate Lahore (000818)
	Application Form Dy. No / Tracking ID & date of submission	(HD3-U2H-D2HD, 2024-08-19)
	Detail of Fee Submitted	30000.0, 2024-03-19,
	The proposed proprietary name / brand name	VONAZET 20mg
	Label Claim	Each Tablet Contain 20mg Vonoprazane
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14s-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	Xianqiang Pharmaceutical Pvt. Ltd. No. 6, Industrial Avenue, Conghua Economic Development zone, Guangzhou city, Guangdong Province, 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	
	Firm has submitted exactly same Chromatograms along with stability data of drug product as submitted by another firm along with their registration application.	
	Decision	
	Rejected	
	Registration Board decided to reject the instant application, considering that the firm had submitted exact same chromatograms along with stability data of drug product that had been submitted by M/s. Dew-Max Pharmaceutical (Pvt.) Ltd., Islamabad along with its registration application.	
357	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	Zeta Pharmaceuticals 494-A Sundar Industrial Estate Lahore (000818)
	Application Form Dy. No / Tracking ID & date of submission	(5MQ-7UG-R4R2, 2025-02-14)
	Detail of Fee Submitted	30000.0, 7000.0 2024-03-14, 2024-09-19
	The proposed proprietary name / brand name	VONAZET
	Label Claim	Each Tablet Contains 10mg Vonoprazane
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14s-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	Xianqiang Pharmaceutical Pvt. Ltd. No. 6, Industrial Avenue, Conghua Economic Development zone, Guangzhou city, Guangdong Province, 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	

	Firm has submitted exactly same chromatograms along with stability data of drug product as submitted by another firm.	
	Decision	
	Rejected	
	Registration Board decided to reject the instant application, considering that the firm had submitted exact same stability data (including chromatograms and calculation sheets) that had been submitted by M/s. Dew-Max Pharmaceutical (Pvt.) Ltd., Islamabad along with its registration application.	
358	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	Kaizen Pharmaceuticals (Pvt) Ltd Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi (000755)
	Application Form Dy. No / Tracking ID & date of submission	(SWJ-VPT-LMRR, 2024-05-28)
	Detail of Fee Submitted	75000.0, 75000.0 2023-12-05, 2024-01-16
	The proposed proprietary name / brand name	Memorin 28mg ER Capsule
	Label Claim	Each capsule contains : 175mg of Memantine HCl 16% SR pellets equivalent to..... 28mg of Memantine HCl
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	2 YearStore in a cool and dry place. Below 30 oC
	For generic drugs (me-too Status)	None
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Pellets Pharma Limited Address: Factory: Plot No.: 8&9, TSIIC- EPIP, Pashamylaram, Patancheru [Mandal], Sangareddy [Dist], Telangana [T.S] 502307
	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	Food and Drug Administration (FDA) USA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Firm has submitted exactly same chromatograms along with the comparative dissolution data as submitted by another firm, only changes the name of analyst and title of the firm.	
	Decision	
	Rejected	
	Registration Board decided to reject the instant application, considering that the firm had submitted the exact same chromatograms along with the comparative dissolution data as submitted by another firm, only changes the name of analyst and title of the firm.	

359	Case Category	Routine (Saima Hussain)
	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	(G25-Z9Y-VVGX, 2024-09-09)
	Detail of Fee Submitted	75000.0, 2024-08-07,
	The proposed proprietary name / brand name	Finerenone Tablet 10mg
	Label Claim	Finerenone Tablet.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10s-As per SRO,20s-As per SRO,30s-As per SRO
	Shelf Life (Unit)	2 Yearstore below 30C in a dry place and protect from sunlight
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	
	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	Kerendia Film-coated Tablet 10mg
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
	Firm shall submit fee for pre-registration variation as per the latest fee SRO prior the issuance of Registration letter.	
360	Case Category	New Molecule/Formulation (Saima Hussain)
	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	(UY4-74H-VX4L, 2026-02-10)
	Detail of Fee Submitted	75000, 2025-12-12,
	The proposed proprietary name / brand name	Xantro 50mg/20mg Capsules
	Label Claim	Xanomeline and Trospium Chloride 50mg and 20mg/Capsule
	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, 90 & 100's Tablets-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	NA

	Pharmacotherapeutic Group of (API)	Xanomeline Tartrate & Trospium Chloride: This is a novel combination: centrally acting muscarinic agonist (Xanomeline) plus a peripherally selective muscarinic antagonist (Trospium chloride) formulated to treat schizophrenia
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	GANSU HAOTIAN PHARMACEUTICAL CO., LTD No.11, Chongqing Road, Baiyin District, Baiyin City, Gansu Province, China
	Detail of stability batches of drug product	Attached in Module 3 in section 3.2.P.8
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached in Module 3 in section 3.2.P.8
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in Module 3 in section 3.2. P.2.2
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached in Module 3 in section 3.2. S.7
	The status in reference regulatory authorities	COBENFYTM (Xanomeline and Trospium chloride) capsules, for oral use, Capsules: (Xanomeline/Trospium chloride): 50mg/20mg, 100mg/20mg, 125mg/30mg, Initial U.S. Approval: 2024, Marketed by: Bristol-Myers Squibb Company, Princeton, NJ 08543 USA
	GMP status of the firm	Attached in Module 1 in section 1.3.5
	Evidence of approval of manufacturing facility	Attached in Module 1 in section 1.3.5
	Evaluation Remarks	
	Registration Board in its 357th meeting decided to defer the instant application for submission of : 1. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation. 2. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07 3. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division. Firm submitted RMP of applied product. Further firm submitted the evidence confirming the nomination of Pharmacovigilance officer.	
	Decision	
	Approved	
	Firm shall submit fee for pre-registration variation as per the latest fee SRO prior the issuance of Registration letter.	
361	Case Category	New Molecule/Formulation (Saima Hussain)
	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	(EGN-H9U-GEB8, 2026-02-10)
	Detail of Fee Submitted	75000, 2025-12-12,
	The proposed proprietary name / brand name	Xantro 100mg/20mg Capsules
	Label Claim	Xanomeline and Trospium Chloride 100mg and 20mg/Capsule
	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, 90 & 100's Tablets-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Xanomeline Tartrate & Trospium Chloride: This is a novel combination: centrally acting muscarinic agonist (Xanomeline) plus a peripherally selective muscarinic antagonist (Trospium chloride) formulated to treat schizophrenia
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	GANSU HAOTIAN PHARMACEUTICAL CO., LTD No.11, Chongqing Road, Baiyin District, Baiyin City, Gansu Province, China
	Detail of stability batches of drug product	Attached in Module 3 in section 3.2.P.8
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached in Module 3 in section 3.2.P.8
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in Module 3 in section 3.2. P.2.2
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached in Module 3 in section 3.2. S.7
	The status in reference regulatory authorities	COBENFY (Xanomeline and Trospium chloride) capsules, for oral use, Capsules: (Xanomeline/Trospium chloride): 50mg/20mg, 100mg/20mg, 125mg/30mg, Initial U.S. Approval: 2024, Marketed by: Bristol-Myers Squibb Company, Princeton, NJ 08543 USA
	GMP status of the firm	Attached in Module 1 in section 1.3.5
	Evidence of approval of manufacturing facility	Attached in Module 1 in section 1.3.5
	Evaluation Remarks	
	Registration Board in its 357th meeting decided to defer the instant application for submission of : 1. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation. 2. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07 3. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division. Firm submitted RMP of applied product. Further firm submitted the evidence confirming the nomination of Pharmacovigilance officer.	
	Decision	
	Approved	
	Firm shall submit fee for pre-registration variation as per the latest fee SRO prior the issuance of Registration letter.	
362	Case Category	New Molecule/Formulation (Saima Hussain)
	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	(4ZL-JZ5-2RR9, 2026-02-10)
	Detail of Fee Submitted	75000, 2025-12-15,

	The proposed proprietary name / brand name	Xantro 125mg/30mg Capsules
	Label Claim	Xanomeline and Trospium Chloride 125mg and 30mg/Capsule
	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, 90 & 100's Tablets-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Xanomeline Tartrate & Trospium Chloride: This is a novel combination: centrally acting muscarinic agonist (Xanomeline) plus a peripherally selective muscarinic antagonist (Trospium chloride) formulated to treat schizophrenia
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	GANSU HAOTIAN PHARMACEUTICAL CO., LTD No.11, Chongqing Road, Baiyin District, Baiyin City, Gansu Province, China
	Detail of stability batches of drug product	Attached in Module 3 in section 3.2.P.8
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached in Module 3 in section 3.2.P.8
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in Module 3 in section 3.2. P.2.2
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached in Module 3 in section 3.2. S.7
	The status in reference regulatory authorities	COBENFY (Xanomeline and Trospium chloride) capsules, for oral use, Capsules: (Xanomeline/Trospium chloride): 50mg/20mg, 100mg/20mg, 125mg/30mg, Initial U.S. Approval: 2024, Marketed by: Bristol-Myers Squibb Company, Princeton, NJ 08543 USA
	GMP status of the firm	Attached in Module 1 in section 1.3.5
	Evidence of approval of manufacturing facility	Attached in Module 1 in section 1.3.5
	Evaluation Remarks	
	Registration Board in its 357th meeting decided to defer the instant application for submission of : 1. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation. 2. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07 3. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division. Firm submitted RMP of applied product. Further firm submitted the evidence confirming the nomination of Pharmacovigilance officer.	
	Decision	
	Approved	
	Firm shall submit fee for pre-registration variation as per the latest fee SRO prior the issuance of Registration letter.	
363	Case Category	Import (Saima Hussain)
	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	(2WR-LGL-71UR, 2025-03-26)
Detail of Fee Submitted	300000.0, 2025-03-10,
The proposed proprietary name / brand name	Evya-H Gel
Label Claim	Composition: 17-β Estradiol Hemihydrate USP (Expressed as 17-β Estradiol) 0.06% W/W
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	1's-As per SRO
Shelf Life (Unit)	36 Year(s)Store in dry place below 30°C
For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	West-Coast Pharmaceutical Works Ltd-New Survey No.181, 182,183, 205,206, Old Survey No. 129 144,145,146, NR. Bhagwat Glass Factory Chhartral- Vadaswami Rode, Village: Vadaswami, TAL-KALOL Dist.-Gandhinagar – 382 740 Gujarat State, India-India
Pharmaceutical Equivalence and Comparative Dissolution Profile	submitted
Name, address of Marketing Authorization Holder:	West-Coast Pharmaceutical Works Ltd, New Survey No.181, 182,183, 205,206, Old Survey No. 129 144,145,146, NR. Bhagwat Glass Factory Chhartral- Vadaswami Rode, Village: Vadaswami, TAL-KALOL Dist.-Gandhinagar – 382 740 Gujarat State, India, India
Details of Certificates (CoPP/FSC/cGMP):	GMP certificate 2309452 dated 15/09/2023 is submitted
Details of Authorization Letter :	NA
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	stability data submitted
The status in reference regulatory authorities	US FDA Approved Estrogel (Estradiol) Gel by ASCEND THERAPS US
Evaluation Remarks	
Firm submitted CoPP certificate no. MFG/WHO GMP/COPP/2024/0744254544 dated 18-Jul-2024 issuing authority The Commissioner Food & Drugs Control Administration, Gujarat State, Jivraj Mehta Bhavan, India. Valid uptill 14/09/2026. Firm submitted letter of authorization dated 23-03-2026 in which they stated that "West Coast Pharmaceutical Works Ltd., having its registered office and Manufacturing Site at NEW SURVEY NO.-181, 182, 183, 205, 206, OLD SURVEY NO.-129, 144, 145, 146,NR.BHAGWATI GLASS FACTORY, CHATTRAL - VADASWAMI ROAD, VILLEGE: VADASWAMI, TAL-KALOL, DIST.: GANDHINAGAR - 382740, hereby authorizes Bristol Mayer Biotech Pakistan a company duly registered in PAKISTAN, having its registered office at 73 B Guldasth Town Zarrar Shaheed Road Lahore Cant Pakistan to represent itself in all matters with regards to the registration, licensing, import, promote, store, distribute and participate tender for the Bristol Mayer Biotech Pakistan as specified below within the limits specified (valid from 26-03-2026 to 25-03-2031).	
Decision	
Approved	
As per policy for inspection abroad.	
364	Case Category Routine (Sara Mehreen)

	Name, address of Applicant.	GT Pharma Pvt. Ltd 713- Sundar Industrial Estate, Sundar Raiwind Road, (000829)
	Application Form Dy. No / Tracking ID & date of submission	(HWZ-TA9-7NAT, 2024-08-21)
	Detail of Fee Submitted	30000.0, 2024-07-23,
	The proposed proprietary name / brand name	Aqua G 5ml
	Label Claim	Each 5mL Ampoule contains: Water for Injection 5mL
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO,20's-As per SRO
	Shelf Life (Unit)	2 YearControlled Room
	For generic drugs (me-too Status)	Sterile Water for Injection 5ml Islam Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	GT Pharma Pvt. Ltd
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	US-FDA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm was requested to submit six-month stability data for the trial batches manufactured. Upon review, it was observed that the batch numbers reported in the stability study did not correspond to the batch numbers of the stability data initially submitted in the application. After this discrepancy was highlighted, the firm claimed that the mismatch was due to a typographical error and subsequently submitted revised stability data bearing different batch numbers. However, it was observed that batch numbers of trial batches manufactured were also different from the stability studies batches. Moreover, evaluation of BMRs and stability testing reports revealed that dates do not conform to the minimum period required for sterility testing. The reliability of the BMRs and stability data cannot be established. Submitted for consideration of the Board, please.	
	Decision	
	Rejected	
	Significant discrepancies were observed between the batch numbers of the manufactured trial batches and those reported in the submitted stability data. Following identification of the discrepancy, the firm attributed the issue to a typographical error and submitted revised documents containing different batch numbers.	
	The case was placed before the Board. The Registration board, after consideration and deliberation on the case decided to "Reject" the instant case on basis of data integrity, document control and traceability.	
365	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	GT Pharma Pvt. Ltd 713- Sundar Industrial Estate, Sundar Raiwind Road, (000829)
	Application Form Dy. No / Tracking ID & date of submission	(2WL-81A-NA8U, 2024-10-08)

	Detail of Fee Submitted	30000.0, 7000.0 2024-06-25, 2024-09-19
	The proposed proprietary name / brand name	Aqua G 10ml
	Label Claim	Each 10ml ampoule contains: 10ml Sterile water for injection
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO, 100's-As per SRO, 5's-As per SRO
	Shelf Life (Unit)	2 Year(s) Controlled Room
	For generic drugs (me-too Status)	Islam Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	GT Pharma Pvt. Ltd
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	MHRA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm was requested to submit six-month stability data for the trial batches manufactured along with BMRs of trial batches. Upon review, it was observed that the batch numbers reported in the stability study did not correspond to the batch numbers of the stability data initially submitted in the application. After this discrepancy was highlighted, the firm claimed that the mismatch was due to a typographical error and subsequently submitted revised stability data bearing different batch numbers. However, it was observed that batch numbers of trial batches manufactured were also different from initially submitted stability data. Moreover, evaluation of BMRs and stability testing reports revealed that dates do not conform to the minimum period required for sterility testing. The reliability of the BMRs and stability data cannot be established. Submitted for consideration of the Board, please.	
	Decision	
	Rejected	
366	Case Category	Routine (Sara Mehreen)
	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	(DVQ-1UY-11VN, 2024-08-26)

	Detail of Fee Submitted	30000.0, 2024-07-02,
	The proposed proprietary name / brand name	Betapro Ointment 0.05%
	Label Claim	Each gram contains: Betamethasone dipropionate (equivalent to betamethasone).....0.05% (USP Spec's)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Provate ointment, Manufacturer: Saffronpharmaceuticals (Pvt.) Limited
	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	Brand Name:Alphatrex, Manufacturer: Savage Labs, (USFDA Approved)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
367	Case Category	Routine (Sara Mehreen)
	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	(M64-TA3-U5ZG, 2024-08-19)
	Detail of Fee Submitted	30000.0, 2024-05-02,
	The proposed proprietary name / brand name	Tomogex-P Forte
	Label Claim	Each film coated tablet contains: Tramadol Hydrochloride 75mg Paracetamol.....650mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	24 Monthstore below 30 oC
	For generic drugs (me-too Status)	Tramal Plus Forte Tablets by M/s Searle Pharmaceutica ls
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. Aurobindo Pharma Limited,PHARMAGEN LIMITED
	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	Clanderon Tablets, Spain Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	On GMP certificate of drug substance manufacturer it was written as M/s Aurobindo Pharma Limited, Plot No. 2, Maitri Vihar, Ameerpet, Hyderabad -500038. On M/s SLR Pharma Private Limited, Plot No. A-69, API Estate, Settupalli Post, Tirupati -517506, Chottor District, Andhara Pradesh. In response, firm submitted License Retention Certificate and GMP certificated issued in name of M/s SLR Pharma Private Limited, Plot No. A-69, API Estate, Settupalli Post, Tirupati -517506 and stated that "M/s. SLR Pharma and M/s. Aurobindo Pharma were formerly engaged in a manufacturing partnership under a loan letter agreement; however, this contractual association has since been formally dissolved. Consequently, in alignment with Good Manufacturing Practices (GMP), M/s. SLR Pharma has assumed the status of Legal Authorization Holder, retaining full regulatory accountability for the products independently of Aurobindo Pharma". Submitted for consideration of the Board, please.	
	Decision	
	Approved	
368	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	P.D.H Pharmaceuticals (Pvt) Ltd 19 Km Ferozepur Road Lahore (000459)
	Application Form Dy. No / Tracking ID & date of submission	(7MJ-TS5-56RT, 2024-08-29)
	Detail of Fee Submitted	30000.0, 2024-05-21,
	The proposed proprietary name / brand name	TRASMA CAPSULE 50MG
	Label Claim	Each capsule contains: Tramadol HCL 50mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10s-As per SRO
	Shelf Life (Unit)	2 Year(s)15 to 30 degree Centigrade
	For generic drugs (me-too Status)	TONOFLEX CAPSULE 50MG
	Pharmacotherapeutic Group of (API)	Non-narcotics analgesic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	AUROBINDO PHARMA LTD
	Detail of stability batches of drug product	Firm submitted 6 months stability data of three trial batches manufactured.
	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	Tamadol HCl 50mg
	GMP status of the firm	GMP certificate issued to firm dated 09.01.2024.

	Evidence of approval of manufacturing facility	As per GMP certificate firm has Capsule (General) Section.
	Evaluation Remarks	
	On GMP certificate of drug substance manufacturer it was written as M/s Aurobindo Pharma Limited, Plot No. 2, Maitri Vihar, Ameerpet, Hyderabad -500038. On M/s SLR Pharma Private Limited, Plot No. A-69, API Estate, Settipalli Post, Tirupati -517506, Chottor District, Andhara Pradesh. Firm was asked to confirm manufacturer, they replied manufacturer is M/s Aurobindo Pharma and provided GMP certificate of M/s Apitoria Pharma and stated that name has been changed from m/s Aurobindo to Apitoria Pharma. It is written on certificate that “With reference to the application cited, you are hereby informed that as the constitution and firm name of M/s. AUROBINDO PHARMA LIMITED, Unit-VIII, Survey.No.10 & 13, IDA, Kazipally, Gaddapotharam Village, Jinnaram Mandal, Sangareddy District, Telangana State, India, has been changed to M/s. APITORIA PHARMA PRIVATE LIMITED, Unit-II, Survey.No.10 & 13, IDA, Kazipally, Gaddapotharam Village, Jinnaram Mandal, Sangareddy District, Telangana State, India, and as you obtained a Change of constitution and firm name license in Form-25, Vide Lic. No. 38/MD/AP/2001/B/R, dated: 20.08.2001”. firm provided a document with title as “Pre-notification to customers on proposed change of Organization name. Logo, Manufacturing unit number of Aurobindo Pharma” but address of manufacturer mentioned on CoAs of API is not mentioned in such document. Firm submitted undertaking stating that “At the time of Sample taken, address on GMP and COA were same. Date on GMP is june0-2020 which is valid for 3 years. Jaskon Imported material on 2021, Mfg and Exp of sample mentioned on COA is Aug-2021 and July-2026 respectively. Aurobindo changed its name to Apitoria on 14-08-2023, new GMP and Pre-notification letter with its active sites attached for reference. Our all documents and submissions are up-to-date, Kindly acknowledge”. However, on initial GMP certificate M/s Aurobindo Pharma on M/s SLR pharma was mentioned. Later firm stated that Aurobindo Pharma changed to M/s Apitoria but manufacturing site address of M/s Aurobindo was not mentioned on pre notification letter for change. Submitted for consideration of the Board, please.	
	Decision	
	Approved	
369	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	Martin Dow Marker Limited 7, Jail Road Quetta. (000028)
	Application Form Dy. No / Tracking ID & date of submission	(N2N-SGB-V3DP, 2024-07-14)
	Detail of Fee Submitted	75000.0, 2023-09-27,
	The proposed proprietary name / brand name	Bempedoic acid + Ezetimibe Tablet 180mg/10mg
	Label Claim	Each Film-coated contains: Bempedoic acid.....180mg Ezetimibe.....10mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	As per DPC-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	IND-SWIFT LABORATORIES LIMITED Village – Bhagwanpur, Barwala Road, Derabassi – 140 507 District – S.A.S. Nagar (Mohali) Punjab, INDIA ,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	
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	Nustendi Tablet 180mg/10mg - MHRA UK
GMP status of the firm	
Evidence of approval of manufacturing facility	

Evaluation Remarks

Water content (KF) and microbial purity tests neither have been performed nor included under finished product specification. (https://www.ema.europa.eu/en/documents/assessmentreport/nustendi-epar-public-assessment-report_en.pdf)	At the time of dossier submission, Water content (KF) and Microbial Purity tests were not included in the Finished Product Specification. As per EMA Assessment Report, both tests have now been incorporated into the Finished Product Specification. It is hereby committed that these tests will be performed routinely at the time of commercial production and release. The revised Finished Product Specification is attached for reference. Note that stability studies (shelf life) of the product batches has already been completed. The requested test (Water content & purity) can not be performed as the product will remain available for additional testing. Therefore we hereby commit that the requested test will be performed routinely at commercial production. (Commitment and revised Method of Analysis)
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Decision

Approved

370	Case Category	Contract Manufacturing (Shahrukh Ali)
	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	(PMP-2MP-LPPU, 2024-07-01)
	Detail of Fee Submitted	75000.0, 2024-06-21,
	The proposed proprietary name / brand name	FODIC 2% CREAM
	Label Claim	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 Year(s)20-25C
	For generic drugs (me-too Status)	Ucid 2% Cream BY Ciba Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Antibiotic for Topical use (ATC code: D06AX01)
	Name, address of Manufacturing site:	M/s Winbrains Research Laboratories- PLOT #69/1, BLOCK B, PHASE-I&II, INDUSTRIAL ESTATE, HATTAR.-

	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches Batch Size 200 tubes
	Documents for the procurement of API with approval from DRAP (in case of Import)	224/2021 21.10.21
	Pharmaceutical Equivalence and Comparative Dissolution Profile	fudic cream M/s shaigan
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	MHRA approved
	GMP status of the firm	Certificate no 41/2023-dRAP-k dated 23-06-23
	Evidence of approval of manufacturing facility	No F.3-7/2007-Lic dated 11-04-17 mentioning cream section
	Evaluation Remarks	
	3.2.P.5.1 Revise Specs of assay as per B.P specs as firm has submitted in house method for assay 3.2.P.8.3 Assay is not performed as per pharmacopeia specs. Submit studies as per B.P specs. Top of Form Bottom of Form Top of Form Bottom of Form	The product has already been approved in the 357th DRB meeting. For your reference, the relevant meeting minutes and declaration are attached.
	Decision	
	Approved	
	In light of Registration Board decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LRA) Rules, 1976 is also needed as part of module-1 of Form 5F.	
371	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	ICU Pharmaceuticals (SMC-Private) Limited Khewat No. 13/13, Khatooni 57/66, Mouza Mirpur Kehna, Tehsil Sharakpur, District Sheikhpura, (000956)
	Application Form Dy. No / Tracking ID & date of submission	(1BG-GX2-H22J, 2024-08-29)
	Detail of Fee Submitted	30000.0, 2024-07-12,
	The proposed proprietary name / brand name	Rubal 40mg Tablet
	Label Claim	Each Enteric Coated Tablet Contains: Pantoprazole as Sodium sesquihydrate.....40mg (USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at temperature 15 to 30 C away from sunlight
	For generic drugs (me-too Status)	Pantberg Tablet (JSK Medica Pharma) Reg. 079782
	Pharmacotherapeutic Group of (API)	Anti ulcer
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches 1500 tablet

Documents for the procurement of API with approval from DRAP (in case of Import)	loan from obson pharmaceuticals
Pharmaceutical Equivalence and Comparative Dissolution Profile	zopent 40mg M/s hilton
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Iv-A
The status in reference regulatory authorities	USFDA approved.
GMP status of the firm	-
Evidence of approval of manufacturing facility	No F.1-24/15-Lic (Vol-V-II)dated 03-feb-2025 mentioning tablet general section
Evaluation Remarks	
3.2.p.2.2.1 Submit chromatograms of CDP study and raw data sheets along with performance calculations	Comparative Dissolution Profile (CDP) study was performed using UV spectrophotometric method; therefore, no chromatograms are generated for this study. Submitted USP method for dissolution is on LC.
usp recommends runtime NLT 3 times however same is not performed justification required	Submitted chromatogram have RT at 3.5 minutes and total RT of 5.5 minutes. Current method is being routinely performed with a runtime of 2 times, which has been found sufficient for proper separation, peak identification, and system suitability compliance during analysis.
3.2.p.8.3 Submit HPLC 21 CFR complaint audit trail, attached is system log	Firm has submitted same file again
Decision	
Deferred	
Deferred for	
1. Submission of chromatograms for dissolution testing of stability batches of drug product	
2. Justification of selecting a run time which is not according to USP for drug product assay	
3. clarification for submitted audit trail reports / system log.	
372	Case Category
	New Molecule/Formulation (Shahrukh Ali)
	Name, address of Applicant.
	Helix Pharma (Pvt)., Ltd. Hakimsons House, A-56, S.I.T.E, Manghopir Road, Karachi-75700 (000030)
	Application Form Dy. No / Tracking ID & date of submission
	(WY1-S21-LH91, 2024-07-08)
	Detail of Fee Submitted
	75000.0, 2024-05-15,
	The proposed proprietary name / brand name
	BEMPA Tablets 180mg
	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)
	24 Year(s)Store below 30C
	For generic drugs (me-too Status)
	Not Available
	Pharmacotherapeutic Group of (API)
	Lipid-Lowering Agents, ACL Inhibitors / antihyperlipidemic agents
	Name, address of Manufacturing site:
	Self Manufacturing

