

**MINUTES OF 348TH MEETING OF REGISTRATION BOARD
HELD ON 01ST – 02ND JULY, 2025**

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**DRUG REGULATORY AUTHORITY OF PAKISTAN
PRIME MINISTER'S NATIONAL HEALTH COMPLEX,
CHAK SHEHZAD, PARK ROAD,
-----ISLAMABAD -----**

348th meeting of Registration Board was held on 01st – 02nd July, 2025 in the Committee Room, Drug Regulatory Authority of Pakistan, Prime Minister’s National Health Complex Park Road, Chak Shehzad, Islamabad.

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

The meeting was attended by the following:

1.	Malik Muhammad Saleem, Ex Deputy Manager Production. Rhone Poulenc Rorer Pakistan. Rawalpindi.	Member (Online)
2.	Dr. Syed Asad Ali Shah, Principal Animal Husbandry In-Service Training Institute, Peshawar.	Member
3.	Dr. Tehseen Fatima, Dow College of Biotechnology, Dow University of Health Sciences, Karachi.	Member (Online)
4.	Mr. Iftikhar Ahmed Choudhury, Ex-Chief Pharmacist, Hospital Pharmacist, Government of Punjab, Lahore	Member
5.	Mr. Syed Adnan Rizvi, Director, Drugs Testing Laboratory, Govt. of Sindh, Karachi.	Member (Online)
6.	Dr. Ali Jan, Director, Drugs Testing Laboratory, Govt. of Baluchistan Quetta.	Member (Online)
7.	Mr. Imranullah Khan, Director Drugs Testing Laboratory, Govt. of Khyber Pakhtunkhuwa, Peshawar.	Member (Online)
8.	Mr. Muzzamil Waheed, Director DTL, Govt. of Punjab, Faisalabad.	Member (Online)
9.	Mr. Muhammad Aslam, Additional Draftsman, Law & Justice Division, Islamabad.	Member
10.	Mr. Ghulam Mujtaba, Deputy Director, Representative of IPO, Islamabad.	Member
11.	Ch. Zeeshan Nazir Bajar, Director, Quality Assurance & Lab Testing Division, DRAP.	Member
12.	Mr. Babar Khan, Director, Biological Evaluation & Research Division, DRAP.	Member
13.	Miss Sadaf Ahmad, Deputy Director, Representative of MD&MC Division, DRAP.	Member
14.	Hafiz M. Ali Tayyab, Additional Director, Pharmaceutical Evaluation & Registration Division, DRAP.	Member/ Secretary
15.	Dr. Junaid Akhtar, Director, Drugs Testing Laboratory, Govt. of Gilgit Baltistan.	Co-Opted Member (Online)

Mr. Nadeem Alamgir (Pharma Bureau), Mr. Jalal-ud-Din Zafar (Online), Ch. Ansar Farooq (PPMA) and Mr. Shah Nawaz (PCDA) attended the meeting as observers.

Item No. I Confirmation of Minutes of 346th & 347th meeting of Registration Board.

- a. 346th meeting of Registration Board was held on 22nd April, 2025. Accordingly, draft minutes of the 346th meeting of Registration Board were prepared and circulated among the members through email for their perusal / approval / comments (if any). All members agreed to the draft minutes. Accordingly, fair minutes were processed to Chairman, Registration Board for perusal/approval. After approval from Chairman Registration Board, fair minutes of 346th meeting of Registration Board were circulated among concerned divisions/sections for implementation.
- b. 347th meeting of Registration Board was held on 28th – 30th April, 2025. Accordingly, draft minutes of the 346th meeting of Registration Board were prepared and circulated among the members through email for their perusal / approval / comments (if any). All members agreed to the draft minutes. Dr. Asad Abrar, Director, DTL, Bahawalpur has submitted following has submitted following observations/suggestions;

“On behalf of member Registration Board, Punjab, I would like to highlight gaps in validation/verification data requirement for registration of drugs

A- Validation/Verifications Requirements in CTD Dossier

Validation

Validation of an analytical procedure involves laboratory studies to confirm that its performance characteristics meet the requirements for the intended analytical application. Typical analytical performance characteristics include

- Accuracy
- Precision
- Specificity
- Detection limit
- Quantitation limit
- Linearity
- Range
- Robustness

Verification

Verification of compendial test procedures assesses whether the method is suitable for its intended purpose under the actual conditions of use for a specific drug substance and/or product matrix.

With reference to application for registrations, Validation/Verification are the compendial requirements for a finished pharmaceutical product and all the guidelines require that test methods used to assess the compliance of pharmaceutical articles with established specifications meet appropriate standards.

In the drug registration 347th meeting, I asked for 01 Validation report and 01 Verification report from evaluator for review. I regretfully say that these are just papers and such data can be obtained from any website or data source. These reports have no raw data to support the findings and conclusion.

Complete Compendial Testing

Moreover, during the aforementioned meeting, it is also observed that the manufacturers are providing only assay data. However, compendial methods require more comprehensive testing, including impurity profiling and identification of unknown peaks to detect any components and all the excipients. It was also noted that the companies are not even aware of internal standard use and its application in calculation of assay and relevant results as per monographs.

B- Remarks

- i. We acknowledge that, DRAP is in evolving stage and working for the betterment of general public but essential tests are necessary to ensure product quality. We should assure that the manufacturer must comply because they will earn from these products and it is their duty to provide good quality product as per international standard.
- ii. It is highly recommended that our regulatory labs should test the products on the provided methods before registration. Otherwise, Registration Board should at least review the provided validation/verification record along with raw data.
- iii. Impurity profiling or related substance testing is essential as per Good Laboratory Practices guidelines. Thus, other than assay test, the manufactures are required to perform complete compendial tests for compliance of a product as stated in respective monographs which include performance testing, impurity testing and any test stated under specific tests.
- iv. Drug testing require a lot of time and when we need validation/verification data from the manufacturers, they always fail to respond. Most of the manufacturers do not have the technical knowledge of monograph compliance with respect to compendial testing. Number of examples can be provided in this regard.
- v. It is requested to add this issue in next drug registration board agenda to discuss necessity of validation/verification studies.

Accordingly, fair minutes were processed to Chairman, Registration Board for perusal/approval. After approval from Chairman Registration Board, fair minutes of 347th meeting of Registration Board were circulated among concerned divisions/sections for implementation.

Decision: Registration Board noted the information and confirmed the minutes of 346th and 347th meetings. The Board further decided to discuss the above observations/suggestions in the presence of Dr. Asad Abrar, Director, DTL, Bahawalpur.

a. Implementation of Bioequivalence

The Registration Board in its 338th Meeting decided as follows:

Decision: In the light of S.R.O 713(I)/2018 and requirement for WHO Listed Authorities i.e in particular the Maturity Level-1(ML-1) “the procedures of regulatory approval related to registration of generic drugs, shall be made in line with the guidelines of international regulatory agencies, for which implementation of Bio-equivalence study should be initiated.” The Board decided the systematic implementation of Bio-equivalence study in accordance with the WHO and International guidelines.

The Board also suggested to the Division of Pharmacy Services, DRAP to facilitate the process of establishment/approval of new centres for BE studies as per the Bio Study rules 2017.

Accordingly, a number of meetings were conducted with stakeholders to develop a roadmap for implementation of bio-equivalence. Consequently, final meeting was held on 4th June, 2025 in Committee Room, Drug Regulatory Authority of Pakistan, Prime Minister’s National Health Complex, Park Road, Islamabad. The meeting was chaired by Dr. Obaidullah, CEO DRAP and was participated by the representatives from DRAP, PPMA and Pharma Bureau.

The following risk based criteria for selection of molecules for BE studies was discussed:-

- a) Biopharmaceutics Classification System (BCS) Class IV-Drugs;
- b) Drugs having a narrow therapeutic range / index;
- c) Drugs used in National programs including: Malaria Control Programme, Tuberculosis (TB) Control Programme, Human immunodeficiency virus (HIV)/ acquired immune deficiency syndrome (AIDS) control program and belongs to BCS Class-II and IV.

Resultantly, a roadmap was recommended for placement before the Registration Board. The same was placed before the Board.

Decision:

- a. The Board deliberated that the implementation of Bioequivalence is a further step forward to enhance the safety and efficacy of pharmaceutical products and is also in line with its previous decision taken in 338th Meeting that aligns with the provisions of S.R.O. 713(I)/2018 and recommendations of World Health Organization’s (WHO) made in the Global Benchmarking of Pakistan’s National Regulatory System (NRS).
- b. Accordingly, the Board decided to implement the recommended roadmap which includes phased implementation. In Phase-I the compulsory submission of Bioequivalence studies for the following drugs shall be implemented from date of notification, which shall be issued without waiting for finalization of minutes:

Sr. No	Drug Substance	Pharmacological class	BCS Class	Therapeutic Window
1.	Abiraterone acetate	Anti-androgen (Prostate cancer)	IV	Large

2.	Acyclovir	Anti-viral	IV	Large
3.	Avacopan	Immunosuppressant	IV	Large
4.	Avapritinib	Anticancer	IV	Large
5.	Azathioprine	Immunosuppressant	IV	Large
6.	Clonidine	Cardio Vascular Drugs (Hypotensive agent)	I	Narrow ϕ
7.	Cyclosporin	Immunosuppressant	II	Narrow *, †, ϕ
8.	Digoxin	Cardiac glycoside	IV	Narrow *, †, ϕ
9.	Ethinyl Estradiol	Oral contraceptive	I	Narrow ϕ
10.	Everolimus	Immunosuppressant / anticancer	III	Narrow *, †
11.	Haloperidol	Antipsychotic	IV	Large
12.	Isoprenaline	Cardio vascular drugs (Adrenergic drug)	III	Narrow ϕ
13.	Lapatinib	Anticancer	IV	Large
14.	Lithium Carbonate	Antipsychotic / anti manic	I	Narrow *, †, ϕ
15.	Mercaptopurine	Immunosuppressant	IV	Large
16.	Methotrexate	Anticancer	IV	Narrow ϕ
17.	Mifepristone	Antiprogestogen for abortion	IV	Large
18.	Phenytoin Sodium	Anti-epileptic	II	Narrow *, †, ϕ
19.	Ponesimod	Immunosuppressant	IV	Large
20.	Procainamide	Cardio vascular drugs (Antiarrhythmic)	III	Narrow ϕ
21.	Quinidine	Cardio vascular drugs (Antiarrhythmic)	I	Narrow ϕ
22.	Relugolix	Gonadotropin-releasing hormone receptor antagonists.	IV	Large
23.	Levothyroxine	Hormone	III	Narrow *, †
24.	All Anti-TB drugs (both single ingredient as well as in combination requiring BE studies as per BCS criteria)			
25.	All Anti-HIV / AIDS Drugs (both single ingredient as well as in combination requiring BE studies as per BCS criteria)			

* USFDA, † EMA, ‡ Health Canada, ϕ Japan

b. Approval to Process Solvent Component of Ciprofloxacin Dry Suspension in Approved Section.

M/s. Solaris Life Sciences Private Limited, Rawat has submitted a request wherein they have stated as under:

“We would like to inform you that our product, Ciprofloxacin Dry Suspension, has been approved under DRB M-347 in accordance with USP specifications, containing Ciprofloxacin base. The innovator’s formulation includes a reconstitution solvent composed of soya lecithin, medium chain triglycerides, flavor, sucrose, and purified water. This solvent is an essential part of the product and is critical for ensuring appropriate solubility and bioavailability of the active ingredient. Its absence significantly compromises the product’s intended therapeutic performance.

The Given solvent comprises only excipients and is presented in a separate container as a part of the finished product; it should not be considered as separate drug requiring individual registration. Furthermore, its preparation does not involve any pharmacological active substances or pose cross-contamination risks. Therefore, it does not required special processing equipment or a separate manufacturing area.

It is well precedented that several approved products already available in the market containing the active ingredient in sachet form, accompanied by a separate solvent provided in a glass bottle. We intend to provide the solvent using dedicated equipment within the same approved section used for the dry suspension. This approach ensures continuity of quality control and regulatory compliance as per the USP monograph, while also aligning with innovator product practices.

We are respectfully requesting you to grant us permission to process with all necessary procedure to comply USP standards for the Ciprofloxacin Dry Suspension. This will enhance compliance and ensure product quality in line with established regulatory and pharmacopeial standards.”

Registration Board in its 290th meeting considered the case “**Manufacturing Requirement of Diluent for Ciprofloxacin Dry Powder Suspension**”. Case is being reproduced as under:

• **Description of reference product:**

Ciprofloxacin Oral Suspension is a white to slightly yellowish suspension with strawberry flavor which may contain yellow-orange droplets.

It is composed of ciprofloxacin microcapsules and diluent which are mixed prior to dispensing.

The components of the suspension have the following compositions:

- Microcapsules—ciprofloxacin, povidone, methacrylic acid copolymer, hypromellose, magnesium stearate, and Polysorbate 20.
- Diluent—medium-chain triglycerides, sucrose, lecithin, water, and strawberry flavor.
- Five (5) mL of 5% suspension contains approximately 1.4 g of sucrose and 5 mL of 10% suspension contains approximately 1.3 g of sucrose.
- USP 41 monograph of —Ciprofloxacin suspension¹, mentions Ciprofloxacin RS instead of Ciprofloxacin

HCl RS for identification and other tests. Hence it could be inferred that Ciprofloxacin suspension contains

Ciprofloxacin in base form.

- Registration Board in previous meetings has deferred the applications of Ciprofloxacin suspension for deliberation upon manufacturing requirement of diluent.
- In this regard it is pertinent to mention that it is evident that the efficacy and bio-availability of ciprofloxacin has only been established with the above mentioned diluent. Hence like other formulations wherein diluent is integral part of the formulation for re-constitution and it is registered separately, the diluent for Ciprofloxacin suspension may be registered separately. But since this diluent does not have any Pharmacopoeial monograph so it will be more suitable that the diluent may be registered along with the drug and hence the overall quality of the product may be controlled as per USP monograph after reconstitution with the said diluent.
- The case is presented before the Board for consideration.

Decision of 290th meeting of the Board

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

- **All registration holders of ciprofloxacin granules for oral suspension shall ensure the supply of ciprofloxacin granules along with the solvent / diluent having following composition as per the innovator product.**

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

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

Submitted for consideration of the Board.

Decision:

Registration Board after the detailed deliberations decided to encourage the practice of providing diluent containing Soya Lecithin and other ingredients with Ciprofloxacin Dry Suspension in line with the approved products in the US FDA. This step is also in line with the already taken decision of the Registration Board taken in its 290th meeting. It was decided that no separate Registration for inclusion of Diluent with Ciprofloxacin Dry Suspension is required. As far as manufacturing in the Dry Suspension Area is concerned, the applicant shall approach Division of Drug Licensing to obtain the permission for provision of Diluent Manufacturing Area for Dry Powder Suspension.

c. Registration of Sildenafil, Tadalafil & Vardenafil Tablets

Registration Board in its 345th and 347th meeting approved various products containing Sildenafil, Tadalafil & Vardenafil Tablets. The Board in its 347th meeting direction to conduct product specific inceptions of all drug products containing Sildenafil, Tadalafil & Vardenafil in Tablet dosage, which are approved in said meetings, before issuance of registration letter by the panel constituted by Chairman Registration Board.

In light of above decision of the Board, panel has submitted product specific inspection reports which are being presented for consideration of the Registration Board.

Proceeding of 348th Meeting:

Following report has been Presented before Registration Board:

Status of Product Specific Inspections of Sildenafil, Tadalafil, Vardenafil for the Registration Board.			
I	II	III	IV
Names of firms whose data has been verified against the data submitted to DRAP.	Names of firms that performed stability testing but whose data could not be verified due to changes in area, retention time of chromatograms etc.	Names of the firms having data other than the data submitted to DRAP.	Names of firms whose data could not be verified due to malfunctioning/ out-of-order HPLC system
M/s Crystolite Pharmaceuticals Plot # 1 & 2 Street S-2 National Industrial Zone, Rawat (000778).	M/s Focus & Rulz Pharmaceuticals (Pvt.) Ltd., Plot No. 44, industrial triangle, Kahuta Road, Islamabad (000628).	M/s Shaigan Pharmaceuticals (Pvt.) Ltd., 14-km Adyala Road, Post Office Dahgal, Rawalpindi (000333).	Pacific Pharmaceutical Ltd 30 km Multan Road Lahore (000295)
M/s Solaris Life Sciences (Pvt.) Ltd., Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat (000992).	M/s NovaMed pharmaceuticals (Pvt.) Ltd 28-KM Ferozepur Road Lahore (000590)	M/s Wimits Pharmaceuticals Pvt. Limited, Plot No. 129, Sunder Industrial Estate Raiwind Road, Lahore (000789) .	M/s Fynk Pharmaceuticals, 19-km G. T. Road, kalaShah Kaku, Lahore (000494) .
M/s Gray's Pharmaceuticals, Plot No.2, Street No. N-3, National Industrial Zone, Rawat (000518).	M/s Bio-Labs(Pvt.) Ltd Plot 145, Industrial Triangle, Kahuta Road (000296)	M/s Macter International Ltd., F-216, S.I.T.E., Karachi (000141).	M/s Vision Pharmaceuticals Pvt. Ltd Plot#22-23, Industrial Triangle, Kahuta Road, Islamabad. (000517)
M/s Highnoon Laboratories Ltd., 17.5 Km Multan Road, Lahore (000155).	M/s Quaper (Pvt.) Ltd., 26-A, Small Industrial Estate, Lahore Road, Sargodha (000609). Data of one Strength of Sildenafil tablet i.e. 50mg, was not verified.		M/s Caliph Pharmaceuticals Plot 17, Special Industrial Zone Risalpur, KPK (000748)

M/s Quaper (Pvt.) Ltd., 26-A, Small Industrial Estate, Lahore Road, Sargodha (000609). Data of one Strength of Sildenafil tablet i.e. 100mg, was verified.	M/s Medizan Laboratories (Pvt.) Ltd Plot No. 313 Industrial Triangle Kahuta Road Islamabad (000572)		
M/s Hilton Pharma (Pvt.) Ltd, Plot No. 13-14 & 43, Sector 15, Korangi Industrial Area Karachi (000136).			
M/s AGP Limited B-23-C, S.I.T.E., Karachi (000348).			
M/s Nabiqasim Industries Private Limited., 17/24, Korangi Industrial Area, Karachi (000105).			
M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E, Karachi (000083).			
M/s Orbis Pharmaceuticals, Plot No. K/138, Phase-II, S.I.T.E., Karachi (000979).			
M/s Genix Pharma (Pvt.) Ltd., Plot No. 44-45-B, Korangi Creek Road, Karachi (000351).			
M/s Platinum Pharmaceuticals A-20, North Western Industrial Zone Bin Qasim, Karachi (000415)			

Decision: Registration Board after through deliberation decided as under:

- i. To issued registration letters to firms mentioned in Column-I without waiting for finalization of minutes.
- ii. To issue show cause / personal hearing notices to all firms mentioned in Column-II-IV and give them personal hearing in the forthcoming meeting i.e., 349th scheduled to be held on 14th July, 2025.
- d. The Board keeping in view of deficient human resource at DRAP to conduct GMP inspections and after detailed deliberations clarified that GMP certificate is issued to companies on their request mainly for export purpose or for tender business, therefore, for issuance of registration certificates of approved products, GMP certificate is not a pre-requisite, except wherein, the Registration Board has specifically directed to verify GMP certificate/Inspection report of the firm.

Pharmaceutical Evaluation Cell (PEC)

Agenda of Adil Saeed (DD PEC-IX)

1.	Name, address of Applicant / Marketing Authorization Holder	M/s MTI Medical (Pvt.)Ltd. 586-587 Sundar Industrial Estate, Lahore.
	Name, address of Manufacturing site.	M/s MTI Medical (Pvt.)Ltd. 586-587 Sundar Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 22605 dated 30.08.2023
	Details of fee submitted	PKR 30,000 /- Vide Slip No. 5155414525
	The proposed proprietary name / brand name	Amphocin 50mg Lyophilized Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Liposomal Amphotericin B.....50mg
	Pharmacotherapeutic Group of (API)	ANTIMYCOTICS FOR SYSTEMIC USE ATC Code J02AA01
	Reference to Finished product specifications	As per Innovator Specifications
	The status in reference regulatory authorities	AMBISOME USFDA approved
	For generic drugs (me-too status)	
	Proposed Pack size	1's
EVALUATION OF DATA		
GMP status of the firm	GMP certificate valid till 30.01.2025 is submitted	
Evidence of approval of manufacturing facility		
Name and address of API manufacturer.	M/s. North China Pharmaceutical Huasheng Co., Ltd. No.8 Yangzi Road, Shijiazhuang Economic and Technological Development Zone, Hebei 052160, China	
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.	
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.	
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 2 °C - 8 °C for 36 months Accelerated: 25°C ± 2°C / 60% ± 5%RH for 6months Batches: HAN0406303, HAN0406304, HAN0407301	
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.	
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence performed against Ambisome Batch No. 03035D1	

Analytical method validation/verification of product		Firm has submitted analytical method validation study reports for drug substance as well as drug product.	
STABILITY STUDY DATA			
API Lot No.	HAN210520IU		
Description of Pack (Container closure system)	Glass Vial		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	AB-001	AB-002	AB-001
Batch Size	1011 vials	3000 vials	1000 vials
Manufacturing Date	08.2021	08.2021	08.2021
Date of Initiation	09.2021	09.2021	09.2021
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			
Reference of previous approval of applications with stability study data of the firm (if any)	NA		
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	No Submitted		
Documents for the procurement of API with approval from DRAP (in case of import).	Not Submitted		
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted		
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted		
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted		
Evaluation by PEC (No IX):			
Sr. No.	Observation	Reply	
1.	Copy of Fee slip is required	The firm has submitted their response vide letter No. nil dated 15.05.2025. Copy of fee slip is submitted (Slip No. 5155414525)	
2.	Evidence of me-too product is required.	Amphogen 50mg Reg No. 045800 by ferozsans.	
3.	3.2.P.2 Pictorial evidence of reference product used in pharmaceutical equivalence is required.	Images of AmBisome Liposomal Amphotericin B 50mg Injection batch No. 030345D1 is submitted	

4.	3.2.P.2 The method for preparation of liposomes needs to be submitted with more detail. The submit method does not give specifications of injections used for preparation of liposomes. The area requirements (Class A maintenance/ isolator) and precautions are also not mentioned.	Firm has submitted that product is lyophilized product, no detailed procedure is submitted regarding preparation of liposomes.
5.	3.2. P.2. The range of size of liposomes is not mentioned in step of size reduction.	The firm has stated that size of liposomes will be between 70nm-130nm. The step of size reduction will be included in section 3.2.P.2.
6.	3.2.P.5 In drug product specifications, content of Amphotericin A is not included.	Firm has stated that product complies with innovator specifications and innovator specifications do not state the Amphotericin A content to be performed. Further firm has stated that USP monograph of Amphotericin B for injection also does not require to perform this test.
7.	3.2.P.5.4 In batch analysis, under heading “Calculations for untrapped Drug”, the absorbance value A is mentioned as 0, as per method submitted, the absorbance is taken in a UV Vis spectrophotometer at wavelength of 383nm. In case of UV spectrophotometry, the instrument cannot give a zero value, it indicates that zero value is just mentioned without performing the analysis.	The firm has stated that that UV method was developed in order to test the entrapped and untrapped drug in liposomal encapsulation. Drug on bulk stage. Beer-Lambert law articles are attached which exhibit that absorbance of spectrophotometer can be zero. Moreover if there is no drug present in untrapped form then reading can be zero.
8.	3.2.P.5 Justification is required that how wavelength of 383nm was selected for performance of analysis.	The firm has states that they have selected this wavelength based on an article (Ambisome Formulations for pediatrics: Stability Cytotoxicity, and costeffectiveness studies, Guendalina et. al. 2024.)
9.	3.2.P.5 The method for liposome size analyses is not submitted. Further evidence is required that facility for liposomal size analyses is available (Zeta sizer)	The firm has stated that this test is performed by third party laboratory. Firm has submitted generic agreement with Bin Rasheed Scientific Pvt. Ltd. 338 Bin Rasheed Square SIE Raiwind Road Lahore. The company Bin Rasheed Scientific appears to be a supplier of scientific equipments rather than a testing laboratory as per their website. Further this test of size analysis is very critical and needs to be performed multiple times during size reduction step to ensure that required sized liposomes are obtained at the end of the milling process. For this, in-house particle size analysis facility is needed.
10.	3.2.P.5 Justification is required why HPLC method of analysis is not used for assessing the entrapped and untrapped drug.	The firm has stated that there are multiple published studies/articles performed on innovator product wherein UV method is used for assessment of drug.

11.	3.2.P.8 In stability studies, particle size analysis and Amphotericin A content tests are not part of stability studies.	Firm has stated that particle size is assured on the finished stage and not required in stability studies. Moreover Amphotericin A content is not required by innovator as well as USP.
12.	Executed production documents of trial batches are required.	Firm has stated that product was registered for export purpose and stability was performed on the commercial scale batches. Copies of BMRs are not submitted. The firm has submitted copy of Export registration letter dated 07.05.2021 wherein in Amphocin Lyophilized Injection 50mg is registered vide Reg. No. 010883.
13.	Evidence of existence, maintenance and approval (from licensing board) of manufacturing facility, including area/rooms for liposomes preparation, size reduction and dialysis is required.	Firm has stated that international guidelines do not require separate or dedicated facility for the manufacturing of liposomal products. The claim of firm is not justifiable. Product of liposomes does require extra steps like liposomes preparation, size reduction, dialysis and drug loading. These steps require specialized equipment and placement of equipment needs to be under Controlled conditions to maintain sterility throughout the process.
14.	Evidence of testing facility for liposomes is required (animal house for abnormal toxicity, zeta sizer for particle size analysis etc)	Firm has stated that they do have animal house where abnormal toxicity studies are performed. And particle size analysis is done by third party.
15.	AD attested invoice or clearance certificate for import of drug substance is required.	Copy of AD attested invoice mentioning 1kg of Amphotericin B is submitted.
16.	Copy of GMP certificate or DML of drug substance manufacturer is required.	Submitted.

Decision: Deferred for following;

- **The firm shall establish in-house facility for particle size analysis of liposomes.**
- **Product Specific Inspection by panel constituted by the Chairman Registration Board.**
- **Pharmaceutical equivalence studies performed against innovator product by any government lab on cost of applicant.**

2.	Name, address of Applicant / Importer	M/s AMGOMED Office # 4, First Floor Ghausia Plaza, Jinnah Avenue Blue area Islamabad Pakistan
	Details of Drug Sale License	License No: DSL-002-ICT/2013 Address: Amgomed office # 4, First floor Ghausia Plaza, Jinnah Avenue Blue area Islamabad Address of Godown: Office number 5, First floor Rose-I plaza, I-8, Markaz Islamabad. Validity: 30/01/2022 Status: Drug License by way of Wholesale

Name and address of marketing authorization holder (abroad)	M/s DEVA Holding A.S., Halkali Merkez Mah. Basın Ekspres Cad. No:1 34303 Kucukcekmece – Istanbul/Turkey.
Name, address of manufacturer(s)	M/s DEVA Holding A.S. Çerkezköy Organize Sanayi Bölgesi, Karaağaç Mah. Fatih Bulvarı No: 26, Kapaklı - TEKIRDAG/TURKEY.
Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
Name of exporting country	Turkey
Detail of certificates attached (CoPP, Free sale certificate, GMP certificate) • Copy of GMP certificate No.TR/GMP/2019/31 dated 28/01/2019 issued by Turkish Medicines and Medical Devices Agency. (Dosage form: SVP / Special requirements: Anticancer (oncologic) liquid injectable vials / Activities: manufacturing at sterile liquid oncologic (anticancer) manufacturing site). • Firm has submitted original, legalized COPP certificate (No. 2020/1390) dated 22-05-2020 issued by Republic of TURKEY MEDICINE AND MEDICAL DIVICES AGENCY For Carbodex 150mg/15mL solution for IV infusion. The applied product is available for free sale in the market of exporting country. The facilities and operations conform to WHO-GMP. The COPP is valid till 03-06-2022. Details of letter of authorization / sole agency agreement: • Copy of letter of authorization is submitted whereby M/s DEVA Holding A.S., Turkey authorized M/s AMgomed to apply for registration, for marketing, distribution and sale of below mentioned product; Carbodex 150mg/15ml solution fir IV injection. The authorization letter is valid till 15-06-2022.	
Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No.17502 : 23/06/2021
Details of fee submitted	PKR 100,000/- : 30-09-2020
The proposed proprietary name / brand name	Carbodex 150mg/15ml Solution for IV Infusion
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Carboplatin.....10mg
Pharmacotherapeutic Group of (API)	Antineoplastic agent
Reference to Finished product specifications	Present in BP (in-house applied)
The status in reference regulatory authorities	Carboplatin 150mg/15ml, concentrate for solution for infusion by M/s Accord Healthcare Limited, MHRA Approved.
For generic drugs (me-too status)	Carboplat 150mg/15ml solution for injection by M/s Rotex Pharma pvt ltd.
Proposed Pack size	As per SRO

Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and product.
Name, address of drug substance manufacturer	Manufacturer: M/s Sicor De Mexico S.A de C.V Av. San Rafael No. 35 Parque Industrial Lerma, Edo. De Mexico C.P 52000, Mexico.
Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	• Real time stability studies have been conducted at 25oC±2 and 60%RH±5% for 60 months of 3 batches • Accelerated stability study is conducted at 40oC±2 and 75%RH±5% for 6 months of 3 batches Batches: (03CBP02A-0CH, 97CBP01A-OC, 97CBP02A-OC)
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence is established against DBL Carboplatin 150mg/15ml by M/s Hospira by performing
Analytical method validation/verification of product	Not submitted.

	Container closure system of the drug product	Amber colored type I glass ampoule
	Stability study data of drug product, shelf life and storage conditions	- Real time stability studies have been conducted at 30oC±2 and 65%RH±5% for 36 months of 3 batches - Accelerated stability studies is conducted at 40oC±2 and 75%RH±5% for 6 months of 3 batches Batches: (A035176, A035177, A035178)

Evaluation by PEC (No I):

Sr. No.	Observation	Reply
1.	Official monograph for Carboplatin drug substance is present in USP/BP while the testing is done according to in-house standard, please clarify.	The firm has submitted their response vide letter No. nil dated 15.05.2025.
2.	Analytical method verification studies performed by drug product manufacturer for drug substance along with the complete method for routine analysis is required.	Analytical verification studies performed by drug product manufacturer are submitted according to In-House specifications.
3.	Stability study data including accelerated and real time for 03 batches is required till shelf life/retest period for the drug substance should be submitted.	No response is submitted against this observations.
4.	Since the official monograph for Carboplatin injection is present in B.P while the applied product is developed according to In-House standards. Provide scientific justification and comparison of BP and In-House specifications or provide complete analysis of all parameters for applied product as described in B.P along with the submission analytical method verification studies including accuracy, specificity and precision.	The has not provided a comparison of In-House and B.P specifications and no clarification is submitted as well regarding the In-House specifications.

Decision of 320th RB:

The Board deferred the case for submission of;

- Clarification since the official monograph of the Carboplatin drug substance present in USP/BP while the testing is done according to in-house standards.**
- Submission of Stability study data including accelerated and real time for 03 batches is required till shelf life/retest period for the drug substance.**
- Since the official monograph for Carboplatin injection is present in B.P while the applied product is developed according to In-House standards. Provide scientific justification and comparison of BP and In-House specifications or provide complete analysis of all parameters for**

applied product as described in B.P along with the submission analytical method verification studies including accuracy, specificity and precision.

Evaluation by PEC-IX

Observation	Response
Clarification since the official monograph of the Carboplatin drug substance present in USP/BP while the testing is done according to in-house standard	Carbodex 150 mg / ml solution for infusion are tested as per official BP Monograph along with some additional test designed In-House as per the general monograph of Eur. Pharmacopeia. Hence, we are following all the tests of official monograph of BP and some additional tests from Eu. Monograph. Please allow us to claim BP specifications for Carbodex 150 mg / 15ml.
Submission of Stability study data including accelerated and real time for 03 batches is required till shelf life/retest period for the drug substance.	Specifications, Analytical methods and Validation of analytical methods as per BP and Eur.ph is attached.
Since the official monograph for Carboplatin injection is present in B.P while the applied product is developed according to In-House standards. Provide scientific justification and comparison of BP and In-House specifications or provide complete analysis of all parameters for applied product as described in B.P along with the submission analytical method verification studies including accuracy, specificity and precision.	Specifications, Analytical methods and Validation of analytical methods as per BP and Eur.ph is attached.

Decision: Approved as per policy of inspection of manufacturer abroad.

Agenda of Maham Misbah (DD PEC)

Case No. 1: Previously deferred cases of Form 5 (Human)

3.	Name and address of manufacturer / Applicant	"M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar"
	Diary No. Date of R& I & fee	Dy.No 32459 dated 28-09-2018 Rs.20,000/- Dated 28-09-2018
	Brand Name +Dosage Form + Strength	Finast 5mg Tablets
	Composition	"Each Film Coated Tablet Contains: Finasteride...5mg"
	Pharmacological Group	Drugs Used In Benign Prostatic Hypertrophy G04CB01 Testosterone-5-alpha reductase inhibitors
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Proscar® (Finasteride) Film Coated Tablets USFDA Approved.
	Me-too status	053361 Prostryl Tablets 5mg M/s Novins International (Pvt) Ltd
	GMP status	04-09-2018 & 26-09-2018. Conclusion:

		As per observation made, facilities of production and quality control inspected, technical staff employed and keeping in view the overall GMP compliance status of the firm, the panel unanimously recommends the renewal of DML 000614 by way of formulation granted to M/s Welmark KPK.
	Remarks of the Evaluator.	
	Decision of 293rd meeting: Deferred for the confirmation of manufacturing facility for the said product.	
	Response of applicant: DML renewal letter No. F.3-3/2006-Lic (Vol-III) dated 06-02-2025 from Licensing Division, DRAP specifies Tablet (general) section. Inspection for DML renewal was conducted on 19-09-2024.	
	Remarks of Evaluator:	
	Decision: Approved.	
4.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651)
	Brand Name + Dosage Form + Strength	CLINDEX LOTION 1% (w/v)
	Composition	Each mL contains: Clindamycin (as phosphate) 10mg
	Diary No. Date of R& I & fee	Dy No.14066 dated 07-03-2019 Fee paid PKR20,000/- vide Deposit Slip No. 0610387 dated 07-03-2019.
	Pharmacological Group	Antiinfectives for treatment of acne ATC Code D10AF01
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	30mL ; As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved
	Me-too status	Veclin-T Lotion M/s. Shrooq Pharmaceuticals Reg. No. 100599
	GMP status	Same as above
	Remarks of the Evaluator ^{xxiii} .	- Evidence of required manufacturing facility / section (External liquid preparation; general antibiotics) from Licensing Division DRAP is required. - Latest GMP inspection report is required (inspection should have been conducted within last three years) clearly mentioning relevant section.
	Decision of 336th meeting: Deferred for submission of response to above-cited shortcomings.	
	Response of Applicant: - Copy of Letter No. F.1-53/2023-Lic (Vol-II) dated 10-03-2021 on the subject Grant of additional/amended sections from Licensing Division of DRAP specifies Cream/Ointment/Lotion section. - GMP certificate issued on the basis of inspection conducted on 20-02-2024 specifies Cream/Ointment/Lotion (general) section	
	Remarks of Evaluator:	
	Decision: Approved.	
5.	Name and address of manufacturer / Applicant	M/s Theramed Pharmaceutical (Pvt) Ltd., 45-Km, Multan Road, Lahore.
	Brand Name + Dosage Form + Strength	Ebtin 5mg/5ml Syrup

Composition	Each 5ml contains: Ebastine ... 5mg
Diary No. Date of R& I & fee	D#7768, PKR 20,000/-:04-07-2017
Pharmacological Group	Antihistamine
Type of Form	Form 5
Finished Product Specification	Firm has claimed in house specification
Pack Size & Demanded Price	30ml, 60ml: As per SRO
Approval status of product in Reference Regulatory Authority	NA
Mee-too status	Kestine 5mg/5ml by Highnoon
GMP status	GMP inspection certificate dated 10-10-2017 showing GMP compliance.
Remarks of the Evaluator	No BP or USP monograph is available. Kestine 1mg/ml by Laboratory Almira, S.A (AEMPS approved) can't be verified.
Decision of 282nd meeting: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275 th meeting.	
Response of Applicant: Applicant has submitted reference of product approved in Spain with following details: Brand name Ebastel 1mg/ml oral solution, MAH: Almira, S.A. General Mitre, 15108022, Barcelona, Spain; Marketing Authorization No. 58358. The details are verifiable from the link https://cima.aemps.es/cima/publico/detalle.html?nregistro=58358	
Remarks of Evaluator:	
Decision: Approved.	

Agenda of Saima Hussain (DD PEC)

6.	Name, address of Applicant / Marketing Authorization Holder	M/s Fortune Pharmaceuticals Private Limited Karachi
	Name, address of Manufacturing site.	M/s Fortune Pharmaceutical Private Limited Plot K/201 S.I.T.E. (SHW) Phase II, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.12972 dated 27/05/2022
	Details of fee submitted	PKR 30,000/-: dated 27/04/2022
	The proposed proprietary name / brand name	Fungazole 150mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Fluconazole...150mg
	Pharmaceutical form of applied drug	A dark blue cap with blue body size "3" hard Gelatin filled capsule having white pallets.

Pharmacotherapeutic Group of (API)	Antifungal
Reference to Finished product specifications	BP
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
The status in reference regulatory authorities	MHRA approved
For generic drugs (me-too status)	Zolanix 150mg capsule of M/s. Glaxo smithkline,Karachi
GMP status of the Finished product manufacturer	New license granted on 21/02/2021 Tablet (General & General Antibiotic) section approved.
Name and address of API manufacturer.	Hema Pharmaceuticals Plot no.6201/A&B Opp. Ewac Alloys Ltd. GIDC Ankleshwar,Gujrat,India
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
Module III (Drug Substance)	Official monograph of Fluconazole is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (12PDFC001,12PDFC002,12PDFC003)
Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the comparator product that is Flozex

		capsule of M/S. Martin Dow Pharmaceuticals Pvt. Ltd,Karachi Batch no. 225 expiry date 03-2023. performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Flozex capsule of M/S. Martin Dow Pharmaceuticals Pvt. Ltd,Karachi Batch no. 225 expiry date 03-2023.in Acid media (pH 1.2), pH 4.5 & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.	
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificty.	
STABILITY STUDY DATA			
Manufacturer of API		Hema Pharmaceuticals Plot no.6201/A&B Opp. Ewac Alloys Ltd. GIDC Ankleshwar,Gujrat,India	
API Lot No.		Not mentioned	
Description of Pack (Container closure system)		Alu-Alu blister packed in unit carton (1×14's)	
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH	
Time Period		Real time: 6 months Accelerated: 6 months	
Frequency		Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.		FL-001	FL-002 FL-003
Batch Size		1500 capsule	1500 capsule 1500 capsule
Manufacturing Date		10-2021	10-2021 10-2021
Date of Initiation		25-10-2021	25-10-2021 25-10-2021
No. of Batches		03	
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document. Because of new DML	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP Certificate No. S-GMP/2062028 dated 12-06-2020 valid till 11/06/2022	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Consignment slip and DHL courier slip has been attached only	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	HPLC software 21CFR not Installed	

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks OF Evaluator:		
Sr.no.	Observations/Shortcomings	Reply of the Form
1.	Clarify the specification of drug product since the JP monograph of fluconazole capsule is not applicable for 150mg strength. Revise your specification along with the requisite fee.	Firm submitted the revised specification of drug product which is neither in comply of BP monograph nor in compliance of JP.
2.	The validation of analytical procedure has been performed using assay method (HPLC) with flow rate 1.0ml/min, column temperature 35°C, UV detector set at 261nm and mobile phase sodium acetate: methanol: acetonitrile while USP recommended flow rate 0.5ml/min, column temperature 40°C, UV detector 260nm and mobile phase Acetonitrile and water (20:80). Justify, how have comply USP specification by keeping the chromatographic condition different from USP monograph of fluconazole.	Not submitted
3.	Clarify, how you have performed accuracy parameter in the verification studies of drug substance that, despite spiking the sample 25%,50%,75%,100%,125% and 150%, the amount of fluconazole has not been changed in all these spiked sample.	Not submitted any reply of this query
4.	Identification test specified on the COA of working standard of fluconazole attached in section 3.2.S.5 stated that IR absorption spectrum of test solution should be concordant with that of clotrimazole working standard, clarification is required in this regard. Further, the COA reflect that batch qualified against Indian pharmacopeia reference standard, justify how you can standardize the drug substance that comply with USP specification to the working standard that qualified against Indian pharmacopeia.	.Not submitted any reply of this query
5.	Scientific justification is required for using 3mg overage of active substance as evident from the composition given in section 3.2. P.1.	Firm has not submitted any reply.
6.	Clarify, that the dissolution method given in section 3.2.P.5.2 is different from the method via which dissolution has been performed in section 3.2.P.2.2.1 for comparative dissolution profile of drug product.	Firm submitted the revised Comparative dissolution profile in which the dissolution were not in accordance with BP monograph.
7.	Justify selection of dissolution parameters i.e. USP apparatus-II paddle with 50rpm, water as dissolution medium and	Firm has not submitted any justification regarding these queries.

	acceptance criteria NLT 75% of the labeled amount of the claim content, since JP monograph of fluconazole capsule is recommending the dissolution testing for 50mg and 100mg fluconazole capsule strength. Justify the variation in dissolution parameters in different section of dossier, acceptance limit specified in section 3.2.P.5.2 is NLT 75% in 45 minutes while the dissolution specifications mentioned on batch analysis report is NLT 80%.	
8.	Provide complete analytical method verification studies of drug product including the specificity and repeatability parameter along with raw data sheets and chromatogram.	Not submitted.
9.	Justify the weight of sample between 33-34mg, while as per the analytical method given in section 3.2.P.5.2 the weight of content equivalent to 50mg of fluconazole should be taken initially for preparation of final dilution of sample solution.	Not submitted
10.	Provide COA of primary / secondary reference standard including source and lot number used for testing of drug product.	Not submitted
11.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted

Decision of 322nd meeting: Deferred for submission of following:

- Clarify the specification of drug product since the JP monograph of fluconazole capsule is not applicable for 150mg strength. Revise your specification along with the requisite fee.
- The validation of analytical procedure has been performed using assay method (HPLC) with flow rate 1.0ml/min, column temperature 35°C, UV detector set at 261nm and mobile phase sodium acetate: methanol: acetonitrile while USP recommended flow rate 0.5ml/min, column temperature 40°C, UV detector 260nm and mobile phase Acetonitrile and water (20:80). Justify, how have comply USP specification by keeping the chromatographic condition different from USP monograph of fluconazole.
- Clarify, how you have performed accuracy parameter in the verification studies of drug substance that, despite spiking the sample 25%,50%,75%,100%,125% and 150%, the amount of fluconazole has not been changed in all these spiked sample.
- Identification test specified on the COA of working standard of fluconazole attached in section 3.2.S.5 stated that IR absorption spectrum of test solution should be concordant with that of clotrimazole working standard, clarification is required in this regard. Further, the COA reflect that batch qualified against Indian pharmacopeia reference standard, justify how you can standardize the drug substance that comply with USP specification to the working standard that qualified against Indian pharmacopeia.
- Justify, for adopting the dissolution parameter specified in JP monograph, since the JP monograph recommends the acceptance limits for 50mg and 100g fluconazole strength.
- Provide complete analytical method verification studies of drug product including the specificity and repeatability parameter along with raw data sheets and chromatogram.
- Provide COA of primary / secondary reference standard including source and lot number used for testing of drug product.
- Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

Response of the Firm:		
Sr.no.	Decision of 322 nd meeting of Registration Board	Response of the Firm
1.	Clarify the specification of drug product since the JP monograph of fluconazole capsule is not applicable for 150mg strength. Revise your specification along with the requisite fee.	Firm submitted the copy of monograph of fluconazole drug substance instead of replying about the specification of drug product.
2.	The validation of analytical procedure has been performed using assay method (HPLC) with flow rate 1.0ml/min, column temperature 35°C, UV detector set at 261nm and mobile phase sodium acetate: methanol: acetonitrile while USP recommended flow rate 0.5ml/min, column temperature 40°C, UV detector 260nm and mobile phase Acetonitrile and water (20:80). Justify, how have comply USP specification by keeping the chromatographic condition different from USP monograph of fluconazole.	Not submitted the reply of this query.
3.	Clarify, how you have performed accuracy parameter in the verification studies of drug substance that, despite spiking the sample 25%,50%,75%,100%,125% and 150%, the amount of fluconazole has not been changed in all these spiked sample.	Not submitted the reply of this query.
4.	Identification test specified on the COA of working standard of fluconazole attached in section 3.2.S.5 stated that IR absorption spectrum of test solution should be concordant with that of clotrimazole working standard, clarification is required in this regard. Further, the COA reflect that batch qualified against Indian pharmacopeia reference standard, justify how you can standardize the drug substance that comply with USP specification to the working standard that qualified against Indian pharmacopeia.	Submitted the COA of working standard of fluconazole.
5.	Justify, for adopting the dissolution parameter specified in JP monograph, since the JP monograph recommends the acceptance limits for 50mg and 100g fluconazole strength.	Not submitted the reply of this query.
6.	Provide complete analytical method verification studies of drug product including the specificity and repeatability parameter along with raw data sheets and chromatogram.	Firm submitted the verification report.