Name & address of API manufacturer	API Source ; M/s. Lee Pharma Limited.
Detail of stability batches of drug product	1000 tablets
Documents for the procurement of API with approval from DRAP (in case of Import)	FORM 6 2104719842471 & unattested invoice attached
Pharmaceutical Equivalence and Comparative Dissolution Profile	Nexletol tablet 180mg
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
The status in reference regulatory authorities	Nexletol® (bempedoic acid 180mg tablets) by Esperion Therapeutics, Inc as approved by USFDA
GMP status of the firm	Certificate No. 33 /2023-DRAP (K) Karachi the, 11 april, 2023
Evidence of approval of manufacturing facility	No. F.2-20/84-Lic (Vol-V)dated 28 December, 2020 mentioning Tablet (General), Liquid Injectable (General)

Evaluation Remarks

3.2.P.2.2.1 Pharmaceutical equivalence:

According to the Innovator's report, The solubility of bempedoic acid is pH-dependent, with solubility increasing with increasing pH over the normal physiological pH range. It is insoluble at low pH values, and solubility increases rapidly above pH 6. Based on its low solubility and high permeability, bempedoic acid is a BCS Class II compound. In CDP summary, you have stated that release of test and reference product is more than 90% in pH1.2 within 15 minutes. Justification required	Bempedoic Acid exhibits poor solubility under acidic conditions (pH 1.2 and pH 4.5), resulting in incomplete dissolution and inability to maintain sink conditions. Therefore, 1.0% SLS was incorporated into both dissolution media as a solubilizing agent to enhance drug solubility, improve wettability, and maintain sink conditions throughout the study. The use of the same dissolution medium for both test and reference products enabled generation of discriminatory and comparable dissolution profiles, allowing scientifically meaningful assessment of product similarity in accordance with FDA and USP recommendations for poorly soluble drug substances.
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Decision

Approved

373	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	Orbis Pharmaceuticals Plot # K-138 , SITE Super Highway Phase 2 , Karachi (000979)
	Application Form Dy. No / Tracking ID & date of submission	(BTB-VZG-2BP1, 2024-10-23)
	Detail of Fee Submitted	93000.0, 2024-10-07,
	The proposed proprietary name / brand name	Cexon
	Label Claim	Each Vial contains:Ceftriaxone Sodium Eq. to Ceftriaxone.....500mg(USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at temperature below 30oC. void exposure to light, heat, and humidity.
	For generic drugs (me-too Status)	Oxidil Injection IV 500mg by Sami Pharmaceutical (Pvt.) Ltd
	Pharmacotherapeutic Group of (API)	3rd Generation Cephalosporin Antibiotic

	Name, address of Manufacturing site:	SHROOQ Pharmaceuticals (Pvt.) Ltd.-21-Km Ferozpur Road, Lahore.-
	Name & address of API manufacturer	Zhuhai United Laboratories Co., Ltd No. 2428, Anji Road, Sanzao Town, Jinwan District,Zhuhai, Guangdong-519040, P.R. China.
	Detail of stability batches of drug product	Batch Size: 500 vials
	Documents for the procurement of API with approval from DRAP (in case of Import)	7783959273614 dated 22.12.23
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Oxidil Injection IV 500mg LYM002
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Rocephin Injection 500mg USFDA
	GMP status of the firm	Certificate no 210/2023 dated 15-12-23 contract acceptor
	Evidence of approval of manufacturing facility	No F.1-29/2001-Lic(vol-I) dated 25-08-2010 mentioning dry powder injection section cephalosporin
	Evaluation Remarks	
	3.2.P.2.2.1 Pharmaceutical Equivalence Reason required for not performing following tests Particulate Matter In Injections, Crystallinity, BACTERIAL ENDOTOXINS TEST, STERILITY TESTS	Firm has submitted same Pharmaceutical Equivalence report adding following tests Particulate Matter In Injections, Crystallinity, BACTERIAL ENDOTOXINS TEST, STERILITY TESTS on expired batches.
	3.2.P.8 Stability: · Ph value is out of specs in 6 month accelerated study justification required	Firm has submitted revised table with correct pH value without any justification
	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 pharmaceutical equivalence data on expired batches the Board decided to reject the case	
374	Case Category	New License (Shahrukh Ali)
	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	(V6H-TZU-X53M, 2025-04-16)
	Detail of Fee Submitted	37000.0, 2024-09-19,
	The proposed proprietary name / brand name	Amoxisky 500mg Injection
	Label Claim	Each vial contains: Amoxicillin Sodium eq. to Amoxicillin.....500mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO / DPC-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature below 30
	For generic drugs (me-too Status)	Amoxil injection 500mg of GSK
	Pharmacotherapeutic Group of (API)	Penicillin antibiotic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Sinopharm Weiqida Pharmaceutical Co., Ltd. Add: Pharmaceutical Industrial Park, Economic

		& Technological Development Zone, Datong, Shanxi, China 037300
	Detail of stability batches of drug product	3 trial batches of 500 vials per batch
	Documents for the procurement of API with approval from DRAP (in case of Import)	Took Loan from M/s Stallion Pharmaceuticals Pvt. Ltd. E-755342825842 dated 5.4.22
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Amoxil Injection 500mg of M/s GSK Pharmaceuticals Pvt. Ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IV-A
	The status in reference regulatory authorities	Amoxicillin 500mg Powder for Solution for Injection of M/s Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK (MHRA Approved)
	GMP status of the firm	NEW DML
	Evidence of approval of manufacturing facility	1-14/2020 issued on 18-09-2023
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
375	Case Category	New Section (Shahrukh Ali)
	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	(VXP-1ZX-RN3S, 2025-07-28)
	Detail of Fee Submitted	37000.0, 2025-05-27,
	The proposed proprietary name / brand name	BACTIPHIN INJECTION 2gm
	Label Claim	Each vial contains: Ceftriaxone (as sodium) 2gm
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	24 Year(s) Below 25 degree
	For generic drugs (me-too Status)	OXIDIL 2gm INJECTION by Sami Pharmaceuticals (Pvt) Ltd.
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Name, address of Manufacturing site:	Self Manufacturing
	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	3 batches 1000 vial each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Computerized No: RO-5FB92E Date of Issue: 28-12-2024
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed against OXIDIL INJECTION 2GM (086609) Manufactured by Sami Pharmaceuticals pvt ltd
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Ceftriaxone 2 g powder for solution for injection/infusion by SANDOZ INC, USFDA Approved

	GMP status of the firm	117/2024-Drap(AD-994015369) 01.07.24 GMP VALID TILL 05-01-2027
	Evidence of approval of manufacturing facility	No F.1-8/2001-Lic dated 29-02-24 mentioning section
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
376	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	Platinum Pharmaceuticals A-20,North Western Industrial Zone Bin Qasim,Karachi (000415)
	Application Form Dy. No / Tracking ID & date of submission	(RJY-NTZ-4HBA, 2024-09-23)
	Detail of Fee Submitted	75000.0, 2024-08-07,
	The proposed proprietary name / brand name	Finerenone Tablet 20mg
	Label Claim	Finerenone.....20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10s-As per SRO,20s-As per SRO,30s-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30C in a dry place and protect from sunlight
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Mineralocorticoid receptor (MR) antagonists.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	03 batches 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 No K-1818020085384
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Kerendia Tablet 10mg Bayer zaydus pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of 3 batches of drug substance as per Zone IV-A is submitted.
	The status in reference regulatory authorities	Kerendia 20mg Film-coated tablet
	GMP status of the firm	Firm has submitted copy of GMP Certificate No. 46/2023-DRAP (K) dated 16-06-2023 issued on the basis of inspection conducted on 14-06-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-3/94-Lic (Vol-III) dated 16-11-2022 mentioning Tablet (General) section.
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality	

	agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
377	Case Category	Routine (Shahrukh Ali)
	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	(WPH-ZS6-6X4T, 2024-10-10)
	Detail of Fee Submitted	37000.0, 2024-09-19,
	The proposed proprietary name / brand name	Defrox Tablet for Oral suspension
	Label Claim	Each tablet contains: Deferasirox.....500mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	7s, 10s, 14s, 20s, 2-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)	Xefra Tablet 500mg by Global Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Iron Chelation (ATC code: V03AC03)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Golden Drugs Private Limited (subsidiary of Bal Pharma Pvt Ltd.), C-155, Mewar Industrial Area Madri, Udaipur-313003, Rajasthan
	Detail of stability batches of drug product	3 batches Batch Size 1500 tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	K- 2560880621489 form-6 submitted API manufacturer Name: BAL pharma
	Pharmaceutical Equivalence and Comparative Dissolution Profile	EXjade 125mg M/s Novartis
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	EXJADE Tablet 500mg by Novartis Pharma Stein AG Stein, Switzerland
	GMP status of the firm	Certificate no 41/2023-dRAP-k dated 23-06-23
	Evidence of approval of manufacturing facility	No F.2-12/93-Lic (vOL-v) dated 27-sep-16 mentioning tablet section
	Evaluation Remarks	
	2.S.2.1 Submitted Form -6 is not for manufacturing site, previously COA was submitted from Unit -II of Bal Pharma and stability data was submitted by manufacturing site of Golden drugs Justification submitted is not from any authority it is from Bal pharma itself. please clarify which is manufacturing site and submit its GMP moreover justification required why form-6 was not taken for manufacturing site	We would like to clarify that Bal Pharma Ltd. Unit-II and Golden Drugs Pvt. Ltd. have been merged, and the manufacturing activities are being carried out under the merged entity. Therefore, the previously submitted COA from Bal Pharma Unit-II and the stability data generated by Golden Drugs Pvt. Ltd. pertain to facilities operating under the same merged organization.
	Decision	
	Approved	
	Approved. The firm will submit valid GMP certificate of drug substance manufacturer	
378	Case Category	Routine (Shahrukh Ali)
	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	(884-2Z9-BQMA, 2024-10-10)
	Detail of Fee Submitted	37000.0, 2024-09-19,
	The proposed proprietary name / brand name	Defrox Tablet for Oral suspension
	Label Claim	Each tablet contains: Deferasirox.....125mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	7s, 10s, 14s, 20s, 2-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)	Xefra Tablet 125mg by Global Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Iron Chelation (ATC code: V03AC03)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Golden Drugs Private Limited (subsidiary of Bal Pharma Pvt Ltd.), C-155, Mewar Industrial Area Madri, Udaipur-313003, Rajasthan
	Detail of stability batches of drug product	3 batches Batch Size 1500 tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	K- 2560880621489 form-6 submitted API manufacturer Name: BAL pharma
	Pharmaceutical Equivalence and Comparative Dissolution Profile	EXjade 125mg M/s Novartis
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	EXJADE Tablet 125mg by Novartis Pharma Stein AG Stein, Switzerland
	GMP status of the firm	Certificate no 41/2023-dRAP-k dated 23-06-23
	Evidence of approval of manufacturing facility	No F.2-12/93-Lic (vOL-v) dated 27-sep-16 mentioning tablet section
	Evaluation Remarks	
	2.S.2.1 Submitted Form -6 is not for manufacturing site, previously COA was submitted from Unit -II of Bal Pharma and stability data was submitted by manufacturing site of Golden drugs Justification submitted is not from any authority it is from Bal pharma itself. please clarify which is manufacturing site and submit its GMP moreover justification required why form-6 was not taken for manufacturing site	We would like to clarify that Bal Pharma Ltd. Unit-II and Golden Drugs Pvt. Ltd. have been merged, and the manufacturing activities are being carried out under the merged entity. Therefore, the previously submitted COA from Bal Pharma Unit-II and the stability data generated by Golden Drugs Pvt. Ltd. pertain to facilities operating under the same merged organization.
	Decision	
	Approved	
	Approved. The firm will submit valid GMP certificate of drug substance manufacturer	
379	Case Category	Routine (Shahrukh Ali)
	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	(QRA-NMU-VBHE, 2024-10-11)
	Detail of Fee Submitted	75000.0, 2024-10-01,
	The proposed proprietary name / brand name	Rapicort 5mg Solu Tablet

Label Claim	Each tablet contains: Prednisolone (as the sodium phosphate ester) 5mg BP Specification
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	10's-Controlled,100's-Controlled,20's-Controlled,6's-Controlled
Shelf Life (Unit)	2 Year(s)Store below 30oC
For generic drugs (me-too Status)	New Drug Product
Pharmacotherapeutic Group of (API)	A01AC Corticosteroids
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	NA
Detail of stability batches of drug product	3 Batches Size 1500 tablets
Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 Computerized No: K-2804101227561
Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference product: Prednisolone 5mg tablets, Manufactured by M/s MDpharm
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
The status in reference regulatory authorities	Soluble Prednisolone 5mg Tablets Amdipharm UK Limited MHRA Approved
GMP status of the firm	Certificate no 33.24-DRAP-k-lic dated 01-04-24
Evidence of approval of manufacturing facility	No F.2-5/87-Lic(vol-III) dated 30-06-2020 mentioning Tablet section
Evaluation Remarks	
"The application is complete as per codal formalities for consideration by the Registration Board"	
Decision	
Approved	

Item No. III Division of Quality Assurance & Laboratory Testing

S. No.	CASE TITLE
1.	Substandard Fungo Tablet, Reg. No. 052506 Batch No # 8520 Manufactured By M/S Alfalah Pharma (Pvt) Ltd, Lahore.
2.	Manufacture And Sale of Substandard, Spurious and Misbranded Products By M/S Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha
3.	Manufacture And Sale of Spurious S-Kyne Tablet Batch No. 335, Reg No. 100245 Manufactured by Manufactured By M/S Weather Folds Pharmaceuticals, Haripur
4.	Manufacture And Sale of Substandard and Misbranded Carefen Suspension Batch No. Cn-037, Reg No. 066500 And Spurious and Misbranded Carenol Ammonium Chloride Cough Syrup, Batch No. Cl-036, Reg No. 026907 Manufactured By M/S Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha
5.	Substandard Maverick 500mg Inj., Reg. No. 065444 Batch No 250901, And Wafin Inj. (Water For Injection) Reg. No. 066643 Batch No. 250101 Manufactured By M/S Crest Pharmaceuticals, Islamabad Dml No.000694

Case No. 1: SUBSTANDARD FUNGO TABLET, REG. NO. 052506 BATCH NO # 8520 MANUFACTURED BY M/S ALFALAH PHARMA (PVT) LTD, LAHORE.

The Federal Inspector of Drugs, DRAP, Lahore during inspection of M/s Alfalah Pharma (Pvt) Ltd, Lahore dated 25th September 2024 took samples of the FunGo Tablet on Form-3 and sent to the Federal Government Analyst, CDL Karachi for test/analysis on Form-4.

2. Federal Government Analyst, CDL Karachi vide test report No LHR-10-24-000006 dated 17th December, 2024, declared the batch KF23006 of product M/s Alfalah Pharma (Pvt) Ltd, Lahore as of "Substandard Quality". Details of CDL test report are as below.

Product	Mfg. by	Reg.No	B. No.	Mfg.	Exp.Date	CDL Test Result
FunGo Tablet Reg. No. 052506 Terbinafine HCl	M/s Alfalah Pharma (Pvt) Ltd, Lahore	052506	8520	07-2024	07-2026	Sample has been declared as " Substandard " on the basis of Dissolution Does not Comply Limit: Each unit is not less than

3. Federal Inspector of Drugs Lahore was directed to investigate the matter and submit a comprehensive report in the matter.

4. Federal Inspector of Drugs, DRAP, Lahore, submitted the company's request of Appellate testing vide letter No. AP/DRAP/24002 dated 17th January 2025, after receiving letter along with CDL report from FID, Lahore (which was sent on 11th December, 2024).

5. In this regard it is submitted that the Registration Board in its 313th meeting decided as under:

"Proceedings and Decision of 313th Meeting of Registration Board.

The Board, after thorough deliberations and considering the facts of the case decided as:

i. *The firm will provide OOS investigation and complete testing record of the concerned batch along with scientific justifications/grounds with the request of Appellate testing under section 22(4) of the Drugs Act 1976.*

ii. *Federal Government Analyst, Karachi will provide OOS investigation and complete testing record of such reports.*

iii. *Registration Board advised QA&LT Division to present all cases of Appellate Testing with these both set of documents along with technical report of the case."*

6. In the light of above-mentioned decision of the Board, the division of QA&LT vide letter F. No.03-58/2024-AD(QALT-IV) dated 3rd March, 2025 requested the Federal Government Analyst CDL Karachi and M/s. Aries Pharmaceuticals (Pvt.) Ltd., Peshawar for the submission of Out of specification (OOS) investigation as directed by the Registration Board.

7. Summary of evaluation of Out of specification (OOS) investigation by the division of QA&LT is given as under:

Summary of OOS investigation submitted by Central Drugs Laboratory, Karachi:

Federal Government Analyst, CDL Karachi has submitted OOS investigation wherein it is informed that the sample is tested in accordance with the test/analysis method provided in the USP 2023 and has ruled out any possibility of error in the method of test/analysis, equipment and/or any operator or analyst related error.

Summary of OOS investigation submitted by M/s Alfalah Pharma (Pvt) Ltd, Lahore

M/s Alfalah Pharma (Pvt) Ltd, Lahore in their reply has provided OOS investigation at laboratory and manufacturing level along with relevant evidences and has also ruled out any chance of error in the manufacturing or testing of the product in question.

Technical Evaluation of OOS Investigation:

- i. The product was declared by CDL as sub-standard on the basis of Dissolution
- ii. CDL and manufacturer both performed the test as per USP
- iii. There may be issues during formulation development, manufacturing processes, quality of API, and instability of product.

8. Proceedings and Decision of 351st meeting of Registration Board

The Board after considering the facts of the case and thorough deliberations decided to accede request of firm for appellate testing of product FunGo Tablet (052506), Batch No. 8520 Manufactured by M/s Alfalah Pharma (Pvt) Ltd, Lahore, under Section 22 (5) of the Drugs Act, 1976.

The Registration Board portion was sent to the Appellate laboratory for resting under Section 22(5) of the Drug Act 1976. Appellate laboratory vide letter No F.03-47/2025-QALT (351-RB) dated 29th October 2025.

9.

10. The appellate laboratory declared the sample as *substandard* vide report No. F. 1-20/07-M/2025-DC&TMD dated 8th April 2026. (on dissolution, as all six tablets are deviated from the Limit (Limit: NLT 80%).

11. In the light of Appellate report show Cause notice vide office letter No F. No.03-58/2024-AD(QALT-IV) dated 5th May 2026 under Section 42 of the Drugs Act 1976 was issued to the firm.

12. Accordingly, the firm has been issued notice of personal hearing to appear before the Board, vide office letter No F. No.03-29/2026-QALT (359-RB) dated 3rd June 2026 under Section 42 of the Drug Act 1976.

13. Proceedings and Decision of 359th meeting of Registration Board

Division of QA & LT presented the case before the Registration Board. No person on behalf of M/s Alfalah Pharma (Pvt) Ltd, Lahore appeared before Board.

The Board, after considering the facts of the case and after thorough deliberation, decided:

- i. ***Product-specific inspection, including verification of the Root Cause Analysis (RCA) and Corrective and Preventive Actions (CAPA), to be conducted by a panel of inspectors/experts to be nominated by the Director (QA/LT).***
- ii. ***Suspension of the Registration of FunGo Tablet Registration No. 052506 manufactured by M/s Alfalah Pharma (Pvt) Ltd, Lahore under section 42 of the Drugs Act, 1976 and rules framed thereunder, for a period of six months or till verification of Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) by a panel with satisfactory report; whichever is earlier.***
- iii. ***Destruction of the recalled stock shall be carried out in the presence of the Area FID.***

CASE NO. 02: MANUFACTURE AND SALE OF SUBSTANDARD, SPURIOUS AND MISBRANDED PRODUCTS BY M/S WELL CARE PHARMACEUTICALS PVT LTD., A/7 P.S.I.E SARGODHA

Provincial Quality Control Board, Punjab vide No. PQCB/MSS-206562, 206564, 206563, 206561/2024 has informed that Provincial Inspector of Drugs, Licensed/Enlisted Manufacture of Therapeutic goods FSD/ GRW/SGD/Guj, took sample of following drugs on Form-4 for the purpose of test and analysis from the premises of M/s Well Care Pharmaceuticals Pvt Ltd. A/7 P.S.I.E, Sargodha

2. The sample of Suspension Paracare 450ml has been declared “**Substandard**” vide test Report No.01-75009953/DTL dated 29-11-2024 Syrup Carenol ammonium Chloride cough syrup has been declared “**Spurious and Misbranded**” vide test Report No.01-75009951/DTL dated 05-12-2024 Syrup Histacare 450ml has been declared “**Spurious**” vide test Report No.01-75009950/DTL dated 05-12-2024 Suspension Carefen 90ml has been declared “**Spurious and Misbranded**” vide test Report No. 01-75009954/DTL dated 24-12-2024 by Drug Testing Laboratory, Punjab Rawalpindi

Name of Drug	Manufactured by	Reg. No	Batch No	Mfg. Date	Exp. Date	DTL Test Report Details
Suspension Paracare 450ml (Each 5ml contains: Paracetamol 120mg)	M/S Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha	024998	PE-036	09-2024	09-2026	“Substandard” on the basis of assay of Paracetamol Assay: Stated: 120 mg/5ml Determined: 34.674 mg/ 5ml (HPLC) Percentage: 28.97% (Does Not Comply) Limit: 95.0-105.0%
Syrup Carenol Ammonium Chloride Cough Each 5ml contains: Ammonium Chloride....125mg Sodium Citrate.... 55mg Chlorpheniramine maleate.....2.5mg	M/s Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha	026907	CL-037	09-2024	09-2026	“Spurious” on the basis of assay of Chlorpheniramine Maleate Assay: Stated: 2.5mg/5ml Determined: 0.000 mg/ 5ml (UV Spectrophotometer) Percentage: 0.0% (Does Not Comply) Limit: 95.0-105.0% “Misbranded” on the basis of Manufacturing specifications are not mentioned, neither on the label nor on the unite carton of the sample
Syrup Histacare 450ml Each 5ml contains:	M/s Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha	066498	HE-036	09-2024	09-2026	“Spurious” on the basis of Assay of Chlorpheniramine maleate Assay: Stated: 2mg/5ml

Chlorpheniramine maleate.....2mg						Determined:0.00mg/5 ml (UV-Visible Spectroscopy) Percentage: 0.00% (Does Not Comply) Limit: 90.0-110.0%
Suspension Carefen 90ml (Each 5ml contains: Ibuprofen 100mg)	M/S Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha	066500	CN-035	09-2024	09-2026	“Spurious” on the basis of assay of Ibuprofen Assay: Stated: 100mg/5ml (USP-2024) Determined: 0.00 mg/ 5ml (HPLC) Percentage: 0.0% (Does Not Comply) Limit: 90.0-110.0% “Misbranded” on the basis of Manufacturing specifications are not mentioned, neither on the label nor on the unite carton of the sample
Syrup Wellfer 60ml	M/S Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha	066496	WR-020			Noncompliance regarding the provision method of Analysis to DTL, Rawalpindi

3. The case was presented before the Provincial Quality Control Board in its 293rd meeting. The Board after perusal of case record and scrutiny of DTL report observed that sample of Suspension Paracare 450ml was declared “*Substandard*” sample of Syrup Carenol ammonium Chloride cough syrup was declared “*Spurious and Misbranded*” Sample of Syrup Histacare 450ml was declared *Spurious*” and sample of Suspension Carefen 90ml was declared “*Spurious and Misbranded*” by DTL, Rawalpindi and the Licensed Manufacturer M/s Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha committed the offense of Manufacturing and sale of *Substandard, Spurious Misbranded* drug and disobedience of lawful Authority.

4. The Provincial Quality Control Board, Punjab recommended to the Drug Regulatory Authority of Pakistan, for cancellation of the DML/DRC’s of the firm M/s Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha for manufacturing of *Spurious* drug.

5. Division of QA&LT issued Show Cause Notice No. F.04-04/2026-DD(QALT) dated 16th April 2026 under Section 42 of the Drugs Act 1976.

6. Accordingly, the firm has been issued notice of personal hearing to appear before the Board, vide office letter No F. No.03-29/2026-QALT (359-RB) dated 3rd June 2026 under Section 42 of the Drug Act 1976.

7. **Proceedings and Decision of 359th meeting of Registration Board**

Division of QA & LT presented the case before the Registration Board. Mr. Malik Saeed Akhtar Managing Director of M/s Well Care Pharmaceuticals Pvt Lt., Sargodha. appeared before Board and reiterated that he had already submitted the detailed written reply on the matter, which is placed in the agenda.

The Board, after considering the facts of the case and after thorough deliberation, decided:

- i. ***Suspension of the Registration of following products of M/s Well Care Pharmaceuticals Pvt Lt., Sargodha under section 42 of the Drugs Act, 1976 and rules framed thereunder, till final decision taken by Board in next meeting.***

S. No	Product	Reg. No	S. No	Product	Reg. No
i.	<i>Suspension Paracare 450ml</i>	<i>024998</i>	iv.	<i>Suspension Carefen 90ml</i>	<i>066500</i>
ii.	<i>Syrup Carenol Ammonium Chloride Cough</i>	<i>026907</i>	v.	<i>Syrup Wellfer 60ml</i>	<i>066496</i>
iii.	<i>Syrup Histacare 450ml</i>	<i>066498</i>			

- ii. ***To grant the applicant a final opportunity for personal hearing in its forthcoming meeting. The applicant shall present all relevant documentary evidence before the Board for its consideration.***

CASE NO. 3: MANUFACTURE AND SALE OF SPURIOUS S-KYNE TABLET BATCH NO. 335, REG NO. 100245 MANUFACTURED BY MANUFACTURED BY M/S WEATHER FOLDS PHARMACEUTICALS, HARIPUR

Provincial Quality Control Board, Punjab vide No. PQCB/MSS-211804/2025 has informed that Provincial Inspector of Drugs, Tehsil Pind Dadan Khan, District Jhelum, took sample of following drug on Form-4 for the purpose of test and analysis from the premises of M/s Butt Pharmacy, situated near Masjid Bilal, Main Bazar Dharyala Jalap, Tehsil Pind Dadan Khan, District Jhelum.

8. The sample has been declared “***Spurious***” by Drug Testing Laboratory, Punjab Rawalpindi vide test report No. 01-74012721/DTL dated 17-01 2025.

Name of Drug	Manufactured by	Reg. No	Batch No	Mfg. Date	Exp. Date	DTL Test Report Details
Tablet S-Kyne (Each Film Tablet contains: Dydrogesterone 10mg)	M/s Weather Folds Pharmaceuticals, HARIPUR. K.P.K	100245	335	11-2023	11-2025	Physical Description: White colored, round shaped, biconvex tablets, plain from both sides, packed in ALU/ALU blister of 1*10's pack, further

						packed in labelled outer carton. (20 tablets) IDENTIFICATION: Dydrogesterone is not identified (FTIR) (USP-2024) (Does Not Comply) Assay: Stated: 10mg/Tablet Determined: 0.000 mg/ Tablet (HPLC) (USP-2024) Percentage: 0.00% (DOES NOT COMPLY) Limit: 90.0-110.0% RESULT: <i>The above sample is "Spurious" as defined under clause (i) of sub-section (z-b) of section 3 of The Drugs Act 1976</i>
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9. The case was presented by the Provincial Quality Control Board in its 293rd meeting held on 25-09-2025. The Board, after perusal of case record and scrutiny of DTL report observed that sample of Tablet S-Kyne Batch No. 335 was declared *Spurious* by DTL, Rawalpindi and the Licensed Manufacturer M/s Weather Folds Pharmaceuticals, Haripur. K.P.K committed the offense of Manufacturing and sale of *Spurious* drug.

10. The Provincial Quality Control Board, Punjab recommended to the Drug Regulatory Authority of Pakistan, for cancellation of the DML of the firm M/s Weather Folds Pharmaceuticals, Haripur for manufacturing of *Spurious* drug.

11. Division of QA&LT issued Show Cause Notice No. F.04-1/2026-AD(QALT) dated 7th January 2026 under Section 41 of the Drugs Act 1976.

12. In response to said show cause, Weather Folds Pharmaceuticals vide letter nil dated 22nd January 2026 replied as under:

*“With reference to your letter No. F.04-1/2026-AD(QALT) dated 7th January, 2026, received on 15th January, 2026, we, M/s Weather Folds Pharmaceuticals, respectfully submit our reply as under:
 The declared product S-KYNE Tablets (Batch No. 335, Manufacturing Date: November 2023, Expiry Date: November 2025) was manufactured at Weather Folds Pharmaceuticals, Hattar, as per our manufacturing records.
 At the outset, we would like to clarify that the imported API used for this product was duly approved by CDL Karachi, in accordance with DRAP Policy, vide Report No. RM-6-22-000010 dated 27th June, 2022. The API was declared as compliant with USP specifications, and the relevant documents are attached as Annexure-I.
 Subsequently, a pilot batch of 500 packs of S-KYNE Tablets was manufactured exclusively for market survey purposes. The batch was tested repeatedly at our Quality Control laboratory, and all quality parameters were found to be within USP limits. Copies of our internal analytical reports are attached for reference.*

We further submit that at the time the product was declared sub-standard, or thereafter, no portion of the official sample was provided to us for verification. Therefore, while we confirm that Batch No. 335 (November 2023) was manufactured by us, it cannot be conclusively established that the sample tested by the Drug Testing Laboratory (DTL) was indeed manufactured by Weather Folds Pharmaceuticals, in the absence of a manufacturer's warranty sample.

Although the product has since expired, we again performed assay and dissolution testing on the retained samples available at our premises. The results were found to be within USP Specification limits.

The reported result of 0% assay strongly indicates that the tested sample was not manufactured by us, as such a result is practically impossible for a finished pharmaceutical product manufactured under controlled GMP conditions. This leads us to believe that the product may have been

counterfeit or falsely attributed by an unauthorized source using similar batch details. It is also pertinent to mention that we formally requested that the samples be referred to NIH for further investigation, which was unfortunately rejected by the Board. Moreover, the mandatory requirement of providing a manufacturer's warranty sample was not fulfilled by the DTL, rendering the case incomplete and inconclusive. In view of the above facts, we respectfully submit that the present case does not warrant holding Weather Folds Pharmaceuticals responsible for the alleged manufacture of a spurious drug.

We therefore humbly request that the Show Cause Notice may kindly be withdrawn, and the DTL may be directed to re-test the retained samples available in our QC store (although expired, yet analytically compliant). We further request that the samples may be referred to NIH for independent verification in the interest of transparency, impartiality, and justice. We trust that our submission will be considered objectively, ensuring fairness and preservation of the reputation of our esteemed manufacturing unit.

13. Division of QA&LT issued a notice of personal hearing vide letter F.03-21/2026-QALT (317-CLB) dated 21st April 2026 under Section 41 of the Drug Act 1976.

14. **Proceedings and Decision of 317th meeting of Central Licensing Board**

The representative of QA&LT presented the case before the Board. Mr. Aftab Alam, Quality Control Manager, and Mr. Munawar Javed Khattak Production Manager of M/s Weather Folds Pharmaceuticals, Haripur, appeared before the Board. The representatives of the firm reiterated and endorsed the reply already submitted by the firm.

The Board after considering the facts of the case and after thorough deliberations decided to refer the case to Registration Board, being registered drug under Section 7 of the Drugs Act, 1976 and Rules framed thereunder, for further necessary action.

15. Accordingly, the matter is placed before Registration Board

16. **Proceedings and Decision of 359th meeting of Registration Board**

Division of QA & LT presented the case before the Registration Board.

The Board, after considering the facts of the case and after thorough deliberation, decided to refer the matter to the Legal Division for its opinion on whether a Board to whom recommendation had been made by a Provincial Quality Control Board can refer a case to another Board.

CASE NO. 4: MANUFACTURE AND SALE OF SUBSTANDARD AND MISBRANDED CAREFEN SUSPENSION BATCH NO. CN-037, REG NO. 066500 AND SPURIOUS AND MISBRANDED CARENOL AMMONIUM CHLORIDE COUGH SYRUP, BATCH NO. CL-036, REG

**NO. 026907 MANUFACTURED BY M/S WELL CARE
PHARMACEUTICALS PVT LTD., A/7 P.S.I.E SARGODHA**

Provincial Quality Control Board, Punjab vide No. PQCB/MSS-212827, 212828/2025 has informed that Provincial Inspector of Drugs, Tehsil & District Sargodha, took sample of following drugs on Form-4 for the purpose of test and analysis from the premises of M/s Al Usman Medicine company, Al Muneer Market Block #4 Sargodha

2. The sample of Carefen Suspension has been declared “**Substandard and Misbranded**” vide test Report No. 01-75010318/DTL dated 27-01-2025 and sample of Carenol Ammonium Chloride Cough Syrup “**Spurious and Misbranded**” vide test Report No.01-75010319/DTL dated 27-01-2025 by Drug Testing Laboratory, Punjab Rawalpindi

Name of Drug	Manufactured by	Reg. No	Batch No	Mfg. Date	Exp. Date	DTL Test Report Details
Suspension Carefen 90ml (Each 5ml contains: Ibuprofen 100mg)	M/S Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha	066500	CN-037	11-2024	10-2026	“Substandard” on the basis of assay of Ibuprofen Assay: Stated: 100mg/5ml (USP-2024) Determined: 23.139 mg/ 5ml (HPLC) Percentage: 23.14% (DOES NOT COMPLY) Limit: 90.0-110.0% “Misbranded” on the basis of Product specifications are not mentioned, neither on the label nor on the unite carton of the sample
Syrup Carenol Ammonium Chloride Cough Each 5ml contains: Ammonium Chloride....125mg Sodium Citrate.... 55mg Chlorpheniramine maleate.....2.5mg	M/s Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha	026907	CL-036	08-2024	08-2026	“Spurious” on the basis of Chlorpheniramine maleate Assay: Stated: 2.5mg/5ml Determined: 0.000 mg/ 5ml (U V Spectrophotometer) Percentage: 00% (DOES NOT COMPLY) Limit: 95.0-105.0% Misbranded” on the basis of Product specifications are not mentioned,

						neither on the label nor on the unite carton of the sample
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3. The case was presented by the Provincial Quality Control Board in its 293rd meeting. The Board after perusal of case record and scrutiny of DTL report observed that sample of Suspension Carefen 90ml Batch No. CN-037 was declared **Substandard and Misbranded** and sample of Syrup Caremol Ammonium Chloride Cough Batch No. CL-036 was declared Spurious and Misbranded by DTL, Rawalpindi and the Licensed Manufacturer M/s Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha committed the offense of Manufacturing and sale of *Substandard, Spurious* and *Misbranded* drug.

4. The Provincial Quality Control Board, Punjab recommended to the Drug Regulatory Authority of Pakistan, for cancellation of the DML/DRC's of the firm M/s Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha for manufacturing of *Spurious* drug.

5. Division of QA&LT issued Show Cause Notice No. F.04-04/2026-DD(QALT) dated 12th January, 2026 under Section 41 of the Drugs Act 1976.

6. In response to said show cause, Weather Folds Pharmaceuticals vide letter nil dated 12th February 2026 replied as under:

"We received this show cause notice but were unable to reply in time due to our family issues my younger brother was suffering from lungs cancer and he was admitted in Cancer Care Hospital Lahore but unfortunately he died last week that is the reason for late reply, you are requested to please accommodate us in this regards thanks.

"It is stated that we are under crises because of only ONE provincial drug inspector Mr Muhammad Iqbal (Now he is member Drug court Faisalabad) he and his colleagues are against us from the last many years, for which we complain many time to CEO DRAP, Secretary Health, PQCB, Grievance Commissioner (copies enclosed) our point is that they (Drug inspectors) changed our samples before sending to DTL that is the reasons of spurious, Substandard etc, results.

In some case in DTL Punjab our sample declared substandard where as in DTL Karachi of the same product and batch declared of slandered quality. Which shows MALAFYDY.

In PQCB meetings we always highlighted all above things, but they only favour Drug inspectors.

But because in PQCB almost all team members are colleagues of Provincial inspectors of drugs and only favour them, we are not expecting any type of JUSTICE from them.

We have always endeavored to maintain good quality and standards. Due to extra financial burdens and pressures my factory has been totally ruined. As of today we have a total of six workers in factory and six cases are in the drug court. No patient has been harmed or even complained against our drugs but our business and family has been totally ruined. I have spent my entire life in Pharma and at old age I have no way out. I shall therefore request to please consider my problem with magnanimity and save me and my business from total collapse.

In this case you are requested to please help me out and save us please"

7. Division of QA&LT issued a notice of personal hearing vide letter F.03-21/2026-QALT (317-CLB) dated 21st April, 2026 under Section 41 of the Drug Act 1976.

7. **Proceedings and Decision of 317th meeting of Central Licensing Board**

The representative of QA&LT presented the case before the Board. Mr. Malik Saeed Akhtar Managing Director of M/s Well Care Pharmaceuticals Pvt Lt., Sargodha. The representatives of the firm reiterated and endorsed the reply already submitted by the firm.

The Board after considering the facts of the case and after thorough deliberations decided to refer the case to Registration Board, being registered drug under Section 7 of the Drugs Act, 1976 and Rules framed thereunder, for further necessary action.

8. Accordingly, the matter is placed before Registration Board

9. **Proceedings and Decision of 359th meeting of Registration Board**

Division of QA & LT presented the case before the Registration Board. Mr. Malik Saeed Akhtar Managing Director of M/s Well Care Pharmaceuticals Pvt Lt., Sargodha. appeared before Board and reiterated that he had already submitted the detailed written reply on the matter, which is placed in the agenda.

The Board, after considering the facts of the case and after thorough deliberation, decided:

- i. ***Suspension of the Registration of following products of M/s Well Care Pharmaceuticals Pvt Lt., Sargodha under section 42 of the Drugs Act, 1976 and rules framed thereunder, till final decision taken by Board in next meeting.***

S. No	Product	Reg. No	S. No	Product	Reg. No
i.	<i>Suspension Carefen 90ml</i>	<i>066500</i>	ii.	<i>Syrup Carenol Ammonium Chloride Cough</i>	<i>026907</i>

- ii. ***To grant the applicant a final opportunity for personal hearing in its forthcoming meeting. The applicant shall present all relevant documentary evidence before the Board for its consideration.***

CASE NO.5: SUBSTANDARD MAVERICK 500MG INJ., REG. NO. 065444 BATCH NO 250901, AND WAFIN INJ. (WATER FOR INJECTION) REG. NO. 066643 BATCH NO. 250101 MANUFACTURED BY M/S CREST PHARMACEUTICALS, ISLAMABAD DML NO.000694

The Federal Inspector of Drugs-I, DRAP, Islamabad took samples of Maverick 500mg Injection (Reg# 065444) Batch No. 250901, and Wafin Injection (Water for Injection) (Reg# 066643) Batch No. 250101 manufactured by M/s Crest Pharmaceuticals Plot No 43, Industrial Triangle Kahuta Road, Islamabad from the premises of M/s Crest Pharmaceuticals Plot No 43, Industrial Triangle Kahuta Road, Islamabad on 28-01-2026 under Schedule V(1)(c) of the DRAP Act, 2012 read with Section 18(1)(c) of the Drugs Act, 1976 and sent to the Federal Government Analyst, CDL Karachi for test/analysis.

2. The observations of the area FID, along with list of deficiencies, conclusion and recommendations as mentioned in the inspection report are being reproduced below:

“OBSERVATIONS:

Premises:

The manufacturing facility comprises of two separate buildings/blocks. In the old building at the back, tablet General Section and Dry Powder Injection (Vial) Cephalosporin Section are established. There were other sections/rooms along these sections in the same building with Cone mixer, dry powder filling and capsule filling machines installed. Mr. Tariq Mahmood Malik, the Production incharge and owner of the firm, who joined later, informed that these are unapproved areas and intended to be approved as Dry Powder Suspension (Cephalosporin) Section and Capsule (Cephalosporin) Section.

In another multistory adjacent building at the front, the firm has established, Capsule

Section (General), Dry Powder Suspension Section (General), Liquid injection ampoule Section (General), Dry Powder Injection Vials (General) and Eye/Ear Drops Section on ground floor. While in the basement raw materials, packing material and finished goods store and dispensing rooms are established. The first floor and second floor comprises of several sections, approval for which yet to be granted. The quality control laboratory was at the first floor.

Change rooms:

Male and female change rooms are established in the front building having Capsule Section (General), Dry Powder Suspension Section (General), Liquid injection ampoule Section (General), Dry Powder Injection Vials (General) and Eye/Ear Drops Section. The air curtains were non-functional. Step over benches and cabins for personnel belongs were installed. No SOPs and cleaning record of change rooms or log books were available. No gowning protocols/SOPs were being observed as workers were found roaming in production corridor in street clothes.

Entry into the building at the back, having Tablet General Section and Dry Powder Injection (Vial) Cephalosporin section, is through single door that enters into a corridor. Single Change rooms are being provided, one each for the tablet general section and dry powder injection cephalosporin section.

Production Areas:

Front Block/Building:

Capsule Section (General), Dry Powder Suspension Section (General), Liquid injection ampoule Section (General), Dry Powder Injection Vials Section (General) and Eye/Ear Drops Section.

Ms Farzana Safdar, who claimed to be the production pharmacist, was present at the premises. There was no other qualified person present. Neither Production incharge available. It appeared that manufacturing operations were halted in hurry and the workers left the production areas. The sections were inspected. The HVAC system was not operational at the time of inspection. In the liquid injection ampoule section, the floor (epoxy painted) is covered with hard rough plastic sheet, probably to prevent the epoxy paint from getting damage. Status of equipment/machinery were not mentioned. The Calibration tag/slip affixed to Dry Heat Sterilizer, Model/ Sr. No. PK-02, has an expiry date of 03-12-2024.

In the capsule general section, capsule shells were found in the hoppers, while capsule shell carton was also found in the section, indicating that capsule filling process was stopped intentionally. No log books of manufacturing equipment were available, neither batch manufacturing record was provided.

The in-process stocks of various products were found placed under uncontrolled storage conditions without bearing complete identification labels/status, without manufacturing record. Such as filled unlabeled vials in SS trays were found in the dry powder filling area, without any status. Cartons having blisters of Zanxy DS (Tizanidine) found placed in bottle blowing area without any label. Wafin (WFI) ampoules, Batch No. 250101 were found placed in de-cartoning/bottle blowing area in SS buckets. Empty capsule shells cartons for Capsule Sabizole 40mg were lying in dry powder suspension filling area.

Back side Block/Building:

Tablet General section and Dry Powder Injection (Vial) Cephalosporin Section

The tablet general and dry powder injectable (cephalosporin) sections are established in a separate block, located at the back. Entry into this building is through a single door, that leads into a corridor. Separate change rooms, one each for the tablet general and dry powder injectable

(cephalosporin) sections are established. Laminar flow cabinet was found installed in the dispensing room, instead of a proper dispensing booth. In the tablet general section, various equipment such as wet mixer, tray dryer, cone mixer, granulator, compression and coating pans are installed. The inner surfaces/side of the exhaust duct mounted above the coating pan was covered with powder, from previously processed batches. In the dry powder Injection (cephalosporin) section, a dry powder filling machine under laminar flow cabinet was installed. Calibration tags/slips were either expired or were missing on various monitoring gauges of the machinery. In the same building, capsule filling and dry powder filling machines are also installed in separate cubicles, that were labeled as capsule (Cephalosporin) and Dry powder suspension (Cephalosporin) sections. It was informed by Mr. Tariq Mahmood Malik, the Production incharge and owner of the firm, that these sections are not approved yet. It is pertinent to mention that the firm hold registrations of Cresxime (Cefixime) 400mg tablet, Reg.No. 072127, Hemisef (Cefixime) 400mg capsule, Reg.No. 068714 and Hemisef (Cefixime) 100mg dry powder suspension, Reg.No. 068715. Moreover, the firm also hold registration of Nupenam (Imipenem Monohydrate...500mg & Cilastatin Sodium....500mg), Reg.No. 066481 and having no dedicated facility for manufacturing of carbapenems drugs. The approval status of the requisite/relevant sections will be confirmed from Licensing Division and the matter will be processed accordingly.

In the tablet general section, various unlabeled drums having in-process powders and tablets are found stored without proper identifications tags/slips and batch manufacturing record. The HVAC in the areas was non-operational.

Quality Control:

The firm has established a separate quality control laboratory. The quality control manager Ms. Annum Malik D/o Tariq Mehmood was not present. Two inexperienced pharmacists Ms Fatima and Ms Muqaddas, graduated in 2025 were present to supervise the quality control activities. No microbiologist was available. During discussion with the analysts, it became evident that they couldnot operate the HPLC system. The UV Visible Spectrophotometer is being used for analysis of drug products. No calibration record of the quality control instruments was presented at the time of inspection. No record of area monitoring was available. Chemical and Biological indicators were not available. No evidence of use of indicators (biological and chemical) in the BMR of liquid injectable products was mentioned. Log book of Liquid Particle counter was available. Critical instruments such as Total Organic Carbon, FTIR, Air sampler, Particle counter were missing in the quality control laboratory. The stability chambers were without data loggers.

Quality Assurance:

The firm has not established a quality assurance department, as no Quality Assurance incharge is employed to oversee the quality assurance activities. No record of cleaning validation studies, Annual product quality review, vendor qualification, self-inspection, analytical method validation and verification record, qualification of dry heat sterilizer and autoclave, vendor qualification etc were available. Poor implementation of GMP protocols/SOPs was observed during inspection. Storage of in-process materials (bulk powder, blisters, coated and core-tablets) in unauthorized areas without proper/complete identification slips/tags was observed. Calibration of gauges of production equipment such as dry heat sterilizers, autoclave, tray dryer and other equipment were found expired.

HVAC and Water treatment system:

HVAC system and Water treatment system were installed. However, validation and qualification record for both was not shown/provided. The differential pressures across the various production areas were not maintained.

Technical personnel:

The firm lack sufficiently qualified competent technical personnel in production, quality control,

LIST OF DEFICIENCIES:

S.No	Deficiencies/Non-Compliance	Classification of Deficiency Guidance Document No. QALT/GL/CG/002 Effective Date: 30-03-2023	Reference (LRA Rules including Schedule B/ Decision of RB vide No.F.313-DRB/2021 (PE&R) dated 29.12.2021/ WHO TRS)
1.	The air curtains were non-functional. No SOPs and cleaning record of change rooms or log books were available. No gowning protocols/SOPs were being observed as workers were found roaming in production corridor in street clothes. Change rooms were not maintained.	Critical	Schedule B-II: Premises & Personnel (Change Rooms, Protective Clothing, Hygiene WHO TRS 961 Annex 6
2.	Neither Production in-charge nor Quality Control In-charge were present at the premises at the time of inspection.	Major	Schedule B-II: Technical Staff & Supervision WHO TRS 961 Annex 3
3.	The HVAC system was not operational at the time of inspection.	Critical	B-II: Premises – Environmental Control / Air Handling WHO TRS 961 Annex 6
4.	In the liquid injection ampoule section, the floor (epoxy painted) is covered with hard rough plastic sheet, probably to prevent the epoxy paint from getting damage. The presence of plastic sheet will make difficult to qualify the sterile formulation and filling rooms for performing sterile operations.	Major	Schedule B-II: Premises – Cleanable Surfaces WHO TRS 961 Annex 6
5.	Status of equipment/machinery in production areas were not mentioned.	Major	Schedule B-II: Equipment Identification & Status Labelling WHO TRS 961 Annex 3
6.	The Calibration tag/slip affixed to Dry Heat Sterilizer, Model/ Sr. No. PK-02, has an expiry date of 03-12-2024.	Critical	Schedule B-II: Equipment Calibration & Maintenance WHO TRS 961 Annex 6
7.	Empty capsule shells were found in the hoppers, while capsule shell carton was also found in the section, indicating that capsule filling process was stopped intentionally. while no log book of capsule filling machine was available, neither batch manufacturing record was provided, for the in-process batch at the time of inspection.	Critical	Schedule B-II: Documentation & Batch Records WHO TRS 961 Annex 3
8.	The in-process stocks of various products were found placed under uncontrolled storage conditions without bearing complete identification labels/status and without manufacturing record. Such as filled unlabeled vials in SS trays were found in the dry powder filling area, without any status. Cartons having blisters of Zanxy DS (Tizanidine) found placed in bottle blowing area without any label.Wafin (WFI) ampoules, Batch No. 250101 were found	Critical	Schedule B-II: Storage, Labeling & Status Control WHO TRS 961 Annex 3

	<i>placed in de-cartoning/bottle blowing area in SS buckets. Empty capsule shells cartons for Capsule Sabizole 40mg were lying in dry powder suspension filling area.</i>		
9.	<i>Laminar flow cabinets were found installed in the dispensing rooms of general and cephalosporin sections, instead of proper dispensing booth.</i>	Major	Schedule B-II: Premises Design for Dispensing WHO TRS 961 Annex 3
10.	<i>The inner surfaces/side of the exhaust duct mounted above the coating pan was covered with powder/residue, from previously processed batches.</i>	Major	Schedule B-II: Sanitation & Cleaning of Premises WHO TRS 961 Annex 3
11.	<i>Calibration tags/slips were either expired or were missing on various monitoring gauges of the machinery.</i>	Major	Schedule B-II: Calibration of Instruments WHO TRS 961 Annex 3
12.	<i>In the tablet general section, various unlabeled drums having in-process powders and tablets are found stored without proper identifications tags/slips and batch manufacturing record. The HVAC in the areas was non-operational.</i>	Critical	Schedule B-II: Environmental Control + In-process Control
13.	<i>The quality control Incharge Ms. Annum Malik D/o Tariq Mehmood was not present. The firm has employed two inexperienced pharmacists Ms Fatima and Ms Muqaddas, both graduated in 2025 were present to supervise the quality control activities, who were unable to run the HPLC system.</i>	Critical	Schedule B-II: Qualified QC Staff & Testing Facilities WHO TRS 961 Annex 3
14.	<i>No microbiologist available, while the firm has the injectable sections (Dry powder cephalosporin, liquid ampoule general and dry powder vial general sections.</i>	Critical	Schedule B-II: Qualified Personnel for Sterile Products
15.	<i>The UV Visible Spectrophotometer is being used for analysis of most of the products drug products through non-pharmacopoeial methods.</i>	Major	Schedule B-II: Validated Test Methods WHO TRS 961 Annex 6
16.	<i>No calibration record of the quality control instruments was presented at the time of inspection.</i>	Critical	Schedule B-II: Calibration & Maintenance of QC Instruments
17.	<i>No record of area monitoring was available.</i>	Critical	Schedule B-II: Environmental Monitoring Program WHO TRS 961 Annex 6
18.	<i>Chemical and Biological indicators were not available.</i>	Critical	Schedule B-II: Sterilization Controls & Indicators WHO TRS 961 Annex 6
19.	<i>No evidence of use of indicators (biological and chemical) in the BMR of liquid injectable products was mentioned.</i>	Critical	Schedule B-II: Batch Records – Sterilization Data
20.	<i>Critical instruments such as Total Organic Carbon, FTIR, Air sampler, Particle counter were missing in the quality control laboratory.</i>	Critical	Schedule B-II: Adequate QC Facilities & Environmental Monitoring
21.	<i>The stability chambers were without data loggers.</i>	Major	Schedule B-II: Stability Studies &

			<i>Environmental Control</i>
22.	<i>The firm has not established a quality assurance department, as no Quality Assurance in-charge is employed to oversee the quality assurance activities.</i>	<i>Critical</i>	<i>Schedule B-II: Quality Assurance System WHO TRS 961 Annex 3</i>
23.	<i>No record of cleaning validation studies, Annual product quality review, vendor qualification, self-inspection, analytical method validation and verification record, qualification of dry heat sterilizer and autoclave, vendor qualification etc were available.</i>	<i>Critical</i>	<i>Schedule B-II: Validation, Self-Inspection, Vendor Qualification, APQP P WHO TRS 961 Annex 3;</i>
24.	<i>Validation and qualification record for HVAC & Water Treatment System was not provided.</i>	<i>Critical</i>	<i>Schedule B-II: Qualification of Critical Utilities (HVAC, WTS) WHO TRS 961 Annex 6</i>

Conclusion & Recommendation:

During inspection a number of critical observations and gross violations of cGMP guidelines/principles observed. These were related to production areas, quality control, quality assurance, utilities, Storage areas, documentation, qualified personnel (both in production and quality control) and implementation of SOPs etc. The firm lack critical quality control equipment such as FTIR, TOC, Karl Fisher, Air sampler and particle counter in the Quality Control Laboratory, while instruments such as HPLC and Liquid Particle Counter were either not in use or non-functional as no log book or analysis record was provided during inspection. In view of the critical and major deficiencies/observations, noted during inspection and are being mentioned in the above sections, the firm M/s Crest Pharmaceuticals, Plot No. 43, Industrial Triangle Kahuta Road, Islamabad may be directed to immediately stop production activities in all their sections, till submission of CAPA, its verification and subsequent approval of production resumption by the competent authority. ”

3. The Federal Government Analyst, CDL, Karachi vide test reports No. IP-2-26-000022 dated 19th March, 2026, and No. IP-2-26-000023 dated 18th March, 2026 declared the following samples as “Sub-Standard” quality.