7.	Provide COA of primary / secondary reference standard including source and lot number used for testing of drug product.	Not submitted the reply of this query.
8.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm replied that, they has not installed the 21CFR compliance HPLC system.

Decision of 340th meeting:

Deferred for submission of following:

- Clarify the specification of drug product since the JP monograph of fluconazole capsule is not applicable for 150mg strength. Revise your specification along with the requisite fee.
- The validation of analytical procedure has been performed using assay method (HPLC) with flow rate 1.0ml/min, column temperature 35°C, UV detector set at 261nm and mobile phase sodium acetate: methanol: acetonitrile while USP recommended flow rate 0.5ml/min, column temperature 40°C, UV detector 260nm and mobile phase Acetonitrile and water (20:80). Justify, how have comply USP specification by keeping the chromatographic condition different from USP monograph of fluconazole.
- Clarify, how you have performed accuracy parameter in the verification studies of drug substance that, despite spiking the sample 25%,50%,75%,100%,125% and 150%, the amount of fluconazole has not been changed in all these spiked sample.
- Justify, for adopting the dissolution parameter specified in JP monograph, since the JP monograph recommends the acceptance limits for 50mg and 100g fluconazole strength.
- Provide complete analytical method verification studies of drug product including the specificity and repeatability parameter along with raw data sheets and chromatogram.
- Provide COA of primary / secondary reference standard including source and lot number used for testing of drug product.

Response of the Firm:

Sr.no.	Decision of 340th meeting	Response of the Firm
1.	Clarify the specification of drug product since the JP monograph of fluconazole capsule is not applicable for 150mg strength. Revise your specification along with the requisite fee.	Firm replied that “Fluconazole Capsule 150mg strength is available in BP Monograph, so we have revised the Specification on BP Monograph and details is enclosed.”
2.	The validation of analytical procedure has been performed using assay method (HPLC) with flow rate 1.0ml/min, column temperature 35°C, UV detector set at 261nm and mobile phase sodium acetate: methanol: acetonitrile while USP recommended flow rate 0.5ml/min, column temperature 40°C, UV detector 260nm and mobile phase Acetonitrile and water (20:80). Justify, how have comply USP specification by keeping the chromatographic condition different from USP monograph of fluconazole.	Firm submit the analytical verification report of drug substance without including the results of accuracy parameter.
3.	Clarify, how you have performed accuracy parameter in the verification studies of drug substance that, despite spiking the sample 25%,50%,75%,100%,125% and 150%, the amount of fluconazole has not been changed in all these spiked sample.	Firm replied that, it was human error/typographical mistake has done, so we had validated the analytical procedure is as per USP Monograph, details is enclosed. However, results of accuracy parameters were not included in the submitted analytical verification report.

4.	Justify, for adopting the dissolution parameter specified in JP monograph, since the JP monograph recommends the acceptance limits for 50mg and 100mg fluconazole strength.	Firm replied that Fluconazole Capsule 150mg strength is available in BP Monograph, so we have revised the Specification on BP Monograph and details is enclosed. However, the assay procedure outlined by the applicant in their reply is not in accordance with BP monograph of fluconazole capsule.
5.	Provide complete analytical method verification studies of drug product including the specificity and repeatability parameter along with raw data sheets and chromatogram.	Submitted. However, the assay procedure outlined by the applicant in their reply is not in accordance with BP monograph of fluconazole capsule.
6.	Provide COA of primary / secondary reference standard including source and lot number used for testing of drug product.	Submitted the COA of reference standard bearing the validity date june,2021.

Decision of 343rd meeting of Registration Board:

Deferred for submission of following shortcomings:

- Submit analytical verification report of drug substance performed by drug product manufacturer including all three parameters of analytical verification studies.
- Submit assay method of drug product in accordance with BP monograph of Fluconazole Capsule and accordingly submit the performance report in-line with revised assay method performed at next time point of stability study.
- Provide COA of primary / secondary reference standard including source and lot number used for testing of drug product.

Response of the Firm:

Sr.no.	Shortcomings	Response of the Firm
1.	Submit analytical verification report of drug substance performed by drug product manufacturer including all three parameters of analytical verification studies.	The firm has submitted the verification report of the drug substance, which was performed by the drug product manufacturer. However, the target concentration (100% concentration) specified in the USP is 0.5 mg/mL, whereas the firm has used a target concentration of 1 mg/mL. Furthermore, the sample peak area obtained at 100% concentration is approximately 1,986,735 in the accuracy parameter, while the corresponding peak area at 100% concentration in the repeatability and system suitability parameters is around 3,928,334.
2.	Submit assay method of drug product in accordance with BP monograph of Fluconazole Capsule and accordingly submit the performance report in-line with revised assay method performed at next time point of stability study.	Firm has only submitted the revised analytical procedure of the drug product, without providing the corresponding performance report conducted at the next stability time point.
3.	Provide COA of primary / secondary reference standard including source and lot number used for testing of drug product.	Submitted

Decision: The Registration Board was observed that case was deferred for multiple times in previous Registration Board meetings. Despite being given several opportunities for clarification no adequate compliance was ensured by the firm. Hence, the Board decided to reject the instant case, on the following communicated shortcomings:-

- Assay verification report is not in line with the assay method of USP monograph.**

ii. Non submission of performance report of stability studies at next time point (after six months).		
7.	Name, address of Applicant / Marketing Authorization Holder	M/s Fortune Pharmaceuticals Private Limited Karachi
	Name, address of Manufacturing site.	M/s Fortune Pharmaceutical Private Limited Plot K/201 S.I.T.E. (SHW) Phase II, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 12391 dated 21/05/2022
	Details of fee submitted	PKR 30,000/-: dated 27/04/2022
	The proposed proprietary name / brand name	F -EZOLE 40mg Gastro resistant Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Esomeperazole Magnisium Trihydrate E.q to to Esomeperazole 40mg
	Pharmaceutical form of applied drug	A dark blue cap with blue body size “3” hard Gelatin filled capsule having white pallets.
	Pharmacotherapeutic Group of (API)	Drugs for acid-related disorders, Proton pump inhibitors
	Reference to Finished product specifications	USP
	Proposed Pack size	1×14’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	NEXIUM 40mg Capsule USFDA. Esomeprazole 40mg Gastro – resistant capsule MHRA
	For generic drugs (me-too status)	ACIREG CAPSUL 40 mg BARRETT HODGSON PAKISTAN (PVT) LTD
	GMP status of the Finished product manufacturer	New license granted on 21/02/2021 Tablet, Capsule (General & General Antibiotic) section approved.
	Name and address of API manufacturer.	SAAKH PHARMA. Address: Plot # C -7/1, North West Industrial Zone,Karachi
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers,

		description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Esomeprazole Mg is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (ESO-EC – 22.5-001-19, ESO-EC – 22.5-002-19, ESO-EC – 22.5-003-19)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is ACIREG CAPSULE 40 mg Capsule by BARRETT HODGSON PAKISTAN (PVT) LTD. performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is ACIREG CAPSULE 40 mg by BARRETT HODGSON PAKISTAN (PVT) LTD.in Acid media (pH 1.2), pH 4.5 & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.
STABILITY STUDY DATA		
Manufacturer of API	SAAKH PHARMA. Address: Plot # C -7/1, North West Industrial Zone,	
API Lot No.	21GT1 2003	

Description of Pack (Container closure system)		Alu-Alu blister packed in unit carton (1×14's)	
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH	
Time Period		Real time: 6 months Accelerated: 6 months	
Frequency		Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.	FE-001	FE-002	FE-003
Batch Size	1400 capsule	1400 capsule	1400 capsule
Manufacturing Date	03-2021	03-2021	03-2021
Date of Initiation	02-03-2021	02-03-2021	02-03-2021
No. of Batches	03		
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document. Because of new DML	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP Certificate No. 83/2020-DRAP(K) dated 23-06-2022	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Local purchase from M/s. Saakh Pharma, Karachi	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	HPLC software 21CFR not Installed	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted	
Remarks OF Evaluator:			
Sr.no.	Observations/Shortcomings	Reply of the Form	
1.	Justify how you claim USP specification for drug substance, when the submitted analytical method is not in accordance with USP neither similar to the assay method of drug substance manufacturer. Further, the assay method given in section 3.2. S. 4.2 is different from the method which is validated in section 3.2.S.4.3, clarification is required in this regard.	Firm submitted the specification of drug substance by drug substance manufacturer which is also not in compliance of USP monograph with reference to the assay results.	
2.	Provide COA of primary / secondary reference standard including source and lot number used for testing of drug substance.	Firm submitted the COA of working standard of Esomeprazole, while the USP recommends Omeprazole RS for the assay testing of Esomeprazole delayed release capsule.	

3.	Clarification is required regarding the assay results of stability data of drug substance, either the quantity is of dried basis of omeprazole magnesium or the labelled amount of omeprazole, since the COA of drug substance claim the content of active on dried basis.	Firm submitted the stability data sheet of drug substance in which assay results are specified on anhydrous basis, while in USP monograph the content of active should be quantify on the basis of labelled amount of Esomeprazole. Further the dissolution result of acidic stage has not been included in the stability data sheet of the drug substance.
4.	Provide complete method of dissolution testing along with details of HPLC parameters used during the dissolution testing of drug product in line with USP.	Firm has submitted the reply in response of this query.
5.	Provide complete analytical method verification studies of drug product including the specificity and repeatability parameter along with raw data sheets and chromatogram.	Firm has not submitted the analytical verification report of drug product neither the drug substance.
6.	Performance of comparative dissolution profile is not in accordance with guidelines approved in 293rd meeting of Registration Board with reference to following points: ✓ For f2 calculations a minimum of three time points (excluding point zero) must be used; mentioned the time point which were considered for the calculation of f2 value. ✓ A maximum of one time-point should be considered after 85% dissolution of the innovator / reference product has been reached; but as per the submitted documents you have used all time point until 30minutes, which are all below 85%. Clarify how you have calculated the f2 without considering the time point after 85% drug release.	Firm submitted the revised Comparative dissolution profile data in which all 12 units of both test product and reference shows below 65% release in pH 6.8 medium till 45 minutes while the dissolution results of stability data reveals that more than 90% drug release at pH 6.8 medium within 30 minutes.
7.	Clarify, why you have not mentioned the results of dissolution test in acidic medium in the stability data of drug product. Further, the specification of dissolution test did not mention the time limit in which NLT 75% (Q) should be achieved.	Firm has submitted the revised stability data in which more than 90% drug release at buffer stage within 30 minutes.
8.	Raw data sheets of dissolution testing and assay testing have not been attached in section 3.2. P.8., provide raw data sheet to analyse the result of dissolution and assay. Firm has submitted the raw data sheets and chromatograms of dissolution and assay testing, which evident that the assay was not performed in comply with USP specification in term of sample and standard solution conc and the total run time which is consist of 25 minutes' gradient elution program. Further, the chromatogram of standard evident that the esomeprazole has been used as a standard, while USP monograph recommends omeprazole RS for the Esomeprazole capsule.	
9.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted

Decision: Deferred for submission of following:

- Justify how you claim USP specification for drug substance, when the submitted analytical method is not in accordance with USP neither similar to the assay method of drug substance manufacturer. Further, the assay

method given in section 3.2. S. 4.2 is different from the method which is validated in section 3.2.S.4.3, clarification is required in this regard.

- Scientific justification for use of Esomeprazole as reference standard in analytical procedures instead of Omeprazole RS as specified by USP monograph.
- Stability data sheet of drug substance including the results of dissolution test of acidic stage.
- Provide complete analytical method verification studies of drug product including the specificity and repeatability parameter along with raw data sheets and chromatogram.
- Justify the dissolution results of stability data in which more than 90% drug release at pH 6.8 medium within 30 minutes, while the revised Comparative dissolution profile data evident that both test product and reference product release below 65% in pH 6.8 medium till 45 minutes.
- Scientific justification for using assay method different from that specified in USP monograph in term of gradient program, total run time and reference standard.
- Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

Sr.no.	Decision of 322 nd meeting	Response of the Firm
1.	Justify how you claim USP specification for drug substance, when the submitted analytical method is not in accordance with USP neither similar to the assay method of drug substance manufacturer. Further, the assay method given in section 3.2. S. 4.2 is different from the method which is validated in section 3.2.S.4.3, clarification is required in this regard.	In the reply firm has only submitted the copy of USP monograph of omeprazole without any clarification and verification studies.
2.	Scientific justification for use of Esomeprazole as reference standard in analytical procedures instead of Omeprazole RS as specified by USP monograph.	There was a typographical mistake we have used Omeprazole RS as specified by USP monograph.
3.	Provide complete analytical method verification studies of drug product including the specificity and repeatability parameter along with raw data sheets and chromatogram.	Firm submitted the analytical verification of drug product in which again esomeprazole reference standard has been used instead of omeprazole reference standard as recommended by USP.
4.	Stability data sheet of drug substance including the results of dissolution test of acidic stage.	The firm submitted stability data for the drug substance covering only 6 months, which includes the results of the dissolution test for the acidic stage.
5.	Provide complete method of dissolution testing along with details of HPLC parameters used during the dissolution testing of drug product in line with USP.	Submitted
6.	Justify the dissolution results of stability data in which more than 90% drug release at pH 6.8 medium within 30 minutes, while the revised Comparative dissolution profile data evident that both test product and reference product release below 65% in pH 6.8 medium till 45 minutes.	Firm submitted the CDP report of omeprazole delayed release capsule showing that more than 80% drug release at acidic pH, while the release pattern at pH 6.8 reflects that less than 80% drug release within 30 minutes, since the USP monograph of omeprazole delayed release recommends that NLT 75%(Q) of drug release within 30 minutes.
7.	Revised stability data of drug product specify the results of assay of esomeprazole, clarification is required in this regard.	Firm submitted the stability data of drug product without the results of dissolution test performed at acidic stage

Decision of 340th meeting of Registration Board:

Deferred for submission of following shortcomings:

- Justify how you claim USP specification for drug substance, when the submitted analytical method is not in accordance with USP neither similar to the assay method of drug substance manufacturer. Further, the assay method given in section 3.2. S. 4.2 is different from the method which is validated in section 3.2.S.4.3, clarification is required in this regard.
- Submit stability data of drug substance including all the test of reference specification till the claimed re-test date.
- Scientific justification for use of Esomeprazole as reference standard in verification of analytical procedures instead of Omeprazole RS as specified by USP monograph.
- Provide complete analytical method verification studies of drug product including the specificity and repeatability parameter along with raw data sheets and chromatogram.
- Provide a scientific justification for the release pattern of the drug product at acidic pH as evident from the submitted CDP report, where more than 80% of the drug is released, despite the formulation consisting of enteric-coated pellets.
- Submit the stability data of drug product including all the test mentioned in the finished product specification.

Response of the Firm:

Sr.no.	Decision of 340 th meeting	Response of the Firm
1.	Justify how you claim USP specification for drug substance, when the submitted analytical method is not in accordance with USP neither similar to the assay method of drug substance manufacturer. Further, the assay method given in section 3.2. S. 4.2 is different from the method which is validated in section 3.2.S.4.3, clarification is required in this regard.	Firm replied that as we previously not further reviewed our documents that's the main reason we submitted API Specification and testing method (Omeprazole) instead of Omeprazole Delayed Release 2 Capsule, so we have revised our Specification and Testing Method as per USP Specification. However, the API of applied formulation is delayed release pellets while firm submitted the analytical procedure of finished product in their reply.
2.	Submit stability data of drug substance including all the test of reference specification till the claimed re-test date.	Firm submit the stability data of drug substance, in which one of the tests is Gastric resistant with the acceptance criteria of NLT 90%, which seems that it is the dissolution test performed at acid resistant stage. However, the limits of dissolution test performed at acid resistant stage should be NMT 10% for delayed release pellets.
3.	Scientific justification for use of Esomeprazole as reference standard in verification of analytical procedures instead of Omeprazole RS as specified by USP monograph.	Firm replied that, it was Human error / typographical error instead of Omeprazole we typed Esomeprazole.
4.	Provide complete analytical method verification studies of drug product including the specificity and repeatability parameter along with raw data sheets and chromatogram.	Submitted
5.	Provide a scientific justification for the release pattern of the drug product at acidic pH as evident from the submitted CDP report, where more than 80% of the drug is released, despite the formulation consisting of enteric-coated pellets.	Firm in their reply state that "As we previously not further reviewed our documents that's the main reason we submitted in-correct file, now we are submitting correct file as per WHO Dissolution profiling".
6.	Submit the stability data of drug product including all the test mentioned in the finished product specification.	Firm submitted the stability data of drug product in which the results of dissolution test performed at acid resistant stage has not been included.

Decision of 343rd meeting:

Deferred for the submission of following shortcomings:

- Submit specification and analytical procedure of drug substance that has been used by the drug product manufacturer for the quality analysis of drug substance.
- Clarification is required regarding the mentioned acceptance limit of gastric resistant stage i.e. NLT 90% in the stability data sheets of drug substance, since the limits of dissolution test performed at acid resistant stage for delayed release pellets should be NMT 10%.
- Submit the stability data of drug product including all the test mentioned in the finished product specification.

Response of the Firm:

Sr.no.	Shortcomings	Response of the Firm
1.	Submit specification and analytical procedure of drug substance that has been used by the drug product manufacturer for the quality analysis of drug substance.	Firm submit the specification and analytical procedure of drug substance that has been used by the drug product manufacturer for the quality analysis of drug substance.
2.	Clarification is required regarding the mentioned acceptance limit of gastric resistant stage i.e. NLT 90% in the stability data sheets of drug substance, since the limits of dissolution test performed at acid resistant stage for delayed release pellets should be NMT 10%.	Firm replied that was human error/typographical mistake instead of NLT 10%, we typed NLT 90%. However, now we are submitting the revised stability data of drug substance. Furthermore, a similar typographical error was observed in the Comparative Dissolution Profile (CDP) study conducted by the drug product manufacturer for the applied formulation versus the comparator product. The firm later acknowledged the error and submitted a revised CDP report accordingly.
3.	Submit the stability data of drug product including all the test mentioned in the finished product specification.	Firm submit the stability data sheets in which results of identification test, assay, average weight and dissolution test is included. Further, the acceptance criteria of identification mentioned against the test is not in accordance with USP.

Decision: The Registration Board decided to defer the case and advised QA & LT Division for sampling of the Esomeprazole pellets from M/s. Saakh Pharma, Karachi. The sampled product shall be sent to CDL, DRAP Karachi, for test and analysis and submit the analysis report for the consideration of Registration Board.

Case No. 01: Registration of Baricitinib 2mg and 4mg Tablets.

M/s. CCL has submitted a letter while referring Baricitinib containing drug products (Barib 2mg & 4mg Tablet) approved in the name of their firm stated as under:

The honorable Lahore High Court, Lahore through order dated 02-05-2024 passed F.A.O No. 22656 of 2024, suspended operation of Order by the learned Intellectual Property Tribunal, Lahore, in the following words:

C.M. No. 2/2024

6. Notice for the above-said dated. Till the next date of hearing, the impugned order of the learned *Tribunal* only to the extent of the present appellant/DRAP shall remain suspended.

Case was referred to Legal Affairs Division for status of case and their opinion. Accordingly, opinion of said division is as under:

- i. The background of the matter is that registration of drugs containing Baricitinib including that of CCL Pharma Pvt. Ltd. were approved in various meeting of the Registration Board. Subsequently, before the Drug Registration Certificates could be issued, Suits were filed by Incyte Holding Corporation/ Eli Lilly Pakistan Pvt. Ltd. before the learned Intellectual Property Tribunal, Lahore. The Suits contended that Drug Registration Certificates should not be issued by placing reliance on the concept of Patent-Linkage. Ad-Interim Injunctions were issued against various firms whose registration of generic/ me-too of Baricitinib containing drugs had been approved by the Registration Board including CCL Pharma Pvt. Ltd. Learned Tribunal restrained all other companies from seeking drug registration from DRAP and also simultaneously restrained DRAP from processing their applications.

Ad-Interim Injunction was granted by the learned Intellectual Property Tribunal against CCL Pharma. Pvt. Ltd. [through Order dated 03-03-2023](#). The Application for Interim Relief under Order 39 Rule 1 and 2 C.P.C. was decided through [Order dated 03-04-2024](#).

- ii. Being aggrieved, DRAP filed appeal against the order dated 03.04.2024 in Lahore High Court, Lahore bearing FAO No. 22656 of 2024 in which interim relief was given by the High Court through [Order dated 02-05-2024](#). Relevant excerpt thereof is as under: **“C.M. No. 2/ 2024**

6. Notice for the above-said date. Till the next date of hearing, the impugned order of the learned *Tribunal* only to the extent of the present appellant/ DRAP shall remain suspended.”

Subsequently, the said FAO was decided in favor of DRAP [through Judgment dated 27-05-2024 \(Certified copy is attached\)](#). Under the Doctrine of Merger, the Interim Order dated 02-05-2024 merged into the Final Judgment dated 27-05-2024. The Final Judgment dated 27-05-2024 set aside the Interim Injunction/ Stay Order granted by the learned Intellectual Property Tribunal, Lahore to the extent of CCL Pharmaceutical Pvt. Ltd., in the following words:

“(ii). The interim injunction granted by the learned Tribunal, to the extent of DRAP for restraining DRAP to proceed with pending application of respondent No. 4 may be vacated;”

- iii. After the grant of the above mentioned final relief by the Honorable Court, both CCL Pharma Pvt. Ltd. is free to seek Drug Registration from DRAP and further DRAP is also free to process and grant Drug Registration to CCL Pharma Pvt. Ltd. In other

words, DRAP is free to perform its functions to the extent of application by CCL Pharma Pvt. Ltd.

After Order by the Honorable Lahore High Court, Lahore dated 02-05-2024 and Final Judgment by the Honorable Court dated 27-05-2024, there is no legal impediment to the issuance of Drug Registration Certificates for drugs containing Baricitnib of CCL Pharma Pvt. Ltd. It must be emphasized that as the Honorable Court has specifically directed DRAP to proceed with CCL Pharmaceutical Pvt. Ltd.'s pending application for registration, therefore, it is a legal responsibility of the relevant persons/Board to abide by the Order and not delay the issuance of Drug Registration Certificate. Please note that any further unnecessary delay might tantamount to Contempt of Court.

- iv. Furthermore, the Registration Board in its 297th Meeting held on 12th to 15th of January, 2021, held that barring the cases where interim injunction is granted by the Honorable Court, the drug registration shall not be stopped. The decision is reproduced as under:

“After detailed deliberations, Registration Board decided that grant of marketing authorization/ registration has no linkage with patent status of the originator's product and advised to process cases for issuance of registration letters except for cases of restraining orders from any court.”

As the restraining order by the learned Tribunal has been completely set aside by the Honorable High Court through Judgment dated 27-05-2024 **only to the extent of CCL Pharma Pvt. Ltd.** therefore, as per decision of the 297th Meeting of the Registration Board, there is no legal impediment in the grant of Drug Registration to CCL pharma. **It is again clarified that any delay in complying with the aforementioned direction of the Honorable Court is contemptuous in nature and therefore, the competent authority should promptly issue CCL Pharma Pvt. Ltd.'s Drug Registration Certificate as long as the Company meets all requirements under the drug laws.**

- v. As discussed in detail above, the Honorable High Court through Judgment dated 27-05-2024 has granted relief only to the extent of CCL Pharma Pvt. Ltd. Therefore, it is a relief which is ‘in personam’ granted to the extent of parties to the case i.e. CCL Pharma. This concept has been defined by the Honorable High Court in judgment reported as **2014 PLC (CS) 288** in the following words:

“It differs from a judgment in personam as this judgment is in form as well as substance between the parties claiming the right, and that it is so inter parties appears by the record itself.”

- vi. Furthermore, since the Judgment dated 27-05-2024 does not lay down a Principle of Law, therefore, it is a judgment ‘in personam’ which only benefits the party to the lis i.e. CCL Pharma Pvt. Ltd.

It is pertinent to mention here that Learned Tribunal has restrained all other companies from seeking drug registration from DRAP and also simultaneously restrained DRAP from processing their applications. Therefore, unless and until the Honorable High Court sets aside the learned Tribunal's both aforementioned directions to the extent of DRAP completely in relation to all other companies, DRAP cannot issue Drug Registration Certificate to other companies. Any violation of learned Tribunal's Order would be contemptuous as noted by the Honorable High Court in judgment reported as PLD 1975 Lahore 126 in the following words:

“5... When an injunction order has been issued, it must be obeyed; and the only remedy of the aggrieved party is to come up in appeal to a superior Court to have the order vacated. So long as the order stands and its operation has not been suspended by another

Court or by the Court which passed the order, it will not be tolerated that any person should disobey that order.”

- vii. In the light of above facts and legal position, the Judgment dated 27-05-2024 by Lahore High court is ‘in personam’, therefore, its benefit can only be granted to CCL Pharma Pvt. Ltd. and Drug Registration Certificate can only be issued to it. The registration letters regarding the product containing namely Baricitinib cannot be granted to the other companies against whom the Incyte Holdings and ELi Lilly filed suit in Intellectual Property Tribunal, Lahore due to the operative stay orders.

It is pertinent to mention here that it is also mentioned in Hon'ble High Court Order dated 27.05.2024 that

" 4 (iii) ‘the above, however, shall not be construed as permitting respondent No. 4 to advertise, market or deal with Baricitinib in any manners and the injunctive order to the extent of respondent No. 4 may be examined in appeal No. 22665 of 2024 filed by respondent No. 4."

Proceeding of 343rd Meeting:

Registration Board was appraised that during meeting of the Board, on behalf of i. Incyte Holdings Corporation ii. Eli Lilly and company and iii. Eli Lilly Pakistan (Pvt) Ltd., Mr. Hassan Irfan Khan Advocate has sent a reference stating that CCL has submitted a letter, willfully and purposely misrepresenting the actual facts and legal position with regard to litigation by their clients against CCL for infringement of patents relating to baricitinib.

Copy of above reference has been handed over to Law expert of M/o Law & Justice, Islamabad for review and discussion in forthcoming meeting of the Board.

Decision of 343rd Meeting:

Registration Board, in-order to complete review of the case in light of reference submitted by Mr. Hassan Irfan and Lahore High Court deferred the case for further deliberation.

Proceedings of 344th meeting

Registration Board deliberated the matter in detail. There are other companies including M/s CCL pharma who also filed the applications for registration of the same molecule before Board. However, M/s Incyte Holdings and M/s Eli Lilly filed suits before Intellectual Property Tribunal, Lahore against all said companies/firm & DRAP and obtained ad-interim injunctions. As stated above, The Lahore High Court, Lahore while vacating ad-interim order against DRAP, directed DRAP to proceed with pending application of respondent No. 4 i.e M/s. CCL Pharma. It is pertinent to mention here that the ad-interim injunction orders against other companies are not vacated so far by the IPT, Lahore or Lahore High Court, Lahore till date.

Decision of 344th Meeting of the Board:

In view of the above, the Registration Board decided to proceed with the pending Registration Letter of M/s CCL Pharma regarding Baricitinib with additional condition of registration that ‘the registration letter shall not be construed as permitting M/s CCL Pharmaceuticals to advertise, market or deal with Baricitinib in any manners till final adjudication of FAO No. 22665 of 2024 filed by the Company."

Moreover, The Board also directed PE&R Division to place all pending applications of Baricitinib of all companies/firms in next meeting. Further, the Board also directed Deputy Director (Legal Affairs) of DRAP to give a comprehensive presentation in next meeting on latest status of court orders by IPT, Lahore or Lahore high court.

Legal affair’s Division has now prepared a presentation.

Decision of 345th Meeting of RB:

Registration Board deferred the case for further deliberation in forthcoming meeting.

Proceedings and Decision: Legal Affairs Division has presented the following;

SUMMARY OF THE CASES FILED BY INCYTE HOLDINGS AND THEIR STATUS

Background of the matter is that Incyte Holdings claims to be the patent holder of 'Baricitnib' registered under the Patent No. 142331 and 142333. Eli Lilly Pakistan Pvt. Ltd. claims to have obtained drug registration of this product on behalf of Incyte Corporation under the brand name 'OLUMIANT'. It filed several Suits before the Intellectual Property Tribunal, Lahore, claiming patent-linkage for its aforementioned Patent and for restraining the grant of drug registration for 'Baricitnib' containing products to generic manufacturers. The details of the pending is as under:

1. **Incyte Holdings Vs. Himmel Pharma and others:** Ad-Interim Injunction has been granted on the first date on [REDACTED] (**Annexure 'A'**) restraining **Himmel Pharma** from proceedings with the application for drug registration and also restraining DRAP from issuing Drug Registration. DRAP has filed its Reply but **Himmel Pharma** has continuously not appeared for arguments and the matter is pending due to its continuous requests for adjournments.
2. **Incyte Holdings Vs. Jenner Pharma and others:** Ad-Interim Injunction has been granted on the first date on 01-06-2022 (**Annexure 'B'**) restraining **Jenner Pharma** from proceedings with the application for drug registration and also restraining DRAP from issuing Drug Registration. DRAP has filed its Reply but **Jenner Pharma** has continuously not appeared for arguments and the matter is pending due to its continuous requests for adjournments.
3. **Incyte Holdings Vs. McOLSON Pharma and others:** Ad-Interim Injunction has been granted on the first date on 30-05-2022 (**Annexure 'C'**) restraining **McOLSON Pharma** from proceedings with the application for drug registration and also restraining DRAP from issuing Drug Registration. DRAP has filed its Reply but **McOLSON Pharma** has continuously not appeared for arguments and the matter is pending due to its continuous requests for adjournments.
4. **Incyte Holdings Vs. CCL Pharma and others:** The Honorable Lahore High Court through Order dated 27-05-2024 (**Annexure 'D'**) directed DRAP to proceed with its application. The learned Intellectual Property Tribunal has since framed issued through Order dated 29-01-2025 (**Annexure 'E'**) and also heard final arguments by DRAP and CCL Pharma regarding maintainability of the case. The matter is fixed for final arguments by Incyte Holdings on 01-03-2025.
5. **Incyte Holdings Vs. Dyson Research Laboratories Pvt. Ltd. and others:** Ad-Interim Injunction has been granted on the first date on 03-03-2023 (**Annexure 'F'**) restraining **Dyson Research Laboratories** from proceedings with the application for drug registration and also restraining DRAP from issuing Drug Registration. DRAP has filed its Reply but **Dyson Research Laboratories** has continuously not appeared for arguments and the matter is pending due to its continuous requests for adjournments.

6. **Incyte Holdings Vs. Hiranis Pharmaceuticals Pvt. Ltd. and others:** Ad-Interim Injunction has been granted on the first date on 04-03-2023 (**Annexure ‘G’**) restraining **Dyson Research Laboratories** from proceedings with the application for drug registration and also restraining DRAP from issuing Drug Registration. DRAP has filed its Reply but **Hiranis Pharma** has continuously not appeared for arguments and the matter is pending. Hiranis Pharma challenged the ad-interim injunction before the Honorable Lahore High Court through W.P. No. 22632/ 2023 (**Annexure ‘H’**), in which the injunction granted by the Intellectual Property Tribunal was suspended through ad-interim order. Since then, Hiranis Pharma has been seeking continuous adjournments. Learned Tribunal through its Order dated 04-03-2023 had restrained DRAP from processing the application of Hiranis Pharma. Therefore, unless and until the Honorable High Court sets aside the learned Tribunal’s both aforementioned direction to the extent of DRAP completely in relation to Hiranis Pharma, DRAP cannot issue Drug Registration Certificate to it.

7. **Incyte Holdings Vs. ATCO and others:** Ad-Interim Injunction has been granted on the first date on 04-03-2023 (**Annexure ‘I’**) restraining **ATCO** from proceedings with the application for drug registration and also restraining DRAP from issuing Drug Registration. The application for interim injunction was decided against DRAP and ATCO through Order dated 12-07-2023.

DRAP challenged it through FAO No. 48677/ 2023 in which stay order was granted to DRAP through Order dated (**Annexure ‘J’**). ATCO did not appear in the said case and has since been held ex-parte through Order dated 20-11-2023 (**Annexure ‘K’**), due to which it cannot seek benefit of the said stay order. No application for restoration has been filed by ATCO even after more than a year.

ATCO filed FAO No. 51729/ 2023 in which Notices were issued through Order dated 18-08-2023 (**Annexure ‘L’**) but no stay order has been granted to ATCO. Its maintainability has yet to be decided.

Since then ATCO has filed W.P. No. 56941/ 2024 seeking issuance of drug registration, in which notices have not yet been issued to DRAP. Till decision of the matters before the Honorable High Court, drug registration cannot be issued to it.

8. **Incyte Holdings Vs. Novamed and others:** Ad-Interim Injunction has been granted on the first date on 31-07-2024 (**Annexure ‘M’**) restraining **Novamed** from proceedings with the application for drug registration and also restraining DRAP from issuing Drug Registration. DRAP has filed its Reply but **Novamed** has continuously not appeared for arguments and the matter is pending due to its continuous requests for adjournments.

9. **Incyte Holdings Vs. Horizon Pharma and others:** Ad-Interim Injunction has been granted on the first date on 25-09-2024 (**Annexure ‘N’**). DRAP is contesting the matter however, Horizon Pharma has given an undertaking in its Written Statement (**Annexure ‘O’**) as under:

“That Defendant No. 1 undertakes to refrain from any activities, including importing, exporting, manufacturing, formulating, stocking, advertising or selling, that may infringe upon Patent No. 142331 and 142333 related to Baricitnib.”

Due to admission by Horizon Pharma, the drug registration cannot be granted till decision by the learned Tribunal.

10. **Incyte Holdings Vs. High-Q Pharma and others:** By the time that this Suit was filed, DRAP had successfully pleaded its case in the CCL Pharma Case whereby it had sensitized

the learned Intellectual Property Tribunal about the lack and want of jurisdiction against DRAP. The learned Tribunal while granting ad-interim injunction dated 25-09-2024 (**Annexure ‘P’**) has not granted any order restraining the grant of drug registration. Therefore, there is no bar in the grant of drug registration to High-Q Pharma.

11. Incyte Holdings Vs. AGP Ltd. and others: By the time that this Suit was filed, DRAP had successfully pleaded its case in the CCL Pharma Case whereby it had sensitized the learned Intellectual Property Tribunal about the lack and want of jurisdiction against DRAP. The learned Tribunal while granting ad-interim injunction dated 19-10-2024 (**Annexure ‘Q’**) has not granted any order restraining the grant of drug registration. Therefore, there is no bar in the grant of drug registration to AGP Ltd.

Decision: After thorough deliberation, the Registration Board concluded that apparently there are no restraining orders on DRAP to grant registration letters to M/s. AGP, M/s. High-Q, and M/s. CCL. However, for better understanding of the Court order and related proceeding, the Board decided to refer complete case to seek guidance from Member Law & Justice Division on whether the Registration letters to aforesaid companies be issued unconditionally or otherwise in light of Court and IPT orders.

Case No. 02: Change of contract Manufacturer from M/s EG Pharmaceuticals, 13/A Industrial Triangle Kahuta Road, Islamabad to M/s. Biogen Life Sciences, 8-km, Chakbeli Road, Rawat, Rawalpindi before issuance of registration letter.

Following registration applications have been approved in 333rd meeting (*Page # 1480-1490*) of Drug Registration Board (DRB) regarding applications of M/s Nagarsons Pharmaceuticals. Plot No. 34, St. No. NS-2, National Industrial Zone, Rawat on prescribed Form 5-F, for registration of Drug products by way of contract manufacturing, from M/s. Biogen Life Sciences, 8-km, Chakbeli Road, Rawat, Rawalpindi wherein Board approved the registration of the drug products by way of contract manufacturing. Before issuance of registration letters, the applicant decided to change the contract manufacturer and submitted applications on prescribed Form 5F (CTD) Module – I only, before issuance of registration letter. As per the requirement / guidelines in DRAP’s Letter No. 1-2/2022-DMMC dated 13th June 2023, the applicants submitted applications on Form 5F Module I only for the formulations to be manufactured by proposed contract manufacturer i.e. M/s. Biogen Life Sciences, 8-km, Chakbeli Road, Rawat, Rawalpindi who already possess Previous Registration Approval of the Drug Registration Board (DRB) of same formulations with the product development and stability data. Detail is as under:

S. #	Already registered Product Name with composition & details	Previous Contract Manufacturer	Current Contract Manufacturer	Details of Application & fee received	Products already Approved on CTD format for the proposed manufacturing site
1.	NAGZONE 500mg Injection IM Each Vial Contains:	M/s EG Pharmaceuticals , 13/A Industrial Triangle Kahuta	M/s. Biogen Life Sciences, 8-km, Chakbeli	Fee: PKR 46500/- <i>Vide slip #</i> 894673643055	Ceftigen 500mg Injection IM Each vial contains:

	Ceftriaxone (as sodium).....500mg USP	Road, Islamabad.	Road, Rawat, Rawalpindi	Tracking ID: NYQ-EGH-ZM1J Dated 26-05-2025	Ceftriaxone (as sodium) ... 500mg (USP Specifications) Reg. No. 108042 Meeting of RB: 297 Case No.: 222 Page no. 269– 272
2.	NAGZONE 1g Injection IV Each Vial Contains: Ceftriaxone (as sodium).....1g USP	M/s EG Pharmaceuticals , 13/A Industrial Triangle Kahuta Road, Islamabad.	M/s. Biogen Life Sciences, 8-km, Chakbeli Road, Rawat, Rawalpindi	Fee: PKR 46500/- <i>Vide slip #</i> 18549960297 Tracking ID: NYQ-EGH-ZM1J Dated 26-05-2025	Ceftigen 1g Injection IV Each vial contains: Ceftriaxone (as sodium) 1g (USP Specifications) Reg. No. 108046 Meeting of RB: 297 Case No.: 226 Page no. 280– 282

Decision: Registration Board acceded to the request of M/s Nagarsons Pharmaceuticals. Plot No. 34, St. No. NS-2, National Industrial Zone, Rawat for change of contract manufacturer of above mentioned products from M/s EG Pharmaceuticals, 13/A Industrial Triangle Kahuta Road, Islamabad to M/s. Biogen Life Sciences, 8-km, Chakbeli Road, Rawat.

RRR Section

Case No.01: M/s Safina Pharma (Pvt) Ltd, 17Km Sheikhpura Road, Lahore

M/s Safina Pharma (Pvt) Ltd, has requested for grant of registration to following products applied on Form5 in the light of decision of Registration Board 343rd meeting as under:

Registration Board deliberated the matter that previously DRAP Authority has allowed exemption of Form-5F to those products for which registrations were cancelled due to late / nonsubmission of renewal of registration applications. In instant case registrations were cancelled after cancellation of DML due to late submission of DML renewal application. Hence, Registration Board referred the case to DRAP Authority for seeking guidance to further process such cases.

The DRAP Authority in 199th meeting (held on 31st January, 3rd and 4th February 2025) after thorough deliberation, in continuation of its previous decision in 180th meeting exempted Form 5F to those products which were cancelled due to cancellation of DML on account of late/non submission of renewal.