Sr.No.	Drug Sample	Mfg. Date	Exp. Date	Tests	CDL Report No.	Manufacturer
1.	Maverick 500mg Injection (065444) Batch No. 250901	09-2025	09-2027	Sterility: Must Comply Result: Non Sterile Does not comply. USP-NF 2026	IP-2-26-000022 dated 19 th March, 2026 The sample is of sub-standard quality under the Drugs Act 1976.	M/s Crest Pharmaceuticals, Islamabad.
2.	Wafin Injection (Water for Injection) (066643) Batch No. 250101	01-2025	01-2028	Sterility: Must Comply Result: Non Sterile Does not comply. USP-NF 2026	IP-2-26-000023 dated 18 th March, 2026 The sample is of sub-standard quality under the Drugs Act 1976.	M/s Crest Pharmaceuticals, Islamabad

4. Federal Inspector of Drugs-I, Islamabad, issued an explanation letter to the firm vide letter No.F.03-05/09-FID-I, dated 30-03-2026.

5. Subsequently, FID-I, Islamabad, forwarded the company's request for Appellate testing, which was submitted to his office vide letters No. CP-FID1-19/26 and No. CP-FID1-20/26 dated 06.04.2026.

6. In this regard it is submitted that the Registration Board in its 313th meeting decided as under:

“Proceedings and Decision of 313th Meeting of Registration Board.

The Board after thorough deliberations and considering the facts of the case decided as:

- i. *The firm will provide OOS investigation and complete testing record of the concerned batch along with scientific justifications/grounds with the request of Appellate testing under section 22(4) of the Drugs Act 1976.*
- ii. *Federal Government Analyst, Karachi will provide OOS investigation and complete testing record of such reports.*
- iii. *Registration Board advised QA&LT Division to present all cases of Appellate Testing with these both set of documents along with technical report of the case.”*

7. In the light of above-mentioned decision of the Board, the division of QA&LT vide letter No.F.03-22/2026-DD(QALT-VI) dated 05-05-2026 requested the Federal Government Analyst CDL Karachi to submit of Out of specification (OOS) investigation as directed by the Registration Board.

8. Furthermore, M/s. Crest Pharmaceuticals Plot No 43, Industrial Triangle Kahuta Road, Islamabad was directed to submit Out of specification (OOS) investigation and complete testing record of their products namely “Maverick 500mg Injection” Batch No. 250901 and “Wafin Injection (Water for Injection)” Batch No. 250101 along with scientific justifications/grounds vide letter No.F.03-22/2026-DD(QALT-VI) dated 05-05-2026.

9. In response received through e-App, the firm only provided BMRs of the above-mentioned products, whereas OOS investigation as well as scientific justification/grounds were not submitted by the firm. Furthermore, equipment validations and other prerequisites of sterility testing such as Growth Promotion Test were also not provided. The firm was therefore, once again directed to submit the above-mentioned documents at the earliest for the processing of their request for appellate testing vide letter No.F.03-22/2026-DD(QALT-VI) dated 11-05-2026.

10. The reply of the firm was received vide letter No. CP-DDQAVI-29/26 dated 18-05-2026 wherein failed to provide a scientific rationale for the appellate testing. The reply of the firm is being reproduced below:

“Reference is your subject letter, dated 11-05-2026, received on 12-05-2026, we submit as follows:

Out of Specs Investigation

- We analysed the retained samples of the 005 batches and found them within USP specs. Certificate of analysis is attached.*
- Source water was analysed and found within specification. COA attached.*
- Area was monitored for viable and non viable particles and found within specs.*

Scientific Justification

We found serious discrepancy while studying the Test Reports of Federal Government Analyst.

Report No. IP-2-26-000022 is dated 19-03-2026

Report No. IP-2-26-000023 is dated 18-03-2026

Report No. IP-2-26-000022 has been generated one day after Report No. IP-2-26-000023, which reflects that these reports have been prepared and crafted without performing the tests.

Tests like identification, assay, physical appearance and pH are done in 1-2 hours, while sterility test takes two weeks. Federal Government Analyst did not perform the tests which take less time, as depicted from reports rather he preferred to go for the test which takes two weeks. Reports do not reflect how many plates have been inoculated with each medium? Whether the analyst compared it with positive or negative control? Did he repeat the test as described in USP? Growth promotion test requires minimum 20 samples for each media (Fluid Thioglycolate and Soyabean-Casein Digestive media) i.e., 40 sample for one test and 40 samples for repeat test as desired by USP. How many

samples did he receive from the FID. Did he use 80 samples in sterility test? If yes, what about the other tests?

Report is signed by Dr. Saif-ur Rehman Khattak. Dr. Saif-ur Rehman is pharmacist by education, hence cannot perform/ supervise Sterility Test as it is the domain of Microbiologist and against the spirit of GLP also. Test results of these batches at the time of production and test results of retained sample tested in April 2026 are within specification.

Equipment Validation

Certificates Attached.

Growth Promotion Test

Certificate of Analysis attached

Keeping in view all the above findings and discrepancy in test reports it is requested to drop the proceedings against us.”

11. The firm has failed to submit a recall log of Maverick 500mg Injection Batch No. 250901, and Wafin Injection (Water for Injection) Batch No. 250101.

12. Summary of evaluation of OOS investigation by the division of QA&LT is given as under:

Summary of OOS investigation submitted by Central Drugs Laboratory, Karachi:

Federal Government Analyst, CDL Karachi has submitted OOS investigation along with complete testing record wherein it is informed that the sample is tested in accordance with the test/analysis method provided in the USP-NF 2026 and has ruled out any possibility of error in the method of test/analysis, equipment and/or any operator or analyst related error.

Summary of OOS investigation submitted by M/s Crest Pharmaceuticals, Islamabad.

M/s. Crest Pharmaceuticals Plot No 43, Industrial Triangle Kahuta Road, Islamabad in their reply submitted that they had analyzed the retained samples of the OOS batches and found them within USP specs and attached Certificate of analysis. Source water was analyzed and found within specification. COA attached. Area was monitored for viable and non-viable particles and found within specs. The firm however, did not conduct OOS investigations in accordance with International Guidelines but resorted to finding fault with CDL report. Details regarding technical evaluation of OOS Investigation are given below.

Technical Evaluation of OOS Investigation:

- i. Both products were declared as sub-standard by CDL with respect to Sterility
- ii. CDL performed the sterility test as per USP-NF 2026.
- iii. The COAs provided in the BMRs of “Maverick 500mg Injection” Batch No. 250901 and “Wafin Injection (Water for Injection)” Batch No. 250101 respectively, do not mention with which official monograph do both products comply.
- iv. The firm provided BMR of both “Maverick 500mg Injection” Batch No. 250901 and “Wafin Injection (Water for Injection)” Batch No. 250101.
- v. The COA of Maverick 500mg (Ceftriaxone base) includes Assay, Foreign particle, pH, Pyrogen test, and Sterility test. However, according to the inspection report of the area FID, conducted on 28-01-2026, the firm does not have a microbiologist. The Quality Control In-Charge employed by the firm is daughter of the owner and was absent on the day of inspection. During the visit of FID, two analysts were present who were both fresh pharmacy graduates of 2025.
- vi. The firm provided Growth Promotion Test (GPT) of Fluid Thioglycollate Medium (FTM) and Soybean–Casein Digest Medium conducted from 03-04-2026 to 17-04-2026 claimed to be performed in accordance with USP 2025 on retained samples whereas review of the GPT showed that the firm had not complied with USP 2025 Chapter <71>.
- vii. The absence of Microbiologist further raises doubts concerning the availability of appropriate provisions such as ATCC strains for Area Monitoring and Quality Control Testing of the sterile products as well as BET kits as the COA only mentions that the product is pyrogen-free.
- viii. The firm has failed to provide the validation or calibration certificates of the relevant equipment i.e., Autoclave and Dry Heat Sterilizer (DHS).
- ix. The COA of bulk Purified Water and Bulk WFI provided by the firm states that it complies USP 35 specs whereas, in 2025 when bulk purified & bulk WFI were produced, USP 2025

- i.e., USP 48 was in effect. Consequently, the firm was producing bulk purified & bulk WFI which was neither in compliance with official USP nor BP in terms of conductivity and TOC.
- x. The firm released bulk purified for use without conducting microbial content & bulk WFI for use without conducting Bacterial Endotoxin Test (BET).
 - xi. The Sterilization technique being used to produce WFI (product) was membrane filtration followed by aseptic filling without a scientific rationale.
 - xii. The correct limit of conductivity in accordance with USP monograph for WFI is not mentioned on the COA of Wafin Injection (Water for Injection).
 - xiii. Media-fill trials have not been provided by the firm considering the fact that both substandard products were being aseptically manufactured.
 - xiv. CDL, Karachi has provided complete OOS investigation of both substandard products.

13. Proceedings and Decision of 359th meeting of Registration Board

Division of QA & LT presented the case before the Registration Board. The Board, after considering facts of the case, thorough deliberations, and considering the lack of OOS investigation conducted by the firm as well as gross deficiencies in the submitted data, decided as follows:

- i. *“Not to accede to the firm’s request for retesting of samples from Appellate Laboratory under section 22 (5) of the Drugs Act, 1976.*
- ii. *To issue show cause notice to M/s. Crest Pharmaceuticals, Plot No. 43, Industrial Triangle, Kahuta Road, Islamabad, under Section 42 of the Drugs Act, 1976.*
- iii. *To call the representatives of the firm for personal hearing before Registration Board in its forthcoming meeting.*



Drug Regulatory Authority of Pakistan

(Biological Evaluation & Research Division)



Item No. IV Division of Biological Evaluation & Research

Sr. No	Title	Description
1	Case Category	New Section (Anam Saeed)
	Name, address of Applicant.	Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (000644)
	Application Form Dy. No / Tracking ID & date of submission	(YRD-ZU9-T5YG, 2025-12-02)
	Detail of Fee Submitted	75000, 2025-11-12,
	The proposed proprietary name / brand name	Terza 7.5mg/0.5ml Single Dose Prefilled Syringe
	Label Claim	Each PRE-FILLED SYRINGE (0.5mL) Contains: Tirzepatide.....7.5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Hangzhou Patience Chemical Co., Ltd. Address: No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, Hangzhou, ZheJiang, China.
	Detail of stability batches of drug product	Stability data of 3 batches attached.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Invoice of 300gm API attached which is not DRAP attested.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 3 batches attached.
	The status in reference regulatory authorities	EMA Approved
	GMP status of the firm	New section granted on 25th June 2025.
	Evidence of approval of manufacturing facility	New section granted on 25th June 2025.
	Evaluation Remarks	
	Decision of 357th meeting:DeferredThe Registration Board decided to grant the firm an opportunity for a personal hearing to clarify the observations raised by the BE&R Division. In the light of above decision, a personnel hearing letter was issued to M/s Weather Folds Pharmaceuticals, Hattar.	
	Decision	
	Approved	

The Registration Board decided to approve the product, subject to verification of the Goods Declaration (GD) from the Customs online portal regarding the import of Tirzepatide API, and submission of a revised formulation aligned with that of the innovator product and with following conditions:

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.
2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.
3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.
4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.
5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.
6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

2	Case Category	New Section (Anam Saeed)
	Name, address of Applicant.	Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (000644)
	Application Form Dy. No / Tracking ID & date of submission	(VLY-WU1-7VJV, 2025-12-02)
	Detail of Fee Submitted	75000, 2025-11-12,
	The proposed proprietary name / brand name	Terza 12.5mg/0.5ml Single Dose Prefilled Syringe
	Label Claim	Each PRE-FILLED SYRINGE (0.5mL) Contains: Tirzepatide.....12.5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Hangzhou Patience Chemical Co., Ltd. Address: No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, Hangzhou, ZheJiang, China.
	Detail of stability batches of drug product	Stability data of 3 batches attached.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Invoice of 300gm API attached which is not DRAP attested.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 3 batches attached.
	The status in reference regulatory authorities	EMA Approved
	GMP status of the firm	New section granted on 25th June 2025.
	Evidence of approval of manufacturing facility	New section granted on 25th June 2025.
	Evaluation Remarks	
	Decision of 358th meeting:DeferredThe Registration Board decided to grant the firm an opportunity for a personal hearing to clarify the observations raised by the BE&R Division. In the light of above decision, a personnel hearing letter was issued to M/s Weather Folds Pharmaceuticals, Hattar.	
	Decision	
	Approved	
	The Registration Board decided to approve the product, subject to verification of the Goods Declaration (GD) from the Customs online portal regarding the import of Tirzepatide API, and submission of a revised formulation aligned with that of the innovator product and with following conditions:	
	1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP. 4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. 5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022. 6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	
3	Case Category	New Section (Anam Saeed)
	Name, address of Applicant.	Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (000644)
	Application Form Dy. No / Tracking ID & date of submission	(T7X-NX2-74DW, 2025-12-02)
	Detail of Fee Submitted	75000, 2025-11-12,
	The proposed proprietary name / brand name	Terza 10mg/0.5ml Single Dose Prefilled Syringe
	Label Claim	Each PRE-FILLED SYRINGE (0.5mL) Contains: Tirzepatide.....10mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C

For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Hangzhou Patience Chemical Co., Ltd. Address: No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, Hangzhou, ZheJiang, China.
Detail of stability batches of drug product	Stability data of 3 batches attached.
Documents for the procurement of API with approval from DRAP (in case of Import)	Invoice of 300gm API attached which is not DRAP attested.
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 3 batches attached.
The status in reference regulatory authorities	EMA Approved
GMP status of the firm	New section granted on 25th June 2025.
Evidence of approval of manufacturing facility	New section granted on 25th June 2025.
Evaluation Remarks	
Decision of 358th meeting:DeferredThe Registration Board decided to grant the firm an opportunity for a personal hearing to clarify the observations raised by the BE&R Division. In the light of above decision, a personnel hearing letter was issued to M/s Weather Folds Pharmaceuticals, Hattar.	
Decision	
Approved	
The Registration Board decided to approve the product, subject to verification of the Goods Declaration (GD) from the Customs online portal regarding the import of Tirzepatide API, and submission of a revised formulation aligned with that of the innovator product and with following conditions:	
1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.	
2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.	
3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP’s licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.	
4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.	
5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.	
6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	
Case Category	New Section (Anam Saeed)
Name, address of Applicant.	Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan.

	(000644)
Application Form Dy. No / Tracking ID & date of submission	(RY3-AGH-YSNW, 2025-12-02)
Detail of Fee Submitted	75000, 2025-11-12,
The proposed proprietary name / brand name	Terza 15mg/0.5ml Single Dose Prefilled Syringe
Label Claim	Each PRE-FILLED SYRINGE (0.5mL) Contains: Tirzepatide.....15mg (Product complies Innovator's Specs)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per SRO-De-Controlled
Shelf Life (Unit)	2 Year(s)Store at 2-8°C
For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Hangzhou Patience Chemical Co., Ltd. Address: No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, Hangzhou, ZheJiang, China.
Detail of stability batches of drug product	Stability data of 3 batches attached.
Documents for the procurement of API with approval from DRAP (in case of Import)	Invoice of 300gm API attached which is not DRAP attested.
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 3 batches attached.
The status in reference regulatory authorities	EMA Approved
GMP status of the firm	New section granted on 25th June 2025.
Evidence of approval of manufacturing facility	New section granted on 25th June 2025.
Evaluation Remarks	
Decision of 358th meeting:DeferredThe Registration Board decided to grant the firm an opportunity for a personal hearing to clarify the observations raised by the BE&R Division. In the light of above decision, a personnel hearing letter was issued to M/s Weather Folds Pharmaceuticals, Hattar.	
Decision	
Approved	
The Registration Board decided to approve the product, subject to verification of the Goods Declaration (GD) from the Customs online portal regarding the import of Tirzepatide API, and submission of a revised formulation aligned with that of the innovator product and with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.	

3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.

4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.

6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

5	Case Category	New Section (Anam Saeed)
	Name, address of Applicant.	Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (000644)
	Application Form Dy. No / Tracking ID & date of submission	(L6Q-MA9-PDEV, 2025-12-02)
	Detail of Fee Submitted	75000, 2025-11-12,
	The proposed proprietary name / brand name	Terza 5mg/0.5ml Single Dose Prefilled Syringe
	Label Claim	Each PRE-FILLED SYRINGE (0.5mL) Contains: Tirzepatide.....5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Hangzhou Patience Chemical Co., Ltd. Address: No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, Hangzhou, ZheJiang, China.
	Detail of stability batches of drug product	Stability data of 3 batches attached.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Invoice of 300gm API attached which is not DRAP attested.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 3 batches attached.
	The status in reference regulatory authorities	EMA Approved
	GMP status of the firm	New section granted on 25th June 2025.
	Evidence of approval of manufacturing facility	New section granted on 25th June 2025.
	Evaluation Remarks	
	Decision of 358th meeting:DeferredThe Registration Board decided to grant the firm an opportunity for a personal hearing to clarify the observations raised by the BE&R Division. In the light of above decision, a personnel hearing letter was issued to M/s Weather Folds Pharmaceuticals, Hattar.	
	Decision	
	Approved	

The Registration Board decided to approve the product, subject to verification of the Goods Declaration (GD) from the Customs online portal regarding the import of Tirzepatide API, and submission of a revised formulation aligned with that of the innovator product and with following conditions:

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.
2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.
3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.
4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.
5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.
6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

6	Case Category	New Section (Anam Saeed)
	Name, address of Applicant.	Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (000644)
	Application Form Dy. No / Tracking ID & date of submission	(HBL-2VX-UYXY, 2025-12-02)
	Detail of Fee Submitted	75000, 2025-11-12,
	The proposed proprietary name / brand name	Terza 2.5mg/0.5ml Single Dose Prefilled Syringe
	Label Claim	Each PRE-FILLED SYRINGE (0.5mL) Contains: Tirzepatide.....2.5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Hangzhou Patience Chemical Co., Ltd. Address: No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, Hangzhou, ZheJiang, China.
	Detail of stability batches of drug product	Stability data of 3 batches attached.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Invoice of 300gm API attached which is not DRAP attested.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A

Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 3 batches attached.
The status in reference regulatory authorities	EMA Approved
GMP status of the firm	New section granted on 25th June 2025.
Evidence of approval of manufacturing facility	New section granted on 25th June 2025.
Evaluation Remarks	
Decision of 358th meeting:DeferredThe Registration Board decided to grant the firm an opportunity for a personal hearing to clarify the observations raised by the BE&R Division. In the light of above decision, a personnel hearing letter was issued to M/s Weather Folds Pharmaceuticals, Hattar.	
Decision	
Approved	
The Registration Board decided to approve the product, subject to verification of the Goods Declaration (GD) from the Customs online portal regarding the import of Tirzepatide API, and submission of a revised formulation aligned with that of the innovator product and with following conditions:	
1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.	
2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.	
3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.	
4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.	
5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.	
6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	
7	
Case Category	Routine (Anam 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	(HN3-P6M-ZX3Q, 2025-07-09)
Detail of Fee Submitted	37000.0, 2024-11-21,
The proposed proprietary name / brand name	Peg-Filgen PFS 6mg/0.6ml
Label Claim	Each PFS (0.6ml) Contains: Peg-Filgrastim.....6mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's-As per SRO
Shelf Life (Unit)	2 Year(s)Store at 2°C to 8°C.
For generic drugs (me-too Status)	Neulastim 6mg of M/s Roche Pakistan Ltd.

Pharmacotherapeutic Group of (API)	Immunostimulants (Colony Stimulating Factors) ATC Code : L03AA13		
Name, address of Manufacturing site:	Self Manufacturing		
Name & address of API manufacturer	Name: Zydus Lifesciences Ltd., Address: Zydus Biologics (Unit-1) Plot No. 23, 25/P, 37, 40/P, 42 TO 47, Sarkhej – Bavla, N.H. 8A, Changodar Road, Opp. Ramdev Masala, Ahmedabad – 382213, Gujarat, India		
Detail of stability batches of drug product	Accelerated stability testing was performed on three batches—047D0 (Batch size 237 PFS) 1, 047D02 (236 PFS), and 047D03 (236 PFS)—at a temperature of 25°C (±2°C) and relative humidity of 60% RH (±5%) till 6 months. In parallel, real-time stability studies were carried out on the same three batches at a temperature of 5°C (±3°C) till 6 months.		
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate Computerized No. 6461022241693 dated 04-09-2023		
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A		
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches DS-403-001, DS-403-002, and DS-403-003 at accelerated conditions with time intervals 0, 1st, 2nd ,3rd, 6th. The real time stability data is conducted at 25 ± 5 °C, at the intervals of 0, 3rd, 6th , 9th , 12th , 18th , 24th , 36th months.		
The status in reference regulatory authorities	NEULASTA Injection of Amgen Inc. One Amgen Center Drive Thousand Oaks, California approved by USFDA		
GMP status of the firm	GMP certificate was issued to M/s BF Biosciences on 05-09-2024.		
Evidence of approval of manufacturing facility	Pre-filled syringe section granted on 07-05-2024.		
Evaluation Remarks			
The application was evaluated and some queries were asked from the applicant. The reply of the applicant is tabulated below along with remarks;			
Sr.No.	Queries	Response of the firm	Remarks
1	Manufacturer mentioned in the dossier is M/s Zydus Lifesciences India while the manufacturer as per clearance certificate, Form 3 and Form 7 is M/s Candila Healthcare India. Clarification required.	Cadila Healthcare is the former name of Zydus Lifesciences Limited; the company officially changed its name in 2022. Mfg. license is attached as Annexure A for Clarification	Evidence of approval of change of name of manufacturer by their regulatory authority is required.
2	Submit Legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same	CoPP from the Country of Origin is attached as Annexure B	COPP of final product that has been manufactured by same concentrate/ready to fill bulk is required.

	concentrate/ready to fill bulk.		
3	Submit complete Bio-similarity studies of the finished product of same source (bulk concentrate or ready to fill) manufactured either from country of origin or by any reference regulatory authority as adopted by Registration Board to demonstrate the bio-similarity.	Not Applicable as it is a generic product. The comparative studies with the reference product are attached in Annexure F.	The product is of rDNA origin. Complete Bio-similarity required including non-clinical and clinical part also.
4	Submit Module 3.2.S.2.2 to 3.2.S.2.6	Module 3.2.S.2.2 to 3.2.S.2.6 attached as Annexure C	Submitted.
5	Provide agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.	Quality Agreement between BF Biosciences Ltd. & Zydus Lifesciences is attached as Annexure D	Required agreement not provided.
6	Submit Raw data and chromatograms of stability data of finished product.	Its testing is bioassay based. Raw Data sheets of Bioassay are attached as Annexure E.	Complete raw data of all the tests performed in stability of finished product is required.
7	Comparative testing of finished product is performed with Neupeg of M/s Intas Pharmaceuticals India which is not innovator product.	At the time of testing, the innovator product NEULASTA® (pegfilgrastim) injection was not available. So, we performed comparative testing with Neupeg (M/s Intas Pharmaceuticals India). Comparative Studies are attached as Annexure F.	Comparative testing of applied product with innovator is required.
8	Undertakings required as per guidelines of bulk concentrate import approved in 278th meeting.	Attached as Annexure G.	Not provided.

Concluding remarks: i. Evidence of approval of change of name of manufacturer by their regulatory authority is required. ii. COPP of final product that has been manufactured by same concentrate/ready to fill bulk is required. iii. Complete Bio-similarity studies of the finished product of same source (bulk concentrate or ready to fill) manufactured either from country of origin or by any reference regulatory authority as adopted by Registration Board to demonstrate the bio-similarity is required. iv. Complete raw data of all the tests performed in stability of finished product is required. v. Comparative testing of applied product with innovator is required. vi. Undertakings required as per guidelines of bulk concentrate import approved in 278th meeting. vii. Agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents. Decision of 352nd

meeting:DeferredRegistration Board deferred the case for the submission of following documents/clarifications;i. Evidence of approval of change of name of manufacturer by their regulatory authority is required.ii. COPP of final product that has been manufactured by same concentrate/ready to fill bulk is required.iii. Complete Bio-similarity data required including non-clinical and clinical part also.iv. Complete raw data of all the tests performed in stability of finished product is required.v. Comparative testing of applied product with innovator is required.vi. Undertakings required as per guidelines of bulk concentrate import approved in 278th meeting.vii. Agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents. Remarks by BE&R: The case is of drug substance import and local manufacturing and the applicant has submitted the comprehensive analytical data by drug substance manufacturer. However the finished product manufacturer i.e M/s BF Biosciences has only performed few comparative tests with innovator. So, following is required to be conducted by the local manufacturer to support similarity of the finished product with the innovator product and as required by EMA in "Guideline on similar biological medicinal products containing recombinant granulocyte-colony stimulating factor (rG-CSF)"; 1. Complete quality comparison of the product manufactured by the local manufacturer using the proposed drug substance with the innovator product is required including Comprehensive comparative characterization encompassing all relevant physicochemical, structural, biological, and purity attributes. 2. Comparative bioassays including receptor-binding studies and functional assays (e.g. cell proliferation assay) with innovator. 3. PK/PD studies of the drug product manufactured by the local manufacturer using the proposed drug substance demonstrating comparability of the product with the innovator and to support the similarity of the finished product.

Decision

Deferred

Registration Board deferred the application for submission of following documents;

1. Complete quality comparison of the product manufactured by the local manufacturer using the proposed drug substance with the innovator product including comprehensive comparative characterization encompassing all relevant physicochemical, structural, biological, and purity attributes.
2. Comparative bioassays including receptor-binding studies and functional assays (e.g. cell proliferation assay) with innovator.
3. PK/PD studies of the drug product manufactured by the local manufacturer using the proposed drug substance demonstrating comparability of the product with the innovator and to support the similarity of the finished product.

8	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	HealthBee Projects Private Limited Ground Floor, Momi Plaza, Plot No 43, Business Square, Phase 7, Bahria Town (01-374-0176-065437D)
	Application Form Dy. No / Tracking ID & date of submission	(DW2-YNX-HET9, 2024-07-01)
	Detail of Fee Submitted	300000.0, 2024-06-12,
	The proposed proprietary name / brand name	CTST
	Label Claim	0.1ml per human dose, containing 5U of Recombinant Mycobacterium Tuberculosis Fusion Protein (EC).
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	1.0ml/vial-As per SRO
	Shelf Life (Unit)	24 Month(s)2-8 C
	For generic drugs (me-too Status)	Not available

Pharmacotherapeutic Group of (API)	tuberculosis diagnostics	
Name, address of Manufacturing site:	Anhui Zhifei Longcom Biopharmaceutical Co.,Ltd-No.100 Fushan Road, High Tech Development Zone, Hefei City-China	
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A	
Name, address of Marketing Authorization Holder:	Anhui Zhifei Longcom Biopharmaceutical Co.,Ltd, No.100 Fushan Road, High Tech Development Zone, Hefei City, China	
Details of Certificates (CoPP/FSC/cGMP):		
Details of Authorization Letter :	N/A	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches of Recombinant Mycobacterium Tuberculosis Fusion Protein (EC) bulk (Batch No.: M20171101, M20171102, and M20171201) were placed under two conditions of $\leq$ -70°C (long-term) and 2-8°C (accelerated) to observe their stability.	
The status in reference regulatory authorities	Not approved in any reference country yet	
Evaluation Remarks		
The application was considered by the Board in 344th meeting and Board decided as under: Decision of 344th meeting: Deferred for provision of evidence of the status in reference regulatory authorities. Response of the firm: The firm submitted a reply as under; "We, M/s HealthBee Projects (Private) Limited, would like to submit the following response for your kind consideration regarding the decision made in the 344th Board Meeting. The CTST product, having a similar composition, has been approved by the European Union and registered with the European Medicines Agency (EMA). Our competitor, Serum Institute of India, has developed a comparable tuberculosis product named Siiltibcy (Common name: rdESAT-6 / rCFP-10). Both products share identical antigens — recombinant ESAT-6 and CFP-10 (rdESAT-6, rCFP-10). As Siiltibcy is already registered with the EMA, we respectfully request that our CTST product be considered equivalent to Siiltibcy. For your reference, please find below the relevant links: 1.https://www.ema.europa.eu/en/medicines/human/EPAR/siiltibcy 2.https://www.ema.europa.eu/en/news/meeting-highlights-committee-medicinal-products-human-use-chmp-14-17-october-2024 3.https://ec.europa.eu/health/documents/communityregister/2025/20250113164661/anx_164661_en.pdf Furthermore, our product CTST has been reviewed and cited in the WHO Consolidated Guidelines on Tuberculosis and the WHO 2022 Report (relevant references enclosed). Please find attached the supporting documents for your review. We sincerely request your favorable consideration of our submission." Remarks of evaluator: The firm has stated in its reply that Siiltibcy is a reference product for the applied product and that both have the same composition. However, the two products are not the same. The differences between them are outlined in the table below;		
Sr.No.	C-TST	Siiltibcy
1	Composition: 0.1ml per human dose, containing 5U of Recombinant Mycobacterium Tuberculosis Fusion Protein (EC).	Composition: One dose (0.1 mL) contains 0.05 microgram of rdESAT-6* and 0.05 microgram of rCFP-10**. *Recombinant dimer of Mycobacterium tuberculosis early secretory antigenic target **Recombinant culture filtrate protein of Mycobacterium tuberculosis
2	Recombinant Mycobacterium Tuberculosis Fusion Protein (EC) is expressed in Escherichia coli	Produced in Lactococcus lactis cells
3	The product comes with three different packing as mentioned, 0.3 ml/vial, 0.5 ml/vial and 1.0 ml/vial while the dosage for each human use is 0.1 ml per human dose.	Multidose vial. One vial (1 mL) contains 10 doses of 0.1 mL.

4	This product is indicated for the diagnosis of Mycobacterium tuberculosis infection, and it is recommended for infants ≥ 6 months, children, and adults ≤ 65 years.	SIILTIBCY is indicated as a diagnostic aid for detection of Mycobacterium tuberculosis infection, including disease, in adults and children aged 28 days or older.
5	Excipients disodium hydrogen phosphate, potassium dihydrogen phosphate, sodium chloride, phenol and polysorbate 80.	Excipients Disodium hydrogen phosphate dehydrate (E339), Potassium dihydrogen orthophosphate (E340), Potassium chloride (E508), Sodium chloride, Polysorbate 20 (E432), Phenol, Water for injections
6	Method of administration 2 methods: · Use this product alone or; · This product combined with TB-PPD	SIILTIBCY should be prepared and administered via intradermal injection by healthcare professionals trained for the Mantoux technique.

Decision of 353 meeting: Deferred Registration Board deferred the case for provision of evidence of availability of formulation in Reference Regulatory Authorities by the firm. Response of the firm: Like Siiltibcy, CTST selects a fusion protein of two specific antigens, namely the 6 kDa Early Secretory Antigenic Target (ESAT6) and Culture Filtrate Protein 10 (CFP10). CTST is similar to Siiltibcy in the general concept of antigen selection and ratio, and it contains a fusion protein instead of two individual antigens. ESAT6 and CFP-10 are small molecular weight proteins (about 10 kDa each), and thus are expected to have relatively low inherent immunogenicity, which may translate into low diagnostic potential. A method to improve the diagnostic performance of the test is to use fusion proteins instead of a combination of non-fusion antigens. Compared with individual antigens (non-fusion), fusion proteins can provide broader sensitivity and specificity, and improve the accuracy of disease diagnosis. At present, there is no comparative evaluation of the immunogenicity between the ESAT6/CFP-10 fusion protein and the combination of these two individual proteins. Existing in vitro studies have compared the ESAT-6/CFP-10 fusion protein with individual proteins (rather than with the combination of the two proteins). Although there is no in vitro data comparing the diagnostic potential of the ESAT-6/CFP10 fusion protein with the combination of ESAT-6 and CFP-10, the results of clinical studies evaluating the diagnostic performance of the CTST protein with other diagnostic tests indicate that our company's concept of using a fusion protein instead of a combination of individual proteins is correct. Conclusion In summary, although there are minor differences in formulation details between CTST and Siiltibcy, these differences do not affect the basic comparability of the two in terms of antigen selection, diagnostic principle and clinical application. In view of the above, our company earnestly requests DRAP to reconsider this application and approve the registration of CTST.

Decision

Rejected

The Registration Board rejected the application due to non-availability of evidence of approval of applied formulation in any of the reference regulatory authorities as approved by Registration Board.

9	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Citi Pharma Limited 3 KM, Phool Nagar, Head Balloki Road, Kasur-Pakistan (05-351-0073-130312D)
	Application Form Dy. No / Tracking ID & date of submission	(NBU-WMN-RMTD, 2026-04-20)
	Detail of Fee Submitted	300000.0, 13500 2025-07-28, 2025-08-29
	The proposed proprietary name / brand name	Glargem-300 Solution for Injection
	Label Claim	Each 3mL Contains: Recombinant Insulin Glargine..... 300 IU (3mL Cartridge) USP Specifications
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's (3mL Cartridge)-As per SRO

	Shelf Life (Unit)	3 YearsStore below 2°C to 8°C in a refrigerator. Do not freeze.
	For generic drugs (me-too Status)	Lantus Optiset Injection 300Units/3mL by Sanofi Aventis Pakistan Limited, Karachi
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Fosun Wanbang (Jiangsu) Pharmaceutical Group Co., -South of Dongshan, Comprehensive Area, Jinshanqiao Development Zone, Xuzhou, Jiangsu, China -China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	Fosun Wanbang (Jiangsu) Pharmaceutical Group Co., , South of Dongshan, Comprehensive Area, Jinshanqiao Development Zone, Xuzhou, Jiangsu , China
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Lantus Solostar Injection 300Units/3mL by Sanofi Aventis US
	Evaluation Remarks	
	Registration Board in its 357th meeting deferred the case for following: 1. Fee adjustment to DSL account by the firm. 2. Submission of Apostille/ Legalized CoPP. 3. Detailed Characterization studies of applied product in comparison with Innovator product. 4. Clarification of manufacturing of Meglumine Adenosine Cyclophosphate Injection a pharmaceutical product on Line 2 along with other rDNA Insulins. 5. Submission of evidence of approval of 24 months shelf life from country of origin. The firm has submitted the following response: 1. The applicable fee will be deposited in the DSL account as per the Board's decision, and the paid fee receipt will be shared accordingly. 2. Clarification from manufacturer that word vial mentioned in CoPP is a translation error and they are processing the application for revised correct CoPP. 3. Biosimilarity data in comparison with Innovator. 4. The firm has submitted SOPs for cleaning and sterilization. 5. Translated Registration Letter indicating 24 months shelf life. The manufacturer abroad has different Injection production lines from 2-5. As per submitted site Master File, the manufacturer is manufacturing both Pharmaceuticals and Biologicals on same lines i.e Line 2, 4 & 5. The applied product is filled on Injection Line 3 which is for Cartridge filling. Moreover, the firm has not submitted evidence of fee adjustment.	
	Decision	
	Rejected	
	Registration Board rejected the application due to non-availability of dedicated Biotech (rDNA) facility.	
10	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Shan Medicine Company Opposit Masij Abdul Majeed, Mian Street, Medicine Market, Town Hall, Ghanta Ghar, Multan. (04-361-0172-97518D)
	Application Form Dy. No / Tracking ID & date of submission	(GS4-NBP-4GGV, 2026-06-04)
	Detail of Fee Submitted	313500, 2026-02-16,
	The proposed proprietary name / brand name	Streptolev
	Label Claim	Each Lyophilized vial contains: Streptokinase 1,500,000 IU Excipients: Glycine 40 mg,

		Sodium L glutamate 4.17 mg, Phosphate buffer to adjust the pH to 7.2
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	5mL-As per SRO
	Shelf Life (Unit)	2 Year+2°C to +8°C
	For generic drugs (me-too Status)	Diclair-ST (DRAP Reg. No.059023) Manufactured by BBT Biotech GmbH Germenay
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	LEVIM BIOTECH LLP.-Vijayapuri North, Nagarjunasagar, Nalgoda District - 508202, Telangana, India. -India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	Livealth Biopharma Pvt Ltd. , 313, Rupa Solitaire, Plot A-1, Sector 1, Millenium Business Park, MIDC, T. T. C. Industrial Area, Mahape - 400710 Navi Mumbai., India
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Diclair-ST (DRAP Reg. No.059023) Imported by Gene-Tech Laboratories
	Evaluation Remarks	
	The same product from same manufacturer has already been rejected by the Board in its 352nd meeting as formulation of Streptokinase of recombinant DNA (rDNA) origin is not approved by any of the Reference Regulatory Authorities designated by the Board. The firm was asked for clarification of same on 15-04-2026 & 28-04-2026. The firm has not yet submitted any response.	
	Decision	
	Rejected	
	Registration Board decided to reject the registration application as the applied formulation of Streptokinase of recombinant DNA (rDNA) origin is not approved by any of the Reference Regulatory Authorities designated by the Board.	
11	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	VET PHARMA TRADING CO NEW STEEL MARKET, G.T. ROAD GUJRANWALA (09-341-0137-069656D)
	Application Form Dy. No / Tracking ID & date of submission	(25Q-ZYA-7Q9V, 2026-02-26)
	Detail of Fee Submitted	313500, 2026-02-24,
	The proposed proprietary name / brand name	Himmvac Dalguban AI Oil Vaccine
	Label Claim	Each dose contains: Inactivated Low pathogenic AI virus (A/Chicken/Korea/01310/2001(H9N2) strain).....at least 10 ^{8.5} EID ₅₀
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1,000 Dose (500 ml)-De-Controlled
	Shelf Life (Unit)	21 Year(s)(2-8°C)
	For generic drugs (me-too Status)	yes
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine

	Name, address of Manufacturing site:	M/s KBNP, INC.,-235-9, Chusaro, Sinam, Yesan, Chungnam, Republic of Korea.-South Korea
	Name, address of Marketing Authorization Holder:	M/s KBNP, INC., 235-9, Chusaro, Sinam, Yesan, Chungnam,, Republic of Korea.
	Details of Certificates (CoPP/FSC/cGMP):	Scanned Apostille CoPP No. 20260840 dated 21-05-2026
	Details of Authorization Letter :	Notarized LOA dated 21-01-2026.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
	Evaluation Remarks	
	The provided COPP is not signed by issuing Authority instead only a stamp is placed with name of person and date in it.	
	Decision	
	Deferred	
	Registration Board deferred the case for following: 1. Immunological relevance and need of applied strain for Pakistan. 2. Clarification of submitted CoPP as it is not signed by issuing Authority instead only a stamp is placed with name of person and date in it.	
12	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	VET PHARMA TRADING CO NEW STEEL MARKET, G.T. ROAD GUJRANWALA (09-341-0137-069656D)
	Application Form Dy. No / Tracking ID & date of submission	(T54-5D7-DT9L, 2026-02-26)
	Detail of Fee Submitted	313500, 2026-02-24,
	The proposed proprietary name / brand name	Himmvac Dalguban ABBN Plus Oil Vaccine
	Label Claim	Each dose (Before inactivation) contains: Low pathogenic AI virus (A/Chicken/Korea/01310/2001(H9N2) strain).....at least $10^{9.0}$ EID ₅₀ IB virus (KM91 strain).....at least $10^{7.5}$ EID ₅₀ IB virus (M41 strain).....at least $10^{7.5}$ EID ₅₀ ND virus (KBNP-C4152R2L strain).....at least $10^{8.5}$ EID ₅₀
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1,000 Dose (500 ml)-De-Controlled
	Shelf Life (Unit)	21 Year(s)(2-8°C)
	For generic drugs (me-too Status)	yes
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	M/s KBNP, INC.,-235-9, Chusaro, Sinam, Yesan, Chungnam, Republic of Korea.-South Korea
	Name, address of Marketing Authorization Holder:	Vet Pharma Trading Company,, New Steel Market, Near Regent Cinema, G.T. Road, Gujrawala., Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Scanned Apostille CoPP No. 20260839 dated 21-05-2026
	Details of Authorization Letter :	Notarized LOA dated 21-01-2026.

13	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
	Evaluation Remarks	
	The provided COPP is not signed by issuing Authority instead only a stamp is placed with name of person and date in it.	
	Decision	
	Deferred	
	Registration Board deferred the case for following:	
	1. Immunological relevance and need of applied strains for Pakistan. 2. Justification of using two strains of IB virus. 3. Clarification of submitted CoPP as it is not signed by issuing Authority instead only a stamp is placed with name of person and date in it.	
	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Kam Pharma Upper Floor Property NoP-246Main Fatima Jinnah Road Millat Abad Sargodha (08-384-0120-120589D)
	Application Form Dy. No / Tracking ID & date of submission	(TUT-QB2-PPUE, 2026-02-27)
	Detail of Fee Submitted	313500, 2026-02-23,
	The proposed proprietary name / brand name	KELIUAN
	Label Claim	Each dose (0.5ml) contains: Inactivated Newcastle disease virus, strain LaSota..... $\geq 10^{8.175}$ EID ₅₀ Inactivated Avian Influenza H9 (Subtype), Strain WD..... $\geq 10^{7.175}$ EID ₅₀
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	500ML (1000 Doses)-De-Controlled
	Shelf Life (Unit)	12 Year(s)The vaccine must be stored at 2°C - 8°C, do not freeze the vaccine
	For generic drugs (me-too Status)	Product Name:: SINVAC ND+H9 Registration No: 101424 Registration Date: 2020-01-14
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine.
	Name, address of Manufacturing site:	Wuhan Keqian Biology,.Co.Ltd-No 419, Gaoxin Second Road, East Lake High Tech Development Zone, Wuhan-China
	Name, address of Marketing Authorization Holder:	Wuhan Keqian Biology,.Co.Ltd, No 419, Gaoxin Second Road, East Lake High Tech Development Zone, Wuhan, China
	Details of Certificates (CoPP/FSC/cGMP):	GMP Certificate NO. (2025) GMP 17002 dated 10-09-2025 valid till 09-09-2030. FSC dated 01-12-2025.
	Details of Authorization Letter :	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
	Evaluation Remarks	
	.	
	Decision	

Approved

Keeping in view the GMP Certificate and FSC; Registration Board approved the product subject to compliance of current Import Policy for finished drugs and confirmation of need of Avian Influenza Virus WD strain for Pakistan by Dr. Syed Asad Ali Shah, Expert Member Registration Board.

14	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan (01-374-0006-118530D)
	Application Form Dy. No / Tracking ID & date of submission	(86D-8UB-M2YP, 2026-06-08)
	Detail of Fee Submitted	313500, 2026-03-20,
	The proposed proprietary name / brand name	Tetanus Vaccine, Adsorbed
	Label Claim	Each human dose of 0.5 ml contains tetanus toxoid with a potency of ≥ 40 IU.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Prefilled Syringe, 1 syringe/box-As per SRO
	Shelf Life (Unit)	24 MonthStore and transport between 2°C and 8°C, and protect from light.
	For generic drugs (me-too Status)	Imatet Registration No. 017373 0.5 mL injection (ampoule/syringe) Pack Size: 10* 0.5ml. Amson Vaccines & Pharma (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Sinovac Life Sciences Co., Ltd. -No. 21, Tianfu Street, Daxing Biomedicine Industrial Base of Zhongguancun Science Park, Daxing District, Beijing, P. R. China No. 37, Simiao Road, Daxing Biomedicine Industrial Base of Zhongguancun-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	Sinovac Life Sciences Co., Ltd. , No. 21, Tianfu Street, Daxing Biomedicine Industrial Base of Zhongguancun Science Park, Daxing District, Beijing, P. R. China , China
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	TT VACCINE,Tetanus Toxoid Vaccine Adsorbed Manufacturer:PT Bio Farma (Persero) WHO Prequalified

Evaluation Remarks

The firm has not submitted Pharmacovigilance system and Risk Management Plan developed by the Importer? The firm was asked to provide evidence that the comparator vaccine Tetanus Vaccine, Adsorbed produced by Chengdu Olymvax Biopharmaceuticals Co., Ltd. ("Chengdu Olymvax") used in Clinical Trials was registered on the basis of clinical trial conducted in comparison with an Innovator/RRA Vaccine, the firm submitted the following statement: "In accordance with the technical guidelines and in communication with the National Medical Products Administration (NMPA), the Tetanus Vaccine, Adsorbed produced by Chengdu Olymvax Biopharmaceuticals Co., Ltd. ("Chengdu Olymvax") is used in clinical trials as control group. It is approved by NMPA and its approval can be checked online from the website of NMPA: NMPA Database search-info Olymvax

Tetanus Vaccine, Adsorbed. Please refer to Annex 2 for the translation of the online approval page. The Tetanus Vaccine, Adsorbed produced by Chengdu Olymvax which has proven efficacy and safety and is widely used in China, was selected as the control vaccine. Please find Annex 3 for the published article from Chengdu Olymvax for the clinical trials of Safety and immunogenicity of the Tetanus Vaccine, Adsorbed, which includes clinical datas."

Decision

Deferred

Registration Board deferred the case for submission of following by the firm:

1. Pharmacovigillence system and Risk Management Plan developed by the Importer?
2. Immunogenicity study data under clinical studies in comparison with any product approved by Reference Regulatory Authorities approved by Registration Board.

15	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Macter International Limited F-216,S.I.T.E.,Karachi-Pakistan (000141)
	Application Form Dy. No / Tracking ID & date of submission	(MLV-ZLU-N5JM, 2024-10-08)
	Detail of Fee Submitted	300000.0, 2024-06-10,
	The proposed proprietary name / brand name	Betrast 440mg (Combipack) r-DNA product
	Label Claim	Each pack contains: Vial-1 Lyophilized for Powder for concentrate for solution for Intravenous Infusion Trastuzumab (rDNA origin).....440mg Vial-2 Bacteriostatic Water for Injection Each vial contains: Benzyl Alcohol USP..... 1.1% v/v Water for Injection.....q.s 10ml
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 vial-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a referigerator at 2 - 8 degree centigrade and do not freeze
	For generic drugs (me-too Status)	Herceptin 440 mg Lyophilized Powder for infusion of M/s Roche Pakistan Ltd (Registration no 087085)
	Pharmacotherapeutic Group of (API)	Monoclonal Antibody
	Name, address of Manufacturing site:	Macter International Limited.-F- 216, S.I.T.E, Karachi 75700, Pakistan-Pakistan
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Biosimilarity data submitted
	Name, address of Marketing Authorization Holder:	Macter International Limited., F- 216, S.I.T.E, Karachi 75700, Pakistan, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Scanned legalized CoPP No. 4247187/TS/2023 valid till 03-10-2023
	Details of Authorization Letter :	Scanned legalized Supply Agreement dated 22-09-2022.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: P5CTD1801, P5CTD1802, P5CTD1803 Long Term (Real Time Condition) Stability Study : -20°C ± 5°C Accelerated