1.	Brand Name + Dosage Form and Strength	Safiron-F Tablet

	Composition	Each Chewable tablet contains Iron (III) Hydroxide Polymaltose Complex eq to Iron.....100mg Folic acid.....0.35mg
	Dairy No. date of R &I fee	Rs.37,000/-dated: 30.04.2025, (37993453) ZQ4-P6U-A33T
	Type of form	Fom-5
	Finished product specifications	Innovator's Specs
	Pack size and Demand Price	As per SRO, 1x10's
	GMP Status	DML inspection report dated 18.02.2021
	RRA status	FERRUM FOL 100 MG / 350 MICROGRAMS CHEWABLE TABLETS (Ireland)
	Remark of the Renewal section	Firm has applied for fresh registration of Safiron-F Tablet (071318) which was cancelled due to DML cancellation on account of non-submission of renewal.
	Remarks:	
	Decision: Approved	
2.	Brand Name + Dosage Form and Strength	Seft DS Tablet
	Composition	Each tablet contains Trimethoprim..... 160mg Sulphamethoxazole.....800mg
	Dairy No. date of R &I fee	Rs.37,000/-dated: 30.04.2025, (39771400027) 9E8-9PN-X43T
	Type of form	Fom-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO, 10x10's, 20x5's
	GMP Status	DML inspection report dated 18.02.2021
	RRA status	Trimethoprim and Sulphamethoxazole tablet by SUN PHARM INDUSTRIES USFDA (USA) Approved
	Remark of the Renewal section	Firm has applied registration for fresh registration of Seft DS Tablet (071311) which was cancelled due to DML cancellation on account of non-submission of renewal.
	Remarks:	
	Decision: Approved	
3.	Brand Name + Dosage Form and Strength	Seft Tablet
	Composition	Each tablet contains Trimethoprim..... 80mg Sulphamethoxazole.....400mg
	Dairy No. date of R &I fee	Rs.37,000/-dated: 30.04.2025, (89135112) 7NH-ME4-LBBY

	Type of form	Fom-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO, 10x10's, 20x10's
	GMP Status	DML inspection report dated 18.02.2021
	RRA status	Trimethoprim and Sulphamethoxazole tablet by SUN PHARM INDUSTRIES USFDA (USA) Approved
	Remark of the Renewal section	Firm has applied for fresh registration of Seft Tablet (071312) which was cancelled due to DML cancellation on account of non-submission of renewal.
	Remarks:	
	Decision: Approved	
4.	Brand Name + Dosage Form and Strength	Sadinor Dry Suspension 125mg
	Composition	Each 5ml after reconstitution contains Cefdinir 125mg
	Dairy No. date of R &I fee	Rs.37,000/-dated: 30.04.2025 (67101667946) U9N-S4T-DTR6
	Type of form	Fom-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO, 60ml
	GMP Status	DML inspection report dated 18.02.2021
	RRA status	Cefdinir 125 mg/5ml Suspension by M/s Lupin Ltd, (USFDA Approved)
	Remark of the Renewal section	Firm has applied for fresh registration of Sadinor Dry Suspension 125mg (057603) which was cancelled due to DML cancellation on account of non-submission of renewal.
	Remarks:	
	Decision: Approved	
5.	Brand Name + Dosage Form and Strength	Safillixy Drops 100mg
	Composition	Each ml after reconstitution contains Cephalexin (as Monohydrate).....100mg
	Dairy No. date of R &I fee	Rs.37,000/-dated:30.04.2025, (1305573056) ZNL-NJX-LTYT
	Type of form	Fom-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO, 10ml
	GMP Status	DML inspection report dated 18.02.2021
	RRA status	GENRX CEPHALEXIN cefalexin (as monohydrate) Dry powder for suspension. TGA approved

	Remark of the Renewal section	Firm has applied for fresh registration of Safillixy Drops 100mg (057602) which was cancelled due to DML cancellation on account of non-submission of renewal.
	Remarks:	
	Decision: Approved	
6.	Brand Name + Dosage Form and Strength	Saflaw Dry Suspension 125mg
	Composition	Each 5ml after reconstitution contains Cefaclor as Monohydrate... 125mg
	Dairy No. date of R &I fee	Rs.37,000/-dated: 30.04.2025, (07403533079) 63H-M33-96N9
	Type of form	Fom-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO, 60ml
	GMP Status	DML inspection report dated 18.02.2021
	RRA status	Cefaclor 125mg/5ml Suspension by M/s Strides Pharma UK (MHRA Approved)
	Remark of the Renewal section	Firm has applied for fresh registration of Saflaw Dry Suspension 125mg (057594) which was cancelled due to DML cancellation on account of non-submission of renewal.
	Remarks:	
	Decision: Approved	
7.	Brand Name + Dosage Form and Strength	Saflaw Dry Suspension 250mg
	Composition	Each 5ml after reconstitution contains Cefaclor as Monohydrate..... 250mg
	Dairy No. date of R &I fee	Rs.37,000/-dated: 30.4.2025 (746965177530) MN9-MJW-VWTL
	Type of form	Fom-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO, 60ml
	GMP Status	DML inspection report dated 18.02.2021
	RRA status	Cefaclor 250mg/5ml Suspension by M/s Strides Pharma UK (MHRA Approved)
	Remark of the Renewal section	Firm has applied registration for fresh registration of Saflaw Dry Suspension 250mg (057596) which was cancelled due to DML cancellation on account of non-submission of renewal..
	Remarks:	
	Decision: Approved	

8.	Brand Name + Dosage Form and Strength	Sepilex 40mg Dry Suspension
	Composition	Each 5ml after reconstitution contains Cefpodoxime as Proxetil..... 40mg
	Dairy No. date of R &I fee	Rs.37,000/-dated: 30.4.2025 (556120825560) (ZPV-3V4-SUBA)
	Type of form	Fom-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO, 50ml
	GMP Status	DML inspection report dated 18.02.2021
	RRA status	Cefodox Paediatric 40mg/5ml Granules for Oral Suspension (HPRA , Ireland)
	Remark of the Renewal section	Firm has applied for fresh registration of Sepilex Dry Suspension 40mg (057601) which was cancelled due to DML cancellation on account of non-submission of renewal.
	Remarks:	
	Decision: Approved	
9.	Brand Name + Dosage Form and Strength	Sorxim Dry Suspension 125mg
	Composition	Each 5ml after reconstitution contains Cefuroxime as Axetil.....125mg
	Dairy No. date of R &I fee	Rs.37,000/-dated: 30.4.2025 (0409548564) (H3J-S1M-S7NS)
	Type of form	Fom-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO, 50ml
	GMP Status	DML inspection report dated 18.02.2021
	RRA status	Zinnat granules for Suspension 125mg/5mL (MHRA approved)
	Remark of the Renewal section	Firm has applied for fresh registration of Sorxim Dry Suspension 125mg (057605) which was cancelled due to DML cancellation on account of non-submission of renewal.
	Remarks:	
	Decision: Approved	
10	Brand Name + Dosage Form and Strength	Gefxil Dry Suspension 250mg
	Composition	Each 5ml contains Cefadroxil (as monohydrate) 250mg
	Dairy No. date of R &I fee	Rs.37,000/-dated: 30.4.2025 (1428940281) YTS-L1R-81HW

	Type of form	Fom-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO, 60ml
	GMP Status	DML inspection report dated 18.02.2021
	RRA status	USFDA (USA) Approved
	Remark of the Renewal section	Firm has applied for fresh Registration of Gefxil Dry Suspension 250mg (057597) which was cancelled due to DML cancellation on account of non-submission of renewal.
	Remarks:	
	Decision: Approved	
11.	Brand Name + Dosage Form and Strength	Gefxil Capsule 500mg
	Composition	Each hard gelatin capsule contains Cefadroxil as monohydrate 500mg
	Dairy No. date of R &I fee	Rs.37,000/-dated: 30.04.2025, (701090264356) HD5-UB8-GGUA
	Type of form	Fom-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO, 1 x 12's
	GMP Status	DML inspection report dated 18.02.2021
	RRA status	Cefadroxil 500mg capsules of M/s Sandoz Limited, UK (MHRA Approved)
	Remark of the Renewal section	Firm has applied for fresh registration of Gefxil Capsule 500mg (057598) which was cancelled due to DML cancellation on account of non-submission of renewal.
	Remarks:	
	Decision: Approved	

Post Registration Variation-I Section

Case No. 1. Change of MAH and Manufacturing Site of Registered Product Effexor 75mg Capsule by M/s AGP Limited, Karachi

Sr.#	Feature	Change of Manufacturing Site & MAH of Registered Product [FROM FINISHED IMPORT/LOCAL REPACKING TO LOCAL MANUFACTURE]
1.	Applicant name	M/s AGP Ltd. B-23-C, S.I.T.E. Karachi
2	Registered Product	Effexor XR 75 mg Capsule Registration No. 093061
3.	Previous Approved MAH	M/s Wyeth Pakistan Limited, B-2. SITE, Karachi DSL No.3242
4.	Previous Manufacturing Site	M/s Pfizer Ireland Pharmaceuticals and Repacking at M/s Pfizer Pakistan Ltd, B-2, S.I.T.E. Karachi
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: 02-12-2024 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	Venalfaxime: Cohance Lifesciences Limited, India GMP Certificate : Provided with validity till Oct 2024 (Valid at the time of submission of application by the firm) 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 Effexor 150mg Capsule of (Packed by M/s Pfizer, Pakistan B-2 SITE, Karachi.
11.	Procurement documents / Clearance from DRAP Office	Provided
12.	Stability Studies	Accelerated Stability studies (06 Months) & Real time Stability studies (06 months) are conducted on following three batches : Batch No. 184DS01, 184DS02, & Batch No. 184DS03 Date of Manufacture : 06-2024, Expiry date : 06-2026 Batch Size : 3000 Capsule Date of Initiation 06-2024
13.	BMR, HPLC Raw data sheets	Submitted

Decision of 347th meeting of the Registration Board:

The Registration Board decided to defer the case for further deliberation.

Minutes of 348th Meeting of Registration Board (01st – 02nd July, 2025)

Submitted for consideration of the Board

Decision:

The Board decided to accede to the request of the firm.

Case No. 2. Change of MAH and Manufacturing Site of Registered Product Effexor 75mg Capsule by M/s AGP Limited, Karachi

Sr.#	Feature	Change of Manufacturing Site & MAH of Registered Product [FROM FINISHED IMPORT/LOCAL REPACKING TO LOCAL MANUFACTURE]
1.	Applicant name	M/s AGP Ltd. B-23-C, S.I.T.E. Karachi
2	Registered Product	Effexor 150mg Capsule Registration No. 093060
3.	Previous Approved MAH	M/s Wyeth Pakistan Limited, B-2. SITE, Karachi DSL No.3242
4.	Previous Manufacturing Site	M/s Pfizer Ireland Pharmaceuticals and Repacking at M/s Pfizer Pakistan Ltd, B-2, S.I.T.E. Karachi
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: 11-9-2023 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	Venalfaxime: Cohance Lifesciences Limited, India GMP Certificate : Provided with validity till Oct 2024 (Valid at the time of submission of application by the firm) 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 Effexor 150mg Capsule of (Packed by M/s Pfizer, Pakistan B-2 SITE, Karachi.
11.	Procurement documents / Clearance from DRAP Office	Provided
12.	Stability Studies	Accelerated Stability studies (06 Months) & Real time Stability studies (06 months) are conducted on following three batches : Batch No. 185DS01, 185DS02, & Batch No. 185DS03 Date of Manufacture : 06-2024, Expiry date : 06-2026 Batch Size : 3000 Capsule Date of Initiation 06-2024

13.	BMR, HPLC Raw data sheets	Submitted

Decision of 347th meeting of the Registration Board:

The Registration Board decided to defer the case for further deliberation.

Submitted for consideration of the Board

Decision:

The Board decided to accede to the request of the firm.

Case No. 3. 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	GSK Specifications	BP Specifications	USP Specifications
<i>Identification</i>	<u>By 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.	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). <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 containing a trace of diphenylamine. An intense blue color is produced.	TLC: meet the requirements as defined in 201 chapter. <u>HPLC</u>: The retention time of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay
<i>RELATED SUBSTANCES</i>	<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	<u>HPLC:</u> CU by Assay LIMIT=> 85-115%	<u>HPLC:</u> LIMIT=> 85-115%	<u>HPLC:</u> LIMIT => 75-135%
ASSAY	<u>HPLC-</u> Average of the uniformity of content results - 85 % - 115%	<u>HPLC-</u> Average of the uniformity of content results - 85 % - 115%	<u>HPLC:</u> 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,	Not available	Not available

	beveled edge.		
STANDARD COMPRESSION WT.	125 mg	Not available	Not available
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 is called for Personnel Hearing .

Submitted for consideration of the Board

Proceedings of 348th Meeting:

Dr. Gohar Siddiqui, MD of the firm along with technical team appeared before the board and stated that the product is in market for several years and no ADR's etc have been reported. Moreover, the product meets the requirement of efficacy and safety. Moreover, the firm is following BP specifications as finished product specifications and the disintegration test is not mentioned/ specified in the BP monograph of Glyceryl Trinitrate tablets. Moreover, the disintegration time of tablets is 5 minutes based on the studies performed by M/s GSK Pakistan Limited.

Decision:

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.

Post Registration Variation-II Section

1. Finished Product Specifications of Mecobalamin/ Methylcobalamine received from Secretary, PQCB Punjab.

Secretary PQCB Punjab has written a letter to DRAP indicating the following:

“With reference to this office letter no. PQCB/Misc-02-7/2023 dated 31-07-2023 and PQCB order no. R-582/2021 dated 22-08-2023 and PQCB Misc 02-7/2023 & R-582/2021 dated 23-11-2023 (Copies enclosed),

The subject case was considered by Provincial Quality Control Board in its 263rd Meeting held on 27-06-2023, wherein the Board decided as follows:

“The Board after detailed discussion on the subject matter was of the view that the subject matter be referred to the DRAP (Drug Regulatory Authority of Pakistan) with the request to the Registration Board of DRAP to issue advice that whether a sample containing Mecobalamin / Methylcobalamin be tested accordingly to the USP specifications as is available in the “Dietary Supplements” Chapter of USP.”

The desired information is still awaited and the same is necessarily needed for disposal of such cases. Hence, your good office is requested to issue the above mentioned advice to this office so that cases can be disposed of accordingly.”

Decision:

Registration Board deliberated that the Mecobalamin/ Methylcobalamine Tablet monograph is available as drug product in Japanese Pharmacopoeia. Hence, all the registration holders should follow JP monograph of Mecobalamin/ Methylcobalamine Tablet.

2. Direction of 14th Provincial pharmacovigilance committee (PPRVC) Meeting

A letter was received from Director, Pharmacy & Pharmacovigilance, Directorate of Drugs Control Punjab, Lahore where in following was informed:

2. Pursuant to the direction of 14th PRVC meeting under the convenorship of Director General, Directorate of Drug Control Punjab held on 29-10-2024 in the committee Room, Drug Testing Laboratory, 1-Birdwood Road, Lahore, it is submitted that provincial Pharmacovigilance Centre (PPC) Punjab Had received several Therapeutic Good Related Problem (TGRP) reports related to Adverse Drug Reaction (ADRs) including abdominal Discomfort/ Cramps, bloating, burning, skin rash, headache, bad taste, nausea, vomiting, itching, swelling in mouth, neck pain, myalgia & diarrhea with capsule Glynib (Imatinib) from Holy Family, Hospital Rawalpindi & Mayo Hospital Lahore. The details of product are as follow:

Sr. no.	Product name	Batch no.	Expiry dated	Manufacturer details
1.	Capsule Glynib 100mg (Imatinib)	T1017	Oct-2024	M/s. Pharmasol Pvt Ltd

3. It is not out of context to mention here that product specification inspection (PSI) of M/s Pharmasol Pvt. Ltd has been conducted by Provincial Inspector of Drugs, Sundar Industrial Estate

& Manga Road, Lahore during which complete product trial including Raw Material, Excipients & Source of the said product was obtained. The committee discussed various aspects of PSI report and Observed that the firm had not obtained Drug Registration Under Form 5, hence no batch trial stability studies conducted. Furthermore, no comparative dissolution profile or bioequivalence studies were performed. It was also highlighted that the firm lacked a dedicated pharmacovigilance department and an ADR monitoring mechanism (Copy enclosed)

4. In the light of above said decision the aforementioned report is submitted to your good office for further necessary action please.

Decision:

Registration Board decided to ask the firm to submit following in light of conditions of registration within two weeks of receipt of decision:

- **Product Development data.**
- **Stability Study Data.**

3. PQCB order dated 19-09-2024 regarding Pivacaine-SP Injection of M/s Bajwa Pharmaceuticals (Pvt.) Ltd., Sheikhpura.

PQCB in its order dated 19-09-2024 directed to seek rectification from NIH regarding the NIH report of subject sample and further directed the Committee to submit their registration certificate of subject sample and take corrective measures by applying to DRAP either for Manufacturer's Specifications or for changing dextrose anhydrous with glucose monohydrate in label and then perform test according to BP specifications.

The above document further states that the subject Sample Injecton Pivacaine-SP (Each 2ml contains: Bupivacaine Hydrochloride BP.....15mg, Dextrose Anhydrous BP.....165mg) batch no. PV-0523 has been declared substandard with regards to Assay Test of Glucose Monohydrate. The sample injection Pivacaine-SP was sent to NIH vide letter No. PQCB/MSS-182677/2024 dated 31-05-2024. The appellate laboratory has communicated vide test report No. 0125-P/2024 dated 07-08-2024, the subject sample as standard, on the basis of Assay Test. The manufacturing specifications for Injection Pivacaine-SP is BP specifications and in BP monograph of Injection Pivacaine-SP Glucose is mentioned as Glucose monohydrate. While NIH declared the report of said sample Standard on the basis of Assay Test of Dextrose Anhydrous while applying BP specifications. The firm also applied BP specifications and performed assay test for dextrose anhydrous instead of of Glucose monohydrate.

It is further informed that M/s Bajwa Pharmaceuticals has applied for change in specifications from BP to USP through E-App vide tracking ID: [XU2-TBV-974Y](#) as per following details:

Reg. No.	Name of Product	Existing Formulation and Specifications	Proposed Formulation and Specifications
078951	Pivacaine-SP Injection	Each ml contains: Bupivacaine HCl BP.....7.5mg Dextrose Anhydrous BP.....165mg BP Specifications	Each ml contains: Bupivacaine HCl BP.....7.5mg Dextrose Anhydrous BP.....165mg USP Specifications

It is pertinent to mention that the product was declared substandard by PQCB because the firm is claiming BP specifications and using Dextrose Anhydrous while BP monograph of this product is with Glucose Monohydrate.

In this context, it is submitted that there is no anomaly in the label claim of the product as BP monograph of the product states the following:

"Bupivacaine Heavy Injection is a sterile solution of Bupivacaine Hydrochloride and either Glucose or Glucose Monohydrate in Water for Injections."

Bupivacaine Heavy Injection

[General Notices](#)

Bupivacaine and Dextrose Injection; Bupivacaine and Glucose Injection

Action and use

Local anaesthetic.

DEFINITION

Bupivacaine Heavy Injection is a sterile solution of Bupivacaine Hydrochloride and either Glucose or Glucose Monohydrate in Water for Injections. No preservative is added. The inclusion of glucose in the formulation assists the gravitational flow of the injection when administered.

The injection complies with the requirements stated under Parenteral Preparations and with the following requirements.

Content of bupivacaine hydrochloride, $C_{18}H_{28}N_2O \cdot HCl \cdot H_2O$

95.0 to 105.0% of the stated amount.

Content of glucose monohydrate, $C_6H_{12}O_6 \cdot H_2O$

72.0 to 88.0 mg per mL.

CHARACTERISTICS

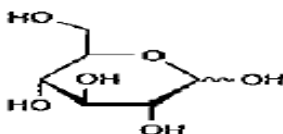
A clear, colourless solution.

IDENTIFICATION

Moreover, the monograph of Glucose available in BP clearly states that it is "Anhydrous Glucose:

Glucose¹

Anhydrous Glucose
(Ph. Eur. monograph 0177)

 $C_6H_{12}O_6$

180.2

50-99-7

Preparations**Glucose Infusion****Compound Glucose, Sodium Chloride and Sodium Citrate****Oral Solution****Oral Rehydration Salts****Potassium Chloride and Glucose Intravenous Infusion****Potassium Chloride, Sodium Chloride and Glucose****Intravenous Infusion****Sodium Chloride and Glucose Intravenous Infusion**

Hence, as per BP monograph of the product, the Bupivacaine Injection can be manufactured either by using Glucose Anhydrous or Glucose Monohydrate and in instant case the firm is using Dextrose Anhydrous which is synonym to Glucose Anhydrous. Moreover, the label claim of innovator product in USFDA is as follows:

“Each mL of MARCAINE SPINAL contains 7.5 mg bupivacaine hydrochloride (anhydrous) (equivalent to 7.9 mg of bupivacaine hydrochloride monohydrate), 82.5 mg dextrose (anhydrous) as baricity agent.”

accessed on 30-12-2024 @
https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/018692s024lbl.pdf

Registration Board in its 344th meeting decided as follows:

“Registration Board deferred the case for further deliberation in next meeting.”

Decision:

Keeping in view, the recommendation of PQCB and application of firm; Registration Board acceded to request for change in specifications to “USP Specifications”.

- 4. Application for standardization of formulation of already registered drug product applied by M/s Lahore Chemical and Pharmaceutical Works Pvt. Ltd. 137- Shahrah Maulana Jalaluddin Roomi, Lahore deferred in 344th meeting of Registration Board.**

Following application of M/s Lahore Chemical and Pharmaceutical Works Pvt. Ltd. 137- Shahrah Maulana Jalaluddin Roomi, Lahore for standardization of formulation of already registered drug. Case was deferred in 344th meeting as per following details:

Title	Description

Name, address of Manufacturing site.	Lahore Chemical and Pharmaceutical Works Pvt. Ltd. 137-Shahrah Maulana Jalaluddin Roomi, Lahore(000064)
Case Category	PRV-II (Muhammad Zubair)
Application Form Dy. No / Tracking ID & date of submission	(1NT-SBR-E65L, 2024-10-08)
Detail of Fee Submitted	12000.0, 2024-10-08,
The proposed proprietary name / brand name	Cyclonorm 2mg Tablet
Existing Label Claim	Each tablet contains: Estradiol Valerate .2mg
Proposed Label Claim	Each 11 white tablet contains: Estradiol Valerate.....2mg Each 10 brown tablet contains: Estradiol Valerate.....2mg Norgestrel.....0.5mg
Reg. No.	065986
Evaluation	The initial registration was granted in 2010 and for last 14 years firm has not applied for correction. More over, Estradiol Valerate 2mg Tablet is also registered as separate product i.e. Zumenon 2mg Film- Coated Tablet @ https://mhraproducts4853.blob.core.windows.net/docs/4ebf29c2a544fb5af648697bb5ab363da7256792 Now, the firm is applying for correction. It is proposed that the application of the firm may be disposed with the advice to the firm to apply afresh on CTD.
Shortcoming	
Decision of 344 th meeting	Registration Board deferred the case for submission of clarification by the firm that which formulation they have been manufacturing & marketing since registration.

Remarks:

The firm has submitted record of three batches of year 2022 & 2025 indicating manufacturing of proposed formulation.

Decision:

Registration Board deferred the case for obtaining the manufacturing record from the firm alongwith justification for manufacturing of the applied combination. Meanwhile, production shall immediately be suspended till the decision of the case by the Board.

5. Contract manufacturing policy notified vide SRO 1347(I)/2021 dated 15-10-2021.

Following amendment in Rule-20A of Drugs LRA Rules 1976 was notified vide SRO 1347(I)/2021 dated 15-10-2021:

In the aforesaid Rules,

(I) for rule 20A, the following shall be substituted, namely: --

Minutes of 348th Meeting of Registration Board (01st – 02nd July, 2025)

"20A. Contract manufacture.- (l) Manufacture or analysis, through contract, either for local sale or export purpose, shall be permissible by contract giver if:-

- (a) a licenced pharmaceutical manufacturer having licence to manufacture by way of formulation; or
- (b) an importer for its already registered drug products in Pakistan for permission from finished drug product import to contract manufacturing by a licenced pharmaceutical manufacturer; or
- (c) a foreign pharmaceutical company (manufacturer or marketing authorization holder) having drug sale licence in Pakistan for their research, innovator, originator drug products or drug products already registered for sale by any of reference regulatory authorities adopted by the Registration Board; or
- (d) licenced pharmaceutical manufacturing unit, which is granted a certificate by Registration Board to the effect that the unit is unable to maintain its production or output level due to reasons beyond its control, including but not limited to repair or upgradation requirements:

Provided that the contract manufacturing under this clause shall be for a period of thirty months extendable for a further period of twenty-four months by the Registration Board on valid grounds.

Later on, Member Law and Justice Division apprised Registration Board that all above four clauses are independent and the proviso is only applicable to above clause (d).

In the light of above, Division of PE&R has processed new registration applications for contract manufacturing and post registration variation applications from self to contract manufacturing of already registered drugs under clause (a) & (d) both.

Division of PE&R has placed this case before Registration Board to discuss that if a firm applies for change in manufacturing site from self to contract manufacturing of one of its products under Clause (d) of aforesaid Rule stating that their Section is unable to maintain its production or output level due to some maintenance issues, in such cases whether the Division should process only that one product or should ask the firm to apply for complete range of registered products manufactured in that particular Section.

Decision:

Registration Board endorsed the practice of PE&R Division of processing registration applications for contract manufacturing under post registration variation applications from self to contract manufacturing of already registered drugs under clause (a) of Rule 20A of The Drugs (Licensing, Registration and Advertising) Rules, 1976. Registration Board further clarified that provisions of clause (d) shall be invoked when a licensed pharmaceutical unit applies for contract manufacturing of all its registered products either for whole licensed unit or for a particular section.

Item No. III Division of Quality Assurance & Laboratory Testing

CASE NO.1: Adulterated & Substandard Paracet 1g Infusion Manufactured By M/s Standpharm (Pvt). Ltd, Lahore

BACK GROUND:

FID DRAP Quetta informed that he has done sampling of product Paracet 1g/100ml Infusion from M/S Usman Traders Yet Road Quetta on 16-11-2022.

S.No	Name of Product	Batch No.	Mfg. date	Expiry Date	Manufacturer	CDL Report
1	Paracet IV 1 G/100 ml Infusion. Reg.No.(083853)	CIJ170	20-09-2022	20-09-2024	M/s StandPharm (Pvt) Ltd, Lahore	Containing black color particles visible to the naked eye Does not comply. <i>Adulterated and Substandard</i>

CDL vide report No. KQ11-22-000234 dated has declared the above said sample to be **ADULTERATED AND SUBSTANDARD** based on the presence of visible black particles. Accordingly, FID issued copy of report to firm and also issued letter for recall and explanation.

2. The Product Recall Alert of Paracet 1g/100mL Infusion was also uploaded on DRAP website.

3. Firm Submitted their reply to FID vide letter Nil dated 03-01-2023 wherein the firm challenged the test result of the CDL section 22, sub-section 5 of Drug Act 1976 and requested for appellate test. Firm also stated that they did not receive manufacture sample portion and also stated that they have checked retained sample and do not found any bottle with black particles.

4. Letters were issued to manufacturer and FGA, dated 18-04-2023 for provision of OOS investigation as per the decision of 313th meeting of DRB

5. Reply has been received from M/s Standpharm, Lahore, dated 02-05-2023 wherein firm has submitted OOS investigation, stating that they have checked retained samples as well as recalled stock and did not find any quality contravention, moreover they have performed OOS investigation and declared that no OOS deviation was found, it is pertained to mention that the

submitted OOS investigation was conducted in response to PQCB Quetta.

"MASTER"		"WORKING COPY"	
STANDPHARM PAKISTAN (PVT) LTD.			
Form No. FQC – 1399 – 01		Investigation Report for Out of Specification Analytical Results	
Reference Document No. QC – 600	Effective Date: 07-04-2023	Page 1 of 4	
1. Summary of OOS Results:			
Product: <u>Paracet Infusion 1g/100ml</u>	SOP number: <u>QC-586-03</u>		
Batch Number: <u>CU170</u>	Product Stage: <u>Finished Product Sample</u>		
Title of SOP: <u>SOP for Finished product testing of Paracet Infusion 1g/100ml</u>	OOS Result: <u>Sample found having foreign matter visible through naked eye. (By DTL Quetta)</u>		
Effective date of SOP: <u>25-01-2023</u>	Specification: <u>FQC-1375-02</u>		
OOS Generated by: <u>DTL Quetta</u>	Analyst / Department: <u>Govt. Analyst</u>		
OOS Investigation number: <u>002/2023</u>	QC Manager / Date: <u>M. Shah Jahan/ 27-4-23</u>		
2. Description and Investigations of OOS:			
All testing results including 'Particulate matter', were found satisfactory at the time of batch release. Investigation performed as sample was declared "Adulterated" by DTL Quetta due to the presence of foreign matter visible to naked eyes. All initial testing record was reviewed as a part of investigation.			
Checklist	YES	NO	Not applicable
Documentation			
Write/transfer error	☐	☒	☐
Calculation error	☐	☐	☒
.....	☐	☐	☐
Carrying out			
Deviation from procedure	☐	☒	☐
Incorrect procedure	☐	☒	☐
.....	☐	☐	☐
Standard			
Correct standard	☐	☐	☒
Expiration date OK	☐	☐	☒
Storage OK	☐	☐	☒
Initial weight OK	☐	☐	☒
Dilution OK	☐	☐	☒
.....	☐	☐	☐



STANDPHARM PAKISTAN (PVT) LTD.

Form No. FQC - 1399 - 01

Investigation Report for Out of Specification Analytical Results

Reference Document No. QC - 600

Effective Date: 07-04-2023

Page 2 of 4

Samples

Correct sample



Storage OK



Initial weight OK



Dilution OK



.....



.....



Instrument (*Liquid Particle Counter*)

Calibration OK



Parameter set correctly



Injector correct



Detector correct



.....



.....



.....



System Suitability Test carried out



.....Not Applicable.....



.....



.....



.....



.....



Comments: No documentation, instrument, performance or sample related problem found. All testing result, including 'Particulate matter', were found satisfactory & valid.

3. Determinate Error ☐

Indeterminate Error ☐

Clerical Error ☐

QC Analyst:

Acc

Supervisor / QC Manager:

LM

 STANDPHARM	STANDPHARM PAKISTAN (PVT) LTD.		
	Form No. FQC – 1399 – 01		Investigation Report for Out of Specification Analytical Results
	Reference Document No. QC – 600	Effective Date: 07-04-2023	Page 3 of 4

4. Investigation

4.1 Result of investigation:
No error found during initial investigation.

4.2 Corrective Action: (only if it is Determinate or Clerical Error)
As there is no OOS hence not applicable

4.3 Remarks:
Description / Appearance of solution, Particulate matter and all other results found satisfactory. Complete testing record is attached.

5. Retest

5.1 Retest by Analyst 'A' Result: NA Pass ☐ Fail ☐
(In case of Determinate Error)

5.1.1 If failed, determine the cause (s) of failure
Determinate Error ☐ Indeterminate Error ☐ Clerical Error ☐

5.1.2 If the result is Pass, Accept the results and release the sample.

5.1.3 Remarks: _____

5.2 Indeterminate Error

Retest Result: Analyst 'A': _____ Pass ☐ Fail ☐
Analyst 'B': _____ Pass ☐ Fail ☐

Remarks: _____

If required Result of Analyst 'C': _____ Pass ☐ Fail ☐

Resample Result: Analyst 'A': _____ Pass ☐ Fail ☐
Analyst 'B': _____ Pass ☐ Fail ☐

Remarks: _____

If required Result of Analyst 'C': _____ Pass ☐ Fail ☐

 STANDPHARM PAKISTAN (PVT) LTD.	
Form No. FQC – 1399 – 01	Investigation Report for Out of Specification Analytical Results
Reference Document No. QC – 600	Effective Date: 07-04-2023 Page 4 of 4

6. **Discussion & Conclusion:**

Testing results at the time of batch release were satisfactory and valid. Retained sample of this batch was tested on 26-12-2022 and found the sample clear and having no sign of particulate matter. Result of other tests were also satisfactory and submitted to PQCB, Quetta on 26-12-2022 & Drug Inspector Zone-N, Quetta Baluchistan on 03-01-2023.

Analyst / Date:

QRC 27/4/2023

QC Manager / Date:

MS 27/4/2023

7. **Remarks by QA:**

Batch recall has already been done. We have recalled 731 packs from market. We have also checked recalled pack and no sign of particulate matter visible to naked eye found in recalled packs.

QA Manager Signature / Date:

[Signature] 27/04/2023

 STANDPHARM PAKISTAN (PVT) LTD.	
Form No. FQC - 1400 - 01	Formal Investigation for Un-Assignable Cause
Reference Document No. QC - 600	Effective Date: 07-04-2023 Page 1 of 2

Section I

Date of test: 26-12-2022	SOP #: QC-586-03
Title of SOP: : SOP for Finished product testing of Paracet Infusion 1g/100ml	Sample description: Paracet Infusion 1g/100ml, batch # CIJ170.
Observed value: No foreign matter found visible	Reason for investigation: Declared "Adulterated" by DTL Quetta
Specification: FQC-1375-02	Analyst name: Asad Nawaz
OOS Investigation number: 002/2023	

Section II

Impact on Process and Product Quality: Determine whether or not Un-assignable OOS has impacted process or Product Quality Yes ☐ The quality of product (s) impacted due to: 1- 2- 3- No ☐ The quality of product (s) impacted due to: 1- 2- 3- NA ☒ Analyst Signature: <u>Asad</u>
Identify batches / Lots / materials that are impacted: NOT APPLICABLE
Material Review Board (MRB) Investigations: From the review of Batch Processing record of Paracet infusion batch no. CIJ170, it was noted that batch was manufactured and filled on 21-09-2022. Vials washing, manufacturing, filtration & filling in closed loop were performed after proper line clearance and area clearance according to SOPs. Bags of pre-autoclaved Bromobutyle Rubber stoppers were opened under LFH and instilled in respective hopper to minimize the chance of contamination. Environmental condition during batch processing were satisfactory. Non-viable count monitoring has been performed on 13-09-2022 with satisfactory results. Filter integrity tests of HEPA filters has been performed on 08-09-2022 with satisfactory results. Visual inspection was performed by 8 trained staff in 2 stages, i.e. first by 5 trained staff & then the passed vials were rechecked by 3 other trained staff.

"MASTER"		"WORKING COPY"	
 STANDPHARM	STANDPHARM PAKISTAN (PVT) LTD.		
Form No. FQC - 1400 - 01	Formal Investigation for Un-Assignable Cause		
Reference Document No. QC - 600	Effective Date: 07-04-2023	Page 2 of 2	
Results of investigation by MRB: Since our said batch was not OOS at the time of release and neither the retained nor the recalled samples found OOS with regards to appearance and particulate matter hence no problem found in our product based on this OOS investigation.			
Conclusion: Investigation concluded that Paracet Infusion 1g/ 100ml batch # CIJ170 is complying with the specifications.			
Signature of MRB: 1- Procurement: _____ 2- Production: _____ 3- Quality Control: _____ 4- Quality Assurance: _____ 5- Others { }: _____			

6. It is further submitted that the Board Sample portion was received in broken form, and letter was issued to area FID Quetta to investigate this matter and fix the responsible person for packing and delivering broken, the reply of which is still pending.

7. It is pertained to mention that firm has mentioned that OOS investigation was conducted in response to PQCB Quetta letter regarding declaration of substandard quality of this batch CIJ170. It seems that the same batch was sampled by Provincial Inspector of Drugs Quetta and the matter of substandard quality is also in process at PQCB Quetta. PQCB Quetta was also request

vide letter No.F.No.13-09/2023-QC dated 10-07-2023 and reminder dated 12-08-2023 to provide details of proceeding and results of DTL Quetta / NIH (if any) regarding this Batch of Paracet Infusion 100 ml batch No. CIJ170. No reply has been received from PQCB Quetta.

8. **Proceedings and decision of Registration Board 339th meeting:**

Board deliberated the case in detail and decided not to accede firm's request of appellant testing and decided to issue showcase notice to firm along for suspension /cancelation/prosecution in Drug Court of subject cited drug to M/s Standpharm Pakistan (Pvt) Ltd, Lahore and called for personal hearing before Registration Board.

9. Division of QA&LT issued show causes notice vide office No F.03-28/2024-DDLT (339-RB) dated 28th October, 2024 under Section 42 of the Drugs Act 1976.

10. In response to said show cause, M/s. Standpharm Pakistan (Pvt) Ltd, Lahore vide letter nil dated 11th November, 2024 replied:

1. This is in response to the show cause notice dated 28-10-2024 (the "**Notice**") wherein your good office has directed M/s Standpharm Pakistan (Private) Limited ("**Standpharm**") to furnish a response to the allegations of violating the conditions of registration and manufacture of Paracet IV 1 G/100 ml Infusion (Registration No. 083853), Batch No. CIJ170 (the "**Product**") purportedly declared "**adulterated and substandard**" vide CDL, Karachi test report No. KQII-22-000234 dated 20-12-2023 (the "**CDL Report**")

2. It is brought to your kind attention that Standpharm has been engaged in the manufacturing, distribution and sale of the Product for the past several years and there has never been any complaint regarding any defect in the quality, safety and efficacy of the Product. Accordingly, the allegations contained in the Notice as well as the contents of the CDL Report are vehemently denied by Standpharm in their entirety

3. Without prejudice to the foregoing, in response to the ill-founded and incorrect allegations contained in the Notice, we submit as under.

- First and foremost, the sample of the warrantor/manufacturer's portion of the Product in question was never received from the Federal Inspector of Drugs by Standpharm in violation of the mandatory sampling requirements stipulated under Section 19 (6) of the Drugs Act, 1976 (the "**Drugs Act**"). As such, Standpharm has duly investigated and verified the batch manufacturing record of the Product and found the aforementioned product to be well within the permissible parameters. Standpharm has recalled the said batch from all distributors and submitted the details to Assistant Director QC-I (Mr. Shahrukh Ali) on 12 January 2023 and later on complete recall updates on 20 March 2023 with filled annexures as per "Guidelines on Recalls and Rapid Alerts of Defective Therapeutic Goods". Out of the 7380 vials released for dispatch (Batch size 8000 vials) only 731 vials were received back. There have never been any complaints launched/ received regarding the consumed 6649 vials by any retailer/distributor/practitioner, leading to assume that the batch in general did not contain any visible particle. The Recalled vials as well as the retain samples within the premises were all checked and verified for any visible particles, but were found satisfactory.
- It is important to mention that for recall verification of said batch on 11 Jan 2023, the Provincial Drug Inspector did a surprise visit at Standpharm facility at 5pm to witness the recalled stock and have a look at our injectable facility. He was unable to indicate any visible particle in the recalled vials. He further took samples of other injectable products, namely

Stanflox Infusion (batch # CIM211), Staxin 400mg Infusion (batch #CIM239) & Protoxil Infusion (batch #CU179) and sent to Drug Testing Laboratory Lahore for complete analysis. All of these sample were found satisfactory with respect to all physical, chemical and microbiological tests.

Report of Test/ Analysis by Govt. Analyst, Punjab of these three products attached herewith as "Enclosures-I & III".

- Moreover, Standpharm also performed OOS investigation and no defect was found in the quality of the Product. This report was submitted before the Registration Board in its 339th Meeting of Registration Board held on 6^a August to 8th August 2024.

Copies of the OOS Investigation report, batch release certificate/report are attached herewith as "Enclosures-IV to V

i. It is pertinent to note that the CDL Report is riddled with infirmities and defects and hence inadmissible as evidence of any violation of the Drugs Act or the rules framed thereunder on part of Standpharm. The CDL Report's findings are based on 'a naked eye test' to ascertain and conclude that the Product allegedly contains "Black particles visible to the naked eye" without carry out the liquid particulate matter test to verify the number, characteristics and type of the 'black particles purportedly found in the Product in question. On the contrary, in light of various precedents it is clear that tiny particles, if found, in any drug will not make by necessary corollary render the drug in question substandard or adulterated. This viewpoint is supported by the following judicial pronouncements:

a. 2003 YLR 3056 Lahore

"Simply remarking that the sample contained suspended particles which were visible to the naked eye, would not be sufficient to declare the drug substandard or adulterated."

b. In ICA No. 127 of 1989 the Lahore High Court, held that particles and fibers are not covered under the definition of adulteration.

c. 1996 PC.LJ 1183

"To hold the drug adulterated or substandard, it must be declared as filthy, putrid or decomposed substance which contains any foreign matter, vermin, worm etc. Thus, the particles and fibers in the drug would not make it adulterated or for that matter substandard".

ii. Be that as it may be, the Product is manufactured at the state-of-the-art manufacturing facility of Standpharm and it is beyond comprehension that any particle could adulterate the Product in question during the manufacturing process or whilst the Product remained in the safe custody of Standpharm. As a matter of fact, to maintain and ensure the integrity and quality of the liquid preparations, Standpharm has made a significant investment in procuring and installing the latest machinery as well as instated strict Standard Operating Procedures. These measures adopted by Standpharm ensure that the highest quality drugs are manufactured and made available for the consumption of the public en mass. Accordingly, there is no possibility of adulteration of the Product and the findings of the CDL Report are highly questionable and non-conclusive

List of the machinery along with its specifications and Standard Operating Procedures employed by Standpharm are attached herewith as "Enclosures VI & VII",

iii. From the registration of this product till date some other batches of said product have also been collected by drug inspectors of relevant areas and all of the samples have been found of Minutes of 348th Meeting of Registration Board (01st – 02nd July, 2025)

"Standard" quality from different drug testing laboratories of the country. Below is the summary of batches and areas from where the samples have been taken:

Batch #	Area	Date
BID061	Rawalpindi	Aug 2021
DIJ138	Umerkot (Sindh)	Feb 2024

Report of Test! Analysis by Govt. Analyst, Punjab (by DTL Rawalpindi for batch # BID051) is attached as "Enclosure VIII".

iv. Moreover, Standpharm has been denied its statutory right provided under Section 22 (4) & (5) of the Drugs Act to raise evidence in contravention of the CDL Report and get the Product in question re-tested from the Appellate Laboratory without any fault or lapse on its part. As such, the burden of lapses in the sampling of the Product has been wrongly placed upon Standpharm outside the bounds of fair regulation and principles of equity since the re-testing request of Standpharm was denied because the Registration Board received broken sample of the Product from the Drug Inspector. Consequently, the safe delivery of the samples received by the CDL for the purpose of test and analysis is also questionable since the warrantor portion was never received by Standpharm and even the Board's sample was received broken which fact is admitted in the 339th Meeting of Registration Board held on 6 August to 8 August 2024. As such, the contents and findings of the CDL report are highly doubtful and lack credibility since the same cannot be verified through re-testing whatsoever.

v. Lastly, it is stressed that Standpharm has an impeccable reputation in the pharmaceutical sector and has never violated any term of registration of the Product or engaged in violation of the drug laws of the Country. Accordingly, it is futile to initiate any action against Standpharm and/or its officials.

4. In view of the foregoing, your good office is requested to withdraw the captioned show cause notice in the interest of justice, equity and fair play. It is further requested that, the Registration Board may reconsider and Standpharm (Private) Limited as well as its Officers be dropped of being misconceived.

11. Division of QA&LT issued a notice of personal hearing vide letter F.03-46/2024-QALT (342-RB) dated 28th November, 2024 under Section 42 of the Drug Act 1976.

12. **Proceedings and Decision of 343rd Meeting of Registration Board**

Mr. Shoaib Ashraf (Production Manager), Mr. Muhammad Shah Jahan (Head of Quality Operations) and Mr. Rao Tahir Umer (CFO / COO) of the firm M/s StandPharm (Pvt) Ltd, Lahore, appeared before the Board.

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

- i. ***Suspend the Registration of Paracet IV 1 G/100 ml Infusion., Registration No. 083853 manufactured by M/s StandPharm (Pvt) Ltd, Lahore under section 42 of the Drugs Act, 1976 and rules framed thereunder, for a period of three months.***

ii. ***Product Specific Inspection by panel of inspectors/experts to be nominated by Director QA/LT.***

13. Suspension of registration of Paracet IV 1 G/100 ml Infusion was granted via letter No. 03-2/2025-QALT (343-RB) dated 13th January 2025.

14. Following panel conducted PSI for product Paracet 1G infusion (083853) on 28.02.2025 in compliance to letter No. 03-2/2025-QALT(343-RB) dated 14.01.2025.

- i. Dr. Ali Jan, Member RB/ Director, DTL, Quetta
- ii. Mr. Ishtiaq Shafiq, Deputy Director, DRAP, Lahore.

15. Panel concluded & recommended as following vide their report submitted by Additional Director, Lahore vide his letter No. 1710/2025-DRAP (L-IV.) dated 12th June 2025:

Conclusion/Recommendations of panel:

"Keeping in view the inspection / review of above mentioned areas and documents, the stability data along with API records of Paracet Infusion of M/S Standpharm Pakistan (Pvt) Ltd. has demonstrated adequate practices in all key areas of the Product-Specific Inspection. The firm has maintained SOPs, conducted thorough quality control tests, and ensured that all equipment and personnel training meet the required standards. The raw material testing, production process, and storage conditions were all found to be in compliance with regulatory requirements. Additionally, the firm's stability testing and quality checks for the Paracetamol Infusion were thoroughly reviewed and found satisfactory."