		Stability Study: 2°C – 8°C Long term 36M Accelerated 6M
	The status in reference regulatory authorities	Herceptin 440 mg powder for concentrate for solution for infusion available for intravenous infusion registered product of Roche Pharma (Schweiz) AG Switzerland approved by Swiss medic
	Evaluation Remarks	
	Registration Board in its 354th meeting deferred the case for following: 1. Stability data provided is of batches having batch size of 95 vials. 2. A clarification from Manufacturer abroad either on their letter head in hard or on official e-mail that as per submitted GMP certificate issued by regulatory authority of country of origin, the product is for Export purpose only. The firm submitted the following: "We hereby confirm that the batch size of 95 vials has been specifically designed for stability studies and is scientifically justified to cover complete testing across all required stability intervals i.e. 0, 3, 6, 9, 12, 18 and 24-months long term storage conditions, well as for shelf-life evaluation. Please see attached annexure for the details of vials required for stability. Furthermore, the proposed batch size is in compliance with Section 3.2.P.8 (Stability) of the CTD guidance document, clause (c), which suggest At least 3 batches having scientifically rational batch size, sufficient enough to perform complete testing till the claimed shelf life. The firm further clarified that although in table in GMP Certificate, the product is mentioned for Export purpose only. However, in the same GMP following statement is also mentioned: "The above products had been authorized to be placed on the market for use in the country and exported countries".	
	Decision	
	Deferred	
	Registration Board deferred the case for submission of complete Physicochemical studies (including Primary & Higher Order Structure and Impurities) along with Biological Activity of product manufactured by finished product manufacturer in comparison with Innovator product of their respective batches having justifiable batch size with respect to the manufacturing equipment/facility.	
16	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Macter International Limited F-216,S.I.T.E.,Karachi-Pakistan (000141)
	Application Form Dy. No / Tracking ID & date of submission	(BBZ-G9S-LG67, 2024-09-13)
	Detail of Fee Submitted	300000.0, 2024-06-10,
	The proposed proprietary name / brand name	Betrast 150mg (Combipack) r-DNA product
	Label Claim	Each pack contains: Vial-1 Lyophilized for Powder for concentrate for solution for Intravenous Infusion Trastuzumab (rDNA origin).....150mg Vial-2 Bacteriostatic Water for Injection Each vial contains: Benzyl Alcohol USP..... 1.1% v/v Water for Injection.....q.s 10ml
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 vial-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a referigerator at 2 - 8 degree centigrade and do not freeze
	For generic drugs (me-too Status)	Herceptin 150 mg Lyophilized Powder for infusion of M/s Roche Pakistan Ltd (Registration

	no 087086)
Pharmacotherapeutic Group of (API)	Monoclonal Antibody
Name, address of Manufacturing site:	Macter International Limited.-F- 216, S.I.T.E, Karachi 75700, Pakistan-Pakistan
Pharmaceutical Equivalence and Comparative Dissolution Profile	Biosimilarity data submitted
Name, address of Marketing Authorization Holder:	Macter International Limited., F- 216, S.I.T.E, Karachi 75700, Pakistan, Pakistan
Details of Certificates (CoPP/FSC/cGMP):	Scanned legalized CoPP No. 4247174/TS/2023 valid till 03-10-2023
Details of Authorization Letter :	Scanned legalized Supply Agreement dated 22-09-2022.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: P5CTD1801, P5CTD1802, P5CTD1803 Long Term (Real Time Condition) Stability Study : -20°C ± 5°C Accelerated Stability Study: 2°C – 8°C Long term 36M Accelerated 6M
The status in reference regulatory authorities	Herceptin 150 mg powder for concentrate for solution for infusion available, for intravenous infusion use registered product of Roche Pharma AG Emil-Barell-Strasse 1 79639 Grenzach-Wyhlen Germany approved by European Medicines Agency (EMA) in 28 August 2000
Evaluation Remarks	
Registration Board in its 354th meeting deferred the case for following: 1. Stability data provided is of batches having batch size of 95 vials. 2. A clarification from Manufacturer abroad either on their letter head in hard or on official e-mail that as per submitted GMP certificate issued by regulatory authority of country of origin, the product is for Export purpose only. The firm submitted the following: "We hereby confirm that the batch size of 95 vials has been specifically designed for stability studies and is scientifically justified to cover complete testing across all required stability intervals i.e. 0, 3, 6, 9, 12, 18 and 24-months long term storage conditions, well as for shelf-life evaluation. Please see attached annexure for the details of vials required for stability. Furthermore, the proposed batch size is in compliance with Section 3.2.P.8 (Stability) of the CTD guidance document, clause (c), which suggest At least 3 batches having scientifically rational batch size, sufficient enough to perform complete testing till the claimed shelf life. The firm further clarified that although in table in GMP Certificate, the product is mentioned for Export purpose only. However, in the same GMP following statement is also mentioned: "The above products had been authorized to be placed on the market for use in the country and exported countries".	
Decision	
Deferred	
Registration Board deferred the case for submission of complete Physicochemical studies (including Primary & Higher Order Structure and Impurities) along with Biological Activity of product manufactured by finished product manufacturer in comparison with Innovator product of their respective batches having justifiable batch size with respect to the manufacturing equipment/facility.	
17	Case Category
	Routine (M. Zubair Masood)
	Name, address of Applicant.
	Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan (01-374-0006-118530D)
	Application Form Dy. No / Tracking ID & date of submission
	(6B1-JH2-AX66, 2025-08-07)
	Detail of Fee Submitted
	300000.0, 2025-07-18,

The proposed proprietary name / brand name	Brolizum 100 IV Infusion
Label Claim	Each 4ml solution contains: Pembrolizumab.....100mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's-As per SRO
Shelf Life (Unit)	12 Month(s)Store at 2-8°C, protecting from light.
For generic drugs (me-too Status)	New product
Pharmacotherapeutic Group of (API)	L01FF02:Antineoplastic agents
Name, address of Manufacturing site:	Geneway Bio-Technology co., Ltd Incepta Pharma-No.6 Anmin Road, Huangdai Town, Xiangcheng, Suzhou, Jiangsu, Dewan Idris Road, Bara Rangamatia, Zirabo, Savar, Dhaka-China Bangladesh
Pharmaceutical Equivalence and Comparative Dissolution Profile	NA
Name, address of Marketing Authorization Holder:	Incepta Pharmaceuticals Ltd., Dewan Idris Road, Bara Rangamatia, Zirabo,Ashulia, Savar, Dhaka-1341, Bangladesh, Bangladesh
Details of Certificates (CoPP/FSC/cGMP):	Scanned Copy of COPP Certificate No.:DA/6-91/04/15Part-1/21842 Date: 24 Dec 2024 Validity: 2 year
Details of Authorization Letter :	Incepta Pharmaceuticals Ltd., Vaccine Division, a company duly organized under the laws of the Peoples' Republic of Bangladesh, having its main office and principal place of business at 40, Shahid Tajuddin Ahmed Sarani, Tejgaon I/A, Dhaka-1208, Bangladesh hereby certify that: M/s. Lab Diagnostic Systems (SMC) Pvt Ltd Address: 36-A,PSIC,SIE,Taxila Rawalpindi as our Exclusive distributor for the territory of Pakistan Validity: December 2026.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	FX01-2015001S FX01-2015002S FX01-2015003S 5C±3C in 0, 3th, 6th month. Below 30C in 0, 6th, 12th month.
The status in reference regulatory authorities	Keytruda Injection Manufacturer name: Merck & Co. Brand name: Keytruda Injection (also referred to as Keytruda®) Strength: 100 mg in 4 ml. This is equivalent to 25 mg/ml. Composition: The ready-to-fill bulk solution, which is similar to Keytruda, contains Pembrolizumab (as the active pharmaceutical ingredient), L- Histidine, Sucrose, Polysorbate 80, and Water for Injections as excipients. USFDA Approved
Evaluation Remarks	
Registration Board in its 351st meeting decided to defer the product for following: i. Comprehensive biosimilarity data (covering Quality, Safety, and Efficacy) from the finished product manufacturer, in accordance with WHO Biosimilarity Guidelines, and in comparison to the innovator product. ii. Process validation data for commercial-scale batches from the finished product manufacturer. iii. Clarification of un-registered status of finished product of bulk manufacturer in country of origin i.e. China. The firm submitted a quality comparison with only raw data for following tests: 1. Identity by SEC-HPLC. 2. Intact Mass 3. Peptide Mapping 4. Protein Content 5. Biological Activity 6. Impurities No data regarding detailed structural comparison including primary & higher order structure, Safety & Efficacy trial is submitted by the firm. 2. The firm has again submitted Process Validation of R&D batches instead of Pilot Scale batches. 3. The firm has not submitted	

	Clarification of un-registered status of finished product of bulk manufacturer in country of origin i.e. China.	
	Decision Deferred Registration Board deferred the case for submission of following by the firm: 1. Complete Physicochemical studies (including Primary & Higher Order Structure and Impurities) along with Biological Activity of product manufactured by finished product manufacturer in comparison with Innovator product of their respective batches having justifiable batch size with respect to the manufacturing equipment/ facility. 2. Process Validation of Pilot Scale batches. 3. Clarification of un-registered status of finished product of bulk manufacturer in country of origin i.e. China.	
18	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	BF Biosciences Limited 5-KM Sundar Raiwind Road, Raiwind, Lahore (000655)
	Application Form Dy. No / Tracking ID & date of submission	(4LS-JL6-UZSD, 2026-06-08)
	Detail of Fee Submitted	38700, 2026-03-24,
	The proposed proprietary name / brand name	Pembrol 100mg Injection
	Label Claim	Each vial contains Pembrolizumab 100mg/4mL
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	24 MonthStore at 2°C and 8°C
	For generic drugs (me-too Status)	Pembroxim Injection 100mg (Himmel Pharma)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	, ,
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Keytruda 100mg Injection (MERCK & Co.,) FDA APPROVED
	Evaluation Remarks	
	1. The address mentioned on GMP Certificate is "No. 96 Galaxy Road, Changshu City, Suzhou City, Jiangsu Province, China while in dossier address is "No. 96, Yinhe Road, Changshu-215500, China". The firm submitted the following clarification: "The manufacturing site address stated in the GMP certificate and the proposed address in the dossier refer to the same facility. The only difference is the inclusion of additional street-level details in one of the documents. The same street is also mentioned in DML Certificate. GMP, DML and the proposed manufacturing site address are attached for reference and verification." The address as per DML is "No. 96 Yinhe Road, South-East Street, Changshu City, Jiangsu Province 215131, China." 2. Initially, the firm submitted comparative characterization of DS manufactured by M/s Intellective Biologics, but as the firm is importing ready-to-fill bulk, hence, it was asked to submit comparative studies of Ready-to-Fill bulk, for which the firm submitted comparative studies of DS manufactured by M/s Geneway. 3. In initially	

submitted comparative study (Performed by Importer), there were two peaks in chromatogram of reference product and one peak in chromatogram of RTF batch no. FX01DS202501. the firm was asked for clarification and they submitted that In comparability report, Under the SEC-HPLC method with UV detection, two peaks are observed for both the reference and test products. The major peak represents the monomeric protein, while the minor peak observed before the main peak represents high molecular weight species (HMWS). The levels of monomer and HMWS are within the predefined acceptance criteria. However, the firm did not submit any chromatogram of RTF in their response and only submitted chromatograms of Reference and locally filled product. 4. The firm was asked that GMP certificate provided is for DS API while the product used in local manufacturing is Ready-to-Fill Bulk, for which the firm submitted that the inspection covered the entire process from cell culture to sterile bulk solution. However, the firm has not submitted the inspection report? Moreover, the submitted DML is showing 03 addresses, in two addresses scope is mentioned, one as Biological products for therapeutic purposes and other as Therapeutic biological products (contract manufacturing) while there is no scope mentioned against the address of proposed DS and RTF manufacturer. 5. Legalized Free Sale Certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same Ready-to-Fill Bulk after submission of data to the concerned regulatory authority. The firm submitted the Appostille FSC issued by Chamber of Commerce for Import & Export of Medicines & Health Products and for CoPP, the firm provided the following statement from manufacturer: "We, Intellective Biologics (Suzhou) Co., Ltd., hereby declare that Pembrolizumab cannot be offered with a COPP certificate. The current patent of this product in China is valid until the year 2028; therefore, a COPP certificate cannot be applied for. Furthermore, Intellective Biologics (Suzhou) Co., Ltd. (China) is currently exporting Pembrolizumab to M/s Beacon Pharmaceutical Limited (Bangladesh) and M/s LLC PROMOMEDRUS (Russia) etc. M/s Himmel Pharmaceuticals (Pvt.) Ltd Pakistan importing Pembrolizumab in Finished form from M/s Beacon Pharmaceutical Limited (Bangladesh) M/s PharmEvo Private Limited Pakistan is currently importing Pembrolizumab in Finished form from M/s LLC PROMOMED RUS (Russia). These are part of our importers of Pembrolizumab: 1-M/s Beacon Pharmaceutical Limited (Bangladesh) 2-M/s LLC PROMOMED RUS (Russia). 3-M/s Healthcare Pharmaceuticals Limited(Bangladesh) 4-M/s Incepta Pharmaceuticals Ltd(Bangladesh) All these Bangladesh companies have COPP in their country. The firm statement was cross verified from record and following was observed: The DS manufacturer of product applied by M/s Himmel Pharma is M/s Geneway Bio-Technology co., Ltd. China and DS manufacturer of product applied by M/s PharmEvo Private Limited Pakistan is M/s JSC BIOCAD, Russia.

Decision

Deferred

Registration Board deferred the case for submission of following by the firm:

1. Complete Physicochemical studies (including Primary & Higher Order Structure and Impurities) along with Biological Activity of product manufactured by finished product manufacturer in comparison with Innovator product of their respective batches having justifiable batch size with respect to the manufacturing equipment/ facility.
2. Complete Biosimilarity Studies (including Quality Safety & Efficacy) of finished product of Ready-to-Fill bulk manufacturer in comparison with Innovator product.
3. The name of Road mentioned in GMP certificate is Galaxy Road while in DML and dossier, it is Yinhe Road.
4. Comparative study Chromatograms performed by finished product manufacturer for RTF bulk and reference product.
5. GMP Inspection report of Ready-to-Fill bulk manufacturer as evidence that whole process of Ready-to-Fill bulk manufacturing was covered in inspection.

19	Case Category	Priority As Per 257-M of RB (Muneeb Ahmed Cheema)
	Name, address of Applicant.	HOSPITAL SERVICES & SALES 13-C Annexe, Block 6, PECHS, Shahrah e Faisal

	(0398)
Application Form Dy. No / Tracking ID & date of submission	(L5Y-6UN-G5UW, 2026-06-06)
Detail of Fee Submitted	313500, 2026-04-02,
The proposed proprietary name / brand name	Poliomyelitis vaccine (Inactivated) - 1 Dose x 0.5ml Vial
Label Claim	Each dose of 0.5 ml contains: Inactivated poliomyelitis virus type 1, Mahoney * 40 D antigen units Inactivated poliomyelitis virus type 2, MEF-I * 8 D antigen units Inactivated poliomyelitis virus type 3, Saukett * 32 D antigen units 2-Phenoxyethanol 2.5 mg Formaldehyde 12.5 mcg *Cultivated on vero-cells. Dose: 0.5 ml by intramuscular or subcutaneous injection. The colour of the vaccine varies from orange-yellow to orange - red and should be administered intramuscularly or subcutaneously.
Reference to Finished product specifications	Any Other
Proposed Pack Size	1 Dose x 0.5ml Vial (Box of 50 vials)-Controlled
Shelf Life (Unit)	36 Month+2°C and +8°C
For generic drugs (me-too Status)	IMOVAX POLIO Vaccine by Sanofi Aventis - France (Now Hoechst Pakistan), Reg. No. 045700.
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Serum Institute of India Pvt. Ltd.-212/2, Hadapsar, Pune - 411 028, INDIA.-India
Pharmaceutical Equivalence and Comparative Dissolution Profile	
Name, address of Marketing Authorization Holder:	Serum Institute of India Pvt. Ltd., 212/2, Hadapsar, Pune - 411 028, INDIA., India
Details of Certificates (CoPP/FSC/cGMP):	
Details of Authorization Letter :	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
The status in reference regulatory authorities	WHO PQ product
Evaluation Remarks	
Applied Vaccine is WHO Prequalified	
Decision	
Approved	
Keeping in view the WHO Prequalification; Registration Board approved the product subject to:-	
1. Compliance of current Import Policy for finished drugs.	
2. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation.	
3. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07	
4. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.	

Case No. 01: Virtual Inspection of Manufacturer Abroad for Rabies Vaccine applied by M/s CLOUD AGRI PAKISTAN, Lahore approved in 350th meeting of Registration Board.

Following product of M/s CLOUD AGRI PAKISTAN, Lahore was approved in 350th meeting of Registration Board as per following details:

Name of Manufacturer	Brand Name & Composition	Decision of 350 th meeting
M/s BIOGENESIE BAGO S.A.-RUTA PANAMERICANA, 38.5 KM. (B16191EA) GARIN, BUENOS AIRES, ARGENTINA.	Biorabia Vaccine Rabies Vaccine, Inactivated Each ml contains: Inactivated rabies virus antigen, Pasteur Strain PV.....≥1 IU	Approved subject to compliance of current Import Policy for finished drugs along with submission of following documents by the firm: • Original Legalized FSC. • Original Letter of Authorization. • Proposed pack

Accordingly, the virtual inspection of manufacturer abroad was conducted by following panel of inspectors of DRAP on 4-12-2025 and 5-12-2025:

- 1- Mrs. Anam Saeed, Deputy Director (BE&R), DRAP, Islamabad.
2. Mrs. Sara Mehreen, Assistant Director (PE&R), DRAP, Islamabad.

Following are the observations & conclusion of Panel:

Observations

The observation noted by the panel members during virtual inspection and its potential impact on quality of product and GMP compliance is tabulated below;

Observations	Impact on quality and GMP compliance
The firm had provided a common production area for the manufacture of inactivated bacterial and viral vaccines including FMD vaccine, rabies vaccine etc. Antigen production activities are carried out in separate, dedicated production lines; however, the emulsification and filling operations for finished product manufacturing are performed within the same area.	The use of a shared area for emulsification/formulation and filling of different vaccine types (viral and bacterial) does not ensure adequate segregation of operations, increasing the potential risk of cross-contamination and mix-ups. This practice is not in compliance with GMP requirements for the physical and operational segregation of processes involving different biological products.
No cleaning validation was conducted for the reactors or tanks used in formulation/emulsification of inactivated vaccines.	The lack of cleaning validation for formulation reactors/tanks represents a major GMP compliance gap , as it fails to demonstrate that equipment is consistently cleaned to prevent cross-contamination. This increases the risk of product contamination.

Conclusion

Based on the virtual inspection of **M/s BIOGENESIE BAGO S.A.-RUTA PANAMERICANA, 38.5 KM. (B16191EA) GARIN, BUENOS AIRES, ARGENTINA** conducted, the documents reviewed, and the interviews held with management and technical personnel, the panel of inspectors is of the view that grant of registration for the below-mentioned cell cultured inactivated virus vaccines is **not recommended**, taking into consideration the potential risk of cross-contamination and mix-ups as detailed in paragraph 7.

Biorabia Vaccine Rabies Vaccine, Inactivated

Each ml contains:

Inactivated rabies virus antigen, Pasteur Strain PV.....≥1 IU

Decision of 354th meeting:

Keeping in view the recommendations of panel of inspectors of DRAP; Registration Board decided to give opportunity of personal hearing to the firm to explain their position regarding non-recommendation of dosage form specific inspection by panel of inspectors of DRAP.

In the light of above decision, a personnel hearing letter was issued to M/s CLOUD AGRI PAKISTAN, Lahore.

Decision of 358th meeting:

The Registration Board decided to provide the firm with an opportunity for a personal hearing in person, as the Board considered a virtual hearing inadequate to fully understand the firm's position.

In the light of above decision, a personnel hearing letter was issued to M/s CLOUD AGRI PAKISTAN, Lahore.

Proceedings of the Board:

The Registration Board provided an opportunity of personal hearing to M/s CLOUD AGRI PAKISTAN, Lahore. The firm's representative, Mr. Rana Shaukat Hussian (CEO, Cloud Agri Pakistan) appeared before the Board.

Decision of 359th meeting:

The Registration Board after hearing the matter from the representative of the firm decided to defer the case until comments are received from the Licensing Division, DRAP, concerning the manufacturing requirements for viral and bacterial vaccines, and the applicant submits the manufacturer's layout plan approved by the relevant regulatory authority of the country of origin.

Case No. 02: Virtual Inspection of Manufacturer Abroad for Biological product applied by M/s Highnoon Laboratories, Lahore approved in 349th meeting of Registration Board.

Following product of M/s Highnoon Laboratories, Lahore was approved in 349th meeting of Registration Board as per following details:

Name of Manufacturer	Brand Name & Composition	Decision of 349th meeting
M/s Beximco Pharmaceuticals Ltd, 19 Dhanmondi R/A, Road No. 7, Dhaka 1205, Bangladesh.	Cleven 20 Injection Each 0.2ml prefilled syringe contains: Enoxaparin sodium 2000 IU eq. to enoxaparin 20mg Cleven 40 Injection Each 0.4ml prefilled syringe contains: Enoxaparin sodium 4000 IU eq. to enoxaparin 40mg Cleven 60 Injection Each 0.6ml prefilled syringe contains:	The Registration Board after thorough deliberation approved the case subject to the submission of the data in accordance with the guidelines approved by the Board in 289th meeting and its approval by the Chairman, Registration Board.

	Enoxaparin sodium 6000 IU eq. to enoxaparin 60mg Cleven 80 Injection Each 0.8ml prefilled syringe contains: Enoxaparin sodium 8000 IU eq. to enoxaparin 80mg	
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Accordingly, the virtual inspection of manufacturer abroad was conducted by following panel of inspectors of DRAP on 01-01-2026:

- 1- Madam Saima Hussain, Deputy Director, PE&R
- 2- Madam Iqra Aftab, Deputy Director, PE&R

Following are the observations & conclusion of Panel:

Observations

The observation noted by the panel members during virtual inspection and its potential impact on quality of product and GMP compliance is as under;

Observation	Impact on quality and GMP compliance
There is no dedicated and self-contained facilities for the production of biological product “Enoxaparin” on the basis of following key findings: • Shared raw material store for biological and non-biological products. • Shared corridor between Vision (Non-Biological) and PFS (Biological) units. • Shared dispensing booth for Ampoule (Non-Biological) and PFS (Biological) units. • Same AHU unit serving PFS (Biological) and Ampoule (Non-Biological) areas.	The manufacturing layout does not ensure physical and operational dedication required for biological products. Shared warehousing, dispensing areas, corridors, and HVAC systems significantly increase the risk of cross-contamination, product mix-ups, and airborne contamination. <i>In order to minimize the risk of a serious medical hazard due to cross contamination, dedicated and self-contained facilities must be available for the production of biological product.</i>
List of registered products under License No. 119 (Biological & Special Products) includes pharmaceutical products (e.g., penicillin and others) along with biological products and no clarification submitted by the applicant.	The inclusion of pharmaceutical products such as penicillin under a license designated for biological and special products raises concerns regarding regulatory classification and facility dedication.
No ion chromatography system for determination of free sulfate content in finished product. Absence of NMR for identification testing. No gel chromatography for molecular weight determination.	Firm has not complied USP standard, since they don't have specialized instrument for performing these critical tests for structural identity, molecular weight and free sulphate content on DP.

Conclusion

Based on the virtual inspection of M/s Beximco Pharmaceuticals Ltd., 19 Dhanmondi R/A, Road No. 7, Dhaka 1205, Bangladesh, as well as the documents reviewed and interviews conducted with management and technical personnel, the panel of inspectors concludes that the grant of registration for the below-mentioned biological products is **not recommended** due to the absence of a dedicated and self-contained

facility for the manufacture of the biological product enoxaparin, along with the observations noted in Paragraph 4.

- **Cleven 20 Injection**
- **Cleven 40 Injection**
- **Cleven 60 Injection**
- **Cleven 80 Injection**

Submitted for consideration of Registration Board please.

Decision of 354th meeting:

Keeping in view the recommendations of panel of inspectors of DRAP; Registration Board decided to give opportunity of personal hearing to the firm to explain their position regarding non-recommendation of dosage form specific inspection by panel of inspectors of DRAP.

In the light of above decision, a personnel hearing letter was issued to M/s Highnoon Laboratories, Lahore.

Decision of 358th meeting:

The Registration Board decided to provide the firm with an opportunity for a personal hearing in person, as the Board considered a virtual hearing inadequate to fully understand the firm's position.

In the light of above decision, a personnel hearing letter was issued to M/s Highnoon Laboratories, Lahore.

Proceedings of the Board:

The Registration Board provided an opportunity of personal hearing to M/s Highnoon Laboratories, Lahore. The firm's representative, Mr. Muqem Akhtar (Manager Regulatory Affairs) appeared before the Board.

Decision of 359th meeting:

After detailed deliberation and hearing the arguments given by the applicant during the personal hearing, the Registration Board decided to reject the case, in view of the observations recorded by the panel during the virtual inspection.

Case No. 03: Request for Approval of Combo Packs of Seglutide Injection with Syringes by M/s Macter International Limited, Karachi.

The firm M/s Macter International Limited, Karachi has applied in post registration variation on e-app vide tracking ID: XH7-ZUB-GAHZ and DH1-2R6-EDGP for approval of combo pack of Seglutide Injection with syringes as follows;

Reg.No.	Brand name	Existing/Approved pack size	Proposed change
120535	Seglutide 2mg/1.5ml (Solution for subcutaneous Injection)	1's vial	1's vial + 4 BD 1ml Ultra-Fine Insulin Syringes in a unit carton.
120536	Seglutide 4mg/3ml (Solution for subcutaneous Injection)	1's vial	1's vial + 3 Apple K1 2ml Auto-Disable Syringes in a unit carton.

The price of semaglutide was de-controlled at the time of issuance of registration letter in August 2024. Later on, Semaglutide Injection is included in WHO Model List of Essential Medicines-24th list and no further registration letter of Semaglutide Injection was issued because of price fixation matter.

Now the firm has applied for approval of combo pack with syringe and the firm has stated that the price will remain the same (although the price is not fixed yet).

Submitted for consideration by the Board.

Decision of 359th meeting:

The Registration Board approved the post-registration variation request of M/s Macter International Limited, Karachi for the combo pack presentation of Seglutide 2mg/1.5ml vial (Reg. No. 120535) and Seglutide 4mg/3ml vial (Reg. No. 120536) with syringes.

Case No. 4: Virtual Inspection of Manufacturer Abroad for Liraglid (Liraglutide) Solution for injection in prefilled Pen 18mg/3ml applied by M/s Getz Pharma (Pvt.) Ltd., Karachi approved in 351st meeting of Registration Board.

Following product of M/s Getz Pharma (Pvt.) Ltd., Karachi was approved in 339th meeting of Registration Board as per following details:

Name of Manufacturer	Brand Name & Composition	Pack Size & Shelf Life	Decision of RB in 339th Meeting
M/s. Hangzhou Jiuyuan Genetic Biopharmaceutical Co., Ltd., East of No.8th Street, Hangzhou Economic and Technological Development Zone, Hangzhou, Zhejiang, China.	Liraglid 18mg/3mL Pre-Filled Pen Solution for Injection Each 3mL Pre-Filled Pen contains: Liraglutide.....18mg	1's Prefilled Pen 2 Years (2 ^o C -8 ^o C)	Keeping in view COPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs subject to submission of fee for pre-registration change in name of bulk labelled Pens manufacturer. M/s Getz Pharma (Pvt.) Ltd., Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi shall be responsible for final batch release.

Accordingly, the virtual inspection of manufacturer abroad was conducted by following panel of inspectors of DRAP on 22nd & 24th December, 2025:

1. Muhammad Zubair Masood, Deputy Director (BE&R) DRAP, Islamabad.
2. Adil Saeed, Deputy Director (PEC) DRAP Islamabad.

Following are the observations & conclusion of Panel:

Observations:

Sr. No.	Observation
1.	Use of same Workshop for the manufacturing of semaglutide & liraglutide drug substances. Section 18 of ICH Q7 addresses specific controls for drug substances manufactured by cell culture. Its subsection 18.44 states that, " <i>Additional controls, such as the use of dedicated chromatography resins or additional testing, may be appropriate if equipment is to be used for multiple products.</i> "

	WHO good manufacturing practices for biological products Replacement of Annex 1 of WHO Technical Report Series, No. 822 subsection 12.7 gives following statement regarding reuse of components for different products; <i>“A wide variety of equipment and components (for example, resins, matrices and cassettes) are used for purification purposes. QRM principles should be applied to devise the control strategy regarding such equipment and associated components when used in campaign manufacture and in multi-product facilities. The reuse of components at different stages of processing of one product is discouraged but, if performed, should be validated. Acceptance criteria, operating conditions, regeneration methods, lifespan and sanitization or sterilization methods, cleaning process, and hold time between the use of reused components should be defined and validated. The reuse of components for different products is not acceptable.”</i> <u>Keeping in view the details mentioned above, panel has serious concerns regarding use of same lines for manufacturing 2 rDNA products as it increases risk of cross contamination of cell culture related impurities.</u>
2.	The steps like dispensing of raw materials and their transfer to mixing area were being performed in class C area. The material was not protected from the class C environment by any means during transfer (No HEPA trolley or closed cabinet was being used). The firm has informed Semaglutide drug product is also being manufactured in the same facility. The panel also have serious concerns regarding dispensing and transfer of materials in class C area without any measures to ensure minimization of contamination, when the product being manufactured is a sterile product. The process till preparation of final solution is not considered aseptic by the manufacturer.
3.	The Laminar flow hoods used in raw material sampling, dispensing and lyophilization areas were open from the sides and were operating at negative pressure allowing entry of surrounding air inside the Laminar Flow Hoods. The firm informed that the negative pressure inside the hoods is for the safety of personnels (although in clarification regarding use of same line for manufacturing drug substance firm has claimed that liraglutide and semaglutide not highly sensitizing or have high pharmacological activity or toxicity).
4.	

Based on the virtual inspection conducted, the documents reviewed, the discussions held with technical personnel and representatives of the importing firm, the panel is of the view to **Not Recommend Registration of applied product i.e Liraglid (Liraglutide) Solution for injection in prefilled Pen 18mg/3ml**. The recommendations are based on following concerns of the panel;

- i. Using same facility for manufacturing of Semaglutide and Liraglutide by rDNA technique.
- ii. Relaxed contamination controls before sterile filtration.

It is pertinent to mention that M/s Getz Pharma (Pvt.) Ltd., Karachi is using Semaglutide Drug Substance of same source for their registered products

Accordingly, the case was considered in 354th meeting of Registration Board wherein the Board decided as follows:

Keeping in view the recommendations of panel of inspectors of DRAP; Registration Board decided as follows:

- To give opportunity of personal hearing to the firm to explain their position regarding non-recommendation of dosage form specific inspection by panel of inspectors of DRAP.

- To issue a show-cause notice to the firm, requiring them to explain their stance regarding manufacturing of their registered Semaglutide-containing formulations in light of the finding of dosage-form-specific inspection of Liraglutide Injection as the Semaglutide API was also being manufactured on the same equipment and premises.

Accordingly, personal hearing letter regarding Liraglutide was issued to the firm on 07-05-2026. Moreover, the firm has submitted the reply of Show Cause Notice regarding Semaglutide.

Decision of 358th meeting:

“The Registration Board deferred the case due to paucity of time.”

The firm vide EApp tracking ID: **B2H-EME-1JH7** submitted the following:

“This is to inform your good office that some of our key representatives responsible for presenting the case are currently on Hajj leaves, which restricts our ability to adequately present and address the queries of Registration Board in this scheduled meeting. Therefore, we kindly request the honorable Board to grant us an opportunity to appear in the next 360th Drug Registration Board Meeting scheduled for June 30th, 2026.”.

Decision:

Registration Board adjourned the hearing as per request of the applicant till its next meeting.

Case No. 5: Imported Veterinary Biologicals applied by M/s Hivet Animal Health Business, Lahore applied in hard and resubmitted via E-App CMS tracking ID: WAR-WBN-YBQJ.

Sr. No.	Name of Manufacturer	Brand Name & Composition	Pack Size, Shelf Life & Storage Condition	Date of Application & Fee Details
1.	M/s Beijing Sinder-vet Technology Co. Ltd., Beijing Tianzhu Airport Economic Development Zone, Shunyi Road 118, Shunyi District, Beijing, China.	Sinvac H9 Avian Influenza (Subtype H9) Vaccine, Inactivated (Strain SS) Each ml contains: Avian influenza antigen inactivated (H9 subtype, SS strain) (before inactivation..... $\geq 5 \times 10^{7.0}$ EID ₅₀)	250ml, 18 months (2°C-8°C)	R&I 02-12-2020 Fee Rs. 100,000/- dated 02-12-2020.
2.		SINVAC ND+1B+EDS+ H9 Newcastle Disease, Infectious Bronchitis, Egg Drop Syndrome and Avian Influenza (H9 Subtype) Vaccine, Inactivated (Strain La Sota + Strain M41+ Strain HSH23 + Strain WD) Each 0.5ml contains: Newcastle Disease antigen inactivated (La Sota strain) $\geq 10^{8.5}$ EID ₅₀ Infectious Bronchitis antigen inactivated (M41 strain) $\geq 10^{6.5}$ EID ₅₀	500ml, 18 months (2°C-8°C)	R&I 02-12-2020 Fee Rs. 100,000/- dated 02-12-2020.

		Egg Drop Syndrome antigen inactivated (HSH23 strain) ≥ 1000 HA Unit Avian influenza antigen inactivated (H9 subtype, WD strain) $\geq 10^{7.5}$ EID ₅₀		
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- Scanned Legalized GMP Certificate No. (2021) GMP 01010 dated 29-11-2021 valid till 28-11-2026.
- Scanned Legalized FSC for product at sr. no. 1 dated 12-01-2022.
- Scanned Legalized FSC for product at sr. no. 2 dated 12-01-2022.

Observations/ Shortcomings:

- For sr. no. 1, the firm has proposed pack sizes of 500ml & 250ml while stability data provided is of 250ml & FSC is indicating pack size as 500ml.
- For sr. no. 2, the firm has proposed pack sizes of 500ml & same is indicated on FSC but stability data provided is of 250ml.
- Valid DSL is not attached in dossier.

Decision:

For product at sr. no. 1:

Registration Board deferred the case for following:

- Details of N subtype of Influenza virus.**
- Immunological relevance and need of SS strain for Pakistan.**
- Valid DSL.**
- Clarification that proposed pack sizes are 500ml & 250ml while stability data provided is of 250ml & FSC is indicating pack size as 500ml.**

For product at sr. no. 2:

Registration Board deferred the case for following:

- Immunological relevance and need of HSH23 strain of EDS virus for Pakistan.**
- Details of N subtype of Influenza virus.**
- Valid DSL**
- Clarification that proposed pack sizes is 500ml & same is indicated on FSC but stability data provided is of 250ml.**

Case No. 6: Product Specific Inspection of M/s Grand Pharma Pvt. Ltd., Rawat for Vaxi-Drop Diluent 1000ml considered in 336th meeting of Registration Board.

Registration Board in its 336th meeting considering the request of following diluent applied by M/s Grand Pharma (Pvt.) Ltd., Rawat decided as follows:

Name of Manufacturer	Brand Name & Composition	Pack Size, Shelf Life & Storage	Decision of RB in 336th meeting
M/s Grand Pharma Pvt Ltd Plot # 5-A, Street No.N-5, RCCI Estate,	Vaxi-Drop Diluent for live Avian vaccines Each ml contains: Monobasic Potassium Phosphate: 0.37 mg	1000ml 2 Years (15°C-25°C)	The board deliberated the matter and decided as under: I. The Board Authorized Director BER to nominate a panel to visit M/s Grand Pharma (Pvt.) Ltd., Rawat, to

Rawat, Islamabad	Disodium Phosphate Dihydrate:..... 0.72 mg Sodium Chloride.....7.65mg		verify the facility of Liquid Injectable (Vial) (General) (Veterinary) Section for “One Little pack size” subject diluent. II. The registration letter will be issued after verification.
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Accordingly, following panel was nominated for inspection:

- i. **Mrs. Tehreem Sara**, Federal Inspector o Drugs-II, DRAP Islamabad.
- ii. **Mr. Muhammad Zubair Masood**, Deputy Director, DRAP Islamabad.

The inspection of manufacturing facility was conducted on 13-04-2026 and following are the list of deficiencies observed during the inspection by panel of inspectors of DRAP:

S. No.	Deficiencies/ Non-Compliance	Classification of Deficiency Guidance Document No. QALT/GL/CG/002 Effective Date: 30-03-2023	Reference (LRA Rules Decision of RB vide No.F.313-DRB/2021 (PE&R) dated 29.12.2021/ WHO TRS)
1	Sodium Chloride not verified as pyrogen-free (no in-house testing)	Critical	LRA rules and WHO TRS 986, Annex 2, Para 5.1–5.2
2	DRAP-approved import/purchase documentation	Major	LRA rules and WHO TRS 970, Chapter 5; TRS 986 Annex 2, 5.29
3	No washing facility for one-litre bottles	Major	LRA rules and WHO TRS 986, Annex 2, Para 6.4
4	Washing arrangement planned after approval	Major	LRA rules and WHO TRS 970, Chapter 3
5	Bottles not compatible with Dry Heat Sterilization (DHS)	Critical	LRA rules and WHO TRS 986, Annex 2, Para 8.1
6	No validated sterilization method available/not considered.	Critical	LRA rules and WHO TRS 986, Annex 2, Para 8.1–8.5
7	Infeasible autoclaving process without validation	Critical	LRA rules and WHO TRS 986, Annex 2, Para 8
9	Risk of cleanroom classification breach	Critical	LRA rules and WHO TRS 986, Annex 2, Para 4.1–4.5
10	Filling machine not suitable for one-litre pack	Major	LRA rules and WHO TRS 986, Annex 2, Para 7.1
11	Lack of understanding of WFI qualification phases	Critical	LRA rules and WHO TRS 970, Annex 2; TRS 1019 Annex 3
12	No sanitization/disinfection program for WFI system	Critical	LRA rules and WHO TRS 970, Annex 2

13	Sampling points not defined in WFI system	Critical	LRA rules and WHO TRS 970, Annex 2
14	No UV lamp life monitoring record	Major	LRA rules and WHO TRS 970, Annex 2, Para 7
15	No change control documentation	Major	LRA rules and WHO TRS 970, Chapter 1 (QMS)
16	Use of plastic piping in WFI system	Major	LRA rules and WHO TRS 970, Chapter 4
17	Silver Nitrate reagent not in usable condition	Major	LRA rules and WHO TRS 970, Chapter 6

Following conclusion & recommendations are of Panel of Inspectors:

Conclusion:

The inspection revealed multiple **critical gaps in GMP compliance**, particularly in:

- Sterilization validation
- Water system qualification
- Raw material verification
- Equipment suitability
- Quality control practices

These deficiencies must be addressed prior to consideration for approval of the **one-litre pack size**

Recommendation:

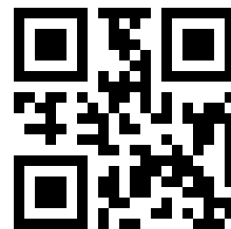
“In light of the above observations, particularly the presence of critical deficiencies related to sterilization, the WFI system, and environmental monitoring, it is recommended that the request of the firm for approval of the one-litre pack size may not be considered at this stage. The panel further recommends that the case may be reviewed again after necessary improvements and in accordance with the applicable policies for Biologicals.”

Decision:

Keeping in view the report of Panel of inspectors of DRAP; Registration Board rejected the application due to non-availability of requisite manufacturing facility. Registration Board further decided to refer the report to QA&LT Division of DRAP for further processing without waiting for finalization of minutes as the observations of panel of inspectors are of Major and Critical classification.



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



Item No. V Additional / Supplementary Minutes:
Pharmaceutical Evaluation Cell (PEC)

Sr. No	Title	Description
1	Case Category	Contract Manufacturing (Dr. Farhad Ullah)
	Name, address of Applicant.	Martin Dow Marker Limited 7, Jail Road Quetta. (000028)
	Application Form Dy. No / Tracking ID & date of submission	(PTT-XE1-6V38, 2025-04-10)
	Detail of Fee Submitted	93000.0, 2025-03-05,
	The proposed proprietary name / brand name	AtheraVance Capsules 0.5g
	Label Claim	Each Soft Gel Capsule contains 0.5g of Icosapentate Ethyl
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per DPC-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	Antilipemic or lipid regulating agents
	Name, address of Manufacturing site:	Martin Dow Marker Limited-F-126, S.I.T.E., Karachi Pakistan-
	Name & address of API manufacturer	Shandong Xinhua Pharmaceutical Co., Ltd. Address: Hutian Chemical Industrial Zone, Zibo, Shandong, P. R. China
	Detail of stability batches of drug product	3 batches having batch size of 10,000 capsule each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of form 6 dated 04-01-2024 specifying 102kg Icosapent Ethyl. Firm has submitted copy of goods declaration, airway bill, commercial invoice, packing list, form 3, form 7
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Vascepa 0.5gm Capsules by M/s Amarin Pharmaceuticals Ireland 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 II
	The status in reference regulatory authorities	Vascepa (Icosapentate Ethyl) Capsule 0.5g USFDA Approved.
	GMP status of the firm	Martin Dow Marker Limited., Karachi Firm has submitted copy of cGMP certificate of the firm based on inspection dated 19-04-2024.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of regularization of sections dated 27-05-2021 specifying Soft Gelatin Capsule.
Evaluation Remarks		
Marked in category of new molecule		
Shortcomings		Firm's Response

Stability study data of API as per Zone IV conditions till claimed shelf life is required	Firm submitted that Icosapent Ethyl is sensitive and not stable when exposed to high temperature for longer period of time. Innovator "Vascepa (Icosapent Ethyl) Capsules" recommended storage condition is 20°C - 25°C. Therefore, complete stability data of API at accelerated conditions (40+2°C, RH 75+5%) and Long term stability conditions (25+2°C, RH 60+5%) is submitted till claimed shelf life i.e., 36 months.
Justification is required for not using tocopherol in applied formulation compared innovator's formulation	Firm submitted that In USFDA, Tocopherol is listed as an inactive ingredient in the innovator product (VASCEPA) as an antioxidant. In our formulation, tocopherol is not added as a separate excipient. However, a controlled trace level of tocopherol is already present within the API specification ($\leq 0.40\%$) as per the Certificate of Analysis. Therefore, no additional incorporation of tocopherol is required in the finished product formulation.
Results of accuracy test are not submitted in analytical method validation report, justify	Accuracy testing is required for finished pharmaceutical products containing excipients. However, in our case, the finished product consists solely of the Active Pharmaceutical Ingredient without any excipients (100% API fill). The added excipients in our formulation are related to the manufacturing of gelatin shell.
Justify the acceptance criteria of NMT 45 minutes for the disintegration test in the finished product specifications, as the submitted results are below 10 minutes.	We have revised specifications with Disintegration time i.e., NMT 30mins as per JP monograph. Please find attached Finished product specifications (Annexure -V) with revised disintegration test limit.
Clarify the climatic zone classification of the stability storage conditions, as 25°C $\pm$ 2°C/60% $\pm$ 5% RH has been designated as real-time and 30°C $\pm$ 2°C/65% $\pm$ 5% RH as accelerated conditions,	As per the innovator product labeling, the recommended storage condition is 20°C to 25°C. Accordingly, Real-time stability studies for Icosapent Ethyl Capsule were conducted at 25°C+2°C, 60%+5% RH and Accelerated stability studies were conducted at 30°C+2°C, 65%+5% RH, and the product demonstrated satisfactory stability throughout the study period. On the basis of these results we will claim storage condition of finished product as 20°C to 25°C
Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation is required	Not submitted
Clarify why innovator specifications have been adopted despite the availability of JP monograph for the applied product.	Although the specification was initially established based on the reference product, it is fully aligned with the current Japanese Pharmacopoeia (JP) requirements. No modifications from the JP monograph have been adopted. Therefore, we hereby commit that we will follow JP specifications in commercial batches once registered. However, we have also revised finished product specifications and testing method as per JP monograph (refer to Annex-V).

Submit the prescribed fee for the submission of revised specifications.	We hereby commit that we will submit the prescribed fee for Change in specifications of Finished Drug Product from In-House to JP monograph before the issuance of registration letter.
API manufacturer has not provided a statement regarding the stability of the API at elevated temperatures. Please clarify, considering that the innovator product is labeled for storage at 20°C–25°C with permitted excursions to 15°C–30°C.	We hereby commit that we will submit the statement from API manufacturer for not performing the stability studies of the API at elevated temperatures
Provide a comparative table of the applied specifications and analytical methods versus the corresponding JP specifications and analytical methods to confirm that no deviations exist.	Only table showing specifications is submitted. However no details of analytical method is provided
Clarify the climatic zone to which the proposed stability storage conditions of 25°C ± 2°C/60% ± 5% RH (real-time) and 30°C ± 2°C/65% ± 5% RH (accelerated) correspond.	We performed long term stability studies at (25°C /60%RH) & accelerated at (40°C /75%RH) and (30°C /75%RH). Due to failure of accelerated stability (40°C /75%RH) at 6th month, therefore, we performed intermediate stability studies (30°C /65%RH) as per ICH Q1(R2) guidelines for 12 Months to justify the stability of our product and results were found satisfactory. Stability data of drug product for 12 months at intermediate stability conditions (30°C /65%RH) is submitted.
Results of accuracy test are not submitted in analytical method validation report, justify	Kindly take note that there was a typo error in provided Analytical Method Validation Report (Pg# 07 of 08) -e., “The accuracy has been performed in triplicate by the addition of Icosapent Ethyl to a placebo mixture, to have theoretical quantity ranging from 80% to 120% range for Icosapent Ethyl, since overall mean of the recovery is within 98% - 102%.” The correct statement is: “The accuracy has to be performed in triplicate by the addition of Icosapent Ethyl to a placebo mixture, to have theoretical quantity ranging from 80% to 120% range for Icosapent Ethyl, since overall mean of the recovery is within 98% - 102%.” The Accuracy testing is required for finished pharmaceutical Products containing excipients. However, in our case, the finished product consists solely of the Active Pharmaceutical Ingredient without any excipients (bulk). The added excipients in our formulation are related to the manufacturing of gelatin shell.

Decision

Deferred

Deferred for submission of following;

1. Stability study data of API as per Zone IV conditions till claimed shelf life
2. Justification for not using tocopherol in applied formulation compared innovator's formulation
3. Results of accuracy test analytical method validation report
4. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation

	5. Fee for revision of specifications. 6. Comparative table of the applied specifications and analytical methods versus the corresponding JP specifications and analytical methods. 7. Scientific justification for the stability of applied formulation, considering that the innovator product recommends storage at 20°C–25°C (with permitted excursions to 15°C–30°C), the applied product is unstable under accelerated conditions as per submitted data, and stability studies have been conducted at 25°C ± 2°C/60% ± 5% RH (long-term) and 30°C ± 2°C/65% ± 5% RH conditions.	
2	Case Category	Contract Manufacturing (Dr. Farhad Ullah)
	Name, address of Applicant.	Martin Dow Marker Limited 7, Jail Road Quetta. (000028)
	Application Form Dy. No / Tracking ID & date of submission	(7HV-TS8-AJAW, 2025-05-29)
	Detail of Fee Submitted	93000.0, 2025-03-05,
	The proposed proprietary name / brand name	Atheravance Capsule 1g
	Label Claim	Each Soft Gel Capsule contains 1g of Icosapentate Ethyl
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per DPC-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	Antilipemic or lipid regulating agents
	Name, address of Manufacturing site:	Martin Dow Marker Limited-F-126, S.I.T.E., Karachi Pakistan-
	Name & address of API manufacturer	Shandong Xinhua Pharmaceutical Co., Ltd. Address: Hutian Chemical Industrial Zone, Zibo, Shandong, P. R. China
	Detail of stability batches of drug product	3 batches having batch size of 10,000 capsule each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of form 6 dated 04-01-2024 specifying 102kg Icosapent Ethyl. Firm has submitted copy of goods declaration, airway bill, commercial invoice, packing list, form 3, form 7
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Vascepa 1gm Capsules by M/s Amarin Pharmaceuticals Ireland 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 II
	The status in reference regulatory authorities	Vascepa (Icosapentate Ethyl) Capsule 1g USFDA Approved.
	GMP status of the firm	Martin Dow Marker Limited., Karachi Firm has submitted copy of cGMP certificate of the firm based on inspection dated 19-04-2024.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of regularization of sections dated 27-05-2021 specifying Soft Gelatin Capsule.
Evaluation Remarks		
Marked in category of new molecule		
	Shortcomings	Firm's Response
	Stability study data of API as per Zone IV conditions till claimed shelf life is required	Firm submitted that Icosapent Ethyl is sensitive and not stable when exposed to high temperature for longer period of time. Innovator "Vascepa (Icosapent Ethyl) Capsules" recommended

	storage condition is 20°C - 25°C. Therefore, complete stability data of API at accelerated conditions (40+2°C, RH 75+5%) and Long term stability conditions (25+2°C, RH 60+5%) is submitted till claimed shelf life i.e., 36 months.
Justification is required for not using tocopherol in applied formulation compared innovator's formulation	Firm submitted that In USFDA, Tocopherol is listed as an inactive ingredient in the innovator product (VASCEPA) as an antioxidant. In our formulation, tocopherol is not added as a separate excipient. However, a controlled trace level of tocopherol is already present within the API specification ($\leq 0.40\%$) as per the Certificate of Analysis. Therefore, no additional incorporation of tocopherol is required in the finished product formulation.
Results of accuracy test are not submitted in analytical method validation report, justify	Accuracy testing is required for finished pharmaceutical products containing excipients. However, in our case, the finished product consists solely of the Active Pharmaceutical Ingredient without any excipients (100% API fill). The added excipients in our formulation are related to the manufacturing of gelatin shell.
Justify the acceptance criteria of NMT 45 minutes for the disintegration test in the finished product specifications, as the submitted results are below 10 minutes.	We have revised specifications with Disintegration time i.e., NMT 30mins as per JP monograph. Please find attached Finished product specifications (Annexure -V) with revised disintegration test limit.
Clarify the climatic zone classification of the stability storage conditions, as 25°C $\pm$ 2°C/60% $\pm$ 5% RH has been designated as real-time and 30°C $\pm$ 2°C/65% $\pm$ 5% RH as accelerated conditions,	As per the innovator product labeling, the recommended storage condition is 20°C to 25°C. Accordingly, Real-time stability studies for Icosapent Ethyl Capsule were conducted at 25°C+2°C, 60%+5% RH and Accelerated stability studies were conducted at 30°C+2°C, 65%+5% RH, and the product demonstrated satisfactory stability throughout the study period. On the basis of these results we will claim storage condition of finished product as 20°C to 25°C
Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation is required	Not Submitted
Clarify why innovator specifications have been adopted despite the availability of JP monograph for the applied product.	Although the specification was initially established based on the reference product, it is fully aligned with the current Japanese Pharmacopoeia (JP) requirements. No modifications from the JP monograph have been adopted. Therefore, we hereby commit that we will follow JP specifications in commercial batches once registered. However, we have also revised finished product specifications and testing method as per JP monograph (refer to Annex-V).
Submit the prescribed fee for the submission of revised specifications.	We hereby commit that we will submit the prescribed fee for Change in specifications of Finished Drug Product from In-House to JP monograph before the issuance of registration letter.

API manufacturer has not provided a statement regarding the stability of the API at elevated temperatures. Please clarify, considering that the innovator product is labeled for storage at 20°C–25°C with permitted excursions to 15°C–30°C.	We hereby commit that we will submit the statement from API manufacturer for not performing the stability studies of the API at elevated temperatures
Provide a comparative table of the applied specifications and analytical methods versus the corresponding JP specifications and analytical methods to confirm that no deviations exist.	Only table showing specifications is submitted. However no details of analytical method is provided
Clarify the climatic zone to which the proposed stability storage conditions of 25°C ± 2°C/60% ± 5% RH (real-time) and 30°C ± 2°C/65% ± 5% RH (accelerated) correspond.	We performed long term stability studies at (25°C /60%RH) & accelerated at (40°C /75%RH) and (30°C /75%RH). Due to failure of accelerated stability (40°C /75%RH) at 6th month, therefore, we performed intermediate stability studies (30°C /65%RH) as per ICH Q1(R2) guidelines for 12 Months to justify the stability of our product and results were found satisfactory. Stability data of drug product for 12 months at intermediate stability conditions (30°C /65%RH) is submitted.
Results of accuracy test are not submitted in analytical method validation report, justify	Kindly take note that there was a typo error in provided Analytical Method Validation Report (Pg# 07 of 08) -e., “The accuracy has been performed in triplicate by the addition of Icosapent Ethyl to a placebo mixture, to have theoretical quantity ranging from 80% to 120% range for Icosapent Ethyl, since overall mean of the recovery is within 98% - 102%.” The correct statement is: “The accuracy has to be performed in triplicate by the addition of Icosapent Ethyl to a placebo mixture, to have theoretical quantity ranging from 80% to 120% range for Icosapent Ethyl, since overall mean of the recovery is within 98% - 102%.” The Accuracy testing is required for finished pharmaceutical Products containing excipients. However, in our case, the finished product consists solely of the Active Pharmaceutical Ingredient without any excipients (bulk). The added excipients in our formulation are related to the manufacturing of gelatin shell.