Proceedings and Decision of 348th 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 threadbare deliberations, decided as follows:

- i. ***To resume production of Paracet IV 1G/100 ml Infusion, Registration Number 083853 of M/s StandPharm (Pvt) Ltd, Lahore.***
- ii. ***Firm shall inform area FID to take sample from 1st commercial batch for the purpose of test/analysis by CDL Karachi and sale of the product is subject to the standard report by the Central Drugs Laboratory, Karachi and subsequent approval by Director (QA&LT).***
- iii. ***Destruction of recalled stocks of Paracet IV 1G/100 ml Infusion Batch # CIJ170 in the presence of officer nominated by the Director QA&LT.***

Case No.2: **SUBSTANDARD FLAGYNASE SUSPENSION, REG. NO. 087528 BATCH NO # 0362 MANUFACTURED BY M/S. ARIES PHARMACEUTICALS (PVT) LTD., PESHAWAR**

Federal Inspector of DRAP, Peshawar, inspected Premises of M/s Aries Pharmaceuticals (Pvt) Ltd., Peshawar, on 6th September, 2024, wherein sample of Flagynase Suspension was taken for the purpose of test/analysis on prescribed Form-3. and sent to the Federal Government Analyst, CDL Karachi for test/analysis on Form-4. Federal Government Analyst, CDL Karachi vide test report No. IP-9-24-000079 dated 15th November, 2024 declared the batch 0362 of product Flagynase Suspension manufactured by M/s. Aries Pharmaceuticals (Pvt.) Ltd., Peshawar as of “*Substandard Quality*”. Details of CDL test report are as under.

Product Name	Manufactured by	Reg. No.	Batch No.	Mfg. Date	Exp. Date	Test Results
Flagynase suspension Metronidazole (200mg/5ml)	M/s. Aries Pharmaceuticals (Pvt.) Ltd., Peshawar.	087528	0362	10-2023	10-2025	Sample has been declared as “ Substandard ” on the basis of Assay: Metronidazole: 83.57% Limit: 95%-105%

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

3. Federal Inspector of Drugs, DRAP, Peshawar, Mr. Atiq ul Bari submitted the complete case along with copies of Form 3 and Form 4. Additionally, he submitted the company's request of Appellate testing vide letter No. AP/QC-009-23 dated 17th December, 2024, after receiving letter along with CDL report from FID, Peshawar dated 16th December, 2024 (which was sent on 11th December, 2024).

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

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

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

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

5. In the light of above-mentioned decision of the Board, the division of QA&LT vide letter F. No.03-55/2024-AD(QALT-IV) dated 31st December, 2024 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.

6. 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 BP 2022 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. Aries Pharmaceuticals (Pvt.) Ltd., Peshawar

M/s. Aries Pharmaceuticals (Pvt.) Ltd., Peshawar 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 assay.
- ii. CDL and manufacturer both performed the test as per BP.
- iii. There may be issues during formulation development, manufacturing processes, quality of API, and instability of product.
- iv. CDL submitted that the final decision of the report is OOS valid.

7. Decision of 336th meeting of RB regarding Flagynase Suspension Batch No. 0244:

The same product 'Flagynase Suspension, Batch No. 0244', was declared '*Substandard*' based on pH and the case was placed before the 336th meeting of Registration Board. “

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

- i. *Suspension of the Registration of Flagynase Suspension, Registration No. 087528 manufactured by M/s. Aries Pharmaceuticals (Pvt) Ltd., Peshawar under section 42 of the Drugs Act, 1976 and rules framed thereunder, for a period of six months or till verification of Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) by a panel with satisfactory report; whichever is later.*
- ii. *Submission of RCA and CAPA by the firm.*
- iii. *Product Specific Inspection including verification of RCA and CAPA by panel of inspectors/experts to be nominated by Director QA/LT.*
- iv. *Firm shall submit complete recall status of aforementioned batch as per Recall Guidelines Doc no. QALT/GL/RA/001 to the QALT Division, DRAP, Islamabad.*

Accordingly, decision of the Registration Board was conveyed to the firm vide letter F.03-21/2024-QC (336-RB) dated 11th September, 2024.

Reply of the firm with regard to point (ii to iv) of the decision is still awaited.

8. Proceedings and Decision of 345th Meeting of Registration Board

Division of QA&LT appraised the Board regarding manufacturing and sale of substandard Flagynase Suspension, Batch No. 0244 and subsequent decision taken in 336th meeting of Registration Board, in which the Board decided to suspend registration of the said product. The Board, after considering the facts of the case and thorough deliberations, decided as follows:

- i. *Not to accede the firm's request for retesting of sample from Appellate Laboratory under section 22 (5) of the Drugs Act, 1976.*
- ii. *To issue show cause notice to M/s. Aries Pharmaceuticals (Pvt) Ltd., Peshawar under Section 42 of the Drugs Act, 1976 and call the representatives of the firm for personal hearing before Registration Board in its forthcoming meeting.*

9. Division of QA&LT issued Show Cause notice vide office F. No. 03-9/2025-QALT (345-RB) dated 17th April, 2025 under Section 42 of the Drugs Act 1976.

10. Accordingly, the firm has been issued notice of personal hearing to appear before the Board, under Section 42 of the Drug Act 1976 vide letter No. F. 5-5/2025-ADQA-V (348-RB) dated 24.06.2025.

11. Moreover, the firm also submitted reconciliation report of recalled stocks, confirming that a total of 19,472 packs were manufactured and distributed in the market. Of these, 2052 packs were recalled. In this regard, the permission for the destruction of stocks recalled by the manufacturer may be granted so that destruction of the recalled stocks be carried out in accordance with implemented guidelines. Moreover, it is further requested that the power to approve destruction of recalled stock be delegated to Chairman Registration Board, please.

Proceedings and Decision of 348th Meeting of Registration Board.

Division of QA & LT presented the case before The Registration Board. Mr. Noor Faraz Production Manager and Shiraz Khan, Quality Control Manager from M/s Aries Pharmaceuticals, Peshawar appeared before the board and resubmitted their stance submitted in the 345th meeting of Registration Board.

Keeping in view the facts of the case and statement of the representatives of the firm, the Board decided as under:

- i. To conduct Product Specific Inspection of product namely Flagynase Suspension manufactured by panel of inspectors/ experts nominated by the Director QA&LT. The registration of product Flagynase Suspension shall remained suspended till satisfactory report received from the nominated panel.*
- ii. Destruction of recalled stocks of Flagynase suspension B# 0362 in the presence of officer nominated by the Director QA&LT.*

Case No.3: SUBSTANDARD MEDI-LOX TABLET (REG. NO. 056133) MANUFACTURED BY M/S. MEDICON PHARMACEUTICAL INDUSTRIES (PVT) LTD, PESHAWAR.

Federal Inspector of DRAP, Peshawar, inspected Premises of M/s Medicon Pharmaceutical Industries (Pvt) Ltd., Peshawar, on 5th December, 2024, wherein sample of Medi-Lox Tablet was taken for the purpose of test/analysis on prescribed Form-3. and sent to the Federal Government Analyst, CDL Karachi for test/analysis on Form-4. Federal Government Analyst, CDL Karachi vide test report No. IP-12-24-000103 dated 13th January, 2025 declared the batch 425 of product Medi-Lox Tablets manufactured by M/s. Medicon Pharmaceutical Industries (Pvt.) Ltd., Peshawar as of '***Substandard Quality***'. Details of CDL test report are as under.

Product Name	Manufactured by	Reg. No.	Batch No.	Mfg. Date	Exp. Date	Test Results
Medi-Lox Tablet Ciprofloxacin (250mg/tablet)	M/s. Medicon Pharmaceutical Industries (Pvt.) Ltd., Peshawar.	056133	425	08-2024	07-2027	Sample has been declared as " <i>Substandard</i> " on the basis of Dissolution

						Dissolution (S ₁) = 61.90% Does not comply. Dissolution (S ₂) = 63.28% Does not comply Dissolution S ₃ = 64.96% Does not comply

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

3. Federal Inspector of Drugs, DRAP, Peshawar, Mr. Atiq ul Bari submitted that the firm has informed that their Chief Executive Officer (Dr. Maqbool Khan) has sadly passed away, creating a temporary leadership transition within the organization. Currently they are in the process of appointing a new CEO in accordance with the company's internal governance procedures and regulatory requirements. Moreover, the firm has requested for extension for the submission of the documents requested by this office.

4. Meanwhile the firm submitted reconciliation report of recalled stocks indicating that a total of 5,500 packs of the product were manufactured and distributed in the market. Of these, 1030 packs have been recalled. In this regard, the permission for the destruction of stocks recalled by the manufacturer may be granted so that destruction of the recalled stocks be carried out in accordance with implemented guidelines. Moreover, it is further requested that the power to approve destruction of recalled stock be delegated to Chairman Registration Board, please.

Proceedings and Decision of 348th Meeting of Registration Board.

Division of QA & LT presented the case before The Registration Board. The board was appraised about firm's reply. The board after thorough deliberation and reviewing firm's request for extension for the submission of documents due to demise of their Chief Executive Officer (Dr. Maqbool Khan) decided as following:

- i. To issue show cause notice to M/s. Medicon Pharmaceutical Industries (Pvt.) Ltd., Peshawar under Section 42 of the Drugs Act, 1976 and call the representatives of the firm for personal hearing before Registration Board.*
- ii. The Board delegated the following function / power to the Chairman, Registration Board.*

<i>Functions / Powers</i>	<i>Functions / Powers Delegated to</i>
<i>Grant of permission of destruction of recalled stock of out of specifications products</i>	<i>Chairman, Registration Board.</i>



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



Item No. IV: Applications submitted on e-App (PE&R)

Sr. No	Title	Description
1	Case Category	Contract Manufacturing (Abdul Mughees)
	Name, address of Applicant.	Rogen Pharmaceuticals Plot No. 30, S-4, National Industrial Zone Rawat, Islamabad. (000692)
	Application Form Dy. No / Tracking ID & date of submission	(15J-53S-XEPR, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2025-01-03,
	The proposed proprietary name / brand name	Rogzone
	Label Claim	Each vial contains: Sterile Powder of Ceftriaxone Sodium USP eq. to Ceftriaxone.....1000mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1,s-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	Oxidil
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Shawan pharmaceuticals-Plot # 37, Road NS-1, RCCI Rawat-
	The status in reference regulatory authorities	Approved by US FDA USFDA approves Alembic's Ketorolac tromethamine injection USP
	Detail of previous approval	Axon 1000mg (IV) Injection, 333th meeting of Registration Board (19th to 20th December, 2023)
	Evaluation Remarks	
	The applied contract manufacturer is M/s Shawan Pharmaceutical, same formulation is already approved in the name of proposed contract manufacturer in 333rd meeting as submitted on Form5F. Said product was already registered in the name of applicant but due to non submission of renewal/ extension of contract manufacturing permission the registration of said product deem cancel. In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	

2	Case Category	Contract Manufacturing (Abdul Mughees)
	Name, address of Applicant.	Rogen Pharmaceuticals Plot No. 30, S-4, National Industrial Zone Rawat, Islamabad. (000692)
	Application Form Dy. No / Tracking ID & date of submission	(3RP-WDD-5Q7X, 2025-04-30)
	Detail of Fee Submitted	93000.0, 2025-01-03,
	The proposed proprietary name / brand name	Rogxime DS
	Label Claim	Each 5ml of Dry Powder for Suspension, when reconstituted, Contains: Cefixime as Trihydrate USP..... 200mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1,s-As per SRO
	Shelf Life (Unit)	2 YearRome Temperature
	For generic drugs (me-too Status)	Cebosh Dry Suspension
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Shawan Pharmaceuticals-SHAWAN PHARMACEUTICALS. Address: Plot No. 37, Road NS 1, National Industrial Zone, Rawat, Islamabad, Pakistan.-
	The status in reference regulatory authorities	Approved by US FDA USFDA approves Alembic's Ketorolac tromethamine injection USP
	Detail of previous approval	Cefit 200mg DS, 336th meeting of Registration Board (4th August to 6th June, 2024),
3	Evaluation Remarks	
	The applied contract manufacturer is M/s Shawan Pharmaceutical, same formulation is already approved in the name of proposed contract manufacturer in 333rd meeting as submitted on Form5F. Said product was already registered in the name of applicant but due to non submission of renewal/ extension of contract manufacturing permission the registration of said product deem cancel.	
	Decision	
	Approved	
	Case Category	Contract Manufacturing (Abdul Mughees)
	Name, address of Applicant.	Acumen Healthcare (Pvt.) Ltd plot#, 39, 40 Street S2, Rawat Industrial Estate, Islamabad (000932)
	Application Form Dy. No / Tracking ID & date of submission	(5M8-88D-S3W8, 2025-06-27)
	Detail of Fee Submitted	93000.0, 2025-01-16,
	The proposed proprietary name / brand name	Rhosy Injection 500mg/10ml
	Label Claim	Each 10ml Vial Contains: Iron as Ferric Carboxymaltose.....500mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C

	For generic drugs (me-too Status)	FERINJECT 500mg/10ml INJECTION by RH Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	Usfda Approved
	Detail of previous approval	Ferrina Injection, DRB 343
	Evaluation Remarks	
	The applicant, vide Tracking ID XB4-99E-GYT9, submitted application for the same product in May 2024 wherein the applicant selected NO in the already approved data section of the application. That application shall be withdrawn. As for instant application where applicant has selected YES in the already approved data section, the FERRINA 500mg/10ml Injection M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar was approved in the 343rd meeting of the Registration Board. In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
4	Case Category	Routine (Abdul Mughees)
	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	(63B-B77-TW43, 2024-03-19)
	Detail of Fee Submitted	75000.0, 2024-03-06,
	The proposed proprietary name / brand name	Tofajak XR 11mg Tablet
	Label Claim	Each film coated extended release tablet contains: Tofacitinib (as Citrate) 11mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per PRC-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C, protect from light, heat & moisture. Keep out of reach of children.
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Glenmark Life Sciences
	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	
	Tofajak XR 11 mg is an extended release tablet and the firm has performed studies in line with US FDA recommended dissolution method. The firm has submitted DS analysis and stability. Analytical validation of the finished product has been performed and CDP with reference product XELJANZ XR 11 mg Tablet Lot.No: ER9192 Exp. Date: 10-2023 Manufactured by Pfizer, Canada has been performed. Stability data has been submitted as per guidance document.	
	Decision	
	Approved	
	Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.	
	Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.	
5	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Seatl Private Limited 45-Km Multan Road, Lahore (000481)
	Application Form Dy. No / Tracking ID & date of submission	(6QN-7ZH-A6Y3, 2024-04-18)
	Detail of Fee Submitted	30000.0, 2023-05-26,
	The proposed proprietary name / brand name	Terbin Lotion 1%
	Label Claim	Each gram contains: Terbinafine Hydrochloride equivalent to Terbinafine 10gm (1%)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10mL, 20mL, 30mL, 60-As per SRO
	Shelf Life (Unit)	24 Year(s) stored below 30°C
	For generic drugs (me-too Status)	Terbiderm by Atco Laboratories
	Pharmacotherapeutic Group of (API)	Terbinafine belongs to the pharmacotherapeutic group of antifungals, specifically allylamines. It is used to treat various fungal infections, including those of the skin, nails, and scalp. Terbinafine is known for its broad spectrum of antifungal activity, particularly against dermatophytes, molds, and certain dimorphic fungi.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Boyuan Pharmaceutical Co., Ltd
	Detail of stability batches of drug product	Batch numbers: 221202061, 221203061, 221204061
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate number E-2215046661359 for Terbinafine Hydrochloride (BP Specification) for Terbin Tab 125mg
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE is performed with Innovator Product: Lamisil Once 1%w/w, Batch No: 245C, Manufacturer: GSK Consumer, Uk, Expiry Date: 09-2024

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Only 06 months stability data has been submitted as per checklist.
	The status in reference regulatory authorities	LAMISIL AT (TERBINAFINE HYDROCHLORIDE) 1% by KARO HEALTHCARE INC (US,FDA)
	GMP status of the firm	.
	Evidence of approval of manufacturing facility	Seattle Pvt. Ltd. DML (Formulation) 000481
	Evaluation Remarks	
	GMP of DS manufacturer is from Shandong Pharmaceutical Profession Association. The applicant has submitted finished product stability data (both accelerated and long-term) for 06 months.	
	Decision	
	Approved	
6	Case Category	Priority As Per 257-M of RB (Abdul Mughees)
	Name, address of Applicant.	Roche Pakistan Ltd 37-B 1st Floor, Block-6 P.E.C.H.S. P.O Box 20021 Karachi-75400 Pakistan (0493)
	Application Form Dy. No / Tracking ID & date of submission	(89P-QJX-8768, 2025-06-27)
	Detail of Fee Submitted	300000.0, 2025-06-13,
	The proposed proprietary name / brand name	Itovebi
	Label Claim	Each Film-coated tablet contains..... 9 mg of inavolisib
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	28's-De-Controlled
	Shelf Life (Unit)	24 Month Store below 30°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Protein-Kinase Inhibitor
	Name, address of Manufacturing site:	F.Hoffmann-La Roche AG, -Wurmisweg, 4303 Kaiseraugst, Switzerland-Switzerland
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A (Innovator Molecule)
	Name, address of Marketing Authorization Holder:	Roche Pharma (Schweiz) AG , Grenzacherstrasse 124, 4058 Basel, Switzerland , Switzerland
	Details of Certificates (CoPP/FSC/cGMP):	Valid
	Details of Authorization Letter :	N/A (To be imported as FFP)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	24 months
	The status in reference regulatory authorities	Swissmedic
	Evaluation Remarks	
	The manufacturer details are: Manufacturer / Packaging (Primary and Secondary) & Release of the Finished Drug Product F. Hoffmann-La Roche AG, Wurmisweg, 4303 Kaiseraugst, Switzerland. Marketing Authorization Holder: Roche Pharma (Schweiz) AG Grenzacherstrasse 124 4058 Basel Switzerland.CoPP issued by Switzerland bearing number 25001819 with 1.3 and 1.4 as Yes and 1.3.1 as No. Market authorization issued date is mentioned 31.01.2025.	
	Decision	
	Approved	

7	Case Category	Import (Abdul Mughees)
	Name, address of Applicant.	Atco Laboratories Ltd B-18 SITE Karachi (025)
	Application Form Dy. No / Tracking ID & date of submission	(LYG-VMD-BUAH, 2025-03-23)
	Detail of Fee Submitted	300000.0, 2025-01-14,
	The proposed proprietary name / brand name	Carbetocin Ferring solution for injection
	Label Claim	Each ml contains: Carbetocin 100 microgram
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1 mL x 10 ampoules-Controlled
	Shelf Life (Unit)	48 Month(s)Don't store & transport above 30degree centigrade
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	Systemic hormonal preparations ATC code H01BB103. Carbetocin is indicated for the prevention of postpartum haemorrhage due to uterine atony.
	Name, address of Manufacturing site:	Ferring Pharmaceuticals (China) Co., Ltd.-No. 6 HuiLing Lu (Ferring Road), National Health Technology Park, 528437 Zhongshan City, Guangdong Province, People's Republic of China-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	WHO Evaluation
	Name, address of Marketing Authorization Holder:	Ferring Pharmaceuticals (China) Co., Ltd., No. 6 HuiLing Lu (Ferring Road), National Health Technology Park, 528437 Zhongshan City, Guangdong Province, People's Republic of China, China
	Details of Certificates (CoPP/FSC/cGMP):	Attached are two documents: a GMP Inspection Notification from the Guangdong Medical Products Administration for Ferring Pharmaceuticals (China) Co., Ltd., bearing number (Y.) Y.R.Zi 20192099 and dated December 25, 2019, and a GMP compliance certificate f
	Details of Authorization Letter :	.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	WHO Evaluation
	The status in reference regulatory authorities	Carbetocin Ferring 100 approve by swissmedic with a marketing authorization number 67157 01 on 27 April 2020
8	Evaluation Remarks	
	The applicant has informed that this application was submitted under the World Health Organization (WHO) Collaborative Registration Procedure (CRP).	
	Decision	
	Approved	
8	Case Category	Contract Manufacturing (Abdul Mughees)
	Name, address of Applicant.	Rogen Pharmaceuticals Plot No. 30, S-4, National Industrial Zone Rawat, Islamabad.

	(000692)
Application Form Dy. No / Tracking ID & date of submission	(MMX-A27-GMZY, 2025-05-12)
Detail of Fee Submitted	93000.0, 2025-01-03,
The proposed proprietary name / brand name	Rogxime
Label Claim	Each 5ml of Dry Powder for Suspension, when reconstituted, Contains: Cefixime as Trihydrate USP..... 100mg (Product complies USP Specs)
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	1,s-As per SRO
Shelf Life (Unit)	2 YearRome Temperature
For generic drugs (me-too Status)	Cebosh Dry Suspension
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Shawan pharmaceuticals-Plot # 37, Road NS-1, RCCI Rawat-
The status in reference regulatory authorities	Approved by US FDA USFDA approves Alembic's Ketorolac tromethamine injection USP
Detail of previous approval	Cefit 100mg Dry Suspension, 336th meeting of Registration Board (4th August to 6th June, 2024)
Evaluation Remarks	
The applied contract manufacturer is M/s Shawan Pharmaceutical, same formulation is already approved in the name of proposed contract manufacturer in 333rd meeting as submitted on Form5F. Said product was already registered in the name of applicant but due to non submission of renewal/ extension of contract manufacturing permission the registration of said product deem cancel. In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
Decision	
Approved	
9	
Case Category	Routine (Abdul Mughees)
Name, address of Applicant.	Bosch Pharmaceuticals (Pvt) Ltd. Plot No. 221-223, Sector-23, Korangi Industrial Area (000350)
Application Form Dy. No / Tracking ID & date of submission	(QQZ-JHD-M3XJ, 2024-01-02)
Detail of Fee Submitted	75000.0, 2023-10-05,
The proposed proprietary name / brand name	Ericig
Label Claim	Each film coated tablet contains: Vericiguat 5mg
Reference to Finished product specifications	Manufacturer Specification
Proposed Pack Size	14's-As per SRO
Shelf Life (Unit)	2 Year(s)Do not store above 30°C
For generic drugs (me-too Status)	Not Applicable

Pharmacotherapeutic Group of (API)	Other vasodilators used in cardiac diseases
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Nantong Chanyoo Pharmatech Co., Ltd (named as "Nantong Chanyoo"), Manufacturing site: No.2 Tonghai Si Road, Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu
Detail of stability batches of drug product	3 batches: 2000 Tablet
Documents for the procurement of API with approval from DRAP (in case of Import)	Not submitted
Pharmaceutical Equivalence and Comparative Dissolution Profile	Verquvo Tablet of Bayer Germany: PE and CDP studies performed
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
The status in reference regulatory authorities	European Medicines Agency (EMA)
GMP status of the firm	10-06-2022: GMP certificate inspection date
Evidence of approval of manufacturing facility	30-06-2020: DML renewal specifies Tablet (General) section
Evaluation Remarks	
The manufacturer has set dissolution acceptance criteria are NLT 85% in 30 minutes, while the dissolution acceptance criteria of the innovator's product are NLT Q in 15 minutes. Moreover, Registration Board in its 293rd meeting decided that "For rapidly dissolving as well as immediate release drug products, wherein the stability batches will be manufactured after 01-06-2020, variation from innovator / reference product with reference to dissolution specification will not be acceptable". The firm has replied, "Kindly note that we have performed dissolution testing at two time points at 15 minutes and at 30 minutes. Our submitted analytical data contains dissolution results at 15 minutes as well and submitted data complies as per innovator dissolution criteria i.e. product NLT Q in 15 minutes (NLT 85 % in 15 minutes).Firm has also submitted evidence of renewal of DML, which is valid till 30/06/2025.	
Decision	
Approved	
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.	
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.	
10	Case Category
	Routine (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
	(S1R-LH8-4DM4, 2024-03-26)
	Detail of Fee Submitted
	75000.0, 2023-11-14,
	The proposed proprietary name / brand name
	Thiorelax
	Label Claim
	Each gram contains: Thiocolchicoside.....2.5mg
	Reference to Finished product specifications
	As per Innovators Specificatio

	Proposed Pack Size	40g-As per SRO
	Shelf Life (Unit)	2 YearStore in a cool and dry place below 30°C.
	For generic drugs (me-too Status)	Nil
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	India Glycol Limited Plot No. 2, 3, 4&5, Pharmacy, Selaqui Industrial Area, Dehradun, Uttarakhand, and Pin Code – 248197. (India)
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	European Medicine Agency (Relief Gel 0.25%)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The shortcomings have been replied except approval in RRAs.	
	Decision	
	Deferred	
	Firm to submit approval status in Reference Regulatory Authorities as approved in 275th meeting of the Registration Board.	
11	Case Category	Contract Manufacturing (Abdul Mughees)
	Name, address of Applicant.	Rogen Pharmaceuticals Plot No. 30, S-4, National Industrial Zone Rawat, Islamabad. (000692)
	Application Form Dy. No / Tracking ID & date of submission	(V8M-7U2-42U9, 2025-05-12)
	Detail of Fee Submitted	93000.0, 2025-01-03,
	The proposed proprietary name / brand name	Rogxime
	Label Claim	Each capsule Contains: Cefixime as Trihydrate..... 400mg (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 YearRome Temperature
	For generic drugs (me-too Status)	Cebosh
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Shawan pharmaceuticals-Plot # 37, Road NS-1, RCCI Rawat-
	The status in reference regulatory authorities	Approved by US FDA USFDA approves Alembic's Ketorolac tromethamine injection USP
	Detail of previous approval	Cefit 400mg Capsule,336th meeting of Registration Board (4th August to 6th June, 2024)

	Evaluation Remarks	
	The applied contract manufacturer is M/s Shawan Pharmaceutical, same formulation is already approved in the name of proposed contract manufacturer in 333rd meeting as submitted on Form 5F. Said product was already registered in the name of applicant but due to non submission of renewal/ extension of contract manufacturing permission the registration of said product deem cancel. In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
12	Case Category	Priority As Per 257-M of RB (Abdul Mughees)
	Name, address of Applicant.	Roche Pakistan Ltd 37-B 1st Floor, Block-6 P.E.C.H.S. P.O Box 20021 Karachi-75400 Pakistan (0493)
	Application Form Dy. No / Tracking ID & date of submission	(VTY-7TN-HZ51, 2025-06-27)
	Detail of Fee Submitted	300000.0, 2025-06-13,
	The proposed proprietary name / brand name	Itovebi
	Label Claim	Each Film Coated Tablet contains..... 3 mg of Inavolisib
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	28's-De-Controlled
	Shelf Life (Unit)	24 Month Store below 30°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Protein-Kinase Inhibitor
	Name, address of Manufacturing site:	F. Hoffmann-La Roche AG, -Wurmisweg, 4303 Kaiseraugst, Switzerland-Switzerland
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A (Innovator Molecule)
	Name, address of Marketing Authorization Holder:	Roche Pharma (Schweiz) AG , Grenzacherstrasse 124, 4058 Basel, Switzerland , Switzerland
	Details of Certificates (CoPP/FSC/cGMP):	Valid
	Details of Authorization Letter :	N/A (To be imported as FFP)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	24 months
	The status in reference regulatory authorities	Swissmedic
	Evaluation Remarks	
	The manufacturer details are: Manufacturer / Packaging (Primary and Secondary) & Release of the Finished Drug Product F. Hoffmann-La Roche AG, Wurmisweg, 4303 Kaiseraugst, Switzerland. Marketing Authorization Holder: Roche Pharma (Schweiz) AG Grenzacherstrasse 124 4058 Basel Switzerland.CoPP issued by Switzerland bearing number 25001819 with 1.3 and 1.4 as Yes and 1.3.1 as No. Market authorization issued date is mentioned 31.01.2025.	
	Decision	

	Approved	
13	Case Category	Import (Abdul Mughees)
	Name, address of Applicant.	HAZALI BROTHERS 1ST FLOOR AZZAINAB COURT CAMPBELL STREET (629)
	Application Form Dy. No / Tracking ID & date of submission	(WY6-33U-BQVN, 2024-03-04)
	Detail of Fee Submitted	150000.0, 150000.0 2022-09-01, 2022-09-01
	The proposed proprietary name / brand name	Calgunate Injection 10% (1g/10ml)
	Label Claim	Each 10 ml ampoule contains Calcium Gluconate 980 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	Type I clear glass a-As per SRO
	Shelf Life (Unit)	3 Year(s)Store not exceed 30°C
	For generic drugs (me-too Status)	Locally registered
	Pharmacotherapeutic Group of (API)	Used in treatment of calcium deficiency
	Name, address of Manufacturing site:	Jiangsu Huayang Pharmaceutical Co., Ltd.-No.21, Changjiang Road, Siyang County, Jiangsu Province, China.-China
	Name & address of API manufacturer	Jiangxi Xinganjiang Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	Firm has submitted stability study data of 3 batches Accelerated Storage Conditions: Duration: 06 months Temperature: 40oC ±2oC, Relative Humidity: 75% ± 5%. Long term Storage Conditions: Duration: 36 months Temperature: 30oC ±2oC, Relative Humidity: 65% ± 5%.
	Documents for the procurement of API with approval from DRAP (in case of Import)	N/A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has done pharmaceutical equivalence with generics of Chenxin Pharmaceutical China and submitted comparison of Pharmaceutical equivalence as testing parameters of BP specifications.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API At accelerated 40 ± 5°C / RH 75% for 06 months. Real time: 30 ± 5°C / RH 65% for 36 months.
	The status in reference regulatory authorities	USFDA & MHRA approved formulation
	GMP status of the firm	CoPP: Firm has submitted CoPP certificate (No. 20230601002) dated 01-06-2023 issued by Anhui Drug Administration China. The CoPP specifies free sale status of the product in country of export along with its availability. CoPP Validity: 31-05-2028 GMP:
	Evidence of approval of manufacturing facility	N/A
Evaluation Remarks		
Agency agreement ID: HYPAK2020003 is submitted. GMP certificate of Jiangsu Huayang Pharmaceutical Co., Ltd No.21 Changjing Road Siyang County Jiang Su submitted with validity till		

27.06.2024. Notarized CoPP from Jiangsu Province Drug Administration Suqian Inspection Branch of The People's Republic of China with the stamp and date of 30.05.2022 bearing number NIL and saying “Yes” for 1.2 and 1.3 has been submitted.

Decision

Approved

14	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Bosch Pharmaceuticals (Pvt) Ltd. Plot No. 221-223, Sector-23, Korangi Industrial Area (000350)
	Application Form Dy. No / Tracking ID & date of submission	(XHL-9TE-UT2J, 2024-01-02)
	Detail of Fee Submitted	75000.0, 2023-10-05,
	The proposed proprietary name / brand name	Ericig
	Label Claim	Each film coated tablet contains: Vericiguat 10mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	2 Year(s) Do not store above 30°C
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	Other vasodilators used in cardiac diseases
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Nantong Chanyoo Pharmatech Co., Ltd (named as "Nantong Chanyoo"), Manufacturing site: No.2 Tonghai Si Road, Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu
	Detail of stability batches of drug product	3 batches: 2000 Tablet
	Documents for the procurement of API with approval from DRAP (in case of Import)	Not submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Verquvo Tablet of Bayer Germany: PE and CDP studies performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	The status in reference regulatory authorities	European Medicines Agency (EMA)
	GMP status of the firm	10-06-2022: GMP certificate inspection date
	Evidence of approval of manufacturing facility	30-06-2020: DML renewal specifies Tablet (General) section

Evaluation Remarks

The manufacturer has set dissolution acceptance criteria are NLT 85% in 30 minutes, while the dissolution acceptance criteria of the innovator's product are NLT Q in 15 minutes. Moreover, Registration Board in its 293rd meeting decided that "For rapidly dissolving as well as immediate release drug products, wherein the stability batches will be manufactured after 01-06-2020, variation from innovator / reference product with reference to dissolution specification will not be acceptable". The firm has replied, “Kindly note that we have performed dissolution testing at two time points at 15 minutes and at 30 minutes. Our submitted analytical data contains dissolution results at 15 minutes as well and submitted data complies as per innovator dissolution criteria i.e. product NLT Q in 15 minutes (NLT 85 % in 15 minutes). Revised Finished Product Specifications are attached.”

Decision

	Approved	
	Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application. Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.	
15	Case Category	Contract Manufacturing (Abdul Mughees)
	Name, address of Applicant.	Rogen Pharmaceuticals Plot No. 30, S-4, National Industrial Zone Rawat, Islamabad. (000692)
	Application Form Dy. No / Tracking ID & date of submission	(XP6-EEU-NMSZ, 2025-05-12)
	Detail of Fee Submitted	93000.0, 2025-01-03,
	The proposed proprietary name / brand name	Rogzone (IM)
	Label Claim	Each vial contains: Sterile Powder of Ceftriaxone Sodium USP eq. to Ceftriaxone.....250mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1,s-As per SRO
	Shelf Life (Unit)	2 Year(s)Rome Temperature
	For generic drugs (me-too Status)	Oxidil
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Shawan pharmaceuticals-Plot # 37, Road NS-1, RCCI Rawat-
	The status in reference regulatory authorities	Approved by US FDA USFDA approves Alembic's Ketorolac tromethamine injection USP
	Detail of previous approval	Axon 250mg Injection,341st meeting of Registration Board (19th to 20th December, 2024)
	Evaluation Remarks	
	The applied contract manufacturer is M/s Shawan Pharmaceutical, same formulation is already approved in the name of proposed contract manufacturer in 333rd meeting as submitted on Form5F. Said product was already registered in the name of applicant but due to non submission of renewal/ extension of contract manufacturing permission the registration of said product deem cancel. In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
16	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	CRYSTOLITE PHARMACEUTICALS Plot # 1 & 2, street S-2, National Industrial Zone Rawat,

	Islamabad (000778)
Application Form Dy. No / Tracking ID & date of submission	(ZYS-YHJ-RN5E, 2024-03-12)
Detail of Fee Submitted	75000.0, 2024-02-23,
The proposed proprietary name / brand name	Tapirif 1% Cream
Label Claim	Each gram contains: Tapinarof 10mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	5g-As per SRO
Shelf Life (Unit)	2 Year(s)Room Temperature
For generic drugs (me-too Status)	Not available new product
Pharmacotherapeutic Group of (API)	Tapinarof is an aryl hydrocarbon receptor agonist indicated for the topical treatment of plaque psoriasis in adults
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Gansu Haotian PharmaTech CO.,Ltd
Detail of stability batches of drug product	B# 20220115 MFG. 2022 B#20220215 MFG. 2022 B#20220315 MFG. 2022
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate E-7016459432196 dated 25 October 2023
Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed against Vtama 1% Cream (US FDA approved) batch number P96B
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	DS manufacturer concluded in the Stability Summary in Section 3.2.S.7.1 that "after placed under accelerated test condition (40±2 C/ RH75±5%) for 12 months, intermediate test condition (30±2°C/ RH65±5%) and long term test condition (30±2 C/RH65±5%) for 12 months, Tapinarof shows no obvious change on its appearance."
The status in reference regulatory authorities	Vtama by Dermavant fda approved
GMP status of the firm	GMP certificate No. F.3-31/2019-Addl. Dir. (QA & LT-1) valid 07.08.2025. GMP of DS manufacturer
Evidence of approval of manufacturing facility	DML (Formulation) 000778
Evaluation Remarks	
The proposed drug product, Tapirif 1% Cream for topical use is an emulsion packed in laminated 5g tube. Applicant has submitted Pharmaceutical Equivalence. The 6th Month stability data along with chromatograms and raw data sheets has been attached.	
Decision	
Approved	
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application. Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.	
17	Case Category New License (Adil Saeed)

	Name, address of Applicant.	Care Pharmaceuticals 8-Km Main Thokar Raiwind Road Lahore (000563)
	Application Form Dy. No / Tracking ID & date of submission	(A2T-G9R-X9TB, 2024-08-28)
	Detail of Fee Submitted	30000.0, 2024-04-23,
	The proposed proprietary name / brand name	Azocare 500 mg
	Label Claim	Each film coated tablet contains: Azithromycin dihydrate equivalent to Azithromycin..... 500 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO, 12's-As per SRO, 6's-As per SRO
	Shelf Life (Unit)	2 Year(s) Below 30 degree
	For generic drugs (me-too Status)	Zetro 500mg Tablet by Getz Pharma
	Pharmaceutical Group of (API)	J01FA10 Macrolides
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches, 1500 tabs each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Locally purchased from M/s Citi Pharma Limited
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Zetro 500mg tablet Batch no. F18011 M/s Getz Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	New Section
	Evidence of approval of manufacturing facility	Letter dated 13.07.2023 is submitted
	Evaluation Remarks	
	Decision	
	Approved	
18	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	Hamaz Pharmaceuticals (Pvt) Ltd. 13-KM Bosan Road, Lutfabad (000427)
	Application Form Dy. No / Tracking ID & date of submission	(4T4-NZY-2SH2, 2024-03-28)
	Detail of Fee Submitted	75000.0, 2024-03-20,
	The proposed proprietary name / brand name	Carizine 3mg Capsule
	Label Claim	Each Capsule contains: Cariprazine Hydrochloride equivalent to Cariprazine..... 3mg (As per Innovator's specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	24 Year(s) Store below 30°C in Cool & Dry Place.
	For generic drugs (me-too Status)	N/A

	Pharmacotherapeutic Group of (API)	N05AX15 Other antipsychotics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD. Chuannan Duqiao Linhai Zhejiang
	Detail of stability batches of drug product	3 batches, 1500 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken Loan from M/s Horizon Lahore. Clearance certificate is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Vraylar 3mg Capsule Batch No. 1164767
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Registered drug by US-FDA as VRAYLAR 3mg (Cariprazine) capsules for oral use.
	GMP status of the firm	GMP certificate issued on basis of inspection dated 13.04.2021 is submitted.
	Evidence of approval of manufacturing facility	Copy of section approval letter dated 29.01.2009
	Evaluation Remarks	
	Decision	
	Approved	
19	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	Care Pharmaceuticals 8-Km Main Thokar Raiwind Road Lahore (000563)
	Application Form Dy. No / Tracking ID & date of submission	(G9R-1YM-XWJ5, 2024-03-05)
	Detail of Fee Submitted	30000.0, 2024-01-30,
	The proposed proprietary name / brand name	Timcare 5mg/ml eye drops
	Label Claim	Each ml contains: Timolol Maleate Equivalent to Timolol 5 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5 ml -As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30 Degree Celsius
	For generic drugs (me-too Status)	Timorex Eye Drops 0.5%
	Pharmacotherapeutic Group of (API)	S01ED01 Beta blocking agents
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Flex Laboratories
	Detail of stability batches of drug product	3 batches, 400 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Tomorex Batch No 30512 Mfg M/s Vega Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	USFDA

	GMP status of the firm	GMP certificate issued on basis of inspection conducted on 01.03.2023
	Evidence of approval of manufacturing facility	Section approval letter dated 13.07.2023
	Evaluation Remarks	
	Decision	
	Approved	
20	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	AGP Limited B-23-C, S.I.T.E., Karachi (000348)
	Application Form Dy. No / Tracking ID & date of submission	(5JQ-NA4-XUQQ, 2024-03-14)
	Detail of Fee Submitted	30000.0, 2024-02-14,
	The proposed proprietary name / brand name	Pagotras 25mg Tablet
	Label Claim	Each film coated Tablet Contains: Eltrombopag Olamine equivalent to Eltrombopag.....25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3 x 10's-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store over 30°C
	For generic drugs (me-too Status)	Revolade 25mg tablet by Novartis (Pakistan) Ltd.
	Pharmacotherapeutic Group of (API)	B02BX05 Other systemic hemostatics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Sichuan D-innovation Pharmaceutical Co., Ltd.No.13, Yulan Road, Western Medical Valley, New Zone, Economic Development Zone, Meishan City, Sichuan Province, China
	Detail of stability batches of drug product	3 batches. 2000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Revolade 25mg Tablets Batch No. B8812R Mfg. Novartis
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	PROMACTA 25mg Tablet by NOVARTIS PHARMACEUTICALS CORP.
	GMP status of the firm	GMP certificate issued on basis of inspection dated 12.06.2023 is submitted
	Evidence of approval of manufacturing facility	Renewal letter dated 30.06.2020 is submitted
	Evaluation Remarks	
	Decision	
	Approved	
21	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	Sarco Chemicals Industries 17-Km. Lahore Road Multan (000203)

	Application Form Dy. No / Tracking ID & date of submission	(5MQ-WJG-6D8E, 2024-02-29)
	Detail of Fee Submitted	75000.0, 2023-10-27,
	The proposed proprietary name / brand name	D-WIM Injection 5mg/ml
	Label Claim	Each 1ml Ampoule Contains:Cholecalciferol(Vitamin D3).....5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x1ml-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at Room Temperature below 25
	For generic drugs (me-too Status)	Indrop-D Injection M/s Neutro Pharma
	Pharmacotherapeutic Group of (API)	Vitamin D
	Name, address of Manufacturing site:	Wimits Pharmaceuticals (Pvt) Ltd-Plot No. 129, Sundar Industrial Estate Raiwind Road, Lahore-
	Name & address of API manufacturer	Jiangxi Tianxin Pharmaceutical Co. Ltd. Leanjiang Industrial Zone Leping Jiangxi China
	Detail of stability batches of drug product	3 batches 80,000 Ampoules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate mentioning 6kg Drug substance is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Indrop-D 5mg/ml Injection batch No. HP988
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted. 25C 60 Acc,,, 5C long term
	The status in reference regulatory authorities	Vitamin D3 Good 200,000 IU/1 ml, oral solution in ampoule M/s Bouchara-Recordati, France (ANSM Appro
	GMP status of the firm	GMP certificate valid till 02.04.2026
	Evidence of approval of manufacturing facility	Section approval letter dated 28.03.2014 is submitted
	Evaluation Remarks	
	Decision	
	Approved	
22	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	Wnsfeild Pharmaceuticals Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK (000610)
	Application Form Dy. No / Tracking ID & date of submission	(7ML-VTZ-6BBV, 2024-03-12)
	Detail of Fee Submitted	75000.0, 2023-10-25,
	The proposed proprietary name / brand name	LYNO-M 2.5MG/500MG TABLET
	Label Claim	Each Film Coated Tablet contains: Linagliptin.....2.5MG Metformin Hydrochloride 500MG (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	A10BD11 Combinations of oral blood glucose lowering drugs
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	AARTI DRUGS LTD Mahendra Industrial Estate Plot No. – 109 – D Road No.29, Sion (East), Mumbai – 400 022. INDIA, Anhui Haikang Pharmaceutical Co., Ltd No. 21 Huancheng West Road Anqing Anhui 246000 China
	Detail of stability batches of drug product	3 batches, 1200 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Both drug substances are taken loan from M/s Weatherfolds.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Jentaduet 2.5mg/500mg Batch No. 1158545 Mfg Boehringer Ingelheim Germany
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of both drug substances is submitted.
	The status in reference regulatory authorities	EMA Approved
	GMP status of the firm	GMP certificate valid till 02.04.2025 is submitted
	Evidence of approval of manufacturing facility	-----
	Evaluation Remarks	
	Decision	
	Approved	
23	Case Category	New License (Adil Saeed)
	Name, address of Applicant.	Care Pharmaceuticals 8-Km Main Thokar Raiwind Road Lahore (000563)
	Application Form Dy. No / Tracking ID & date of submission	(XWP-T7R-97Q7, 2025-04-09)
	Detail of Fee Submitted	37000.0, 2025-03-21,
	The proposed proprietary name / brand name	C-Care
	Label Claim	Each Sachet contains Ascorbic acid 1000mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 x 10's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	C-Prime sachet(Pearl pharma)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Citi Pharma
	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	Melrose vitamin c sachet (TGA Approved)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm was asked to submit valid RRA reference but couldn't provide any. Reference submitted are of dietary supplement or of listed (not registered) product. Product can be applied in H&OTC Division for enlistment.	
	Decision	
	Rejected	
24	Case Category	Contract Manufacturing (Adil Saeed)
	Name, address of Applicant.	Winbrains Research Laboratories Plot No. 69/1 Block B, Phase I-II Industrial Estate, Hattar, Pakistan (000725)
	Application Form Dy. No / Tracking ID & date of submission	(8N3-UD4-UA2P, 2024-03-05)
	Detail of Fee Submitted	75000.0, 2023-12-29,
	The proposed proprietary name / brand name	Cinkal 30mg Tablet
	Label Claim	Each Film Coated Tablet contains: Cinacalcet Hcl eq. to Cinacalcet.....30mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°C.
	For generic drugs (me-too Status)	Censipar Tablet 30 mg by CCL Pharma
	Pharmacotherapeutic Group of (API)	H05BX01 Other anti-parathyroid agents
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK. -
	The status in reference regulatory authorities	UK MHRA Approved
	Detail of previous approval	Data already approved in 347th RB, Cinkal 30mg Tablet
	Evaluation Remarks	
	Decision	
	Approved	
25	Case Category	Contract Manufacturing (Adil Saeed)
	Name, address of Applicant.	Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (000644)
	Application Form Dy. No / Tracking ID & date of submission	(8RM-TWD-DBVU, 2024-03-06)
	Detail of Fee Submitted	75000.0, 2024-01-11,
	The proposed proprietary name / brand name	Cinafold 60mg Tablet
	Label Claim	Each Film Coated Tablet contains: Cinacalcet Hcl eq. to Cinacalcet.....60MG (Product complies

		Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°C
	For generic drugs (me-too Status)	Censipar Tablet 60 mg by CCL Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	UK MHRA Approved
	Detail of previous approval	Data already approved in 343rd RB, Cinkal 60mg Tablet
	Evaluation Remarks	
	Decision	
	Approved	
26	Case Category	Contract Manufacturing (Adil Saeed)
	Name, address of Applicant.	Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (000644)
	Application Form Dy. No / Tracking ID & date of submission	(963-QMY-AJG1, 2024-03-06)
	Detail of Fee Submitted	75000.0, 2024-01-10,
	The proposed proprietary name / brand name	Anestro 1mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Anastrozole (USP)..... 1mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°C
	For generic drugs (me-too Status)	Arimisol 1mg Tablet by Swiss Pharma
	Pharmacotherapeutic Group of (API)	L02B G03 aromatase inhibitors,
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK-
	Name & address of API manufacturer	Sun Pharmaceutical Industries Limited, A-7 & A-8, MIDC Industrial Area Ahmednagar, Maharashtra, 414111, INDIA
	Detail of stability batches of drug product	3 batches 1200 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Arimidex tablet batch No. RB739Astrazeneca USA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	UK MHRA Approved
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 03.04.2023 is submitted
	Evidence of approval of manufacturing facility	Section approval letter is submitted

	Evaluation Remarks	
	Decision	
	Approved	
27	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	Hamaz Pharmaceuticals (Pvt) Ltd. 13-KM Bosan Road, Lutfabad (000427)
	Application Form Dy. No / Tracking ID & date of submission	(9M1-5JY-6QR5, 2024-03-28)
	Detail of Fee Submitted	75000.0, 2024-03-20,
	The proposed proprietary name / brand name	Carizine 4.5mg Capsule
	Label Claim	Each Capsule contains: Cariprazine Hydrochloride eq. to Cariprazine..... 4.5mg (As per Innovator's specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C in Cool & Dry Place.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	N05AX15 Other antipsychotics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches, 1500 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	taken loan from M/s Horizone Lahore. Clearance certificate is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Vraylar 4.5mg Capsule Batch No. 1164855
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Registered drug by US-FDA as VRAYLAR 4.5mg (Cariprazine) capsules for oral use.
	GMP status of the firm	Gmp certificate issued on basis of inspection dated 13.04.2021 is submitted
	Evidence of approval of manufacturing facility	Section approval letter dated 29.01.2009 is submitted
	Evaluation Remarks	
	Decision	
	Approved	
28	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	Kaizen Pharmaceuticals (Pvt) Ltd Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi (000755)
	Application Form Dy. No / Tracking ID & date of submission	(AD7-UMH-ZUT4, 2024-03-05)

	Detail of Fee Submitted	75000.0, 2024-01-03,
	The proposed proprietary name / brand name	Aspirom 81mg/40mg
	Label Claim	Each Tablet Contains: 81mg of Aspirin delayed release 40mg of Omeprazole Immediate release
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30° C
	For generic drugs (me-too Status)	None
	Pharmacotherapeutic Group of (API)	B01AC56 acetylsalicylic acid, combinations with proton pump inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Name :Shandong Xinhua Pharmaceutical Co., Ltd Address No.1 Lutai road, High-tech district, Zibo,Shandong,P.R.China255075(Headq uarters ,Name:Oneiro Chemicals Private Limited , Address 475/P, VILL: EKALBARA, TALUKA-PADRA DIST. VADODARA-391 440 GUJARAT (INDIA).
	Detail of stability batches of drug product	3 batches, 700 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested invoices of both drug substances are submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Yosprala 81mg/40mg Delayed release tablet batch No. 3146921
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Food & Drug Administration (FDA)
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 03.01.2023 is submitted
	Evidence of approval of manufacturing facility	Renewal letter dated 03.03.2023 is submitted wherein Tablet General Section is mentioned.
	Evaluation Remarks	
	The firm has submitted RRA reference of USFDA, one of it is discontinued and another is not approved. The firm was asked to provide valid RRA reference but couldn't provide any. Further there is no me-too product either as applied application is of new drug product. The firm later on submitted evidence that similar product has been approved by the Registration Board in its 335th meeting on basis of USFDA tentative approval.	
	Decision	
	Approved	
	Manufacturer will submit the compliance report in accordance to the decision of authority regarding products not having RRA status, though the instant product posses the tentative approval by USA. 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.	
29	Case Category	New Molecule/Formulation (Adil Saeed)

	Name, address of Applicant.	AGP Limited B-23-C, S.I.T.E., Karachi (000348)
	Application Form Dy. No / Tracking ID & date of submission	(AJJ-H9L-6RTP, 2024-03-10)
	Detail of Fee Submitted	75000.0, 2023-08-31,
	The proposed proprietary name / brand name	Dexdol 25mg/75mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Dexketoprofen trometamol eq. to Dexketoprofen----- --25mg Tramadol Hydrochloride-----75mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3x10's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	New Chemical Entity
	Pharmacotherapeutic Group of (API)	N02AJ14 Opioids in combination with non-opioid analgesics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Saurav Chemicals Limited,Supriya Lifescience Ltd.
	Detail of stability batches of drug product	3 batches, 2600 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form-6 for both drug substances are submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Skudexa 25mg/75mg Tablet Lot No. 39033 Mfg: A. Menarini Farmaceutcial Internazaioanle England.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Skudexa 75mg/25mg by A. Menarini Farmaceutica Internazionale SRL MHRA Approved.
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 12.06.2023 is submitted.
	Evidence of approval of manufacturing facility	Renewal letter dated 30.06.2020 is submitted.
	Evaluation Remarks	
	Decision	
	Approved	
30	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	Wnsfeild Pharmaceuticals Plot No. 122, Phase- V, Block-A, Industrial Estate Hattar, KPK (000610)
	Application Form Dy. No / Tracking ID & date of submission	(B2R-XVX-5P8D, 2024-03-27)
	Detail of Fee Submitted	75000.0, 2023-10-25,
	The proposed proprietary name / brand name	LYNO-M 2.5MG/850MG TABLET
	Label Claim	Each Film Coated Tablet contains: Linagliptin.....2.5MG Metformin Hydrochloride 850mg (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)	N/A
	Pharmaceutical Group of (API)	A10BD11 Combinations of oral blood glucose lowering drugs
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	AARTI DRUGS LTD Mahendra Industrial Estate Plot No. – 109 – D Road No.29, Sion (East), Mumbai – 400 022. INDIA, Anhui Haikang Pharmaceutical Co., Ltd No. 21 Huancheng West Road Anqing Anhui 246000 China
	Detail of stability batches of drug product	3 batches, 1200 tablets each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Both drug substances are taken loan from M/s Weathefolds.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Jentaduetto 2.5mg/850mg Batch No. 1098535 Mfg Boehringer Ingelheim Germany
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of both drug substances is submitted.
	The status in reference regulatory authorities	EMA Approved USFDA Approved.
	GMP status of the firm	GMP certificate valid till 02.04.2025 is submitted
	Evidence of approval of manufacturing facility	Copy of renewal letter dated 11.06.2024 is submitted wherein tablet (General) Section is mentioned.
	Evaluation Remarks	
31	Decision	
	Approved	
	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	Kaizen Pharmaceuticals (Pvt) Ltd Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi (000755)
	Application Form Dy. No / Tracking ID & date of submission	(BGS-H7J-G4S5, 2024-03-05)
	Detail of Fee Submitted	75000.0, 2024-01-03,
	The proposed proprietary name / brand name	Aspirom 325mg/40mg
	Label Claim	Each Tablet Contains: 325mg of Aspirin delayed release 40mg of Omeprazole Immediate release
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30° C
	For generic drugs (me-too Status)	None
	Pharmaceutical Group of (API)	B01AC56 acetylsalicylic acid, combinations with proton pump inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Name :Shandong Xinhua Pharmaceutical Co., Ltd Address No.1 Lutai road, High-tech district, Zibo,Shandong,P.R.China255075(Headq uarters

		,Name: Oneiro Chemicals Private Limited, Address: 475/P, VILL: EKALBARA, TALUKA-PADRA DIST. VADODARA-391 440 GUJARAT (INDIA).
	Detail of stability batches of drug product	3 batches, 1000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested invoices for both drug substances are submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Yosprala 325mg/40mg Batch No. 3149884 Mfg Aralez
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Food & Drug Administration (FDA)
	GMP status of the firm	GMP certificate issued on basis of inspection dated 03.01.2023 is submitted.
	Evidence of approval of manufacturing facility	Renewal letter dated 03.03.2023 is submitted wherein tablet (General) section is mentioned.
	Evaluation Remarks	
	The firm has submitted RRA reference of USFDA, one of it is discontinued and another is not approved. The firm was asked to provide valid RRA reference but couldn't provide any. There is no me-too product, applied product is new drug product. The firm later on shared evidence that similar product has been approved in 335th meeting of Registration Board on basis of USFDA Tentative approval.	
	Decision	
	Approved	
	Manufacturer will submit the compliance report in accordance to the decision of authority regarding products not having RRA status, though the instant product posses the tentative approval by USA.	
	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.	
32	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	Kaizen Pharmaceuticals (Pvt) Ltd Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi (000755)
	Application Form Dy. No / Tracking ID & date of submission	(D58-APT-VVQD, 2024-03-14)
	Detail of Fee Submitted	75000.0, 2023-11-14,
	The proposed proprietary name / brand name	Muflex 750mg/5ml Syrup
	Label Claim	Each 5ml contains: Carbocisteine.....750mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-As per SRO,200ml-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C in a cool and dry place
	For generic drugs (me-too Status)	Nil
	Pharmacotherapeutic Group of (API)	R05CB03 Mucolytics
	Name, address of Manufacturing site:	Self Manufacturing

	Name & address of API manufacturer	WUHAN GRAND HOYO Co. LTD.
	Detail of stability batches of drug product	3 batches, 1 Litre each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate mentioning 1000kg Drug substance is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Carbocysteine 750mg/5ml Sugar free Syrup Batch No. A6021 Mfg Lucis Pharma LTD
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Electronic Medicine Compendium (EMC)
	GMP status of the firm	GMP cert issued on basis of inspection dated 3.01.2023 is submitted
	Evidence of approval of manufacturing facility	Section approval letter is submitted
	Evaluation Remarks	
	Decision	
	Approved	
33	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	Welmark Pharmaceuticals Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan (000614)
	Application Form Dy. No / Tracking ID & date of submission	(G5E-LAB-9UYQ, 2024-03-25)
	Detail of Fee Submitted	30000.0, 2024-02-01,
	The proposed proprietary name / brand name	Savel 800mg Tablet
	Label Claim	Each Film Coated Tablet contains: Sevelamer Carbonate..... 800mg
	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)	NeoVel 800mg tablet Reg # 096586
	Pharmacotherapeutic Group of (API)	V03AE02 Drugs for treatment of hyperkalemia and hyperphosphatemia
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Xinhua Pharmaceutical Company Limited Address : No. 01 Hutain chemical industry zone, Zibon, SHnading P.R, China
	Detail of stability batches of drug product	3 batches, 1200 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Drug import license and FedEx slip is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Neo Vel 800mg Tablet Batch No. OL415 Mfg Seraph
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Renvela 800 mg film-coated tablets

	GMP status of the firm	GMP certificate issued on basis of inspection dated 11.11.2021 is submitted.
	Evidence of approval of manufacturing facility	Section approval letter is submitted
	Evaluation Remarks	
	Decision	
	Approved	
34	Case Category	Contract Manufacturing (Adil Saeed)
	Name, address of Applicant.	Winbrains Research Laboratories Plot No. 69/1 Block B, Phase I-II Industrial Estate, Hattar, Pakistan (000725)
	Application Form Dy. No / Tracking ID & date of submission	(GB4-Q3A-W2E4, 2024-03-05)
	Detail of Fee Submitted	75000.0, 2023-12-29,
	The proposed proprietary name / brand name	Cinkal 60mg Tablet
	Label Claim	Each Film Coated Tablet contains: Cinacalcet Hcl eq. to Cinacalcet.....60mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°C.
	For generic drugs (me-too Status)	Censipar Tablet 60 mg by CCL Pharma
	Pharmacotherapeutic Group of (API)	H05BX01 Other anti-parathyroid agents
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK. -
	Name & address of API manufacturer	Megafine Pharma (P) Ltd. Plot No. 1 to 5, 31 to 35 & 48 to 51, 26 & K/201, Lakhmapur, Tal. Dindori, Dist. Nashik – 422 202, Maharashtra, INDIA
	Detail of stability batches of drug product	3 batch. 1200 tabs each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Mimcipar 60mg tablet Batch no. 010 Mfg M/s Genome pakistan
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	UK MHRA Approved
	GMP status of the firm	Copy of GMP certificate valid till 02.03.2025 is submitted.
	Evidence of approval of manufacturing facility	-----
	Evaluation Remarks	
	Data already approved in 343rd RB "CINAKAL 60mg Tablet"	
	Decision	
	Approved	
35	Case Category	New License (Adil Saeed)

	Name, address of Applicant.	Care Pharmaceuticals 8-Km Main Thokar Raiwind Road Lahore (000563)
	Application Form Dy. No / Tracking ID & date of submission	(HD8-EJN-2ERH, 2024-06-28)
	Detail of Fee Submitted	30000.0, 2024-04-17,
	The proposed proprietary name / brand name	Doxycare 100mg
	Label Claim	Each capsule contains:Doxycycline Hyclate equivalent to Doxycycline =100 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10's-As per SRO,100's-As per SRO,120's-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30 degree
	For generic drugs (me-too Status)	Vibramycin 100mg Capsule by Pfizer
	Pharmacotherapeutic Group of (API)	J01AA02 Tetracyclines
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	KUNSHAN CHEMICALS & PHARMACEUTICAL CO.,LTD NO.60, KUNTAI ROAD, ZHOUSHI TOWN , KUNSHAN CITY CHINA
	Detail of stability batches of drug product	3 batches. 1500 capsules each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan from M/s Kohinoor Industries Sahiwal Pakistan
	Pharmaceutical Equivalence and Comparative Dissolution Profile	VIBRAMYCIN 100 mg capsule batch no: HE7932E
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	MHRA Approved
	GMP status of the firm	New Section
	Evidence of approval of manufacturing facility	Section approval letter dated 13.07.2023
	Evaluation Remarks	
	Decision	
	Approved	
36	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	Wnsfeild Pharmaceuticals Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK (000610)
	Application Form Dy. No / Tracking ID & date of submission	(HTY-JPW-HZUS, 2024-03-12)
	Detail of Fee Submitted	75000.0, 2023-10-25,
	The proposed proprietary name / brand name	LYNO-M 2.5MG/1000MG TABLET
	Label Claim	Each Film Coated Tablet contains: Linagliptin.....2.5MG Metformin Hydrochloride 1000mg (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	A10BD11 Combinations of oral blood glucose lowering drugs
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	AARTI DRUGS LTD Mahendra Industrial Estate Plot No. – 109 – D Road No.29, Sion (East), Mumbai – 400 022. INDIA, Anhui Haikang Pharmaceutical Co., Ltd No. 21 Huancheng West Road Anqing Anhui 246000 China
	Detail of stability batches of drug product	3 batches, 1200 tablets each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Both drug substances are taken loan from M/s Weatherfolds.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Jentaduetto 2.5mg/1000mg Batch No. 367604 Mfg Boehringer Ingelheim Germany
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of both drug substances is submitted.
	The status in reference regulatory authorities	EMA Approved
	GMP status of the firm	GMP certificate valid till 02.04.2025 is submitted
	Evidence of approval of manufacturing facility	Section approval letter is submitted
	Evaluation Remarks	
	Decision	
	Approved	
37	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	Neutro Pharma (Pvt.) Ltd., 9.5-Km, Sheikhpura Road, Lahore (000576)
	Application Form Dy. No / Tracking ID & date of submission	(L9D-GYP-TL1B, 2024-02-09)
	Detail of Fee Submitted	30000.0, 38000.0 2023-12-14, 2025-04-21
	The proposed proprietary name / brand name	Neugliptin 12.5mg Tablet
	Label Claim	Each Film Coated Tablet Contains:Alogliptin Benzoate equivalent to Alogliptin.....12.5mg(As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temprature
	For generic drugs (me-too Status)	Nesina 12.5mg Tablet
	Pharmacotherapeutic Group of (API)	A10BH04 Dipeptidyl peptidase 4 (DPP-4) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	RUYUAN HEC PHARM CO., LTD Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R.China Tel?0086-

		751-5286588 Fax : 0086-751-5286521 FEI No.: 3009740510
	Detail of stability batches of drug product	3 batches 3000 tablets each. 6 months data submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	300gm AD Attested invoice submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Nesina 12.5mg Tablet B347991 Mfg Takeda Pharmaceuticals USA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Nesina Tablet 12.5mg by Takeda Pharmaceuticals USA
	GMP status of the firm	GMP cert valid till 13.04.2025
	Evidence of approval of manufacturing facility	Grant of Additional section letter dated 14.06.2008 submitted
	Evaluation Remarks	
	Decision	
	Approved	
38	Case Category	Contract Manufacturing (Adil Saeed)
	Name, address of Applicant.	Welmark Pharmaceuticals Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan (000614)
	Application Form Dy. No / Tracking ID & date of submission	(LAA-9XW-3PXN, 2024-03-08)
	Detail of Fee Submitted	75000.0, 2023-12-28,
	The proposed proprietary name / brand name	PIRFEN 801MG TABLET
	Label Claim	Each film coated Tablet contains: Pirfenidone 801mg (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)	N/A
	Pharmacotherapeutic Group of (API)	Antifibrotic (Idiopathic Pulmonary Fibrosis)
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No.69/2, Phase - II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	https://www.medicines.org.uk/emc/files/pil.7939.pdf
	Detail of previous approval	Approved in 322nd RB, Pirfend 801mg Tablet
	Evaluation Remarks	
	Decision	
	Approved	
39	Case Category	New License (Adil Saeed)

	Name, address of Applicant.	Care Pharmaceuticals 8-Km Main Thokar Raiwind Road Lahore (000563)
	Application Form Dy. No / Tracking ID & date of submission	(LAX-J5H-GRG4, 2024-06-24)
	Detail of Fee Submitted	30000.0, 2024-04-24,
	The proposed proprietary name / brand name	Fevercare 500mg
	Label Claim	Each tablet contains: Paracetamol.....500mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1000's-As per SRO, 20 x 10's-As per SRO, 500's-As per SRO
	Shelf Life (Unit)	2 Year(s) Below 30 degree
	For generic drugs (me-too Status)	Panadol Tablet 500mg by GSK Pharma
	Pharmaceutical Group of (API)	N02BE01 Anilides
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Purchased from local manufacturer M/s Citi Pharma
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Panadol 500mg tablet batch no: NPPBXF
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	MHRA Approved
	GMP status of the firm	New Section
	Evidence of approval of manufacturing facility	Section approval letter dated 13.07.2023 is submitted
	Evaluation Remarks	
	Observation: The BP monograph suggests use of HPLC method for both assay and dissolution, whereas the submitted method of analysis is based on UV. Please clarify. Reply of firm: HPLC method is recently added in BP monograph while the submitted method of analysis is as per BP monograph 2023 (applicable as per stability study data) in which method of analysis is based on UV. BP monograph of 2023 for the said product is attached here with.	
	Decision	
	Deferred	
	Deferred for submission of following.	
	Development of testing method of drug product and its verification studies as per latest BP monograph.	
	Test and analysis report of all trial batches as per testing method of latest BP monograph.	
40	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	Pacific Pharmaceutical Ltd 30 km Multan Road Lahore (000295)

	Application Form Dy. No / Tracking ID & date of submission	(LGS-GW9-S3SS, 2024-03-12)
	Detail of Fee Submitted	30000.0, 2024-01-19,
	The proposed proprietary name / brand name	Montelukast 4 mg Chewable Tablet
	Label Claim	Each Tablet Contains: Montelukast Sodium Eq. to Montelukast 4 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	2 Year(s)below 30°C
	For generic drugs (me-too Status)	Montiget Tablet (Getz Pharma)
	Pharmacotherapeutic Group of (API)	R03DC03 Leukotriene receptor antagonists
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Dhanuka Laboratories Ltd. SP4-4, Industrial Area, Keshwana Rajput, Kotputli, Shahpura, Jaipur-3 03 1 08, Rajasthan
	Detail of stability batches of drug product	3 batch 10,000 tabs each
	Documents for the procurement of API with approval from DRAP (in case of Import)	1Kg Taken Loan from Cunningham, AD Attested invoice submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Montelukast 4mg Chewable Batch No. BD08337B MFG: Aurobindo Pharma Milpharm Middlesex HA4 UK
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	MHRA Approved
	GMP status of the firm	Certificate valid till 13.09.2023
	Evidence of approval of manufacturing facility	letter dated 04.05.2018
	Evaluation Remarks	
	The case was deferred with following decision in 345th RBDeferred for submission of following.Clarification that which reference product was used in pharmaceutical equivalence. Evidence of gradient HPLC systemClarification for deviating from USP monograph in performance of system suitability and sensitivity assessment.Response: Firm has submitted clarification that pharmaceutical equivalence was performed against comparator product Myteka chewable tablets. Evidence of gradient HPLC system in form of its qualification report and operational screenshots have been submitted.Firm has reperformed system suitability as per USP monograph using the required impurity and with run time (30 minutes) as recommended by the USP	
	Decision	
	Approved	
41	Case Category	New License (Adil Saeed)
	Name, address of Applicant.	Care Pharmaceuticals 8-Km Main Thokar Raiwind Road Lahore (000563)
	Application Form Dy. No / Tracking ID & date of submission	(LMH-PDU-7W7D, 2024-07-30)
	Detail of Fee Submitted	30000.0, 2024-06-12,
	The proposed proprietary name / brand name	Instacare 200mg

	Label Claim	Each film coated tablet contains: Metronidazole.....200 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10's-As per SRO,100's-As per SRO,1000-As per SRO,20's-As per SRO,200's-As per SRO,50's-As per SRO,500's-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30 degree
	For generic drugs (me-too Status)	Flagyle 200mg Tablet by Snofi Aventis
	Pharmacotherapeutic Group of (API)	P01AB01 Nitroimidazole derivatives
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	HUBEI HONGYUAN PHARMACEUTICAL TECHNOLOGY CO.,LTD NO.8,HONGYUAN ROAD, ECONOMIC DEVELOPMENT ZONE FENGSHAN TOWN,LOUTIAN COUNTY,HAUNGGANG CITY, HUBEI PROVINCE
	Detail of stability batches of drug product	3 batches, 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan from M/s Rasco Pharma
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Metrozine 200 mg Tablet by Seale Pharmaceuticals is used in pharmaceutical equivalence batch No. AZF016
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	MHRA Approved
	GMP status of the firm	New Section
	Evidence of approval of manufacturing facility	Section approval letter dated 13.07.2023 is submitted.
42	Evaluation Remarks	
	Decision	
	Approved	
	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	Kaizen Pharmaceuticals (Pvt) Ltd Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi (000755)
	Application Form Dy. No / Tracking ID & date of submission	(N13-UXV-XJY4, 2024-03-14)
	Detail of Fee Submitted	75000.0, 2023-11-14,
	The proposed proprietary name / brand name	Muflex 100mg/ml Oral Solution
	Label Claim	Each ml contains: Carbocisteine.....100
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	120ml-As per SRO,240ml-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C in a cool and dry place
	For generic drugs (me-too Status)	Nil
	Pharmacotherapeutic Group of (API)	R05CB03 Mucolytics

	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	WUHAN GRAND HOYO Co. LTD.
	Detail of stability batches of drug product	3 batches, 1 Liter each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate mentioning 500kg drug substance is submitted,
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pectox Forte 100mg/ml Oral Solution Batch No. 23013 Mfg: Italfarmaco Sa Madrid.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Italian Medicine Agency (AIFA)
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 03.01.2023 is submitted
	Evidence of approval of manufacturing facility	Copy of section approval letter dated 03.03.2023 is submitted.
	Evaluation Remarks	
	Decision	
	Approved	
43	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	Kaizen Pharmaceuticals (Pvt) Ltd Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi (000755)
	Application Form Dy. No / Tracking ID & date of submission	(N5D-JQ6-ZENA, 2024-03-14)
	Detail of Fee Submitted	75000.0, 2024-03-04,
	The proposed proprietary name / brand name	Biotinal
	Label Claim	Each tablet contains:Biotin.....5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	30's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a cool and dry place. Below 30 oC
	For generic drugs (me-too Status)	None
	Pharmacotherapeutic Group of (API)	A11HA05
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhejiang Shengda Bio-Pharm Co., Ltd. Address: No. 789, Renmin East Road, Tiantai, Zhejiang, China, 317200
	Detail of stability batches of drug product	3 batch 1200 tabs each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is submitted. Received from DHL
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Nebiotin 5mg Batch No 19013, mfg Cantabria Labs
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted

	The status in reference regulatory authorities	BIOTIN BAYER 5mg Tab National Agency for the Safety of Medicine and Health Products (ANSM)
	GMP status of the firm	GMP cert. valid till 02.01.2025
	Evidence of approval of manufacturing facility	letter dated 3.03.2023
	Evaluation Remarks	
	The case was deferred in 345th RB with following decision;"Registration Board noted the fact that the formulations containing "Biotin" have been enlisted as Nutraceutical drug product by Health & OTC division, hence Board decided to refer the instant applied formulation to "Committee for Grey area Molecules" for review and recommendations to be placed before Registration Board"It is informed that DRAP Authority in its 74th meeting decided to constitute a committee to decide the placement of therapeutic goods falling in gray areas. For this purpose a list of 54 molecules falling in gray areas were also provided to the committee. The committee has worked on all molecules as per the T.O.Rs and furnished its recommendations, which were considered by the Authority in its 128th and 156th meeting. The instant molecule i.e. "Biotin" is a vitamin (Vitamin B7), and is not included in the list of 54 molecules falling under gray areas.Similar product is registered in ANSM France as a Drug, (Authorization - Minigraphy)The authorization status is mentioned as valid in ANSM France Data Base.	
	Decision	
	Approved	
44	Case Category	Priority As Per 257-M of RB (Adil Saeed)
	Name, address of Applicant.	MSA PHARMA 1304, Green Acre, Pine Avenue (05-352-0066)
	Application Form Dy. No / Tracking ID & date of submission	(N5U-UZ4-MQX2, 2025-04-18)
	Detail of Fee Submitted	300000.0, 2025-03-04,
	The proposed proprietary name / brand name	Acaluxen 100mg Capsule
	Label Claim	Each hard-capsule contains; Acalabrutinib..... 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	60's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C.
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	L01EL02 Bruton's tyrosine kinase (BTK) inhibitors Indicated for the treatment of chronic lymphocytic leukemia, small lymphocytic lymphoma, and in adult patients with Mantle cell lymphoma
	Name, address of Manufacturing site:	Everest Pharmaceuticals Limited.-Plot No: B-45, 46 & 33, BSCIC I/A, Kanchpur, Narayanganj, - Bangladesh
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Calquence 100mg Lot No. CL0157
	Name, address of Marketing Authorization Holder:	Everest Pharmaceuticals Limited., Factory: Plot No: B-45, 46 & 33, BSCIC I/A, Kanchpur, Narayanganj, Bangladesh. Head office Address: Rahman's Regnum Centre (11th Floor) 191/1, Tejgaon C/A, Dhaka-1208, Bangladesh, Bangladesh

	Details of Certificates (CoPP/FSC/cGMP):	Copy of legalized GMP certificate No. DGDA/6-227/2018/17218 dated 01.10.2024, valid till 30.09.2026 is submitted. Issued by DG Drug Administration Bangladesh.
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Calquence 100mg Capsules (Catalent Pharma., UK)
	Evaluation Remarks	
	Legalized Copy of COPP No. DGDA/6-227/2018/18434 dated 22.10.2024 is submitted. Valid till 2 years from date of issuance. As per COPP product is placed on market of country of origin. COPP issued by DG of Drug Administration Bangladesh.	
	Decision	
	Approved	
	As per policy of inspection abroad.	
45	Case Category	New License (Adil Saeed)
	Name, address of Applicant.	Care Pharmaceuticals 8-Km Main Thokar Raiwind Road Lahore (000563)
	Application Form Dy. No / Tracking ID & date of submission	(N8Y-4GR-H8P3, 2025-04-14)
	Detail of Fee Submitted	30000.0, 7000.0 2024-07-02, 2025-04-10
	The proposed proprietary name / brand name	Cyanocare Injection
	Label Claim	Each 1 ml contains: cyanocobalamin....1000 mcg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 ml X 25's, 1ml x 5-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 25 C
	For generic drugs (me-too Status)	Vitamin B12 injection
	Pharmacotherapeutic Group of (API)	B03BA01 Vitamin B12 (cyanocobalamin and analogues)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Xicheng District, Ningjin County, Hebei Province, China, 055550
	Detail of stability batches of drug product	3 batches, 1000 ampoules each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan from M/s Trigon Pharma
	Pharmaceutical Equivalence and Comparative Dissolution Profile	cyanocobalamin injection 1000mcg/1ml (byAmeer Pharmaceuticals) batch no: CN-1662
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Amros Pharmaceuticals
	GMP status of the firm	New Section
	Evidence of approval of manufacturing facility	Section approval letter dated 13.07.2023 is submitted
	Evaluation Remarks	

	Decision	
	Approved	
46	Case Category	Contract Manufacturing (Adil Saeed)
	Name, address of Applicant.	Wnsfeild Pharmaceuticals Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK (000610)
	Application Form Dy. No / Tracking ID & date of submission	(P91-UZG-6PEA, 2024-03-19)
	Detail of Fee Submitted	75000.0, 2024-01-03,
	The proposed proprietary name / brand name	Finro 10mg Tablet
	Label Claim	Each Film Coated Tablet contains: Finerenone.....10mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	C03DA05 Aldosterone antagonists
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK.-
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches, 1200 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan from M/s Horizon, Clearance certificate is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Kerendia 10mg Tablet Batch No. BXJUUH1
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	UK MHRA APPROVED
	GMP status of the firm	-----
	Evidence of approval of manufacturing facility	Section approval letter dated 05.05.2010 is submitted
	Evaluation Remarks	
	Decision	
	Approved	
47	Case Category	Contract Manufacturing (Adil Saeed)
	Name, address of Applicant.	Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (000644)
	Application Form Dy. No / Tracking ID & date of submission	(PTJ-9UZ-4QVR, 2024-03-06)
	Detail of Fee Submitted	75000.0, 2024-01-11,
	The proposed proprietary name / brand name	Cinafold 30mg Tablet

	Label Claim	Each Film Coated Tablet contains: Cinacalcet Hcl eq. to Cinacalcet.....30mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°C
	For generic drugs (me-too Status)	Censipar Tablet 30 mg by CCL Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	UK MHRA Approved
	Detail of previous approval	Data already approved in 347th RB, Cinkal 30mg Tablet
	Evaluation Remarks	
	Data already approved in 347th RB, Cinkal 30mg Tablet	
	Decision	
	Approved	
48	Case Category	Contract Manufacturing (Adil Saeed)
	Name, address of Applicant.	Wnsfeild Pharmaceuticals Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK (000610)
	Application Form Dy. No / Tracking ID & date of submission	(Q4Q-7BM-6HTB, 2024-03-19)
	Detail of Fee Submitted	75000.0, 2024-01-03,
	The proposed proprietary name / brand name	Finro 20mg Tablet
	Label Claim	Each Film Coated Tablet contains: Finerenone.....20mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	C03DA05 Aldosterone antagonists
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK.-
	Name & address of API manufacturer	Fuxin Long Rui Pharmaceutical CO., Ltd Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China
	Detail of stability batches of drug product	3 batches, 1200 tablets each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan from Horizon Healthcare Lahore. Clearance certificate mentioning 350grams drug substance is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Kerendia 20mg tablet Batch No. BXJTVU
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	UK MHRA APPROVED
	GMP status of the firm	-----

	Evidence of approval of manufacturing facility	Section approval letter dated 05.05.2010 is submitted.
	Evaluation Remarks	
	Decision	
	Approved	
49	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	Welmark Pharmaceuticals Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan (000614)
	Application Form Dy. No / Tracking ID & date of submission	(QBH-P3B-DG7Q, 2024-03-25)
	Detail of Fee Submitted	30000.0, 2024-02-14,
	The proposed proprietary name / brand name	DAPZIN M 5/1000mg TABLET
	Label Claim	Each Film Coated Tablet Contains: Metformin Hydrochloride (USP).....1000mg DapagliflozinPropanediol Monohydrate.....5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)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 TABLET5/1000mg Hilton Pharma Pvt Ltd 093072
	Pharmacotherapeutic Group of (API)	A10BD15 Combinations of oral blood glucose lowering drugs
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	AARTI DRUGS LTD Mahendra Industrial Estate Plot No. – 109 – D Road No.29, Sion (East), Mumbai – 400 022. INDIA,HUAINAN SHUNLONG PHARMACEUTICAL CO., LTD. ADDRESS: NO. 9th, YONGXING ROAD, HUAINAN ECONOMIC AND TECHNOLOGY DEVELOPMENT ZONE, HUAINAN CITY, CHINA.
	Detail of stability batches of drug product	3 batches, 1200 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance of both drug substances is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Dapa-Met 5mg+100mg Batch No. 145633 Mfg by M/s Hilton
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	https://www.medicines.org.uk/emc/product/5293/sm
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 11.11.2021 is submitted
	Evidence of approval of manufacturing facility	Section approval letter is submitted

	Evaluation Remarks	
	Decision	
50	Approved	
	Case Category	Contract Manufacturing (Adil Saeed)
	Name, address of Applicant.	Welmark Pharmaceuticals Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan (000614)
	Application Form Dy. No / Tracking ID & date of submission	(QE4-LDS-GWN2, 2024-03-08)
	Detail of Fee Submitted	75000.0, 2023-12-28,
	The proposed proprietary name / brand name	PIRFEN 267MG TABLET
	Label Claim	Each Tablet contains: Pirfenidone 267mg (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)	N/A
	Pharmacotherapeutic Group of (API)	Antifibrotic (Idiopathic Pulmonary Fibrosis)
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No.69/2, Phase - II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	https://www.medicines.org.uk/emc/files/pil.7939.pdf
	Detail of previous approval	Data already approved in 322nd RB, Pirfend 267mg Tablet
	Evaluation Remarks	
	Decision	
	Approved	
51	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	Care Pharmaceuticals 8-Km Main Thokar Raiwind Road Lahore (000563)
	Application Form Dy. No / Tracking ID & date of submission	(QU8-VTX-LM4S, 2024-03-05)
	Detail of Fee Submitted	30000.0, 2024-01-30,
	The proposed proprietary name / brand name	Dolocare
	Label Claim	Each ml Contains: Dorzolamide HCL Equivalent to Dorzolamide..... 20 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	5 ml-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30 Degree Celsius
	For generic drugs (me-too Status)	Trusopt 2% Eye Drops
	Pharmacotherapeutic Group of (API)	S01EC03 Carbonic anhydrase inhibitors
	Name, address of Manufacturing site:	Self Manufacturing

	Name & address of API manufacturer	M/s Flex Laboratories
	Detail of stability batches of drug product	3 batches 400 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Trusopt 2% Eye Drops by OBS Batch No.1RE0057
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Health Canada
	GMP status of the firm	GMP certificate valid till 01.03.2025 is submitted.
	Evidence of approval of manufacturing facility	Letter dated 23.06.2023 is submitted
	Evaluation Remarks	
	3.2.P.5 System suitability is not as per BP monograph (requires use of impurity B & D)The firm has stated; "System suitability is performed but is not as BP monograph because of unavailability of impurity B & D from market"	
	Decision	
	Deferred	
	Deferred for submission of test and analysis method, report and supporting data of drug product as per BP monograph along with fee for preregistration variation.	
52	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	Surge Laboratories (Pvt.) Ltd. 10th KM, Faisalabad Road, Bikhi District, Sheikhpura. (000484)
	Application Form Dy. No / Tracking ID & date of submission	(RL6-XUM-P2XV, 2024-03-05)
	Detail of Fee Submitted	75000.0, 2023-12-07,
	The proposed proprietary name / brand name	SURLIN CR
	Label Claim	Each extended-release film coated tablet contains: Pregabalin.....330mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 14's, 20's, 28-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 degree
	For generic drugs (me-too Status)	not available
	Pharmacotherapeutic Group of (API)	N02BF02 Gabapentinoids
	Name, address of Manufacturing site:	Nabiqasim Industries Private Limited-Plot no 17/24, Korangi Industrial Area, Karachi-Pakistan-
	Name & address of API manufacturer	Atlas Life Sciences Private Limited [C-1/360-361, G.I.D.C. Estate, Ahmedabad-382415, Gujrat.]
	Detail of stability batches of drug product	2 batches 5000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested invoice mentioning 150kg drug substance is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Lyrica 330mg CR Batch No. FW0640

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	FDA Approved-Lyrica CR Extended release tablet 330mg-Pfizer Inc.USA
	GMP status of the firm	GMP certificate issued on basis of inspection dated 22.05.2023 is submitted.
	Evidence of approval of manufacturing facility	Renewal letter dated 27.04.2020 is submitted wherein tablet (general) section is mentioned.
	Evaluation Remarks	
	Decision	
	Approved	
53	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	Pacific Pharmaceutical Ltd 30 km Multan Road Lahore (000295)
	Application Form Dy. No / Tracking ID & date of submission	(RNZ-QMZ-9QNH, 2024-03-12)
	Detail of Fee Submitted	30000.0, 2024-01-19,
	The proposed proprietary name / brand name	Montelukast 5mg Chewable Tablet
	Label Claim	Each Tablet contains:Montelukast sodium eq. to montelukast....5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	2 Year(s)below 30°C
	For generic drugs (me-too Status)	Montiget 5mg Chewable Tablet
	Pharmacotherapeutic Group of (API)	R03DC03 Leukotriene receptor antagonists
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Dhanuka Laboratories Limited (SP4-4, Industrial Area, Keshwana Rajput, Kotputli, Shahpura, Jaipur-3 03 1 08, Rajasthan)
	Detail of stability batches of drug product	3 batch 10,000 tabs each
	Documents for the procurement of API with approval from DRAP (in case of Import)	1Kg Taken Loan from Cunningham, AD Attested invoice submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Montelukast 5mg Chewable Batch No. BA46425 MFG: Generics (UK) Limited T/A Mylan Hertfordshire
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Montelukast 5mg Chewable Tablet by Generics (UK) Limited t/a Mylan
	GMP status of the firm	Certificate valid till 13.09.2023
	Evidence of approval of manufacturing facility	letter dated 04.05.2018
	Evaluation Remarks	
	The case was deferred with following decision in 345th RBDeferred for submission of following.Clarification that which reference product was used in pharmaceutical equivalence. Evidence of gradient HPLC system.Clarification for deviating from USP monograph in performance of system	

	suitability and sensitivity assessment. Response: Firm has submitted clarification that pharmaceutical equivalence was performed against comparator product Myteka chewable tablets. Evidence of gradient HPLC system in form of its qualification report and operational screenshots have been submitted. Firm has re-performed system suitability as per USP monograph using the required impurity and with run time (30 minutes) as recommended by the USP	
	Decision	
	Approved	
54	Case Category	Routine (Adil Saeed)
	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	(RVJ-5AU-T15J, 2024-03-25)
	Detail of Fee Submitted	30000.0, 2023-12-11,
	The proposed proprietary name / brand name	Megrofen-P Tablet
	Label Claim	Each film coated tablet contains: Ibuprofen... 200mg Paracetamol... 500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30's-As per SRO
	Shelf Life (Unit)	2 Year(s) Do not store above 30 degree C
	For generic drugs (me-too Status)	Provas-Duo
	Pharmacotherapeutic Group of (API)	N02BE51 paracetamol, combinations excl. psycholeptics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Hubei Granules-Biocrine Pharmaceutical Co., Ltd 122 Yangwan Road, Jingmen City, Hubei Province 448000 People's Republic of China, Pharmagen Limited Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore.
	Detail of stability batches of drug product	3 batches, 1250 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Ibuprofen Clearance certificate is submitted. Paracetamol purchased from local manufacturer.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provas Duos batch No. 036H, M/s Sami Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Australian Register of Therapeutic Goods (ARTG)
	GMP status of the firm	GMP certificate valid till 12.06.2024
	Evidence of approval of manufacturing facility	Renewal of DML letter dated 30.06.2020 is submitted. Tablet General section is mentioned.
	Evaluation Remarks	
	Decision	
	Approved	
55	Case Category	Routine (Adil Saeed)

	Name, address of Applicant.	Neutro Pharma (Pvt.) Ltd., 9.5-Km, Sheikhpura Road, Lahore (000576)
	Application Form Dy. No / Tracking ID & date of submission	(T6W-NL2-641J, 2024-03-22)
	Detail of Fee Submitted	30000.0, 2023-11-02,
	The proposed proprietary name / brand name	Neucaine Cream 7%/7%
	Label Claim	Each gram contains: Lidocaine.....70mg Tetracaine.....70mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	15gm-As per SRO
	Shelf Life (Unit)	2 Year(s)Store between 15 - 30°C in a dry place, protect from light.
	For generic drugs (me-too Status)	Num Cain Cream by Crystolite Pharma
	Pharmacotherapeutic Group of (API)	N01BB52 lidocaine, combinations
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Gufic Biosciences Ltd. 1st to 4th Floor, S.M. House, 11 Sahakar Road, Vile Parle (East), Mumbai – 400 057, INDIA.
	Detail of stability batches of drug product	3 batches, 100 tubes each
	Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested invoices of both drug substances are submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pliaglis 7%/7% Cream Batch No. 3469001 Mfg: Taro Pharmaceuticals USA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Pliaglis FDA
	GMP status of the firm	GMP certificate issued on basis of inspection dated 14.04.2022 is submitted
	Evidence of approval of manufacturing facility	Section approval of 2005 is submitted.
	Evaluation Remarks	
	Decision	
	Approved	
56	Case Category	New License (Adil Saeed)
	Name, address of Applicant.	Care Pharmaceuticals 8-Km Main Thokar Raiwind Road Lahore (000563)
	Application Form Dy. No / Tracking ID & date of submission	(U7L-TAG-NNML, 2025-04-14)
	Detail of Fee Submitted	30000.0, 7000.0 2024-07-02, 2025-04-10
	The proposed proprietary name / brand name	Diclorcare
	Label Claim	Each 3ml ampoule contains: Diclofenac Sodium..... 75mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5's x 3mL, 10'sx 3mL,-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30 C

	For generic drugs (me-too Status)	Dicloran Injection (SAMI)
	Pharmacotherapeutic Group of (API)	M01AB05 Acetic acid derivatives and related substances
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rutu chemicals
	Detail of stability batches of drug product	3 batches, 1000 ampoules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan from M/s Trigon Pharma
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Dicloran 75mg/3ml injection (Sami pharmaceuticals (PVT)LTD) batch no: BKK110
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	ECONAC Injection (UK)
	GMP status of the firm	New Section
	Evidence of approval of manufacturing facility	Copy of letter dated 13.07.2023 is submitted.
	Evaluation Remarks	
	The assay of finished drug product is done on UV method. The firm was asked why HPLC method was not adopted. Firm has replied that product is on innovator specs and UV method is also used in some BP monographs of Diclofenac Sodium for some other dosage forms (like Diclofenac Prolonged release Capsules, BP 2025.	
	Decision	
	Approved	
57	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	Global Pharmaceuticals Pakistan Plot # 8, Street # S-8, RCCI, Industrial Estate Rawat, Islamabad-Pakistan (000724)
	Application Form Dy. No / Tracking ID & date of submission	(UP8-QX7-THAJ, 2024-03-11)
	Detail of Fee Submitted	75000.0, 2024-01-29,
	The proposed proprietary name / brand name	RELITAM 100MG/2ML INJECTION
	Label Claim	Each 2ml ampoule contains: Tramadol HCl.....100mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10's -As per SRO,20's-As per SRO,5's -As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a cool dry place, below 30oC.
	For generic drugs (me-too Status)	TRAMADOL INJECTION BY CITY PHARMACEUTICALS LABORATORIES
	Pharmacotherapeutic Group of (API)	N02AX02 Other opioids
	Name, address of Manufacturing site:	Global Pharmaceuticals (Pvt.) Ltd-Plot # 204-205 Industrial Triangle, Kahuta Road, Islamabad-Pakistan-
	Name & address of API manufacturer	SUPRIYA LIFESCIENCES LTD. ADDRESS: A-5/2 LOTE PARSHURAM INDUSTRIAL AREA, M.I.D.C. TALUKA-KHED, DISTRICT NATRAGIRI, MAHARASHTRA, INDIA 415 722.

	Detail of stability batches of drug product	2 batches, 100,000 ampoules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested invoice of 1000kg drug substance is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Tramal Injection Batch No. JGE017
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	MHRA
	GMP status of the firm	GMP certificate issued on basis of inspection conducted on 03.01.2022 is submitted
	Evidence of approval of manufacturing facility	-----
	Evaluation Remarks	
	Decision	
	Approved	
58	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	AsianContinental (Pvt.) Ltd. D-32, S.I.T.E II, Super Highway, Karachi (000643)
	Application Form Dy. No / Tracking ID & date of submission	(WUU-DYR-95HN, 2024-03-14)
	Detail of Fee Submitted	30000.0, 2024-01-17,
	The proposed proprietary name / brand name	VILDASIAN-M 50mg/850mg
	Label Claim	Each film coated tabnlet contains: Vildagliptin 50mg Metformin HCl.....850mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	4 x 7's Tablets -As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 °C
	For generic drugs (me-too Status)	Vilget-M Tablet 50/850mg (Getz Pharma Pvt. Ltd.)
	Pharmacotherapeutic Group of (API)	A10BD08 Combinations of oral blood glucose lowering drugs
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Anhui Haikang Pharmaceutical Co. Ltd.
	Detail of stability batches of drug product	3 batches 1500 tabs each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 (license to import) is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Galvus Met 50mg/ 850mg Tablet M/s Novartis Batch No. KFD16
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Galvus Met Tablet (Novartis Pharmaceuticals Australia Pvt. Ltd.
	GMP status of the firm	GMP certificate not submitted
	Evidence of approval of manufacturing facility	Regularization f layout letter dated 22.06.2019 is submitted
	Evaluation Remarks	

	Decision	
	Approved	
59	Case Category	New License (Adil Saeed)
	Name, address of Applicant.	Care Pharmaceuticals 8-Km Main Thokar Raiwind Road Lahore (000563)
	Application Form Dy. No / Tracking ID & date of submission	(XBB-5TS-E41N, 2024-07-30)
	Detail of Fee Submitted	30000.0, 2024-04-24,
	The proposed proprietary name / brand name	Instacare 400mg
	Label Claim	Each film coated tablet contains: Metronidazole.....400 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10's-As per SRO,100's-As per SRO,1000's-As per SRO,20's-As per SRO,200's-As per SRO,50's-As per SRO,500's-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30 degree
	For generic drugs (me-too Status)	Flagyl 400mg Tablet by Sanofi Aventis
	Pharmacotherapeutic Group of (API)	P01AB01 Nitroimidazole derivatives
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	HUBEI HONGYUAN PHARMACEUTICAL TECHNOLOGY CO.,LTD NO.8,HONGYUAN ROAD, ECONOMIC DEVELOPMENT ZONE FENGSHAN TOWN,LOUTIAN COUNTY,HAUNGGANG CITY, HUBEI PROVINCE
	Detail of stability batches of drug product	3 batches, 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan from Rasco
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Flagyl Tablets batch no: AL418
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	MHRA Approved
	GMP status of the firm	New Section
	Evidence of approval of manufacturing facility	Letter dated 13.07.2023 is submitted
	Evaluation Remarks	
	Decision	
	Approved	
60	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	Misaq Pharmaceuticals Pvt Ltd. Plot no.7-B, Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad. (000985)

	Application Form Dy. No / Tracking ID & date of submission	(XYZ-2Z1-U96G, 2024-12-05)
	Detail of Fee Submitted	37000.0, 2024-09-27,
	The proposed proprietary name / brand name	Fungirex 50mg/5ml Powder for Suspension
	Label Claim	After Reconstitution Each 5ml Contains: Fluconazole 50mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	35mlx1's-As per SRO
	Shelf Life (Unit)	2 Year(s)15-30 degree Celsius
	For generic drugs (me-too Status)	Flumag Dry Powder Suspension 35ml by Magns Pharmaceuticals, Faisalabaed-Pakistan
	Pharmacotherapeutic Group of (API)	J02AC01 Triazole and tetrazole derivatives
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Raj Pioneer Laboratories India Pvt. Ltd. 94-A, 95-B, 96-A Industrial Area No. 1 A.B. Road Dewas M.P Dewas Madhya Pradesh
	Detail of stability batches of drug product	3 batches, 200 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan rom M/s Magns Pharmaceuticals Khurrianwala Clearance certificate is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Flumag Oral Suspension Batch No. 23 Mfg Magns Pakistan Ltd
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	US-FDA Approved
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Letter for issuance of DML dated 26.10.2023 is submitted
	Evaluation Remarks	
	Observation: 3.2.P.5, The system suitability as per BP monograph requires use of impurity C to ensure proper resolution of the HPLC system and method, the submitted method does not mention this, neither any chromatogram indicating performance of system suitability as per BP monograph is provided. Please justify. Reply: For trial purpose, only API for stability sample and working standard of API was purchased or loaned. During stability study testing, standard and sample solution were prepared and assay percentage was calculated. Once the product gets registered, we will adopt the complete assay procedure including system suitability solution.	
	Decision	
	Deferred	
	Deferred for following; Submission of revised testing method as per BP monograph along with fee for pre-registration variation. Submission of system suitability performance as per BP monograph.	
61	Case Category	Import (Adil Saeed)

	Name, address of Applicant.	HIMMEL PHARMACEUTICALS (PVT.) LTD Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Zazaria e Pakistan Lahore (05-352-0065)
	Application Form Dy. No / Tracking ID & date of submission	(ZN7-HEE-3A8W, 2025-03-27)
	Detail of Fee Submitted	300000.0, 2025-01-02,
	The proposed proprietary name / brand name	Cabazitaxel AqVida 20mg/ml Concentrate for Solution for Infusion, 3ml Vial
	Label Claim	Each 3ml vial contains Cabazitaxel.....60mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	3 Year(s)Store below 30°C.
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	L01CD04 PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS
	Name, address of Manufacturing site:	AqVida GmbH -Werkstr.21 23942 Dassow- Germany
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Jevtana M/s Sanofi Aventis batch No. 5F010A
	Name, address of Marketing Authorization Holder:	AqVida GmbH , Kaiser-Wilhelm-Str.89, 20355 Humburg, Germany
	Details of Certificates (CoPP/FSC/cGMP):	Copy of GMP certificate issued on basis of inspection dated 08.12.2022 is submitted. Valid till 07.12.2025. Issued by Drug monitoring and testing Center Gral-york Schwerin Germany.
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Jentana 20mg/ml Injection, USA
	Evaluation Remarks	
	COPP No. AQV/130824/42b dated 13.08.2024 issued by Authority for justice and consumer protection, Pharmacy and Medical Devices Hamburg Germany is uploaded. In COPP it is mentioned that product is placed on market of country of origin. Market authorization holder is AqVida GmbH kaiser Wilhelm-str. 89 20355 Hamburg Germany.Product manufacturer: AqVida GmbH Werkstr. 21 23942 Dassow Germany.Copy of letter of authorization is also uploaded wherein M/s AqVida GmbH has authorized M/s Himmel pharmaceutical (Pvt.) Ltd. for registration and marketing of Cabazitaxel 20mg/ml concentrate for solution for infusion in territory of Pakistan.	
	Decision	
	Approved	
	As per policy for inspection abroad	
62	Case Category	Routine (Ammar Ashraf Awan)
	Name, address of Applicant.	AsianContinental (Pvt.) Ltd. D-32, S.I.T.E II, Super Highway, Karachi (000643)
	Application Form Dy. No / Tracking ID & date of submission	(R1H-736-W4TU, 2024-03-14)

	Detail of Fee Submitted	30000.0, 2024-01-26,
	The proposed proprietary name / brand name	VILDASIAN-M 50mg/1000mg
	Label Claim	Each film coated Tablet contains: Vildagliptin 50mg Metformin HCl.....1000mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2 x 7 's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 °C
	For generic drugs (me-too Status)	Vilget-M Tablet 50/1000mg (Getz Pharma Pvt. Ltd.)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Aarti drugs Ltd.,VildagliptiN: Anhui haikang Pharmaceuticals 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	Galvus Met 50/1000mg Tablet (Novartis Pharmaceuticals Australia Pvt. Ltd.
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
63	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Aptly Pharmaceuticals 5-Km, Sargodha Road Bypass, Faisalabad. (000887)
	Application Form Dy. No / Tracking ID & date of submission	(124-8B8-HYXH, 2024-08-07)
	Detail of Fee Submitted	30000.0, 2024-08-02,
	The proposed proprietary name / brand name	MENTHOVIL-20 Oral Liquid
	Label Claim	Each ml Contains: Bromhexine HCl 20 mg Menthol 40 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ml-De-Controlled,1000 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,50 ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)at room temperature
	For generic drugs (me-too Status)	BRONCHOMENT-20 Oral Liquid (reg. # 119754) M/s M.A. KAMIL FARMA KARACHI.

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Recommended for approval.	
	Decision	
	Approved	
64	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	DHAANS Pharma (Pvt) Ltd Plot No.9/A Industrial Estate Bhimber, Azad Jammu Kashmir (000912)
	Application Form Dy. No / Tracking ID & date of submission	(22V-TZA-UA15, 2024-08-21)
	Detail of Fee Submitted	30000.0, 2024-08-20,
	The proposed proprietary name / brand name	I-CLOR 2000 INJECTION
	Label Claim	Each 100ml contains; Ivermectin USP..... 20mg Clorsulon USP..... 10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	IVOBAK SUPER INJECTION (063825) ATTABAK Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommends grant of Additional sections
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Recommended for approval subject to submission of valid GMP certificate.	
	Decision	
	Approved	
	Registration letter shall be issued after submission of valid GMP certificate.	
65	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	DHAANS Pharma (Pvt) Ltd Plot No.9/A Industrial Estate Bhimber, Azad Jammu Kashmir (000912)
	Application Form Dy. No / Tracking ID & date of submission	(1J6-R2M-GLLY, 2024-08-21)
	Detail of Fee Submitted	30000.0, 2024-08-20,
	The proposed proprietary name / brand name	I-CLOR 2000 INJECTION
	Label Claim	Each 100ml contains (USP Spec.) Ivermectin USP..... 20mg Clorsulon

		USP..... 10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10ml-De-Controlled
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	IVOBAK SUPER INJECTION (063825) ATTABAK Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommends grant of Additional sections
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Recommended for approval subject to submission of valid GMP certificate.	
	Decision	
	Approved	
	Registration letter shall be issued after submission of valid GMP certificate.	
66	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	DHAANS Pharma (Pvt) Ltd Plot No.9/A Industrial Estate Bhimber, Azad Jammu Kashmir (000912)
	Application Form Dy. No / Tracking ID & date of submission	(298-HZ8-UY1B, 2024-08-21)
	Detail of Fee Submitted	30000.0, 2024-08-20,
	The proposed proprietary name / brand name	I-CLOR INJECTION
	Label Claim	Each ml contains; Ivermectin USP..... 20mg Clorsulon USP..... 10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	IVOCLOL INJECTION (078244) NAWAL Pharmaceuticals, Rawalpindi.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommends grant of Additional sections
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Recommended for approval subject to submission of valid GMP certificate.	
	Decision	
	Approved	
	Registration letter shall be issued after submission of valid GMP certificate.	
67	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Aptly Pharmaceuticals 5-Km, Sargodha Road Bypass, Faisalabad. (000887)
	Application Form Dy. No / Tracking ID & date of submission	(2EG-Y1B-MQLG, 2024-08-07)

	Detail of Fee Submitted	30000.0, 2024-08-02,
	The proposed proprietary name / brand name	APLA E Oral Liquid
	Label Claim	Each ml contains: Vitamin E 200mg Sorbitol 50 mg Choline chloride 50 mg Selenium as sodium selenite 2.3 mg Zinc as Zinc sulfate 4 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ml-De-Controlled,1000 ml-De-Controlled,150 ml-De-Controlled,250 ml -De-Controlled,500 ml- De-Controlled
	Shelf Life (Unit)	2 Year(s)at room temperature
	For generic drugs (me-too Status)	EG SUPERTONIC Solution (reg. # 074071) M/s Evergreen Pharmaceuticals Lahore.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Recommended for approval.	
	Decision	
	Approved	
68	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	DHAANS Pharma (Pvt) Ltd Plot No.9/A Industrial Estate Bhimber, Azad Jammu Kashmir (000912)
	Application Form Dy. No / Tracking ID & date of submission	(3GU-JXP-7469, 2024-08-21)
	Detail of Fee Submitted	30000.0, 2024-08-20,
	The proposed proprietary name / brand name	I-CLOR 1000 INJECTION
	Label Claim	Each 100ml contains; Ivermectin USP..... 1g Clorsulon USP..... 10g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	ACTIMEC PLUS INJECTION (033251) SELMORE Pharmaceuticals, Lahore.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommends grant of Additional sections
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Recommended for approval subject to submission of valid GMP certificate.	
	Decision	
	Approved	

	Registration letter shall be issued after submission of valid GMP certificate.	
69	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	DHAANS Pharma (Pvt) Ltd Plot No.9/A Industrial Estate Bhimber, Azad Jammu Kashmir (000912)
	Application Form Dy. No / Tracking ID & date of submission	(3J9-V4X-DRYJ, 2024-08-21)
	Detail of Fee Submitted	30000.0, 2024-08-20,
	The proposed proprietary name / brand name	I-CLOR 1000 INJECTION
	Label Claim	Each 100ml contains; Ivermectin USP..... 1g Clorsulon USP..... 10g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	ACTIMEC PLUS INJECTION (033251) SELMORE Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommends grant of Additional sections
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Recommended for approval subject to submission of valid GMP certificate.	
	Decision	
	Approved	
	Registration letter shall be issued after submission of valid GMP certificate.	
70	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	DHAANS Pharma (Pvt) Ltd Plot No.9/A Industrial Estate Bhimber, Azad Jammu Kashmir (000912)
	Application Form Dy. No / Tracking ID & date of submission	(6NQ-7UV-EZ96, 2024-08-21)
	Detail of Fee Submitted	30000.0, 2024-08-20,
	The proposed proprietary name / brand name	GENTO 10% INJECTION
	Label Claim	Each ml contains; Gentamicin (as sulphate) USP 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	GENTON INJECTION 10% (035178) GUYTON PHARMACEUTICALS LAHORE
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommends grant of Additional sections
	Evidence of approval of manufacturing facility	

	Evaluation Remarks	
	Recommended for approval subject to submission of valid GMP certificate.	
	Decision	
	Approved	
	Registration letter shall be issued after submission of valid GMP certificate.	
71	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Aptly Pharmaceuticals 5-Km, Sargodha Road Bypass, Faisalabad. (000887)
	Application Form Dy. No / Tracking ID & date of submission	(741-1NQ-SW8V, 2024-08-07)
	Detail of Fee Submitted	30000.0, 2024-08-02,
	The proposed proprietary name / brand name	APLA GOLD Powder
	Label Claim	Each Kg contains: Vitamin A 0.8 gm Vitamin D3 0.16 gm Vitamin E 0.38 gm Vitamin B1 01 gm Vitamin B2 1.25 gm Vitamin B12 0.001 gm Vitamin B3 6.25 gm copper sulfate 0.25 gm Magnesium Sulfate 25 gm Calcium Chloride 0.023 gm Manganese sulfate 10 gm Potassium Iodide 0.5 gm Sodium Selenite 0.01 gm DCP 150 gm Sodium Chloride 120 gm Vitamin B6 4 gm Zinc Sulfate 2.17 gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gm-De-Controlled,1000 gm-De-Controlled,250 gm-De-Controlled,50 gm-De-Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)at room temperature
	For generic drugs (me-too Status)	WHITE GOLD Powder (reg. # 058842) M/s Leads Pharma Islamabad.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Recommended for approval.	
	Decision	
	Approved	
72	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	BIORISE PHARMACEUTICALS 19KM, LAHORE ROAD, MULTAN (000934)
	Application Form Dy. No / Tracking ID & date of submission	(7VR-W5P-9J19, 2024-08-12)
	Detail of Fee Submitted	30000.0, 2024-08-02,
	The proposed proprietary name / brand name	ADE-Rise Injection 100mL

	Label Claim	Each 1ml contains:Vitamin A (B.P)..... 100000IU Vitamin D3 (B.P).....40000IU Vitamin E (U.S.P).....40mg (Product Complies With Innovator's Specs.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100mL-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in a cool and Dry place, away from moisture and direct sunlight.
	For generic drugs (me-too Status)	ADEKA Injection Reg. No.075792 by A & K Pharmaceutical, Faisalabad
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel of inspectors found the premises satisfactory and recommend the grant of DML.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Recommended for approval.	
	Decision	
	Approved	
73	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Aptly Pharmaceuticals 5-Km, Sargodha Road Bypass, Faisalabad. (000887)
	Application Form Dy. No / Tracking ID & date of submission	(9UH-B18-MAE1, 2024-08-07)
	Detail of Fee Submitted	30000.0, 2024-08-02,
	The proposed proprietary name / brand name	APLA NSK Oral Powder
	Label Claim	Each gram containsNeomycin Sulphate 33.33 mgStreptomycin Sulfate 33.33 mgSulphaguanidine 333.33 mgKaolin 333.33 mgpectin 33.33 mgBismuth Subnitrate 166.66 mgVitamin A Acetate 2.291 mgAs per Innovators Specifications
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gm-De-Controlled,1000 gm-De-Controlled,12 gm-De-Controlled,20 gm-De-Controlled,250 gm- De-Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)at room temperature
	For generic drugs (me-too Status)	DAIRROLEX Water Soluble Powder (Reg. # 080151) M/s Wimits Pharmaceuticals Lahore.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Recommended for approval.	
	Decision	

	Approved	
74	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Evergreen Pharmaceutical 69/70-B, Glaxo Town Industrial Estate.(Opposite Annam Weaving Mills) 20-Km Ferozpur Road, Lahore. (000736)
	Application Form Dy. No / Tracking ID & date of submission	(B7X-5QR-235P, 2024-08-07)
	Detail of Fee Submitted	30000.0, 2024-08-05,
	The proposed proprietary name / brand name	ECTICLOR Injection
	Label Claim	Each ml contains; IVERMECTIN 10 mg CLORSULON 100 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in a cool & dry place. Protect from sunlight.
	For generic drugs (me-too Status)	Actimec Plus Injection Reg.No. 033251 by Selmore Pharmaceuticals.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm is operating at satisfactory level of GMP Compliance at the time of inspection.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Recommended for approval.	
75	Decision	
	Approved	
	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Aptly Pharmaceuticals 5-Km, Sargodha Road Bypass, Faisalabad. (000887)
	Application Form Dy. No / Tracking ID & date of submission	(BZG-HZV-AU3S, 2024-08-07)
	Detail of Fee Submitted	30000.0, 2024-08-02,
	The proposed proprietary name / brand name	STOMIGEST Oral Powder
	Label Claim	Each gram containsPropionic Acid Calcium 250 mgPropionic Acid Sodium 400 mgAcetanilide 150 mgMagnesium Oxide 125 mgIron II sulfate 0.4 mgZinc sulfate 0.1 mgMagnesium Sulfate 0.2 mgCopper sulfate 0.45 mgCobalt Sulfate 0.4 mgSodium Molybdate 0.1 mgSodium Chloride 20 mgAs per Innovators Specifications
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	10 gm-De-Controlled,100 gm-De-Controlled,1000 gm-De-Controlled,250 gm-De-Controlled,50 gm-De-Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)at room temperature
	For generic drugs (me-too Status)	ANIGEST Powder (Reg. # 073906) M/s Mylab (Pvt)Ltd Bahawalpur.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Recommended for approval.	
	Decision	
	Approved	
76	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Aptly Pharmaceuticals 5-Km, Sargodha Road Bypass, Faisalabad. (000887)
	Application Form Dy. No / Tracking ID & date of submission	(DHN-Y8A-R6MT, 2024-08-07)
	Detail of Fee Submitted	30000.0, 2024-08-02,
	The proposed proprietary name / brand name	MENTHOVIL-10 Oral Liquid
	Label Claim	Each ml containsBromhexine HCl 10 mgMenthol 20 mgAs per Innovators specifications
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ml-De-Controlled,1000 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,50 ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)at room temperature
	For generic drugs (me-too Status)	B-MENTHOL Liquid (Reg. # 093825) M/s Farm Aid Group, Haripur..
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Recommended for approval.	
	Decision	
	Approved	
77	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	DHAANS Pharma (Pvt) Ltd Plot No.9/A Industrial Estate Bhimber, Azad Jammu Kashmir (000912)

	Application Form Dy. No / Tracking ID & date of submission	(E6E-LRJ-VGQH, 2024-08-21)
	Detail of Fee Submitted	30000.0, 2024-08-20,
	The proposed proprietary name / brand name	GENTACIN INJECTION
	Label Claim	Each ml contains; Gentamicin as Sulphate BP 50mg Tylosin as tartrate BP 100mg
	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)	G.T.RAAS INJECTION (063709) ZAKFAS PHARMA MULTAN.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommends grant of Additional sections
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Recommended for approval subject to submission of valid GMP certificate.	
	Decision	
	Approved	
	Registration letter shall be issued after submission of valid GMP certificate.	
78	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	DHAANS Pharma (Pvt) Ltd Plot No.9/A Industrial Estate Bhimber, Azad Jammu Kashmir (000912)
	Application Form Dy. No / Tracking ID & date of submission	(EEQ-NV7-S29U, 2024-08-21)
	Detail of Fee Submitted	30000.0, 2024-08-20,
	The proposed proprietary name / brand name	GENTACIN 150 INJECTION
	Label Claim	Each ml contains; Gentamicin as Sulphate BP 100mg Tylosin as tartrate BP 50mg
	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)	B.G.GENTA INJECTION (075624) BIOGEN PHARMA RAWAT
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommends grant of Additional sections
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Recommended for approval subject to submission of valid GMP certificate.	
	Decision	

	Approved	
	Registration letter shall be issued after submission of valid GMP certificate.	
79	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Aptly Pharmaceuticals 5-Km, Sargodha Road Bypass, Faisalabad. (000887)
	Application Form Dy. No / Tracking ID & date of submission	(H2Z-WRM-7V5Q, 2024-08-07)
	Detail of Fee Submitted	30000.0, 2024-08-02,
	The proposed proprietary name / brand name	APLA BROMAC Oral Powder
	Label Claim	Each gram containsBromhexine HCl 10 mgTartaric Acid 150 mgAs per Innovators specifications
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 gm-De-Controlled,100 gm-De-Controlled,1000 gm-De-Controlled,250 gm-De-Controlled,50 gm-De-Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)at room temperature
	For generic drugs (me-too Status)	BROMACID Oral Powder (Reg. # 049723) M/s Biogen Pharma, Rawat.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Recommended for approval.	
	Decision	
	Approved	
80	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Aptly Pharmaceuticals 5-Km, Sargodha Road Bypass, Faisalabad. (000887)
	Application Form Dy. No / Tracking ID & date of submission	(HWD-6TL-EMRD, 2024-08-06)
	Detail of Fee Submitted	30000.0, 2024-08-02,
	The proposed proprietary name / brand name	OXBENZOLE Oral Liquid
	Label Claim	Each Liter ContainsOxfendazole 22.65 gmTriclabendazole 85 gmAs per Innovators specifications
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ml-De-Controlled,1000 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,50 ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)at room temperature

	For generic drugs (me-too Status)	VORCID Suspension (reg no 063563) M/s Breeze pharma Islamabad.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Recommended for approval.	
	Decision	
	Approved	
81	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Aptly Pharmaceuticals 5-Km, Sargodha Road Bypass, Faisalabad. (000887)
	Application Form Dy. No / Tracking ID & date of submission	(J9A-XYW-14RR, 2024-08-06)
	Detail of Fee Submitted	30000.0, 2024-08-02,
	The proposed proprietary name / brand name	APTIN Oral Liquid
	Label Claim	Each ml Contains; Ivermectin 10 mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10 ml-De-Controlled,100 ml-De-Controlled,1000 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,500 ml-De-Controlled,50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)at room temperature
	For generic drugs (me-too Status)	KEPROMEC Oral (reg. no 049560) M/s Better Traders Faisalabad.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Recommended for approval.	
	Decision	
	Approved	
82	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	BIORISE PHARMACEUTICALS 19KM, LAHORE ROAD, MULTAN (000934)
	Application Form Dy. No / Tracking ID & date of submission	(J9E-UP5-HBM8, 2024-08-24)
	Detail of Fee Submitted	30000.0, 2024-08-02,

	The proposed proprietary name / brand name	Aminor G Plus Oral Solution
	Label Claim	EACH 100ML CONTAINS:-NORFLOXACIN 20GM.AMINOPHYLLIN 8GM.GUAIPHENESIN 20MG
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ml, 150ml, 200, -De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in a cool and Dry place, away from moisture and direct sunlight.
	For generic drugs (me-too Status)	NORAMIN G LIQUID By M/S. LEADS PHARMA, ISLAMABAD Reg. No. 044976
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel of inspectors found the premises satisfactory and recommend the grant of DML.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Recommended for approval.	
	Decision	
	Approved	
83	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	BIORISE PHARMACEUTICALS 19KM, LAHORE ROAD, MULTAN (000934)
	Application Form Dy. No / Tracking ID & date of submission	(LP3-Y2B-7G3N, 2024-08-24)
	Detail of Fee Submitted	30000.0, 2024-08-02,
	The proposed proprietary name / brand name	Aspivit-C Water Soluble Powder
	Label Claim	Each 100gm contains: Aspirin (Acetyl Salicylic Acid)..... 6.7g Vitamin C..... 20g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10gm, 50g, 100 gm., -De-Controlled
	Shelf Life (Unit)	2 YearStore in a cool and Dry place, away from moisture and direct sunlight.
	For generic drugs (me-too Status)	Sali-C Powder By Selmore Pharmaceuticals, Lahore Reg No. 043537
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel of inspectors found the premises satisfactory and recommend the grant of DML.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Recommended for approval.	
	Decision	
	Approved	

84	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Aptly Pharmaceuticals 5-Km, Sargodha Road Bypass, Faisalabad. (000887)
	Application Form Dy. No / Tracking ID & date of submission	(P2X-4SZ-L4LJ, 2024-08-07)
	Detail of Fee Submitted	30000.0, 2024-08-02,
	The proposed proprietary name / brand name	APLA AMPRO-50 Oral Powder
	Label Claim	Each gram contains; Amprolium HCl 500 mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100 gm-De-Controlled, 1000 gm-De-Controlled, 200 gm-De-Controlled, 500 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s) at room temperature
	For generic drugs (me-too Status)	PROLIN Powder (reg. # 118447) M/s Inshal Pharmaceuticals Islamabad.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Recommended for approval.	
	Decision	
	Approved	
85	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	DHAANS Pharma (Pvt) Ltd Plot No.9/A Industrial Estate Bhimber, Azad Jammu Kashmir (000912)
	Application Form Dy. No / Tracking ID & date of submission	(Q84-V5L-9H9A, 2024-08-21)
	Detail of Fee Submitted	30000.0, 2024-08-20,
	The proposed proprietary name / brand name	GENTACIN INJECTION
	Label Claim	Each ml contains; Gentamicin as Sulphate BP 50mg Tylosin as tartrate BP 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s) Store Below 30°C
	For generic drugs (me-too Status)	G.T.RAAS INJECTION (063709) ZAKFAS PHARMA MULTAN
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommends grant of Additional sections
	Evidence of approval of manufacturing facility	

	Evaluation Remarks	
	Recommended for approval subject to submission of valid GMP certificate.	
	Decision	
	Approved	
	Registration letter shall be issued after submission of valid GMP certificate.	
86	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	DHAANS Pharma (Pvt) Ltd Plot No.9/A Industrial Estate Bhimber, Azad Jammu Kashmir (000912)
	Application Form Dy. No / Tracking ID & date of submission	(Q8B-RA6-AM37, 2024-08-21)
	Detail of Fee Submitted	30000.0, 2024-08-20,
	The proposed proprietary name / brand name	GENTACIN INJECTION
	Label Claim	Each ml contains; Gentamicin as Sulphate BP 50mg Tylosin as tartrate BP 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	G.T.RAAS INJECTION (063709) ZAKFAS PHARMA MULTAN.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommends grant of Additional sections
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Recommended for approval subject to submission of valid GMP certificate.	
	Decision	
	Approved	
	Registration letter shall be issued after submission of valid GMP certificate.	
87	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	DHAANS Pharma (Pvt) Ltd Plot No.9/A Industrial Estate Bhimber, Azad Jammu Kashmir (000912)
	Application Form Dy. No / Tracking ID & date of submission	(Q9T-LD7-1AHE, 2024-08-21)
	Detail of Fee Submitted	30000.0, 2024-08-20,
	The proposed proprietary name / brand name	GENTO 10% INJECTION
	Label Claim	Each ml contains (USP) Gentamicin (as sulphate) USP 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 YearStore Below 30°C

	For generic drugs (me-too Status)	GENTON INJECTION 10% (035178) GUYTON PHARMACEUTICALS LAHORE
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommends grant of Additional sections
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Recommended for approval subject to submission of valid GMP certificate.	
	Decision	
	Approved	
	Registration letter shall be issued after submission of valid GMP certificate.	
88	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Aptly Pharmaceuticals 5-Km, Sargodha Road Bypass, Faisalabad. (000887)
	Application Form Dy. No / Tracking ID & date of submission	(QTV-4QB-A9E8, 2024-08-07)
	Detail of Fee Submitted	30000.0, 2024-08-02,
	The proposed proprietary name / brand name	APNESUL-72 Oral Powder
	Label Claim	Each gram contains; Neomycin Sulfate 720 mg (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100 gm-De-Controlled,1000 gm-De-Controlled,250 gm-De-Controlled,50 gm-De-Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)at room temperature
	For generic drugs (me-too Status)	NEOM-72 Water Soluble Powder (reg. # 118506) M/s Poulvet Pharmaceuticals, Multan.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Recommended for approval.	
	Decision	
	Approved	
89	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Aptly Pharmaceuticals 5-Km, Sargodha Road Bypass, Faisalabad. (000887)
	Application Form Dy. No / Tracking ID & date of submission	(RA7-XTS-2STY, 2024-08-07)
	Detail of Fee Submitted	30000.0, 2024-08-02,
	The proposed proprietary name / brand name	OXFEN Oral Liquid

	Label Claim	Each ml contains; Oxfendazole BP vet 22.65 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100 ml-De-Controlled,1000 ml-De-Controlled,250 ml-De-Controlled,50 ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)at room temperature
	For generic drugs (me-too Status)	OXASEL Drench (Reg. # 071084) M/s Selmore Pharmaceutical Lahore.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Recommended for approval.	
	Decision	
	Approved	
90	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	DHAANS Pharma (Pvt) Ltd Plot No.9/A Industrial Estate Bhimber, Azad Jammu Kashmir (000912)
	Application Form Dy. No / Tracking ID & date of submission	(TP8-UDH-JZ28, 2024-08-21)
	Detail of Fee Submitted	30000.0, 2024-08-20,
	The proposed proprietary name / brand name	I-CLOR 2000 INJECTION
	Label Claim	Each 100ml contains (USP Spec.) Ivermectin USP..... 20mg Clorsulon USP..... 10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	IVOBAK SUPER INJECTION (063825) ATTABAK Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommends grant of Additional sections
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Recommended for approval subject to submission of valid GMP certificate.	
	Decision	
	Approved	
	Registration letter shall be issued after submission of valid GMP certificate.	
91	Case Category	Routine (Anam Saeed)

	Name, address of Applicant.	DHAANS Pharma (Pvt) Ltd Plot No.9/A Industrial Estate Bhimber, Azad Jammu Kashmir (000912)
	Application Form Dy. No / Tracking ID & date of submission	(W9X-U5D-XXB2, 2024-08-21)
	Detail of Fee Submitted	30000.0, 2024-08-20,
	The proposed proprietary name / brand name	GENTACIN 150 INJECTION
	Label Claim	Each ml contains; Gentamicin as Sulphate BP 100mg Tylosin as tartrate BP 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	B.G.GENTA INJECTION (075624) BIOGEN PHARMA RAWAT
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommends grant of Additional sections
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Recommended for approval subject to submission of valid GMP certificate.	
	Decision	
	Approved	
	Registration letter shall be issued after submission of valid GMP certificate.	
92	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Aptly Pharmaceuticals 5-Km, Sargodha Road Bypass, Faisalabad. (000887)
	Application Form Dy. No / Tracking ID & date of submission	(WM9-U7E-RWN2, 2024-08-06)
	Detail of Fee Submitted	30000.0, 2024-08-02,
	The proposed proprietary name / brand name	CLOCOBEN Oral Liquid
	Label Claim	Each ml contains; Closantel 50 mg Mebendazole 75 mg Cobalt Sulphate 9 mg (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ml-De-Controlled,1000 ml-De-Controlled,250 ml-De-Controlled,500 ml-De-Controlled,50ml -De-Controlled
	Shelf Life (Unit)	2 Year(s)at room temperature
	For generic drugs (me-too Status)	EVERZANTEL-M Suspension (reg. no 088864) M/s Evergreen Pharmaceuticals Lahore.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP Approved
	Evidence of approval of manufacturing facility	

	Evaluation Remarks	
	Recommended for approval.	
	Decision	
93	Approved	
	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	BIORISE PHARMACEUTICALS 19KM, LAHORE ROAD, MULTAN (000934)
	Application Form Dy. No / Tracking ID & date of submission	(XHR-1U4-TPG9, 2024-08-09)
	Detail of Fee Submitted	30000.0, 2024-08-02,
	The proposed proprietary name / brand name	Biofurcin Water Soluble Powder
	Label Claim	EACH KG CONTAINS: - TYLOSIN TARTRATE.....25GM ERYTHROMYCIN THIOCYANATE...30GM FURALTADONE.....50GM PRODUCT COMPLIES WITH INNOVATORS SPECS.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10gm, 20gm, 50gm, 10-De-Controlled
	Shelf Life (Unit)	2 YearStore in a cool and dry place away from moisture and sunlight.
	For generic drugs (me-too Status)	Tylofurcin Water Soluble Powder by Symans Pharmaceuticals, Lahore Reg. No. 013683
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel of Inspectors recommends grant of new DML. Applied for cGMP Inspection.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Recommended for approval.	
	Decision	
	Deferred	
	for review of formulation to Sub-committee on veterinary drugs.	
94	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Evergreen Pharmaceutical 69/70-B, Glaxo Town Industrial Estate.(Opposite Annam Weaving Mills) 20-Km Ferozpur Road, Lahore. (000736)
	Application Form Dy. No / Tracking ID & date of submission	(XRP-L5M-H98M, 2024-08-13)
	Detail of Fee Submitted	30000.0, 2024-08-05,
	The proposed proprietary name / brand name	OXYNIL-34 Injection
	Label Claim	Each ml contain: Nitroxinil 340 mg
	Reference to Finished product specifications	British Pharmacopeia

	Proposed Pack Size	100 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 degree in a cool & dry place.
	For generic drugs (me-too Status)	Troxy34% Injection Reg. No. 034596by Selmore Pharmaceuticals.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm is operating at satisfactory level of GMP Compliance at the time of inspection.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Recommended for approval.	
	Decision	
	Approved	
95	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	DHAANS Pharma (Pvt) Ltd Plot No.9/A Industrial Estate Bhimber, Azad Jammu Kashmir (000912)
	Application Form Dy. No / Tracking ID & date of submission	(Z73-W2Y-8RTH, 2024-08-21)
	Detail of Fee Submitted	30000.0, 2024-08-20,
	The proposed proprietary name / brand name	I-CLOR 1000 INJECTION
	Label Claim	Each 100ml contains; Ivermectin USP..... 1g Clorsulon USP..... 10g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	ACTIMEC PLUS INJECTION (033251) SELMORE Pharmaceuticals LAHORE
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommends grant of Additional sections
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Recommended for approval subject to submission of valid GMP certificate.	
	Decision	
	Approved	
	Registration letter shall be issued after submission of valid GMP certificate.	
96	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	Wilson's Pharmaceuticals Plot No. 387-388 & 366 Sector I/9 Industrial Area, Islamabad (000239)
	Application Form Dy. No / Tracking ID & date of submission	(13Y-56L-J9HM, 2024-03-19)

Detail of Fee Submitted	30000.0, 2024-02-15,
The proposed proprietary name / brand name	Sofvasc-DUO 10/50mg Tablet
Label Claim	Each film coated tablet contains: Amlodipine as besylate.....10.00 mg Losartan potassium 50.00 mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	10-As per SRO,100-As per SRO,20-As per SRO,30-As per SRO,40-As per SRO,60-As per SRO
Shelf Life (Unit)	2 Year(s)20-25°C
For generic drugs (me-too Status)	Losamaay Tablets 10/500mg of TABROS PHARMA. (Reg. No. 127049)
Pharmacotherapeutic Group of (API)	Losartan Potassium: Angiotensin II receptor blockers (ARBs) Amlodipine besylate: Calcium channel blockers
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Prudence Pharma Chem, India,Zhejiang Tianyu Pharmaceutical Co., Ltd. China
Detail of stability batches of drug product	3 batches having batch size of 1500 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate issued dated 23-06-2022 specifying 500kg Losartan potassium. Firm has submitted copy of commercial invoice dated 04-08-2020 specifying 1000kg Amlodipine besylate.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against LosAmlo 10/50mg Tablets.,
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	Los amlo 10/50mg Tablet Germany Approved https://portal.dimdi.de/amguifree/am/docoutput/jpadglobalDoc
GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 28-07-2022.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 30-11-2022 specifying Tablet (General) section.
Evaluation Remarks	

S No.	Shortcomings	Firm's Response
1	Valid copy of cGMP certificate / DML of the Drug Substance manufacturer for amlodipine and losartan potassium issued by relevant regulatory authority of country of origin is required	Firm has submitted notification for cGMP certificate for losartan potassium stating that NMPA no longer issue GMP certificate from December 2019. Firm has also submitted copy of DML#20050431 for API manufacturer of losartan potassium issued by Zhejiang Provincial Food and Drug Administration valid till 02-04-2030

Decision

Approved

97	Case Category	New Section (Dr. Farhad Ullah)
	Name, address of Applicant.	Sunshine Pharmaceuticals Emanabad, G.T Road (000662)
	Application Form Dy. No / Tracking ID & date of submission	(4W1-X8W-HE8Z, 2025-04-11)
	Detail of Fee Submitted	37000.0, 2025-04-08,
	The proposed proprietary name / brand name	Omeron 40mg Capsules
	Label Claim	Each Capsule Contains: Enteric Coated Pellets of Omeprazole eq. to Omeprazole 40mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10x10's-As per SRO, 1x10's-As per SRO, 2x7's-As per SRO, 3x10's-As per SRO, 3x7's-As per SRO
	Shelf Life (Unit)	2 Year(s) 15°C-30°C
	For generic drugs (me-too Status)	Risek 40mg capsule by M/s Getz Pharma (Pvt) Limited
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vision Pharmaceuticals Pvt. Limited
	Detail of stability batches of drug product	3 batches having batch size of 800 capsule each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of invoice dated 23-07-2022 from M/s Vision Pharma specifying 01kg Omeprazole EC Pellets 22.5% in name of M/s Sunshine Pharmaceuticals.,
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE & CDP studies performed against Risek 40mg capsule Capsule by M/s Getz Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV
	The status in reference regulatory authorities	Omeprazole 40mg gastro-resistant capsule MHRA Approved
	GMP status of the firm	Firm has submitted copy of inspection for grant of additional section dated 08-01-2024 in which the panel recommended the grant of additional sections