Decision

Deferred

Deferred for submission of following;

1. Stability study data of API as per Zone IV conditions till claimed shelf life
2. Justification for not using tocopherol in applied formulation compared innovator's formulation
3. Results of accuracy test analytical method validation report
4. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation
5. Fee for revision of specifications.
6. Comparative table of the applied specifications and analytical methods versus the corresponding JP specifications and analytical methods.
7. Scientific justification for the stability of applied formulation, considering that the innovator product recommends storage at 20°C–25°C (with permitted excursions to 15°C–30°C), the applied product is

	unstable under accelerated conditions as per submitted data, and stability studies have been conducted at 25°C ± 2°C/60% ± 5% RH (long-term) and 30°C ± 2°C/65% ± 5% RH conditions	
3	Case Category	New Section (Farooq Aslam)
	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	(ZJB-AMP-4GYE, 2026-04-22)
	Detail of Fee Submitted	38700, 2026-04-14,
	The proposed proprietary name / brand name	Nagodine Solution
	Label Claim	Each ml of cutaneous solution contains: Iodinated Povidone.....100mg (10% w/w)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50 ml, 60 ml, 70 ml, 100 ml, 200 ml, 300 ml, 400 ml, 450 ml, 500 ml, 1000 ml, 4.5 L, 5 L-As per SRO
	Shelf Life (Unit)	2 Year(s)Room temperature
	For generic drugs (me-too Status)	Pyodine by Brooks Pharma
	Pharmacotherapeutic Group of (API)	Antiseptics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	03 batches : 50 bottles each 50mL 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)	Loan letter for 1kg of material along with memorandum of understanding for loan dated 04-08-2025 is submitted. Clearance certificate dated 24-07-2024 issued to M/s Kohinoor Industries is submitted. Stability batches were manufactured in September, 2025.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted against Pyodine 10% by M/s brookes.
	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-A.
	The status in reference regulatory authorities	Health Products Regulatory Authority (HPRA)
	GMP status of the firm	External preparation (Liquid) General Section is approved on 18-03-2026.
	Evidence of approval of manufacturing facility	External preparation (Liquid) General Section is approved.
	Evaluation Remarks	
	The stability batches were manufactured in September, 2025. The firm has taken the Loan from M/s Kohinoor Industries on 04-08-2025 whereas DRAP's notification No.14-1/2022-PEC dated 01.08.2025 permits the borrowing of APIs on a loan basis which was exclusively permitted only to holders of new Drug ManufacturingLicenses (DMLs).	
	The case was deferred in 358th meeting for clarification regarding borrowing of loan after DRAP's notification No.14-1/2022-PEC dated 01.08.2025	
	The firm has stated that Regarding DRAP revised Notification dated 01st August 2025 for borrowing of API for product development and stability, it is respectfully submitted that prior to issuance of cited notification, our firm has already initiated the process for obtaining API on loan basis from Kohinoor Industries. The final MOU in respect of loan was however executed on	

4th August 2025. It is highly regretted that the than QC in charge has not updated the management, if applicable, about revise policy of API borrowing.

Decision

Deferred

The Board decided to refer the case to DRAP Authority for decision regarding the borrowing of drug substance after DRAP's notification No.14-1/2022-PEC dated 01.08.2025.

4	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Biogen Life Sciences 8-KM, Chak Beli Road, Rawat, (000911)
	Application Form Dy. No / Tracking ID & date of submission	(XSL-Y2H-UP7Y, 2024-11-06)
	Detail of Fee Submitted	37000.0, 2024-10-21,
	The proposed proprietary name / brand name	LEVOCARGEN 1G INJECTION IV/IM
	Label Claim	Each 5ml ampoule contains: Levocarnitine 1g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5x5ml-As per SRO
	Shelf Life (Unit)	2 Year(s) Room Condition
	For generic drugs (me-too Status)	Brand Name: L-Carnit Injection 1g/5ml Registration holder: Seraph Pharmaceutical
	Pharmacotherapeutic Group of (API)	Antilipemic drug
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Northeast Pharmaceutical Group Company, Limited Address: No.29 Shexiliu Dong Road, Economic Technology Development District, Shenyang
	Detail of stability batches of drug product	03 batches : 1000 Ampoules 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 28-03-2023 for 1kg of material is submitted issued to M/s Seraph Pharmaceuticals. Loan letter dated 10-02-2024 is submitted from M/s Seraph.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the comparator's product i.e. L-Carnit injection by M/s Seraph Pharmaceuticals.
	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- A.
	The status in reference regulatory authorities	Carnitor injection USFDA Approved
	GMP status of the firm	Last inspection report dated 27-29th May and 16th July, 2025 is submitted for renewal of DML.
	Evidence of approval of manufacturing facility	Ampoule section SVP is approved.
	Evaluation Remarks	
	Verification of loan letter is required.	
	Decision	
	Approved	
	Subject to verification of loan letter.	

5	Case Category	Export Facilitation (Incharge Evaluation Cell)
	Name, address of Applicant.	Scilife Pharma Private Limited FD-57/58-A2, Korangi Creek Industrial Park (KCIP) (000837)
	Application Form Dy. No / Tracking ID & date of submission	(NV9-2PN-TG1G, 2025-01-30)
	Detail of Fee Submitted	37000.0, 2025-01-16,
	The proposed proprietary name / brand name	Renzova 50mg Tablet
	Label Claim	Each film coated tablet contains: Roxadustat.....50MG
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	12's-As per SRO,14's-As per SRO,3's-As per SRO,56's-As per SRO,6's-As per SRO,9's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 25°C. Excursions permitted between 15°C and 30°C.
	For generic drugs (me-too Status)	ROXUDO 50MG TABLET by CCL Pharmaceuticals (Pvt). ltd
	Pharmacotherapeutic Group of (API)	B03XA05; antianemic preparations
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Three batches of 5000 tablets at long term and accelerated conditions of Zone IV
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided Form 6 K-2965444821693
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions of Zone IV
	The status in reference regulatory authorities	EVRENZO 50MG TABLETS by M/s Astellas Pharma Europe.
	GMP status of the firm	GMP certificate dated 21 January 2025
	Evidence of approval of manufacturing facility	Renewal of DML dated 18 June 2021
	Evaluation Remarks	
	Under exports facilitation as per letter dated 12 August 2025	
	Decision	
	Approved	
6	Case Category	Export Facilitation (Incharge Evaluation Cell)
	Name, address of Applicant.	Scilife Pharma Private Limited FD-57/58-A2, Korangi Creek Industrial Park (KCIP) (000837)
	Application Form Dy. No / Tracking ID & date of submission	(MYE-HAL-DR6V, 2025-01-30)
	Detail of Fee Submitted	37000.0, 2025-01-16,
	The proposed proprietary name / brand name	Renzova 100mg Tablet
	Label Claim	Each film coated tablet contains: roxadustat.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	12's-As per SRO,3's-As per SRO,4x14s-As per SRO,6's-As per SRO,9's-As per SRO

	Shelf Life (Unit)	2 Year(s)Store at 25°C. Excursions permitted between 15°C and 30°C.
	For generic drugs (me-too Status)	ROXUDO 100MG TABLET by CCL Pharmaceuticals (Pvt). ltd
	Pharmacotherapeutic Group of (API)	B03XA05; antianemic preparations
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Three batches of 5000 tablets at long term and accelerated conditions of Zone IV
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided Form 6 K-2965444821693
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions of Zone IV
	The status in reference regulatory authorities	EVRENZO 100MG TABLETS by M/s Astellas Pharma Europe.
	GMP status of the firm	GMP certificate dated 21 January 2025
	Evidence of approval of manufacturing facility	Renewal of DML dated 18 June 2021
	Evaluation Remarks	
	Under exports facilitation as per letter dated 12 August 2025	
	Decision	
	Approved	
7	Case Category	Export Facilitation (Incharge Evaluation Cell)
	Name, address of Applicant.	Scilife Pharma Private Limited FD-57/58-A2, Korangi Creek Industrial Park (KCIP) (000837)
	Application Form Dy. No / Tracking ID & date of submission	(2QW-L31-1H7A, 2025-01-30)
	Detail of Fee Submitted	37000.0, 2025-01-16,
	The proposed proprietary name / brand name	Renzova 20mg Tablet
	Label Claim	Each film coated tablet contains: roxadustat.....20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	12's-As per SRO,14's-As per SRO,3's-As per SRO,56's-As per SRO,6's-As per SRO,9's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 25°C. Excursions permitted between 15°C and 30°C.
	For generic drugs (me-too Status)	ROXUDO 20MG TABLET by CCL Pharmaceuticals (Pvt). ltd
	Pharmacotherapeutic Group of (API)	B03XA05; antianemic preparations
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Three batches of 5000 tablets at long term and accelerated conditions of Zone IV
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided Form 6 K-2965444821693

Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions of Zone IV
The status in reference regulatory authorities	EVRENZO 20MG TABLETS by M/s Astellas Pharma Europe.
GMP status of the firm	GMP certificate dated 21 January 2025
Evidence of approval of manufacturing facility	Renewal of DML dated 18 June 2021
Evaluation Remarks	
Under exports facilitation as per letter dated 12 August 2025	
Decision	
Approved	

Case No. 1. Change of MAH and Registration Status [FROM FINISHED IMPORT TO LOCAL MANUFACTURE]

Sr.#	Feature	Change of Manufacturing Site & MAH of Registered Product [FROM FINISHED IMPORT TO LOCAL MANUFACTURE]
1.	Applicant name	M/s AGP Ltd. B-23-C, S.I.T.E. Karachi
2	Registered Product	Detrusitol SR 4mg Prolonged release capsules Registration No. 053805
3.	Previous Approved MAH	M/s Pfizer Pakistan Limited, B-2. SITE, Karachi
4.	Previous Manufacturing Site	M/s. Pfizer Italia S.r.l Ascoli Piceno , Italy
5.	New/ Proposed MAH Holder & Manufacturing Site	M/s AGP Ltd. B-23-C, S.I.T.E. Karachi
6.	NOC from previous MAH Holder	Provided Dated: 11-09-2023 along with request for de-registration/cancellation of Products
7.	Dosage Form	Capsule
8.	Valid DML & Section Approval letter of new proposed Manufacturer	Provided
9.	API Source	Tolterodine tartarate: M/s Pelltech Healthcare Pvt Ltd, India GMP Certificate : Provided with validity till 07-01-2025 Accelerated Stability Studies (06 Months) & Real Time Stability Studies (36 Months) test reports are submitted .
10.	Reference product for PE/CDP	Firm has submitted pharmaceutical equivalence & CDP (in 0.1 N HCl, Acetate buffer & Phosphate buffer of their product against Detrusitol 4 mg Capsule of (Catalant Pharms Solution LLC, Kentucky, USA)
11.	Procurement documents / Clearance from DRAP Office	Provided
12.	Stability Studies	Accelerated Stability studies (06 Months) & Real time Stability studies (06 months) are conducted on following three batches : Batch No. 206DS01, 206DS02, & Batch No. 206DS03 Date of Manufacture : 06-2024 Batch Size : 2500 Capsule Date of Initiation 05-11-2024
13.	BMR, HPLC Raw data sheets	Submitted

Decision:

The Board after threadbare deliberation approved the case with following conditions:

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

Case No. 2. Change of Finished Product Specifications of Angised Tablets (Reg#000352) of M/s GlaxoSmithKline Pakistan Limited, Karachi

M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E., Karachi has submitted application on **E-app vide Tracking ID : SSR-1EH-LH3T** for change of Finished Product Specifications to GSK Specifications.

The firm has submitted that the Provincial QC Board, Punjab has advised the firm for necessary updating product specification to align disintegration time based on GSK's Specifications.

The firm has also submitted DTL test reports (DTL Multan) wherein the samples of Angised Tablets (Reg#000352) are declared substandard on the basis of disintegration test considering BP Specification.

The matter was discussed in 43rd committee meeting(of the PQCB Punjab) held on 29-08-2024 and the detail is as under:

GSK Pakistan Limited submitted to the PQCB Punjab that regarding the emerging trend concerning Angised tablets, for which multiple batches have repeatedly been seized from various locations by drug inspectors as part of routine inspections. These batches are then sent for further analysis to the DTLs.

In this regard, we would like to respectfully mention that the PQCB has informed the firm via order PQCB/R-771/2019 about the current recommendations suggested by the PQCB committee following the product-specific inspections conducted recently and in response to these recommendations, our firm is actively working on implementing the necessary changes and is in the process of submitting evidence of these implementations to the board.

Recently, a batch (M85V) of Angised tablets has been seized from district Attock and sent for analysis to the government analyst, in addition to the previously reported batches for substandard nature (HAPAL, HAPAR, 2R*X, IAPAE and R62G).

Therefore, in the light of ongoing efforts, we request the honorable PQCB board in Lahore to kindly notify all respective drug inspectors, associated authorities and DTLs to implement the necessary action as suggested by the board.

Your prompt attention and action in this matter would be greatly appreciated.

Decision of the PQCB is reproduced as below:

The Secretary PQCB apprised the committee about the subject issue. The firm requested the committee to kindly notify, all respective drug inspectors, associated authorities, and DTLs to hold the performance of Disintegration Test (DT) in Angised Tablet, until the site implements the necessary action as suggested by the board. The committee after due deliberation and discussion, unanimously decided to regret this request of firm and directed to write a letter to DRAP regarding the approval of Manufacturer's specification for Angised Tablets manufactured by GSK Pakistan Limited, if any application is pending there.

The comparison of specs as submitted by the firm are as under :

Tests	GS/ Specifications	BP SPECIFICATION	USP SPECIFICATIONS
IDENTIFICATION	<u>Bv HPLC</u> In the assay by HPLC, the main peak produced from the test solution have similar retention time and shape to the main peak produced from the Standard Solution of Glyceryl Trinitrate.	A. TLC The principal spot in the chromatogram obtained with solution (1) corresponds in position and color to that in the chromatogram obtained with solution (2). B. <u>Qualitative test</u> Extract a quantity of the powdered tablets (750 mg) with 5 mL of ether and filter. Evaporate the ether and dissolve the residue in 0.2 mL of sulfuric acid	A. TLC: meet the requirements as defined in 201 chapter. B. <u>HPLC</u> : The retention time of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay

		containing a trace of diphenylamine. An intense blue color is produced.	
RELATED SUBSTANCES	<u>By HPLC</u> In the chromatogram obtained with solution (1): the area of any secondary peak is not greater than the area of the principal	<u>By HPLC</u> In the chromatogram obtained with solution (1): the area of any secondary peak is not greater than the	Not available
	peak in the chromatogram obtained with solution (2) (1%); the sum of the areas of any such peaks is not greater than three times the area of the principal peak in the chromatogram obtained with solution (2) (3%). Disregard any peak with an area less than 0.1 times the area of the principal peak in the chromatogram obtained with solution (2) (0.1%).	area of the principal peak in the chromatogram obtained with solution (2) (1%); the sum of the areas of any such peaks is not greater than three times the area of the principal peak in the chromatogram obtained with solution (2) (3%). Disregard any peak with an area less than 0.1 times the area of the principal peak in the chromatogram obtained with solution (2) (0.1%).	
UNIFORMITY OF CONTENT	HPLC: CU by Assay LIMIT=> 85-115%	HPLC: LIMIT=> 85-115%	HPLC: LIMIT=> 75-135%
ASSAY	HPLC- Average of the uniformity of content results - 85 % - 115%	HPLC- Average of the uniformity of content results - 85 % - 115%	HPLC: LIMIT=> 90-115%
DISINTEGRATION	NMT: 5 Mins	Not available	NMT: 2 Mins
Microbial Limit Test	Total Aerobic Microbial Count : Not greater than 1000 cfu/g Total Yeast & Mould Count: Not greater than 100 cfu/g Indicator Organisms: Absence in 1 g of Escherichia Coli	Not available 	Not available
APPEARANCE	White flat, branded and scored tablet, beveled edge.	Not available	Not available
STANDARD COMPRESSION	125 mg	Not available	Not available
WT. AVERAGE WEIGHT	LIMIT: 115.625 — 134.375 mg	Not available	Not available

SCORE	Scored	Not available	Not available
HARDNESS	LIMIT: 2 — 3.5Kg	Not available	Not available
THICKNESS	LIMIT: 2.0 — 2.30 mm	Not available	Not available
DIAMETER SIZE	7.4 mm + 0.1	Not available	Not available
UNIFORMITY OF WEIGHT	20 tablets weighed individually. NMT 2 to deviate from the average weight by more than 7.5% and none by more than 15 %	Not available	Not available

The firm was called for Personnel Hearing in the 348th meeting of the Registration Board and the decision of the board is as under:

The Board deliberated the matter and decided to ask the firm to submit complete studies regarding dissolution profile, disintegration time and CDP (Comparative dissolution profile) studies with innovator products / products registered in RRA's.

The decision of the board was communicated to the firm on E-App and in response the firm has replied as under:

We refer to our personal hearing in 348th meeting of the Registration Board wherein the Board asked the Company to submit complete studies regarding dissolution profile, disintegration testing, and Comparative Dissolution Profile (CDP) studies with innovator products or products registered in Reference Regulatory Authorities (RRA's).

At the outset, we wish to reiterate that **Angised Tablet (Reg. No. 000352)** is an exclusive product manufactured solely by GSK for the Pakistan market and is not produced at any other GSK manufacturing facility worldwide. This unique status has presented substantial challenges in identifying and procuring suitable comparator products containing Glyceryl Trinitrate (GTN) in equivalent dosage forms.

Angised Tablet is a long-standing and trusted SKU in GSK's portfolio, specifically indicated for the emergency management of Angina Pectoris. It has been serving the needs of special patient groups for over 49 years with an annual production volume of 60 million tablets.

Also we wish to inform that no adverse events related to Angised have been reported in DRAP's Med Vigilance system. This reaffirms the product's continued safety and efficacy in real-world use.

Since its initial registration, Angised Tablet adhered to GSK specifications until 2nd November 2020, when the specifications were transitioned to align with the British Pharmacopoeia (BP), as approved by DRAP under Letter No. F.49-PRVC/2020 (PR-I). The BP monograph for Glyceryl Trinitrate Tablets monograph does not include specific disintegration testing requirements and specifications; therefore, Angised DT has been assessed under general BP standards.

In line with the Board's directions, GSK has made continuous and extensive efforts to procure comparator products from local and international markets through logistics and general order suppliers. Unfortunately, these efforts have not been successful due to the very limited availability of GTN sublingual tablets in the required dosage form. This situation has unavoidably impacted on our ability to conduct comparative studies as requested by the Board.

Reformulation of Angised was evaluated but not considered viable:

- Sublingual formulations are highly sensitive to formulation changes with potential in vivo impact.
- Conducting BE studies is not feasible as Angised is an R&D-specific product with no equivalent formulation elsewhere in GSK's portfolio.
- Reformulation would take 2–3 years, leading to **market unavailability** of a life-saving medicine for patients in Pakistan.

There is no Dissolution method for Glyceryl trinitrate Tablet (sublingual) in any pharmacopeia. There is no specification (Time and % content dissolve) for Dissolution is available in any international pharmacopeia. The method of analysis is not available in any international pharmacopeia. None of the official compendial dissolution apparatuses and methods simulate these Sublingual conditions. Dissolution testing in 900 mL aqueous media is not biorelevant for sublingual tablets due to the low volume of saliva in vivo (~1–2 mL) and mucosal absorption mechanism. Moreover, GSK has no in vitro tools or methods to assess the change GSK doesn't have any in vitro tools or methods to assess equivalency of different sublingual formulations, to predict the potential impact in vivo.

We respectfully submit that, given the unique position of Angised Tablet as a medically critical Class A product and essential medicine in Pakistan, reformulation or discontinuity of supply could lead to significant risk to patients dependent on this therapy. Copies of HCPs recommendations/letters are enclosed.

Furthermore, the clinical utility and therapeutic effectiveness of Angised Tablet in the management of acute angina and other cardiac emergencies are widely recognized within the Pakistani medical community. The product has been prescribed for decades by leading cardiologists and physicians across the country due to its rapid onset of action and reliable clinical performance in emergency situations. In support of this long-standing clinical experience, GSK has obtained written testimonials and professional opinions from renowned physicians and medical specialists who routinely prescribe Angised Tablet in their clinical practice and acknowledge its efficacy and critical role in the management of angina-related conditions. Additionally, no adverse events or lack of efficacy reports related to Angised Tablet have been received from patients or healthcare professionals during its long history of clinical use and prescribing in Pakistan, which further supports the product's continued safety and therapeutic reliability. Copies of these professional endorsements are enclosed herewith as supporting annexures for the Board's kind consideration.

GSK therefore seeks the Board's kind consideration and allows the company to switch the specification to GSK Own specification.

GSK remains fully committed to maintain uninterrupted patient access to Angised Tablet, and to continuing transparent engagement with the Drug Regulatory Authority of Pakistan. Patient safety remains our utmost priority and we shall be happy to respond to any queries authorities might have in this regard.

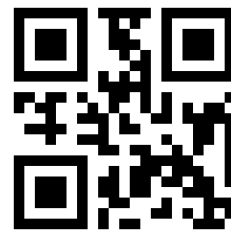
Decision of the 359th meeting of Registration board:

The Board considered the case and decided to give opportunity of personal hearing to the firm in the next meeting of the board



Drug Regulatory Authority of Pakistan

(Biological Evaluation & Research Division)



Division of Biological Evaluation & Research

Sr. No	Title	Description
1	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Getz Pharma (Pvt) Limited 29-30/27, Korangi Industrial Area karachi (000284)
	Application Form Dy. No / Tracking ID & date of submission	(XJM-9LD-SAJX, 2026-05-20)
	Detail of Fee Submitted	38700, 2026-02-10,
	The proposed proprietary name / brand name	Tirzee Solution for Injection 12.5mg/0.5mL in Pre-filled Syringe with Disposable Autoinjector
	Label Claim	Each 0.5mL PFS contains: Tirzepatide....12.5mg (Pre-filled Syringe with Disposable Autoinjector)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	24 Month(s)Store in a refrigerator at 2°C-8°C. Protect from light
	For generic drugs (me-too Status)	Zeptide 12.5mg/0.5mL PFS (Reg. No.: 130064) by M/s BF Biosciences Limited.
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	-
	Detail of stability batches of drug product	Stability data of 2 batches attached with Batch size of 2500PFS.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate No. RO-5E5585 dated 03-07-2025 for import of 900gm of Tirzepatide API.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative testing with Mounjaro is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of 3 batches submitted at accelerated conditions till 6 months and real time conditions till 18 months.
	The status in reference regulatory authorities	Mounjaro Injection 12.5mg/0.5mL by M/s Eli Lilly and Company. (USFDA Approved)
	GMP status of the firm	GMP certificate No. GMP-C-1090F1 dated 16-11-2025
	Evidence of approval of manufacturing facility	PFS section regularized on 12-06-2025
Evaluation Remarks		
Stability data of 2 batches of drug product is submitted at real time and accelerated conditions till 6 months.		
Decision		

Approved

Approved as per innovator's specifications with following conditions:

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.
2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA & LT.
3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.
4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.
5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.
6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

2	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Getz Pharma (Pvt) Limited 29-30/27, Korangi Industrial Area karachi (000284)
	Application Form Dy. No / Tracking ID & date of submission	(98Y-7BD-5AED, 2026-05-20)
	Detail of Fee Submitted	38700, 2026-02-10,
	The proposed proprietary name / brand name	Tirzee Solution for Injection 15mg/0.5mL in Pre-filled Syringe with Disposable Autoinjector
	Label Claim	Each 0.5mL PFS contains: Tirzepatide....15mg (Pre-filled Syringe with Disposable Autoinjector)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	24 Month(s)Store in a refrigerator at 2°C-8°C. Protect from light
	For generic drugs (me-too Status)	Zeptide 15mg/0.5mL PFS (Reg. No.: 130065) by M/s BF Biosciences Limited.
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	-
	Detail of stability batches of drug product	Stability data of 3 batches submitted at real time and accelerated conditions till 6months. Batch size of 2500PFS.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate No. RO-5E5585 dated 03-07-2025 for import of 900gm of Tirzepatide API.

Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative testing with Mounjaro is submitted.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of 3 batches submitted at accelerated conditions till 6 months and real time conditions till 18 months.
The status in reference regulatory authorities	Mounjaro Injection 15mg/0.5mL by M/s Eli Lilly and Company. (USFDA Approved)
GMP status of the firm	GMP certificate No. GMP-C-1090F1 dated 16-11-2025
Evidence of approval of manufacturing facility	PFS section regularized on 12-06-2025
Evaluation Remarks	
Decision	
Approved	
Approved as per innovator's specifications with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA & LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP. 4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. 5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022. 6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	

Case No. 1: TERMINATION OF SOLE AGENCY AUTHORIZATION IN NAME OF M/S IMMUNOWELL PVT LIMITED LAHORE FOR SINOVAC VARICELLA VACCINE (REG. NO: 115173)

The below mentioned vaccine has been registered in name of M/s Immunowell Pvt Limited Lahore as per details provided below:

Reg. No.	Product details	MA Holder and Manufacturer	Pack size & shelf life
115173	Sinovac Varicella Vaccine (Lyophilized Vaccine) Each vial of 0.5mL (after reconstitution) contains: Live varicella herpes zoster virus ≥ 3.3lg PFU Diluent: Each ampoule contains: Water for Injection...0.5ml	Vaccine Manufacturer: Sinovac (Dalian) Vaccine Technology Co., Ltd., 36 2 nd Life Road, DD Port, Economic and Technical Development Zone, Dalian China Diluent Manufacturer: Jiangsu Desano Pharmaceutical Co., Ltd., China	1's vial + 1's Ampoule 24 Months (2°C 8°C)

Now a Legalized Termination letter by the manufacturer M/s Sinovac (Dalian) Vaccine Technology Co., Ltd China and M/s Sinovac Biotech (Singapore) Pte Ltd Singapore has been received in the BE&R Division in name of M/s M/s Immunowell Pvt Limited, Lahore dated January 1, 2026 (legalized May 26, 2026).

In view of above matter is placed before the Registration Board for issuance of show cause in light of section 7(11)(b)(c) read with section 42 of the Drugs Act 1976.

Decision: Registration Board decided to issue show cause notice to M/s Immunowell Pvt Limited Lahore under provisions of Section 7 (11) (b) (c) and under section 42 of the Drug Act, 1976 & under Rule 24 (17) of Drugs (Licensing, Registering & Advertising) Rules, 1976, in light of their termination of sole agency agreement by the manufacture abroad after verification of termination letter by the manufacturer through email.

Meeting ended with a vote of thanks to and from the Chair,

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