Evidence of approval of manufacturing facility		Firm has submitted copy of letter of Additional sections dated 24-04-2024 Capsule-(General)-Additional section
Evaluation Remarks		
S No.	Shortcomings	Firm's response
1	Submit alternative brand name for applied product as the submitted brand name resemble with already registered product	Firm has submitted alternative brand names; Omix, Omezol, Omsun Omirol, Omisun
2	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 request of M/s Vision Pharma dated 23-05-2024 for issuance of GMP certificate
3	You have referred to USP test 2 in finished product specifications for dissolution test while limits of release at both acid and buffer phase are different than USP monograph for dissolution test 2, clarify	The firm has clarified that USP dissolution Test-1 has been adopted for omeron 40mg. The mention of Test-2 was an inadvertent typographical error. Our attached testing method and the associated raw data sheets clearly reflect the use of USP Dissolution Test-1.
4	Analytical method verification for 20mg capsule is submitted	The firm submitted that analytical testing method for both omeprazole 20mg and 40mg capsule is same. Accordingly, the method verification report submitted for 20mg strength is applicable to both products. Furthermore, we utilized the same concentration of pellets in both the 20mg and 40mg formulations. As the 20mg dossier was submitted first, the verification report reflects that strength. However, we confirm that all technical parameters, as outlined in the USP, are identical for both strengths. We kindly request this method verification report be considered applicable to both 20mg and 40mg products.
Decision		
Approved		
98	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	Pharmedic Laboratories (Pvt.) Ltd Lahore 16-Km Multan Road, Lahore (000228)
	Application Form Dy. No / Tracking ID & date of submission	(5N6-688-6H5T, 2024-03-14)

	Detail of Fee Submitted	30000.0, 2024-02-13,	
	The proposed proprietary name / brand name	Regab Capsule	
	Label Claim	Each Capsule contains: Pregabalin.....150mg	
	Reference to Finished product specifications	British Pharmacopeia	
	Proposed Pack Size	A blister Pack -As per SRO	
	Shelf Life (Unit)	2 Year(s)Do not store above 30 C	
	For generic drugs (me-too Status)	Lyrica 150mg by Pfizer Pakistan	
	Pharmacotherapeutic Group of (API)	Antiepileptics, other antiepileptics ATC code: N02BF02	
	Name, address of Manufacturing site:	Self Manufacturing	
	Name & address of API manufacturer	KOPRAN RESEARCH LABORATORIES LIMITED	
	Detail of stability batches of drug product	3 batches having batch size of 1000 capsule each	
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate issued dated 05-01-2023 specifying 3.5kg Pregabalin.	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Lyrica 150mg Capsule by M/s Pfizer.,	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A	
	The status in reference regulatory authorities	Lyrica 150mg Capsule USFDA Approved	
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 04-02-2020.	
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of panel constituted for renewal of DML dated 03-03-2025 specifying capsule (General) section. Firm has submitted copy of cGMP certificate of the firm based on inspection dated 04-02-2020 specifying capsule (Non-Antibiotic) section	
	Evaluation Remarks		
	S. No.	Shortcomings	Firm's Response
	1	Submit alternative brand name for applied product as the submitted brand name resemble with already registered product	Firm has submitted the suggested brand name for applied product. Lyrin, Lyrigab, Nervolin
	2	Copy of cGMP certificate / GMP inspection report of applicant conducted within last three years	Firm has submitted copy of letter to additional director DRAP Lahore for issuance of cGMP certificate
	Decision		
	Approved		
99	Case Category	Routine (Dr. Farhad Ullah)	
	Name, address of Applicant.	Pharmedic Laboratories (Pvt.) Ltd Lahore 16-Km Multan Road, Lahore (000228)	
	Application Form Dy. No / Tracking ID & date of submission	(5X8-B29-4G1G, 2024-03-27)	

	Detail of Fee Submitted		30000.0, 2024-02-13,
	The proposed proprietary name / brand name		Regab Capsule
	Label Claim		Each capsule contains: Pregabalin. 100mg
	Reference to Finished product specifications		British Pharmacopeia
	Proposed Pack Size		A blister Pack -As per SRO
	Shelf Life (Unit)		2 Year(s)Do not store above 30 C
	For generic drugs (me-too Status)		Xilica 100mg (PharmEvo)
	Pharmacotherapeutic Group of (API)		Antiepileptics, other antiepileptics ATC code: N02BF02
	Name, address of Manufacturing site:		Self Manufacturing
	Name & address of API manufacturer		KOPRAN RESEARCH LABORATORIES LIMITED
	Detail of stability batches of drug product		3 batches having batch size of 1000 capsule each
	Documents for the procurement of API with approval from DRAP (in case of Import)		Firm has submitted copy of clearance certificate issued dated 05-01-2023 specifying 3.5kg Pregabalin.
	Pharmaceutical Equivalence and Comparative Dissolution Profile		PE and CDP studies performed against Xilica 100mg Capsule by M/s PharmEvo (Pvt.) Ltd.,
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A
	The status in reference regulatory authorities		Lyrica 100mg Capsule USFDA Approved
	GMP status of the firm		Firm has submitted copy of cGMP certificate of the firm based on inspection dated 04-02-2020.
	Evidence of approval of manufacturing facility		Firm has submitted copy of letter of panel constituted for renewal of DML dated 03-03-2025 specifying capsule (General) section. Firm has submitted copy of cGMP certificate of the firm based on inspection dated 04-02-2020 specifying capsule (Non-Antibiotic) section
Evaluation Remarks			
S No.		Shortcomings	Firm's Response
1		Submit alternative brand name for applied product as the submitted brand name resemble with already registered product	Firm has submitted the suggested brand name for applied product. Lyrin, Lyrigab, Nervolin
2		Copy of cGMP certificate / GMP inspection report of applicant conducted within last three years	Firm has submitted copy of letter to additional director DRAP Lahore for issuance of cGMP certificate
Decision			
Approved			
100	Case Category		Routine (Dr. Farhad Ullah)
	Name, address of Applicant.		TABROS PHARMA (PVT). LTD. Plot No. L-20/B, Sector 22, F.B. Industrial Area (000106)
	Application Form Dy. No / Tracking ID & date of submission		(633-9BE-XHTD, 2024-03-14)

Detail of Fee Submitted	30000.0, 2024-03-11,	
The proposed proprietary name / brand name	Linoxy 5mg Tablet	
Label Claim	Each film coated tablet contains: Linagliptin.....5mg Innovator’s Specification	
Reference to Finished product specifications	As per Innovators Specification	
Proposed Pack Size	1x10’s Tablet-As per SRO,3x10s Tablet-As per SRO	
Shelf Life (Unit)	2 Year(s)Store below 30oC	
For generic drugs (me-too Status)	Lina Tablet 5mg, by CCL Pharma	
Pharmacotherapeutic Group of (API)	Dipeptidyl peptidase 4 (DPP-4) inhibitors	
Name, address of Manufacturing site:	Self Manufacturing	
Name & address of API manufacturer	Ruyuan HEC Pharm Co. Ltd., Xiaba Development Zone, Ruyuan Country, Shaoguan City, Guangdong Province, P.R. China, Postal Code: 512721	
Detail of stability batches of drug product	3 batches having batch size of 1500 tablets each	
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of two form 6 dated 01- 02-2023 and 14-12-2023 specifying 0.51gm Linagliptin respectively.	
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies and CDP performed against Trajenta 5mg Tablet by M/s Boehringer Ingelheim.	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV	
The status in reference regulatory authorities	Tradjenta 5mg Tablet, Boehringer Ingelheim Pharmaceuticals/ Eli Lilly and Company USFDA Approved	
GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 28-03-2024.	
Evidence of approval of manufacturing facility	Firm has submitted copy of letter for renewal of DML dated 30-06-2020 specifying Tablet (General) section.	
Evaluation Remarks		
S No.	Shortcomings	Firm’s Response
1	Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	Firm has submitted copy of cGMP certificate of API manufacturer issued by Guangdong Food and Drug Administration valid upto 07-10- 2026
2	Submit copy of commercial invoice or clearance certificate for the procurement of API with approval from DRAP.	Firm has submitted copy of form 6 dated 14-12-2023 specifying 0.51gm Linagliptin. Firm has submitted copy of invoice specifying 0.51kg linagliptin. However, invoice is not attested by (I&E) DRAP. Firm has also submitted that at the time of procurement of Linagliptin for the development of applied

		product the Custom Clearance based on Form 6 issued from DRAP ADC Office.
	Decision	
	Approved	
101	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	Aspin Pharma Plot # 10 & 25 Sector 20 Korangi Industrial Area Karachi 74900 Pakistan (000045)
	Application Form Dy. No / Tracking ID & date of submission	(VT4-YHP-3DGE, 2023-12-15)
	Detail of Fee Submitted	30000.0, 45000.0 2023-11-15, 2023-11-21
	The proposed proprietary name / brand name	Stugerin Plus
	Label Claim	Each tablet contains: Cinnarizine.....20mg Dimenhydrinate.....40mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1x10's-As per SRO, 2x10's-As per SRO, 3x10's-As per SRO
	Shelf Life (Unit)	2 Year(s) do not store above 3
	For generic drugs (me-too Status)	Novert Tablet (Approved in Minutes for 261st Registration Board Meeting)
	Pharmaceutical Group of (API)	Antivertigo preparations
	Name, address of Manufacturing site:	--
	Name & address of API manufacturer	Fleming Laboratories Ltd, Survey No. 270, Nawabpet Village, Shivampet Mandal, Medak District, Telangana, INDIA- 502 313., S.S.PHARMACHEM K-44/45, M.I.D.C., Tarapur, Boisar, Dist. Palghar – 401 506, Maharashtra. INDIA
	Detail of stability batches of drug product	3 batches of 2500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	clearance certificate issued dated 02-09-2022 specifying 200kg cinnarizine is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP performed against Arlevert tablet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	submitted
	The status in reference regulatory authorities	Arlevert 20 mg/40 mg tablets Germany
	GMP status of the firm	cGMP certificate submitted based on inspection dated 13-06-2022
	Evidence of approval of manufacturing facility	renewal of DML dated 16-06-2021 submitted specifying tablet general section
	Evaluation Remarks	
	Deferred in 343rd meeting of RB for submission of reply to below cited shortcomings.	
	S No	Deferment Reason
	1	Update the details of submitted differential fee in relevant field of
		Firm's response
		Updated

	e-app interphase (online portal) Response Attached as 1.1	
2	Valid copy of cGMP certificate / Drug Manufacturing License of the Drug Substance manufacturer for cinnarizine and Dimenhydrinate issued by relevant regulatory authority of country of origin is required	Cinnarizine Firm has submitted copy of License retention receipt of API manufacturer issued by Drugs Control Administration, Government of Telangana India, valid upto 31-12-2026 Dimenhydrinate Firm has submitted copy of License retention certificate of API manufacturer issued by Food and Drug Administration Maharashtra State India, valid upto 31-03-2025.
3	Clarification shall be submitted for testing the drug substance in batch analysis as per USP monograph by drug product manufacturer instead of BP monograph as by drug substance manufacturer	In the course of the development process, we employed the Reference Standard along with several impurities from the United States Pharmacopeia (USP), as the British Pharmacopoeia (BP) does not provide these standards. Consequently, we opted for the USP monograph for testing the drug substance, as it provides a High-Performance Liquid Chromatography (HPLC) method that is more suitable for testing purposes. In contrast, the British Pharmacopoeia (BP) offers a titration method. Notably, the limits for both assay and related substances are consistent between the USP and BP monographs. Additionally, method verification for the drug substance was conducted using both USP and BP monographs, ensuring that our Testing Method for the Active Pharmaceutical Ingredient (API) complies with specifications from both standards. Furthermore, during the method verification phase, we conducted supplementary tests such as pH and sulphated ash as indicated in the Certificate of Analysis (COA) provided by the manufacturer of the drug substance.
4	Justification shall be submitted for not performing the test for pH and sulphated ash in batch analysis of drug substance by	Same response as per previous question

	drug product manufacturer as per drug substance manufacturer	
5	COA of primary / secondary reference standard Dimenhydrinate including source and lot number shall be provided.	COA of working reference standard Dimenhydrinate including source and lot number is submitted.
6	Justification shall be submitted for not submitting results of dissolution studies of Dimenhydrinate in pharmaceutical equivalence studies of applied product	During the development process, it became evident that a dissolution test for the combination of Cinnarizine and Dimenhydrinate is not available in any Pharmacopeial Monographs or the FDA Dissolution Database. The British Pharmacopoeia (BP) includes separate Monographs for Cinnarizine Tablets and Dimenhydrinate Tablets; however, only the Cinnarizine Monograph contains a dissolution test, while the Dimenhydrinate Monograph does not. Our in-house testing methodology for the Finished Product necessitated the adoption of the dissolution test for Cinnarizine directly from its BP Monograph. Therefore, the absence of a dissolution test for Dimenhydrinate in the Specification is a justified decision based on the existing regulatory framework. This is the definitive reason for not conducting a dissolution test in pharmaceutical equivalence studies, as well as for the omission of the Comparative Dissolution Profile.
7	Justification shall be submitted for not submitting results of CDP studies of Dimenhydrinate in applied product	Same response as per previous question
8	Justification shall be submitted for not including the dissolution test for dimenhydrate in finished product specifications	Same response as per previous question
9	Submit copy of commercial invoice or clearance certificate for the procurement of API (dimenhydrinate) with approval from DRAP.	Firm has submitted copy of form 6 issued dated 01-03-2023 specifying 1.001kg of Dimenhydrinate. Firm has also submitted copy courier receipt. The firm stated that the said API sample was arranged solely for

		testing and evaluation purposes and was procured on a free-of-cost basis through a courier service. We assure you that for any future procurement of this or any other API, we will duly obtain and submit all relevant documentation, including the commercial invoice and clearance certificate, in full compliance with DRAP regulations.
	Decision	
	Approved	
102	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	Pinnacle Biotech (Pvt.) Ltd. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi. (000939)
	Application Form Dy. No / Tracking ID & date of submission	(8QN-A5P-7UWQ, 2024-03-18)
	Detail of Fee Submitted	30000.0, 2023-12-13,
	The proposed proprietary name / brand name	Empaxo-M XR 25mg/1000mg Tablets
	Label Claim	Each film coated tablet contains: Empagliflozin..... 25mg Metformin Hydrochloride (Extended Release) 1000mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14s Tablets-As per SRO
	Shelf Life (Unit)	2 Year(s)30 Celsius
	For generic drugs (me-too Status)	Xenglu-Met XR 25mg-1000mg tablet by Hilton Pharma Pvt Ltd
	Pharmacotherapeutic Group of (API)	Empagliflozin; Sodium-glucose co-transporter 2 (SGLT2) inhibitors Metformin; Biguanides
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Exemed Pharmaceuticals ,Fuxin Long Rui Pharmaceutical Co Ltd
	Detail of stability batches of drug product	3 batches having batch size of 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of commercial invoice cleared dated 10-12-2021 specifying 1.3kg Empagliflozin. Firm has submitted copy of commercial invoice cleared dated 10-12-2021 specifying 150kg Metformin HCl.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE & CDP studies performed against Xenglu-Met XR 25mg/1000mg tablet by M/s Hilton Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV
	The status in reference regulatory authorities	Synjardy XR 25mg-1000mg by Boehringer Ingelheim Pharmaceuticals Inc. Food and Drug Regulatory Auth

	GMP status of the firm	Firm has submitted copy of cGMP certificate based on inspection dated 21-10-2022.	
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 13-09-2021 specifying Tablet (General) section	
	Evaluation Remarks		
	S No.	Shortcomings	Firm's response
	1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3	Copy of Batch Manufacturing Record (BMR) for all the batches of drug product is submitted
	2	Submit stability study data of drug substance empagliflozin at real time conditions till claimed shelf life	Submit stability study data of drug substance empagliflozin at real time conditions till claimed shelf life is submitted
	Decision		
	Approved		
103	Case Category	Routine (Dr. Farhad Ullah)	
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)	
	Application Form Dy. No / Tracking ID & date of submission	(8VV-5U2-P4QH, 2024-03-20)	
	Detail of Fee Submitted	30000.0, 2024-02-27,	
	The proposed proprietary name / brand name	Ibuprofen DS 200mg/5ml Suspension	
	Label Claim	Each 5ml contains: Ibuprofen.....200mg	
	Reference to Finished product specifications	British Pharmacopeia	
	Proposed Pack Size	1x60ml, 1x90ml, 1x12-As per SRO	
	Shelf Life (Unit)	2 Year(s)Store at cool &dry place below 30	
	For generic drugs (me-too Status)	Brufen DS 200mg/5ml Suspension M/s Abbott Laboratories (Pakistan)Ltd. reg.#070851	
	Pharmaceutical Group of (API)	Nonsteroidal anti-inflammatory drugs (NSAIDs)	
	Name, address of Manufacturing site:	Self Manufacturing	
	Name & address of API manufacturer	Zenith Chemical Industries (Pvt) Limited. Address: Moaza dhonday, Jia Bagga, raiwind road Lahore Postcode: 53100	
	Detail of stability batches of drug product	3 batches having batch size of 10 Liter Bottle each (90ml)	
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of invoice dated 01-10-2023 from M/s Zenith Chemical Industries (Pvt.) Ltd. Pakistan specifying 540kg Ibuprofen in name of M/s Wimits Pharmaceuticals.,	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE & CDP studies performed against Brufen DS Suspension	
	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		Fenopine 200 mg/5 ml Oral Suspension HPRA Ireland Approved
	GMP status of the firm		Firm has submitted copy of cGMP certificate of the firm based on inspection dated 03-04-2023.
	Evidence of approval of manufacturing facility		Firm has submitted copy of letter of issuance of DML dated 07-02-2014 Syrup (General Human) section
	Evaluation Remarks		
	S No.	Shortcomings	Firm's response
	1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3	Submitted
	2	Clarify the batch size of applied product in terms of number of units manufactured	The batch size of applied product in terms of number of units manufactured is 111 units or in Liter 10L each Batch.
	3	Stability study data of applied product at 6th month time point shall be submitted	Stability study data of applied product at 6th month time point is submitted
	Decision		
	Approved		
104	Case Category	New Section (Dr. Farhad Ullah)	
	Name, address of Applicant.	PDH Laboratories (Pvt.) Ltd. 9.5 Km Sheikhupura Road, Lahore (000039)	
	Application Form Dy. No / Tracking ID & date of submission	(BA1-B88-E42Z, 2024-12-31)	
	Detail of Fee Submitted	37000.0, 2024-11-19,	
	The proposed proprietary name / brand name	Motilidone suspension 1mg/ml	
	Label Claim	Each ml contains: Domperidone.....1mg	
	Reference to Finished product specifications	As per Innovators Specification	
	Proposed Pack Size	60ml & 120ml-De-Controlled	
	Shelf Life (Unit)	2 Year(s)below 30°	
	For generic drugs (me-too Status)	Motilium oral suspension by M/s Aspin Pharma	
	Pharmacotherapeutic Group of (API)	Dopamine antagonist (antiemetic)	
	Name, address of Manufacturing site:	Self Manufacturing	
	Name & address of API manufacturer		
	Detail of stability batches of drug product	3 batches having batch size of 166 Bottles each (120ml)	
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate dated 16-11-2023 specifying 50kg Domperidone in name of M/s Obsons Pharmaceuticals., The firm have submitted letter of borrowing of API from M/s Obsons Pharmaceuticals.	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Motilium Oral Suspension by M/s Aspin 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	Domperidone 1mg/ml oral suspension by Zentiva Pharma UK Limited. MHRA Approved
GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 26-01-2024.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter for grant of additional section dated 07-06-2022 specifying Oral Liquid Section (General)-Additional

Evaluation Remarks

S No.	Shortcomings	Firm's Response
1	Submit alternative brand name for applied product as the submitted	Firm has submitted alternative brand names for applied product. 1. PD-Dom Suspension 1mg/ml (Prefer) 2. Vomcure Suspension 1mg/ml 3. Gastromol Suspension 1mg/ml 4. Domrest Suspension 1mg/ml
2	Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	Firm has submitted copy of cGMP certificate of API manufacturer issued by Deputy Director & Certifying Authority, Drugs Control Administration, Visakhapatnam Region, AP, India valid upto 30-06-2025
3	Copy of loan agreement for API between the firms and intimation of borrowing of API submitted in DRAP shall be submitted	Firm has copy of Memorandum of understanding for loan of API between the firms and intimation of borrowing of API submitted in DRAP

Decision

Approved

105	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	Kaizen Pharmaceuticals (Pvt) Ltd Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi (000755)
	Application Form Dy. No / Tracking ID & date of submission	(BMB-AM8-ZXPX, 2023-11-24)
	Detail of Fee Submitted	75000.0, 2023-11-10,
	The proposed proprietary name / brand name	Sertagyn 2% Vaginal Cream
	Label Claim	Each gram contains: Sertaconazole Nitrate.....20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	40g tube-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a cool and dry place. Below 30 oC
	For generic drugs (me-too Status)	None
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	--
	Name & address of API manufacturer	Name: Glenmark Life Sciences Limited, Address: Address: Plot no. A-80, MIDC, Kurkumbh, Taluka-Daund, Dist. Pune, Maharashtra State, India Tel : 091- 2117 – 235491 Fax : 091- 2117 – 235171
	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	Ginedermofix 2% vaginal cream CIMA Spain Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Deferred in 343rd meeting of RB for submission of reply to below cited shortcomings.	
	Sr. No	Deferment Reason
	1	Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority.
106	2	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision	
	Approved	
	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	Pinnacle Biotech (Pvt.) Ltd. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi. (000939)
	Application Form Dy. No / Tracking ID & date of submission	(BX1-UPQ-5MTP, 2024-03-11)
	Detail of Fee Submitted	30000.0, 2023-12-13,
	The proposed proprietary name / brand name	Empaxo-M XR Tablets 12.5mg-1000mg
	Label Claim	Each film coated tablet contains:Empagliflozin..... 12.5mgMetformin Hydrochloride (Extended Release) 1000mg

Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	14s Tablets-As per SRO
Shelf Life (Unit)	2 Year(s)Shelf life only applies under appropriate conditions of storage specified on package
For generic drugs (me-too Status)	Xenglu-Met XR 12.5mg-1000mg tablet by Hilton Pharma Pvt Ltd
Pharmacotherapeutic Group of (API)	Empagliflozin; Sodium-glucose co-transporter 2 (SGLT2) inhibitors Metformin; Biguanides
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Exemed Pharmaceuticals,Fuxin Long Rui Pharmaceutical Co Ltd
Detail of stability batches of drug product	3 batches having batch size of 1500 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of commercial invoice cleared dated 10-12-2021 specifying 1.3kg Empagliflozin. Firm has submitted copy of commercial invoice cleared dated 10-12-2021 specifying 150kg Metformin HCl.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE & CDP studies performed against Xenglu-Met XR 12.5mg/1000mg tablet by M/s Hilton Pharma
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV
The status in reference regulatory authorities	Synjardy XR 12.5mg-1000mg by Boehringer Ingelheim Pharmaceuticals Inc. Food and Drug Regulatory Auth
GMP status of the firm	Firm has submitted copy of cGMP certificate based on inspection dated 21-10-2022.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 13-09-2021 specifying Tablet (General) section

Evaluation Remarks

S No	Shortcomings	Firm's Response
1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3	Submitted
2	Submit stability study data of drug substance empagliflozin at real time conditions till claimed shelf life	Submitted

Decision

Approved

107	Case Category	New Section (Dr. Farhad Ullah)
	Name, address of Applicant.	Bio-Labs(Pvt) Ltd Plot 145, Industrial Triangle, Kahuta Road (000296)
	Application Form Dy. No / Tracking ID & date of submission	(BZU-WPZ-JLYR, 2024-12-20)
	Detail of Fee Submitted	30000.0, 2024-03-01,

	The proposed proprietary name / brand name	Miniox 5% topical solution
	Label Claim	Each ml contain: Minoxidil.....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	60ml-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30C
	For generic drugs (me-too Status)	Regro Solution 5% by M/s Seattle Private Ltd.,
	Pharmacotherapeutic Group of (API)	Vasodilator
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Kumar Organic Products Limited
	Detail of stability batches of drug product	3 batches having batch size of 150 Bottles each (60ml)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate issued dated 09-06-2023 specifying 100kg Minoxidil in name of M/s Maxitech Pharma,
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Minoxin 5% Topical Solution by M/s Brookes Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV
	The status in reference regulatory authorities	Rogaine Extra Strength (for Men) 5% Topical Solution USFDA Approved
	GMP status of the firm	Not submitted
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of additional Section dated 27-09-2021 specifying Lotion (General) (in place of licensed Vaccine Veterinary Section).
	Evaluation Remarks	
	Previous Decision; Deferred as decided in application of Miniox Topical Solution 2% (w/v) tracking ID; SH4-3W7-XGSP of M/s Bio-Labs (Pvt.) Ltd., presented in instant meeting.	
	Decision	
	Deferred	
	Deferred as decided in application of Miniox Topical Solution 2% (w/v) tracking ID; SH4-3W7-XGSP of M/s Bio-Labs (Pvt.) Ltd., presented in instant meeting.	
108	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	Kaizen Pharmaceuticals (Pvt) Ltd Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi (000755)
	Application Form Dy. No / Tracking ID & date of submission	(DHE-AQ8-H9H8, 2023-12-19)
	Detail of Fee Submitted	30000.0, 2023-11-10,
	The proposed proprietary name / brand name	Sertaderm 2% Topical Cream
	Label Claim	Each gram contains:Sertaconazole Nitrate.....20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30gm Tube-As per SRO,60gm Tube-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at temperatures not exceeding 30oC. Protect

For generic drugs (me-too Status)		Sertazol Cream 2% by M/s Hudson Pharma (Reg# 92642)	
Pharmacotherapeutic Group of (API)			
Name, address of Manufacturing site:		Self Manufacturing	
Name & address of API manufacturer		Glenmark Life Sciences Limited Address: Plot no. A-80, MIDC, Kurkumbh, Taluka- Daund, Dist. Pune, Maharashtra State, India	
Detail of stability batches of drug product			
Documents for the procurement of API with approval from DRAP (in case of Import)			
Pharmaceutical Equivalence and Comparative Dissolution Profile			
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)			
The status in reference regulatory authorities		ERTACZO (sertaconazole nitrate) 2% cream, for topical use USFDA Approved	
GMP status of the firm			
Evidence of approval of manufacturing facility			
Evaluation Remarks			
Sr. No		Deferment Reason	Firm's Response
1		Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority.	Firm has submitted copy of letter of grant of additional section dated 19-06-2025 specifying Topical Section (Cream/Ointment/Gel/Paste) (General/Steroidal) along with steroidal dispensing) (Revision/Regularization).
Decision			
Approved			
Case Category		New Section (Dr. Farhad Ullah)	
Name, address of Applicant.		shrooq pharmaceuticals pvt ltd 21km feorzpur road lahore (000577)	
Application Form Dy. No / Tracking ID & date of submission		(N5Z-2BE-B6BH, 2024-07-29)	
Detail of Fee Submitted		30000.0, 2024-02-02,	
The proposed proprietary name / brand name		Draz-T Ophthalmic solution 2%/0.5%	
Label Claim		Dorzolamide Hydrochloride and Timolol Maleate 2%/0.5%	
Reference to Finished product specifications		United States Pharmacopeia	
Proposed Pack Size		5ml-As per SRO	
Shelf Life (Unit)		2 Year(s)2-25°C	
For generic drugs (me-too Status)		Co-Dorzal Ophthalmic Solution 2%/0.5% by M/s Sante Private limited	
Pharmacotherapeutic Group of (API)		Dorzolamide as HCl: Carbonic anhydrase inhibitors Timolol as Maleate : beta-blockers	

Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Flax laboratories India
Detail of stability batches of drug product	3 batches having batch size of 192 bottles (5ml volume) each
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of commercial invoice dated 31-05-2022 specifying 01kg Dorzolamide HCl and 01kg Timolol maleate in name of M/s Sharooq Pharmaceuticals. However, invoice is not cleared by AD (I&E) DRAP.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Co-Dorzal ophthalmic solution 2%/0.5% by M/s Sante Private Limited
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A
The status in reference regulatory authorities	COSOPT (dorzolamide hydrochloride and timolol maleate ophthalmic solution), 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 01-12-2023
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of New Section granted dated 20-01-2022 specifying Eye / Ear / Nose drop Section (new Section).

Evaluation Remarks

Deferred in 347th meeting of RB for submission of reply to below cited shortcomings.

Sr. No	Deferment Reason	Firm's Response
1	Deferred for adopting isocratic chromatographic method for assay test of Drozolamide HCl in drug product instead of gradient method as per USP	Firm submitted that we have revised our chromatographic method for assay test of Drozolamide HCl in drug product to gradient method and revised Analytical Testing Method for Draz-T Ophthalmic Solution and Method verification report are also submitted.

Decision

Approved

Approved with following label claim;

Each ml contains:

Dorzolamide as HCl.....20mg

Timolol as Maleate.....5mg

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

110	Case Category	Routine (Dr. Farhad Ullah)	
	Name, address of Applicant.	Wilson's Pharmaceuticals Plot No. 387-388 & 366 Sector I/9 Industrial Area, Islamabad (000239)	
	Application Form Dy. No / Tracking ID & date of submission	(Q89-2LZ-A714, 2024-03-20)	
	Detail of Fee Submitted	30000.0, 2024-02-15,	
	The proposed proprietary name / brand name	Sofvasc DUO 10/100 mg Tablet	
	Label Claim	Each Film Coated tablet contains:- Amlodipine besylate as amlodipine 10 mg Losartan potassium..... 100 mg	
	Reference to Finished product specifications	As per Innovators Specification	
	Proposed Pack Size	10-As per SRO,100-As per SRO,20-As per SRO,30-As per SRO,40-As per SRO,60-As per SRO	
	Shelf Life (Unit)	2 Year(s)20-25 °C	
	For generic drugs (me-too Status)	Losamaay Tablets 10/100mg of TABROS PHARMA. (Reg. No. 125210)	
	Pharmacotherapeutic Group of (API)	Losartan Potassium: Angiotensin II receptor blockers (ARBs) Amlodipine besylate: Calcium channel blockers	
	Name, address of Manufacturing site:	Self Manufacturing	
	Name & address of API manufacturer		
	Detail of stability batches of drug product	3 batches having batch size of 1500 tablets each	
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate issued dated 23-06-2022 specifying 500kg Losartan potassium. Firm has submitted copy of commercial invoice dated 04-08-2020 specifying 1000kg Amlodipine besylate.	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against LosAmlo 10mg/100mg Tablets.,	
	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	Los Amlo 100/10 mg Germany Approved. https://portal.dimdi.de/amguifree/am/docoutput/jpadglobalDocId=8	
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 28-07-2022.	
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 30-11-2022 specifying Tablet (General) section.	
Evaluation Remarks			
S No.		Shortcomings	Firm's Response
1		Valid copy of cGMP certificate / DML of the Drug Substance manufacturer for amlodipine and losartan potassium issued by relevant regulatory authority of country of origin is required	Firm has submitted notification for cGMP certificate for losartan potassium stating that NMPA no longer issue GMP certificate from December 2019.Firm has also submitted copy of

		DML#20050431 for API manufacturer of losartan potassium issued by Zhejiang Provincial Food and Drug Administration valid till 02-04-2030
	Decision	
	Approved	
111	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	Scotmann Pharmaceuticals Plot #5D , Industrial Area, I-10/3 Islamabad (000498)
	Application Form Dy. No / Tracking ID & date of submission	(S4J-HD6-ND5D, 2024-03-10)
	Detail of Fee Submitted	75000.0, 2023-12-15,
	The proposed proprietary name / brand name	Sunny D Consta Ampoule 300,000 IU/ml
	Label Claim	Each ml contains: Vitamin D3..... 300,000 IU/ml (7.5mg) (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's-As per SRO,10's-As per SRO,2's-As per SRO,5's-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 25 °C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Vitamin D
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Source of Drug Substance: DSM Nutritional Products Ltd. Address: 1 Boulevard D Alsace, Village Neuf, 68128, France
	Detail of stability batches of drug product	3 batches having batch size of 1000 ampoules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate dated 11-11-2021 specifying 20kg Vitamin D3 crystalline.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Dibase solution for injection 300,000IU/ml by Abiogen Pharma S.p.A Italy.
	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	Dibase 300,000 IU/ml Solution for Injection , Registered in Italian Medicine Agency (AIFA)
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 22-02-2024.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for renewal of DML dated 26-04-2024 specifying Injection Ampoule section (General).
	Evaluation Remarks	
	S No.	Shortcomings
	1	Analytical Method Verification studies including specificity, accuracy and repeatability
		Firm's Response
		Submitted

		(method precision) performed by the Drug Product manufacturer for drug substance shall be submitted.	
	Decision		
	Approved		
112	Case Category	Routine (Farooq Aslam)	
	Name, address of Applicant.	Helix Pharma (Pvt)., Ltd. Hakimsons House, A-56, S.I.T.E, Manghopir Road, Karachi-75700 (000030)	
	Application Form Dy. No / Tracking ID & date of submission	(1LA-G1J-2HZJ, 2024-03-18)	
	Detail of Fee Submitted	30000.0, 2023-09-20,	
	The proposed proprietary name / brand name	Angolix ER Tablet 10	
	Label Claim	Each film coated extended release tablet contains: Ranolazine.....1000mg Another strength of the same formulation i.e Ranolazine film coated extended release tablet 500mg was approved in 347th meeting.	
	Reference to Finished product specifications	As per Innovators Specification	
	Proposed Pack Size		
	Shelf Life (Unit)	24 Month(s)Store below 30C	
	For generic drugs (me-too Status)	Ranola ta blet 1000mg by Highnoon labs	
	Pharmacotherapeutic Group of (API)	Anti-anginal	
	Name, address of Manufacturing site:	Self Manufacturing	
	Name & address of API manufacturer		
	Detail of stability batches of drug product	Batches: TR-193, TR-194, TR-195 (Batch Size: 1000 tablets) 06 months accelerated and 09 months real time stability data is submitted.	
	Documents for the procurement of API with approval from DRAP (in case of Import)	DHL receipt for Ranolazine dated23-02-2021 is submitted. Copy of form 6 dated 10-03-2021 for 6.8kg Ranolazine is submitted. DRAP Attested (10-03-2021) Invoice no. HH2021303 dated 04-02-2021 along with the packing list.	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Rancard XR tablet 1000mg mfg by Searle .	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Real time stability data for 60months and accelerated till 06 months for 03 batches according to zone IV-A is submitted.	
	The status in reference regulatory authorities	Ranolazine extended release tablet 1g by M/s Chartwell RX, USFDA Approved	
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 04-07-2022.	
	Evidence of approval of manufacturing facility	Tablet General Section is approved.	
	Evaluation Remarks		
	.		
	Decision		

	Approved	
113	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(2LU-BLN-L5GR, 2024-03-10)
	Detail of Fee Submitted	30000.0, 2023-10-20,
	The proposed proprietary name / brand name	Rebadec 100mg Tablet
	Label Claim	Each Film coated tablet contains: Rebamipide 100mg (JP specifications)
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	1x10's, 2x10's,5x10'-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at Room Temperature below 30
	For generic drugs (me-too Status)	Mucosta 100mg Tablet of M/s Otsuka Pakistan Limited
	Pharmacotherapeutic Group of (API)	Antacids or anti-reflux agent
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Jiangxi Synergy Pharmaceutical Co. Ltd.,
	Detail of stability batches of drug product	Batches: TRB001, TRB002, TRB003 (Batch size: 2500 tab) 06 month real time and 06 month accelerated stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 16-06-2023 for 1.5kg material is submitted. Commercial invoice No. KXS611351 dated 30th May, 2023, and form 3 are submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e Mucosta 100mg tablet by M/s Ohara Pharmaceutical Co., Japan.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	72 months real time stability and 06 months accelerated stability data is submitted according to the conditions of zone IV-A.
	The status in reference regulatory authorities	REBAMIPIDE TAB 100mg of M/s OHARA Pharmaceutical Co., Ltd (PMDA Approved)
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 03-04-2023.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	.	
	Decision	
	Approved	
114	Case Category	New Section (Farooq Aslam)
	Name, address of Applicant.	Carer Pharmaceuticals industries Plot no.27, Main Road Rawat Industrial Estate, Rawat (000925)
	Application Form Dy. No / Tracking ID & date of submission	(2WH-D8E-96Q7, 2025-01-14)

	Detail of Fee Submitted	37000.0, 2024-12-11,
	The proposed proprietary name / brand name	Fibricar 250mg/5ml injection
	Label Claim	Each 5ml ampoule contains: Tranexamic acid 250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store between 15C-30C
	For generic drugs (me-too Status)	Transamin injection 250mg/ml by Hilton pharma
	Pharmacotherapeutic Group of (API)	Anti-fibrinolytic agent
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Changzhou Yinsheng Pharmaceutical Co., Ltd. Manufacturing site address: Weitang Chemical Zone, Xinbei District, Changzhou, Jiangsu Province, 213033, China Tel: 86-519-85777178, 85771157, Fax: 86-519-85771157, E-mail: czysyy@126.com Website: www.czyspharm.
	Detail of stability batches of drug product	Batches: trial001, trial002, trial003 6 months stability data is submitted including real time and accelerated stability.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 07-06-2022 for 2.5kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against Transamin 250mg/5ml mfg by Hilton Phrma pvt. ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Batches: 100301, 100302, 100303 Accelerated and real time stability data (till 48th months) is submitted according to zone IV-A for 3 batches..
	The status in reference regulatory authorities	PMDA Japan Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 26-08-2024 is submitted,.
	Evidence of approval of manufacturing facility	Ampoule General Section is approved vide letter No. F.1-32/2016-Lic dated 7th June, 2021.
	Evaluation Remarks	
	.	
	Decision	
	Approved	
115	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Pacific Pharmaceutical Ltd 30 km Multan Road Lahore (000295)
	Application Form Dy. No / Tracking ID & date of submission	(53J-7HR-9349, 2024-03-12)
	Detail of Fee Submitted	30000.0, 2024-01-19,
	The proposed proprietary name / brand name	Montelukast 10mg film coated Tablet
	Label Claim	Each film coated tablet contains: Montelukast sodium eq. to montelukast.....10mg
	Reference to Finished product specifications	United States Pharmacopeia

	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	2 Year(s)below 30°C
	For generic drugs (me-too Status)	Montiget 10mg film coated Tablet
	Pharmacotherapeutic Group of (API)	leukotriene receptor antagonists / anti-allergic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Dhanuka Laboratories Limited (SP4-4, Industrial Area, Keshwana Rajput, Kotputli, Shahpura, Jaipur-3 03 1 08, Rajasthan)
	Detail of stability batches of drug product	Batches: LP0108R, LP0208R, LP0308R (Batch size: 20,000 tab) 06 month real time and 06 months accelerated stability is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	ADC attested invoice dated 09-01-2019 (Dy.No. 1254/202-DRAP dated 21-01-2020 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e Montelukast 10mg tablet by Aurobindo Pharma, UK.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	36month real time and 06 month accelerated stability data of 03 batches according to the conditions of zone IV-A is submitted.
	The status in reference regulatory authorities	Montelukast 10mg film coated Tablet by Aurobindo Pharma-Milpharm Ltd.
	GMP status of the firm	GMP Inspection report dated 31-12-2024, 01-01-2025 and 08-05-2025 is submitted.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	.	
	Decision	
	Approved	
116	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	SNB Pharma (Pvt) Ltd Plot # 142, Industrial Estate Hayatabad, Peshawar, KP, (000759)
	Application Form Dy. No / Tracking ID & date of submission	(6EH-1R3-JYSB, 2024-03-19)
	Detail of Fee Submitted	30000.0, 2024-02-29,
	The proposed proprietary name / brand name	SN ALPHA 0.4MG CAPSULE
	Label Claim	Each capsule contains: Tamsulosin Hydrochloride (as sustained release pellets).....0.4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	3 Year(s)room condition
	For generic drugs (me-too Status)	Maxflow 0.4mg Capsule by CCL
	Pharmacotherapeutic Group of (API)	Alpha blocker
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. Vision Pharmaceuticals
	Detail of stability batches of drug product	Batches: T001, T002, T003 (Batch size: 1000 cap) 06 months real time and 06 month accelerated

		stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Invoice from M/s Vision Pharma dated 28-09-2023 for 1kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Tamsuna 0.4mg Cap manufactured by M/s Novartis Pakistan Ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 year real time and 06 month accelerated stability data is submitted for 03 batches according to the conditions of zone IV-A.
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	Inspection report dated 02-12-2021 is submitted.
	Evidence of approval of manufacturing facility	Capsule General Section is approved.
	Evaluation Remarks	
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	Decision	
	Approved	
117	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Martin Dow Limited Plot No. 37, Sector 19, Korangi Industrial Area Karachi-74900, Pakistan (0639)
	Application Form Dy. No / Tracking ID & date of submission	(6MH-H4N-TL3T, 2024-12-05)
	Detail of Fee Submitted	300000.0, 2024-12-02,
	The proposed proprietary name / brand name	Cabozanib
	Label Claim	Each film coated tablet contains: Cabozantinib (S)-MalateEq. to Cabozantinib.....40mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30s-As per SRO
	Shelf Life (Unit)	24 Month(s)Store below 30°C
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	other protein Kinase inhibitor
	Name, address of Manufacturing site:	BDR PHARMACEUTICALS INTERNATIONAL PVT. LTD.-R.S. No. 578, Near Effluent Channel Road, Luna, Taluka- Padra, City: Luna - 391 440, Dist. – Vadodara Gujarat state, India-India
	Name & address of API manufacturer	Not Applicable
	Detail of stability batches of drug product	3 batches, 42000 tablet
	Documents for the procurement of API with approval from DRAP (in case of Import)	Not applicable
	Pharmaceutical Equivalence and Comparative Dissolution Profile	submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches; as per Zone IVA conditions
	The status in reference regulatory authorities	Cabometyx-US FDA
	GMP status of the firm	Yes

	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Deferred in 347th meeting for further deliberation.	
	Decision	
118	Approved	
	as per import policy for inspection of manufacturer abroad.	
	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	AMB HK ENTERPRISES (PVT) LTD, LAHORE 2nd floor plaza 60, Commercial Block K, Phase-1 DHA, Lahore. (05-352-0058)
	Application Form Dy. No / Tracking ID & date of submission	(6U1-H85-VEZB, 2024-08-21)
	Detail of Fee Submitted	300000.0, 2024-07-31,
	The proposed proprietary name / brand name	Xyloxurea
	Label Claim	to treat a certain type of chronic myelogenous leukemia (CML; a type of cancer of the white blood cells) and certain types of head and neck cancer.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10 X 10 Alu-PVC Blis-As per SRO
	Shelf Life (Unit)	36 Month(s)Store at temperature below 30°C.
	For generic drugs (me-too Status)	Generic
	Pharmacotherapeutic Group of (API)	Antineoplastic agent
	Name, address of Manufacturing site:	GLOBELA PHARMA PVT LTD-Plot number:357 & 358,Road No.3,GIDC,Sachin,Surat-394230,Gujarat,India-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not submitted
	Name, address of Marketing Authorization Holder:	M/s AMB HK ENTERPRISES (PVT) LTD, 2nd Floor, Plaza 60, Commercial Block-K, Phase-1,DHA, Lahore, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Submitted
	Details of Authorization Letter :	Not applicable
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches; not as per Zone IVA conditions
	The status in reference regulatory authorities	FDA
	Evaluation Remarks	
	Deferred in 347th meeting for further deliberation.	
	Decision	
	Approved	
	as per import policy for inspection of manufacturer abroad.	
119	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Pacific Pharmaceutical Ltd 30 km Multan Road Lahore (000295)

	Application Form Dy. No / Tracking ID & date of submission	(7ED-S1E-5Y7Y, 2024-03-18)
	Detail of Fee Submitted	30000.0, 2024-01-19,
	The proposed proprietary name / brand name	Metronidazole 400mg Tablet
	Label Claim	Each film coated Tablet contains: Metronidazole....400mg
	Reference to Finished product specifications	The International Pharmacopeia
	Proposed Pack Size	200's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in the original package in order to protect from heat and light
	For generic drugs (me-too Status)	Metrozine 400mg Tablet
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Hubei Hongyuan Pharmaceutical Technology Co., Ltd. No.8 Hongyuan Road, Economic Development Zone, Fengshan Town, Luotian County, Huanggang City, Hubei Province, China
	Detail of stability batches of drug product	Batches: , IZ0102S, IZ0202S, IZ0302S (Batch size: 10,000 Tablet) 06 months real time and 06 month accelerated data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 22-09-2022 is submitted for 50kg Material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed agaist the reference product i.e. Metronidzole tablet 400mg by Aventis Pharma Ltd., UK
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06month accelerated and 48 months real time stability data is submitted for 03 batches according to the conditions of Zone IV-B.
	The status in reference regulatory authorities	Flagyl 400mg Tablet by Aventis Pharma, MHRA Approved
	GMP status of the firm	GMP Inspection report dated 31-12-2024, 01-01- 2025 and 08-05-2025 is submitted
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
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	Decision	
	Approved	
120	Case Category	New License (Farooq Aslam)
	Name, address of Applicant.	May and Baker (Pvt.) Ltd 23-Ghouri Block, Bahria Town, Lahore (000953)
	Application Form Dy. No / Tracking ID & date of submission	(7QX-JNM-T56E, 2024-12-19)
	Detail of Fee Submitted	37000.0, 2024-09-19,
	The proposed proprietary name / brand name	Lonsar 15mg capsule

	Label Claim	Each capsule Contains: EC pellets of Lansoprazole eq to Lansoprazole = 30mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's,6's,7's, 14's, 2-As per SRO
	Shelf Life (Unit)	2 Year(s)below 24 degree
	For generic drugs (me-too Status)	Lanzol cap 30mg by M/s Pharmatech
	Pharmacotherapeutic Group of (API)	Anti-ulcer
	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	Batches: Trial01, Trial02, Trial03 (Batch size: 1500 capsule) 06 month real time and 06 months accelerated stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	.Invoice No. 60009 dated 09-05-2022 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CEDP studies have been performed against Lanzol Cap 30mg by M/s Pharmatech.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted.
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	New DML was granted w.e.f 28-04-2022.
	Evidence of approval of manufacturing facility	Capsule Section (General) is approved.
	Evaluation Remarks	
	The case was deferred in 345th meeting:Submission of certificate of analysis for the batch used for product development from drug product manufacturer. (Submitted)Submission of complete testing and method adopted for precision parameter of analytical method verification studies for drug product including repeatability and reproducibility. (Submitted)Submission of documents confirming procurement of pellets (Invoice No. 60009 dated 09-05-2022 from M.s Vision pharma is submitted.)	
	Decision	
	Approved	
121	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Helix Pharma (Pvt)., Ltd. Hakimsons House, A-56, S.I.T.E, Manghopir Road, Karachi-75700 (000030)
	Application Form Dy. No / Tracking ID & date of submission	(8AH-B4X-GG28, 2024-03-12)
	Detail of Fee Submitted	30000.0, 2023-12-07,
	The proposed proprietary name / brand name	Linaglip Tablets 5mg
	Label Claim	Each Film Coated Tablet Contains: Linagliptin 5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	24 Month(s)Store below 30C
	For generic drugs (me-too Status)	Lina Tablets 5mg by CCL
	Pharmacotherapeutic Group of (API)	Anti-diabetic

	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s RUYUAN HEC PHARM CO., LTD. Address: Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R. China
	Detail of stability batches of drug product	Batches: TR190, TR191, TR192 (Batch Size: 1000 tablets) 06 months real time and 06 months accelerated stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 26th May, 2022 for 0.25kg material, invoice number W1S220042 dated 17th May, 2022. Copy of GD No. KPAF-3874-2022 Date: 24-05-2022 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the product i.e. Trajenta Tablet 5mg by M/s Boehringer Ingelheim Ilac Ticaret A.S EEsentepe Mah Haman, Istanbul.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Batches: LGLT-201405001, LGLT-201405002, LGLT-201405003 36 months real time and 6 months accelerated stability data of 03 batches according to the conditions of zone IV-A is submitted.
	The status in reference regulatory authorities	Trajenta Tablets 5mg by Boehringer Ingelheim Pharmaceuticals Inc. approved by USFDA
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 04-07-2022.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
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	Decision	
	Approved	
122	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Carer Pharmaceuticals industries Plot no.27, Main Road Rawat Industrial Estate, Rawat (000925)
	Application Form Dy. No / Tracking ID & date of submission	(9UD-64J-P7HM, 2025-01-23)
	Detail of Fee Submitted	37000.0, 2024-12-11,
	The proposed proprietary name / brand name	Trevlig 250 mg tablets
	Label Claim	Each film coated tablet contains Azithromycin as dihydrate 250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	6's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store between 15C-30C
	For generic drugs (me-too Status)	Plazo 250 mg tablets
	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	Batches: Trial001, trial002, trial003 Stability data of 03 batches is submitted including real time and accelerated stability studies for 06 months.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loam letter dated 31-05-2024 is submitted from Caliph Pharmaceuticals pvt. ltd 2 kg material. Clearance certificate issued to M/s Caliph Pharmaceutical dated 09-06-2024 is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Plazo tablet 250mg by M/s Platinum pvt. ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Batches: 11900109009, 11900109011, 11900109012 12 month real time and 06 months accelerated stability data according to the conditions of zone IV-A is submitted for 03 btaches.
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted 26-08-2024.
	Evidence of approval of manufacturing facility	Tablet General section is approved vide letter No. F.1-32/2016-Lic dated 7th June, 2021.
	Evaluation Remarks	
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	Decision	
123	Approved	
	subject to verification of loan letter.	
	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Pacific Pharmaceutical Ltd 30 km Multan Road Lahore (000295)
	Application Form Dy. No / Tracking ID & date of submission	(9Y4-U26-7JVM, 2024-03-19)
	Detail of Fee Submitted	30000.0, 45000.0 2024-01-19, 2024-03-13
	The proposed proprietary name / brand name	Levopraid 2.5% Oral Drops
	Label Claim	Each ml contains Levosulpiride....25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	20ml-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	could not be confirmed
	Pharmacotherapeutic Group of (API)	Psycholeptic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Taizhou Xingcheng ChemPharma Co., Ltd. Address:Yantou Industrial Park Jiaojiang District, Taizhou City, Zhejiang China.
	Detail of stability batches of drug product	Batches: IM0112R, IM0212R, IM0312R (Batch size: 2500 bottles) 06 month real time and 06 months accelerated stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 21-12-2022 for 50kg material is submitted.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the reference product i.e. Dislep 2.5% Oral Drops by Ms/ Ferrer Barcelona, SPain,
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	36 months real time and 06 month accelerated stability data is submitted according to zone IV-A.
	The status in reference regulatory authorities	AIFA Italy approved
	GMP status of the firm	Inspection report dated 31-12-2024, 01-01-2025 & 08-05-2025 is submitted for renewal of DML.
	Evidence of approval of manufacturing facility	Oral Liquid General Section is approved.
	Evaluation Remarks	
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	Decision	
	Approved	
124	Case Category	New Section (Farooq Aslam)
	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	(AB2-RRU-68GB, 2025-02-11)
	Detail of Fee Submitted	37000.0, 2024-11-08,
	The proposed proprietary name / brand name	Indihale-G
	Label Claim	Each DPI capsule contains: 143 micrograms of indacaterol maleate eq to 110 micrograms of indacaterol base 63 micrograms of glycopyrronium bromide eq to 50 micrograms of glycopyrronium base Each delivered dose (the dose that leaves the mouthpiece of the inhaler)contains: 110 micrograms of indacaterol maleate equivalent to 85 micrograms of indacaterol base. 54 micrograms of glycopyrronium bromide equivalent to 43 micrograms of glycopyrronium base.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's,10's,14's,20's28-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature between 15-25° C.
	For generic drugs (me-too Status)	Ultivair ,Highnoon Laboratories,Reg No:113986 Ltd,
	Pharmacotherapeutic Group of (API)	Adrenergic in combination with anticholinergics (ATC code: R03AL)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Melody Healthcare Pvt Ltd,Vamsi Labs Limited
	Detail of stability batches of drug product	Data of 3 batches of 4000 DPI capsules each submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Glycopyrronium bromide: 23.04.2024, Drug import License (form 6) Submitted. Indacaterol: DIL (Form 6) dated 12-12-2023 for 25grams material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	(Ultibro® Breezhaler® 110mcg/50mcg; Pharmaceutical equivalence performed including

		tests of Uniformity of Delivered Dose and Aerodynamics Particle Size Distribution by Cascade Impactor.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of 3 batches as per Zone-IV A conditions submitted.
	The status in reference regulatory authorities	Ulbitro Breezhaler, Novartis Pharmaceuticals UK Limited
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	New Section DPI Capsule (Steroid) vide No. F. 2-12/93-Lic (Vol-VI) dated 27.12.2023 granted.
	Evaluation Remarks	
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	Decision	
	Approved	
125	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Amarant Pharmaceuticals Private Limited 158 D. Tore, Gadap Road, Super Highway, Karachi (000584)
	Application Form Dy. No / Tracking ID & date of submission	(AS6-T2D-689V, 2024-03-11)
	Detail of Fee Submitted	30000.0, 2023-11-20,
	The proposed proprietary name / brand name	Pruclo tablets 1 mg
	Label Claim	Each film Coated tablet contains: Prucalopride as succinate..... 1mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO, 14's-As per SRO, 7's-As per SRO
	Shelf Life (Unit)	2 Year(s) Store below 30 oC
	For generic drugs (me-too Status)	PRU-CIC 1mg Tablet of Searle company Ltd. (Reg #116035)
	Pharmacotherapeutic Group of (API)	5-HT4 receptor agonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Symed Labs limited
	Detail of stability batches of drug product	Batches: T001, T002, T003 (Batch Size: 2500 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)	ADC attested invoice (dated 17-12-2021) for 0.80Kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Resolor 1mg tablet by M/s Janssen Cilag SPA.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 60 months real time stability data is submitted for 03 batches conducted under the conditions of Zone IV-B.
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 11-01-2023.

	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
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	Decision	
	Approved	
126	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan (01-374-0006)
	Application Form Dy. No / Tracking ID & date of submission	(B3H-JLA-RN5S, 2024-03-13)
	Detail of Fee Submitted	300000.0, 2024-02-27,
	The proposed proprietary name / brand name	Femati 2.5mg Tablet
	Label Claim	Femati 2.5mg Tablet Each Film Coated Tablet contains: Letrozole..... 2.5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	30's (3x 10's)-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature, away from light and moisture.
	For generic drugs (me-too Status)	Femara 2.5mg Tablet MAH: Novartis Pharma (Pakistan)Limited Reg.No.021129
	Pharmacotherapeutic Group of (API)	Aromatase inhibitor
	Name, address of Manufacturing site:	Atipharmmed Pharmaceutical Company -Barkat St., Shafa St., Supa Blvd., Km 12 Qazvin Exp. way Karaj, Iran.-Iran
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have performed against Femara 2.5mg tablet by Novartis Switzerland.
	Name, address of Marketing Authorization Holder:	Atipharmmed Pharmaceutical Company, Barkat St., Shafa St., Supa Blvd., Km 12 Qazvin Exp. way Karaj, Iran., Iran
	Details of Certificates (CoPP/FSC/cGMP):	Facilities and operations conform to WHO-GMP as per CoPP. GMP certificate is submitted valid till December 2024.
	Details of Authorization Letter :	COPP: Legalized copy of CoPP No. 665/37203 dated 25-09-2021 is submitted. The applied product is available in free sale in exporting country. Facilities and operations conform to WHO-GMP as per CoPP. Distribution certificate: AS per the certificate, M/s Lab Diagnostic System is exclusive distributor of the applied product in Pakistan. DSL: DSL is submitted valid till 04-08-2024.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	48 months real time and 06 month accelerated stability studies according to zone IV-A is submitted.
	The status in reference regulatory authorities	Femara 2.5mg Tablet , Novartis USFDA Approved
	Evaluation Remarks	
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	Decision	

	Approved	
	as per import policy for inspection of manufacturer abroad.	
127	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	(B6A-EPS-9M4V, 2024-03-05)
	Detail of Fee Submitted	75000.0, 2024-01-22,
	The proposed proprietary name / brand name	Unigraf 0.2mg Granules for Oral Suspension
	Label Claim	Each sachet contains: Tacrolimus as monohydrate 0.2mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C in a cool and dry place
	For generic drugs (me-too Status)	could not be confirmed
	Pharmaceutical Group of (API)	Immunosuppressant
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s North China Pharmaceutical Huasheng Co., Ltd Address: No.8 Yangzi Road, Shijiazhuang Economic and Technological Development Zone, Hebei 052160, China
	Detail of stability batches of drug product	Batches: TF01, TF02, TF03 (Batch size: 1000 sachet) 18 months real time and 06 months accelerated stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	ADC attested commercial invoice (Dy. No. 9608 dated 20-08-2020) for 0.05kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed the reference product i.e. Modigraf 0.2mg sachet by M/s Astellas. USK.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	36 months real time and 06 months accelerated stability studies conducted according to the conditions of zone IV-A of 03 batches.
	The status in reference regulatory authorities	Modigraf 0.2mg sachet, MHRA Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 03-01-2023.
	Evidence of approval of manufacturing facility	Dry powder suspension General Section is approved.
	Evaluation Remarks	
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	Decision	
	Approved	
128	Case Category	New License (Farooq Aslam)
	Name, address of Applicant.	Fortune Pharma (Pvt.) LTD Plot 20/K SITE,Super High Way Phase II Karachi (000924)

	Application Form Dy. No / Tracking ID & date of submission	(DMZ-7J8-VRGQ, 2024-11-27)
	Detail of Fee Submitted	37000.0, 2024-11-19,
	The proposed proprietary name / brand name	NEWGAB
	Label Claim	Each Hard Gelatin Capsule Contains:Pregabalin.....300mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	2x7's-As per SRO
	Shelf Life (Unit)	2 Year(s)BELOW 30 DEGREE
	For generic drugs (me-too Status)	GABICA 300mg CAPSULE
	Pharmacotherapeutic Group of (API)	Anti-convulsant
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Batches: T004, T005, T006 Batch size: 1500 tablets Date of manufacturing: 05/2024
	Documents for the procurement of API with approval from DRAP (in case of Import)	The firm has submitted copy of form 6 No. 3662 dated 22-12-2021 (Quantity: 3kg, Batch: PG213041), attested invoice number EX/RU/035/21-22 dated 22-11-2021.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and Pharmaceutical equivalence is submitted against the comparator's product i.e Gabica 300mg capsule by Getz Pharma.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	API Stability data according to the conditions of zone VI-A is submitted for the following batches till 60months for real time and 6months for accelerated stability studies. Batches: PG120001, PG120002, PG120003
	The status in reference regulatory authorities	Lyrica Capsule 300 mg® Hard Gelatin Capsule is Approved in USFDA.
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
Evaluation Remarks		
Analytical method verification studies performed by drug product manufacturer.(Submitted)certificate of analysis of the relevant batch of API from API manufacturer and drug product manufacturer used for product development.(Submitted)specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances. (Submitted)latest GMP inspection report. (Inspection report 27-10-2020 for grant of DML is submitted)complete module III.(Submitted)		
Decision		
Approved		
129	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Cell Health Sciences , Plot No 217, Industrial Triangle, Kahuta Road, Islamabad (000711)
	Application Form Dy. No / Tracking ID & date of submission	(EE1-MPP-6NHG, 2024-03-12)
	Detail of Fee Submitted	30000.0, 2024-01-24,
	The proposed proprietary name / brand name	Lavit 200mg Tablets

	Label Claim	Each tablet contains: Lamotrigine..... 200mg (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)25c
	For generic drugs (me-too Status)	Product Name: Lamictal 200mg tablet Composition: Each tablet contains: Lamotrigine..... 200mg Manufacturer: GSK Pharmaceuticals (Pvt.) Ltd. Registration No. 014918
	Pharmacotherapeutic Group of (API)	Anti-epileptic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CTX LifeSciences Pvt. Ltd.
	Detail of stability batches of drug product	Batches: T01LG200I23, T02LG200I23, T03LG200I23 (Batch size: 1000 tablets) 06 months real time and 06 months accelerated stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 05-09-2023 is submitted for 50kg material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Lamitor Tablet 200mg by M/s Genetics.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	72 months real time and 06 months accelerated stability data for 03 batches is submitted according to the conditions of zone IV-A.
	The status in reference regulatory authorities	SRA Registration Status: FDA approved Brand Name: Lamotrigine....200mg tablets Manufacturer: Milpharm
	GMP status of the firm	Inspection report dated 28-10-2024 is submitted.
	Evidence of approval of manufacturing facility	Tablet General Section is approved
	Evaluation Remarks	
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	Decision	
	Approved	
130	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	(EJD-317-5S5G, 2024-03-05)
	Detail of Fee Submitted	75000.0, 2024-01-22,
	The proposed proprietary name / brand name	Unigraf 2mg IR Capsule
	Label Claim	Each hard gelatin capsule contains: Tacrolimus as monohydrate 2mg
	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 Year(s)Store below 30°C in a cool and dry place

	For generic drugs (me-too Status)	Nil
	Pharmacotherapeutic Group of (API)	Immunosuppressant
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s North China Pharmaceutical Huasheng Co., Ltd Address: No.8 Yangzi Road, Shijiazhuang Economic and Technological Development Zone, Hebei 052160, China
	Detail of stability batches of drug product	Batches: TF01, TF02, TF03 (Batch size: 1000 cap) 18 months real time and 06 months accelerated stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	ADC attested commercial invoice (Dy. No. 9608 dated 20-08-2020) for 0.05kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Adoport 2mg Capsule by M/s Sandoz Limited.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	36 months real time and 06 months accelerated stability studies conducted according to the conditions of zone IV-A of 03 batches.
	The status in reference regulatory authorities	MHRA approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 03-01-2023.
	Evidence of approval of manufacturing facility	Capsule General Section is approved.
	Evaluation Remarks	
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	Decision	
	Approved	
131	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	PHARMAQIO RAWALPINDI 10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. (000978)
	Application Form Dy. No / Tracking ID & date of submission	(G74-V56-HLTE, 2024-12-18)
	Detail of Fee Submitted	37000.0, 2024-12-12,
	The proposed proprietary name / brand name	Qiocin 125mg/5ml Dry Suspension
	Label Claim	Each 5ml Reconstituted Suspension contains: Clarithromycin.....125 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1s-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	KLARICID125mg/5ml Dry suspension
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Vision Pharmaceuticals Pakistan(Plot No,22,23 Industrial Triangle Kahuta ,Road Islamabad, Pakistan
	Detail of stability batches of drug product	6 months accelerated and real time stability data is submitted, Batch size: 60 bottles

	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)	24 months data real time and 6 months accelerated data is submitted.
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	New License was granted w.e.f. 25-10-2023
	Evidence of approval of manufacturing facility	Sachet general section is approved
	Evaluation Remarks	
	Submission of analytical method verification studies performed by drug product manufacturer for drug substance. The submitted studies have been performed by drug substance manufacturer. (Submitted)Submission of P.E studies against reference / comparator's product by performing all the quality tests along with the detail of the product including batch number, expiry, manufacturer etc.(PE studies have been performed against Klaricid dry suspension 125/5mL by M/s Abbot Labs)Submission of documents confirming procurement of API including invoice, clearance certificate, form 6 etc(The firm has submitted copy of delivery challan No. 232401798 dated 08-01-2024 from M/s Vision pharma for 3kg of material)	
	Decision	
	Approved	
132	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	AMB HK ENTERPRISES (PVT) LTD, LAHORE 2nd floor plaza 60, Commercial Block K, Phase-1 DHA, Lahore. (05-352-0058)
	Application Form Dy. No / Tracking ID & date of submission	(GTX-H73-P4X4, 2024-08-23)
	Detail of Fee Submitted	300000.0, 2024-07-31,
	The proposed proprietary name / brand name	MERCAPREX
	Label Claim	Each uncoated tablet contains: Mercaptopurine.....50MG
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-Controlled
	Shelf Life (Unit)	3 Year(s)Store below 30°C, protect from light and Moisture
	For generic drugs (me-too Status)	Generic
	Pharmacotherapeutic Group of (API)	Antineoplastic agent
	Name, address of Manufacturing site:	GLOBELA PHARMA PVT LTD-Plot number:357 & 358,Road No.3,GIDC,Sachin,Surat-394230,Gujarat,India-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not submitted
	Name, address of Marketing Authorization Holder:	GLOBELA PHARMA PVT LTD, Plot number:357 & 358,Road No.3,GIDC,Sachin,Surat-394230,Gujarat,India, India
	Details of Certificates (CoPP/FSC/cGMP):	Submitted
	Details of Authorization Letter :	Not applicable

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches; as per Zone IVA conditions
	The status in reference regulatory authorities	FDA
	Evaluation Remarks	
	Deferred in 347th meeting for further deliberation.	
	Decision	
133	Approved	
	as per import policy for inspection of manufacturer abroad.	
	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	
	The case was deferred in 347th meeting for:Clarification since assay results of accelerated stability studies are well out of specifications at 6th month time points since the shelf life of 2 years is granted on the basis of stability study data of 6 months (including real time and accelerated).Reply: The firm has referred ICH Q1F guidelines. The relevant portion of the guideline is reproduced below:If significant change occurs between three and six months' testing at the accelerated storage condition, the proposed shelf life should be based on the data available from the long-term storage condition.If significant change occurs within the first three months' testing at the accelerated storage condition, a discussion should be provided addressing the effect of short-term excursions outside the label storage condition, e.g. during shipment and handling. This discussion can be supported, if appropriate, by further testing on a single batch of the FPP for a period shorter than three months but with more	

frequent testing than usual. It is considered unnecessary to continue to test a product throughout six months when a significant change has occurred within the first three months of accelerated studies at the specific condition chosen in accordance with the risk analysis. Evaluation by PEC:1. The firm has submitted 24 months real time stability data at 2-8oC and has claimed a shelf of 24 months.2. Significant change in assay results has been observed at 3rd month time point of accelerated stability data at 25oC&60%RH.3. Out of specs assay results have been observed at 6 month time point of accelerated stability studies at 25oC&60%RH.

Decision

Deferred

for clarification / submission of further studies addressing the short term excursions outside the label storage conditions on a single batch of FPP for a period shorter than three months with more frequent testing as per the ICH guidelines.

134	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	REVIVE HEALTH CARE 503, 5TH FLOOR EDEN HEIGHTS 6 MAIN GULBERG JAIL ROAD (05-352-0065)
	Application Form Dy. No / Tracking ID & date of submission	(HZ6-2MB-55QY, 2024-03-08)
	Detail of Fee Submitted	300000.0, 2024-02-01,
	The proposed proprietary name / brand name	Vagacyte Tablets 450 mg
	Label Claim	Each film coated tablet contains: Valganciclovir Hydrochloride USP eq. to Valganciclovir 450 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5x2's Blister Pack-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 degree centigrade
	For generic drugs (me-too Status)	Valcyte Tablets 450 mg by Roche, Reg# 052253
	Pharmacotherapeutic Group of (API)	Antiviral
	Name, address of Manufacturing site:	Panacea Biotec Pharma Limited -Malpur, Baddi, Solan District, Himachal Pradesh - 173 205 INDIA -India
	Name, address of Marketing Authorization Holder:	Panacea Biotec Pharma Limited , Malpur, Baddi, Solan District, Himachal Pradesh - 173 205 INDIA , India
	Details of Certificates (CoPP/FSC/cGMP):	GMP certificate valid till 10-10-2025 is submitted.
	Details of Authorization Letter :	CoPP: Copy of legalized CoPP No. MNB/05/202/WHO/GMP/23-182 valid till 10-10- 2025 is submitted. The applied product is available in free sale and the facilities & operations conform to WHO-GMP asper submitted CoPP. DSL: DSL is valid till 21-05-2027. LOA: Authorization letter is submitted wherein M/s Revive Healthcare hs been declared as exclusive distributor for Pakistan.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	48 months real time data (25oC & 60%RH) and 06 months accelerated stability data of 03 batches is submitted.
Evaluation Remarks		
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	Decision	
	Approved	
	as per the import policy for inspection of manufacturer abroad.	
135	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan (01-374-0006)
	Application Form Dy. No / Tracking ID & date of submission	(P3A-TQP-URB6, 2024-03-13)
	Detail of Fee Submitted	150000.0, 150000.0 2023-10-25, 2024-03-04
	The proposed proprietary name / brand name	MYDOELN-25
	Label Claim	Each capsule contains:- Lenalidomide.....25 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 capsules per bott-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Excursion permitted between 15°
	For generic drugs (me-too Status)	Relidomide 25mg Capsule (Lenalidomide), by M/s Helix Pharma (Pvt)., Ltd., Registration number:
	Pharmacotherapeutic Group of (API)	Immunomodulator
	Name, address of Manufacturing site:	NAPROD LIFE SCIENCES PVT LTD-PLOT NO. G-17/1, MIDC, TARAPUR, BOISAR- 401506-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have submitted against the reference product i.e. Revlimid 25mg Caapsule.
	Name, address of Marketing Authorization Holder:	NAPROD LIFE SCIENCES PVT LTD, PLOT NO. G-17/1, MIDC, TARAPUR, BOISAR- 401506, India
	Details of Certificates (CoPP/FSC/cGMP):	GMP certificate valid till 27th April 2025 is submitted.
	Details of Authorization Letter :	CoPP: Copy of legalized CoPP NO. COPP/CERT/KD/123168/2023/11/44062/213619 valid till 27th April 2025 is submitted. The applied product is available in free sale in exporting country and operations & facilities conform to WHO-GMP as per submitted CoPP. LOA: Product specific letter of Authorization is submitted. DSL: DSL valid till 15-08-2029 is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Avra Laboratories: 03 months real time (25oC & 60% RH) and 03 months accelerated stability data is submitted. Mac Chem Products (India) : 06 months accelerated and 18 moths real time stability data according to the conditions of zone IV-A is submitted.
	The status in reference regulatory authorities	Revlimid (Lenalidomide) Capsules by Bristol Mayer, USFDA Approved
	Evaluation Remarks	

	03 months real time (25oC & 60% RH) and 03 months accelerated stability data is submitted for drug substance manufactured by M/s Avra Laboratories Pvt. Ltd. India.	
	Decision	
	Deferred	
	for submission of complete stability studies of drug substance till shelf life manufacturer by M/s Avra Laboratories Pvt. Ltd., Address: Plot No. A-21, Road No. 10, IDA, Nacharam, Hyderabad – 500076, Telangana State, India.	
136	Case Category	New License (Farooq Aslam)
	Name, address of Applicant.	May and Baker (Pvt.) Ltd 23-Ghuri Block, Bahria Town, Lahore (000953)
	Application Form Dy. No / Tracking ID & date of submission	(PHJ-J8M-HY4B, 2025-03-13)
	Detail of Fee Submitted	37000.0, 2024-09-19,
	The proposed proprietary name / brand name	Lonsar 15mg capsule
	Label Claim	Each capsule contains: Ec pellets of Lansoprazole eq. to Lansoprazole=15mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's,6's,14's, 28's-As per SRO
	Shelf Life (Unit)	2 Year(s)below 24 degree
	For generic drugs (me-too Status)	Q-Pro 15 mg
	Pharmacotherapeutic Group of (API)	Anti ulcer
	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	Batches: Trial001, Trial 002, Trial 003 (Batch Size: 1500 Capsule) 06 months real time and 06 months accelerated.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Invoice No. 60009 dated 09-05-2022 is submitted from M/s VIsion Pharma.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Q-Pro Cap 15mg by M/s Bosch.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	New DML was granted w.e.f 28-04-2022.
	Evidence of approval of manufacturing facility	Capsule Section (General) is approved.
	Evaluation Remarks	
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	Decision	
	Approved	
137	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	PHARMAQIO RAWALPINDI 10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. (000978)

	Application Form Dy. No / Tracking ID & date of submission	(PZS-5HR-VYTG, 2024-12-18)
	Detail of Fee Submitted	37000.0, 2024-12-12,
	The proposed proprietary name / brand name	Qiocin 250mg/5ml Dry Suspension
	Label Claim	Each 5ml Reconstituted Suspension contains: Clarithromycin.....250 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1s-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	KLARICID250mg/5ml Dry suspension
	Pharmaceutical Group of (API)	Antibiotic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Vision Pharmaceuticals Pakistan(Plot No,22,23 Industrial Triangle Kahuta ,Road Islamabad, Pakistan
	Detail of stability batches of drug product	6 months accelerated and real time stability data is submitted, Batch size: 60 bottles
	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)	24 months data real time and 6 months accelerated data is submitted.
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	New License was granted w.e.f. 25-10-2023
	Evidence of approval of manufacturing facility	Sachet general section is approved
	Evaluation Remarks	
	The case was deferred in 345th meeting for submission of:analytical method verification studies performed by drug product manufacturer for drug substance. (Submitted)P.E studies against reference / comparator's product by performing all the quality tests.(The firm has submitted PE studies against Klaricid Dry Suspension 250mg/5mL (Btach: 532272XV) by performing quality tests)documents confirming procurement of API.(The firm has submitted delivery challan No.3003010912 dated 08-01- 2024 for 3kg material)	
138	Decision	
	Approved	
	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Nabiqasim Industries (Pvt) Ltd., 17/24, Korangi Industrial Area, Karachi. (000105)
	Application Form Dy. No / Tracking ID & date of submission	(RDV-5L9-4SV5, 2024-03-13)
	Detail of Fee Submitted	75000.0, 2024-01-30,
	The proposed proprietary name / brand name	Linaglu-Met tablet 2.5mg/500mg
	Label Claim	Each film coated tablet contains: Linagliptin 2.5mg Metformin HCl (USP)....500mg (Innovator's Specification)

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's, 10's, 14's, 20'-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 Degree Celsius Temperature
	For generic drugs (me-too Status)	could not be confirmed
	Pharmacotherapeutic Group of (API)	antidiabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Aarti drugs limited,Anhui Haikang Pharmaceutical Co. Ltd.
	Detail of stability batches of drug product	Batches: 529DS01, 529DS02 (Batch Size: 5000 tablets) 06 months real time and 06 month accelerated stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Linagliptin: Clearance certificate dated 30-10-2022 for 14kg material is submitted. Metformin HCl: Clearance certificate dated 27-09-2022 for 1000kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Jentaduetto 2.5/500 mg by BOEHRINGER INGELHEIM, USA.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Linagliptin: 4 years real time and 06 months accelerate stability according to zone IV-A for 03 batches. Metformin HCl: 60 months real time and 06 months accelerate stability according to zone IV-A for 03 batches.
	The status in reference regulatory authorities	Jentaduetto (Linagliptin 2.5mg + Metformin Hcl 500mg) USFDA Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 27-05-2022
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
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	Decision	
	Approved	
139	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Martin Dow Limited Plot No. 37, Sector 19, Korangi Industrial Area Karachi-74900, Pakistan (0639)
	Application Form Dy. No / Tracking ID & date of submission	(V8Y-742-NPST, 2024-04-17)
	Detail of Fee Submitted	150000.0, 2023-05-25,
	The proposed proprietary name / brand name	Oncopal
	Label Claim	Each Capsule contains:Palbociclib 75mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	21's HDPE Bottle 21-As per SRO
	Shelf Life (Unit)	36 Month(s)stored below 30°C
	For generic drugs (me-too Status)	Ibrance Capsule 75mg by Pfizer Laboratories Ltd
	Pharmacotherapeutic Group of (API)	Anticancer

	Name, address of Manufacturing site:	Aizant Drug Research Solutions Pvt Ltd.-Survey No 172 & 173, Apparel Park Road, Dulapally Village, Dundigal Gandimaisamma Mandal, Medchal Malkajgiri district, Telangana State-500100, India.-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted
	Name, address of Marketing Authorization Holder:	Aizant Drug Research Solutions Pvt Ltd., Survey No 172 & 173, Apparel Park Road, Dulapally Village, Dundigal Gandimaisamma Mandal, Medchal Malkajgiri district, Telangana State-500100, India., India
	Details of Certificates (CoPP/FSC/cGMP):	GMP certificate issued by DCA Telangana submitted
	Details of Authorization Letter :	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
	The status in reference regulatory authorities	IBRANCE 75 mg Hard Capsules by Pfizer Manufacturing Deutschland GmbH Betriebsstätte Freiburg Mooswal
	Evaluation Remarks	
	Reason for deferment	Response
	justification/acceptance criteria for higher % RSD values in comparative dissolution profile studies especially at 15 min time point.	The firm has provided a reference of USP General Chapter <1092> which is reproduced below: Dissolution results may be considered highly variable if the relative standard deviation (RSD) is greater than 20% at time points of 10 minutes or less and greater than 10% RSD at later. RSD is within limit at 15minute timepoint for the applied product and innovator product.
	For further deliberation for whether data of commercial batches is required till shelf life or otherwise.	“Finished product manufacturer has clarified that the stability data of finished product has been generated for exhibit batches till the assigned shelf life which are representative of the full commercial scale production process”. Moreover, the batches were manufactured using the same equipment, procedure and materials as commercial production”.
	For scientific justification of reported relative standard deviation of more than 10% from second time point onwards in the CDP studies of pH 6.8 medium against the recommendations of the Guidelines for Comparative Dissolution Profile.	“Palbociclib is a BCS class II drug therefore, incomplete drug release observed in buffer of pH 6.8 for both reference and test product which contributes to higher RSD values”. Moreover,the firm has submitted BE report of the applied product.
	Decision	
	Deferred	
	for submission of stability data (including accelerated and real time) of finished pharmaceutical product (FPP) according to the conditions of zone IV-A for commercial batches.	
140	Case Category	Routine (Farooq Aslam)

	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	(W8H-XVQ-LUUP, 2025-01-06)
	Detail of Fee Submitted	75000.0, 2024-12-30,
	The proposed proprietary name / brand name	Abiton 500mg Tablet
	Label Claim	Each Film Coated Tablet contains: Abiraterone Acetate.....500MG
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s) Store below 25°C
	For generic drugs (me-too Status)	N/A
	Pharmaceutical Group of (API)	Anti-androgen / anti-cancer
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	BDR Lifesciences Pvt. Ltd., R.S. No. 578, near effluent channel, village: Luna-391440, Ta. Padra, Dist. Vadodara. Gujarat
	Detail of stability batches of drug product	6 months real time and 6 months accelerated data is submitted for 3 batches. (batch size: 400 tablets)
	Documents for the procurement of API with approval from DRAP (in case of Import)	copy of invoice and GD dated 08-01-2024 is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been submitted against the reference product abiraterone tablet by Novugen Pharma USA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	48 months real time and 6 months accelerated stability data according to zone IV-B is submitted for 3 batches.
	The status in reference regulatory authorities	MHRA Approved.
	GMP status of the firm	GMP certificate (for export) is issued on the basis of inspection conducted on 12-10-2022.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	Deferred in 345th meeting for submission of documents (Form 6 and clearance certificate) confirming import of API. (The firm has submitted Copy of GD No. IPAF-109-2024 Date: 08-01-2024, copy of Air way bill)	
	Decision	
	Approved	
141	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Cell Health Sciences , Plot No 217, Industrial Triangle, Kahuta Road, Islamabad (000711)
	Application Form Dy. No / Tracking ID & date of submission	(WS4-6QQ-MRPW, 2024-03-12)
	Detail of Fee Submitted	30000.0, 2024-01-24,
	The proposed proprietary name / brand name	Lavit 25mg tablets
	Label Claim	Each tablet contains; Lamotrigine.....25mg

Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	As per SRO -As per SRO
Shelf Life (Unit)	2 Year(s)25c
For generic drugs (me-too Status)	Lamictal 25mg tablet(Each tablet contains: Lamotrigine..... 25mg Manufacturer: GSK Pharmaceuticals (Pvt.) Ltd. Registration No. 014918)
Pharmacotherapeutic Group of (API)	Anti-epileptic
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	CTX LifeSciences Pvt. Ltd.
Detail of stability batches of drug product	Batches: T01LG25I23, T02LG25I23, T03LG25I23 (Batch size: 1000 tablets) 06 months real time and 06 months accelerated stability data is submitted.
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 05-09-2023 is submitted for 50kg material.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Lemictal Tablet 25mg by M/s GSK.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated stability data for 03 batches is submitted.
The status in reference regulatory authorities	USFDA Approved
GMP status of the firm	Inspection report dated 28-10-2024 is submitted.
Evidence of approval of manufacturing facility	Tablet General Section is approved
Evaluation Remarks	
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Decision	
Approved	
Case Category	Routine (Farooq Aslam)
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	(WSQ-T4J-WHVG, 2025-01-06)
Detail of Fee Submitted	37000.0, 2024-12-30,
The proposed proprietary name / brand name	Abiton 250mg Tablet
Label Claim	Each Film Coated Tablet contains:Abiraterone Acetate.....250mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 Year(s)Store below 25°c
For generic drugs (me-too Status)	Abytiga Tablet by Ocnogen Pharma
Pharmacotherapeutic Group of (API)	Anti-androgen / anti-cancer
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	BDR Lifesciences Pvt. Ltd., R.S. No. 578, near effluent channel, village: Luna-391440, Ta. Padra, Dist. Vadodara. Gujarat
Detail of stability batches of drug product	6 months real time and 6 months accelerated data is submitted for 3 batches. (batch size: 400 tablets)

	Documents for the procurement of API with approval from DRAP (in case of Import)	copy of invoice and GD dated 08-01-2024m is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product Abiraterone Acetate 250mg by Novugen Pharma, USA.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	48 months real time and 6 months accelerated stability data according to zone IV-B is submitted for 3 batches.
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	GMP certificate (for export) is issued on the basis of inspection conducted on 12-10-2022.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	Deferred in 345th meeting for submission of documents (Form 6 and clearance certificate) confirming import of API.(The firm has submitted copy of invoice, GD No. IPAF-109-2024 Date: 08-01-2024 and airway bill)	
	Decision	
	Approved	
143	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	SNB Pharma (Pvt) Ltd Plot # 142, Industrial Estate Hayatabad, Peshawar, KP, (000759)
	Application Form Dy. No / Tracking ID & date of submission	(WW5-7PZ-V81D, 2024-03-14)
	Detail of Fee Submitted	30000.0, 2024-01-25,
	The proposed proprietary name / brand name	SN Dexo 30mg Capsules
	Label Claim	Each capsule contains: Dexlansoprazole Dual Delayed release pellets eq. to Dexlansoprazole 30mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30's-As per SRO
	Shelf Life (Unit)	2 Year(s)room condition
	For generic drugs (me-too Status)	Dextol 30mg DDR Capsule Registration holder: M/s Seraph Pharmaceutical, Islamabad
	Pharmacotherapeutic Group of (API)	PPI
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. Vision Pharmaceuticals
	Detail of stability batches of drug product	Batches: T001,T002, T003 (Batch Size: 800 Cap_06 month real time and 06 months accelerated data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Commercial invoice dated 02-10-2023 from M/s Vision Pharma is submitted 1 kg material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have conducted against Dexilent Cap 30mg by Takeda Pharma USA.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 36 months is submitted for 03 batches is submitted according to the conditions of Zone IV-A is submitted.

	The status in reference regulatory authorities	Dexilant 30mg Capsule Takeda Pharmaceuticals America, Inc. USFDA Approved.
	GMP status of the firm	Inspection report dated 02-12-2021 is submitted.
	Evidence of approval of manufacturing facility	Capsule General Section is approved.
	Evaluation Remarks	
	.	
	Decision	
144	Approved	
	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Martin Dow Limited Plot No. 37, Sector 19, Korangi Industrial Area Karachi-74900, Pakistan (0639)
	Application Form Dy. No / Tracking ID & date of submission	(WWB-UG9-U8A9, 2024-03-26)
	Detail of Fee Submitted	150000.0, 2023-05-25,
	The proposed proprietary name / brand name	Oncopal
	Label Claim	Each capsule contains: Palbociclib 125mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	21's HDPE Bottle 21-As per SRO
	Shelf Life (Unit)	36 Monthstored below 30°C
	For generic drugs (me-too Status)	Ibrance Capsule 125mg by Pfizer Laboratories Ltd
	Pharmaceutical Therapeutic Group of (API)	
	Name, address of Manufacturing site:	Aizant Drug Research Solutions Pvt Ltd.-Survey No 172 & 173, Apparel Park Road, Dulapally Village, Dundigal Gandimaisamma Mandal, Medchal Malkajgiri district, Telangana State-500100, India.-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	Aizant Drug Research Solutions Pvt Ltd., Survey No 172 & 173, Apparel Park Road, Dulapally Village, Dundigal Gandimaisamma Mandal, Medchal Malkajgiri district, Telangana State-500100, 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	IBRANCE 125 mg Hard Capsules by Pfizer Manufacturing Deutschland GmbH Betriebsstätte Freiburg Mooswa
	Evaluation Remarks	
	Reason for deferment	Response
	justification/acceptance criteria for higher % RSD values in comparative dissolution profile studies especially at 15 min time point.	The firm has provided a reference of USP General Chapter <1092> which is reproduced below: Dissolution results may be considered highly variable if the relative standard deviation

		(RSD) is greater than 20% at time points of 10 minutes or less and greater than 10% RSD at later. RSD is within limit at 15minute timepoint for the applied product and innovator product.
	For further deliberation for whether data of commercial batches is required till shelf life or otherwise.	“Finished product manufacturer has clarified that the stability data of finished product has been generated for exhibit batches till the assigned shelf life which are representative of the full commercial scale production process”. Moreover, the batches were manufactured using the same equipment, procedure and materials as commercial production”.
	For scientific justification of reported relative standard deviation of more than 10% from second time point onwards in the CDP studies of pH 6.8 medium against the recommendations of the Guidelines for Comparative Dissolution Profile.	“Palbociclib is a BCS class II drug therefore, incomplete drug release observed in buffer of pH 6.8 for both reference and test product which contributes to higher RSD values”. Moreover,the firm has submitted BE report of the applied product.
	Decision	
	Deferred	
	for submission of stability data (including accelerated and real time) of finished pharmaceutical product (FPP) according to the conditions of zone IV-A for commercial batches.	
145	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	SNB Pharma (Pvt) Ltd Plot # 142, Industrial Estate Hayatabad, Peshawar, KP, (000759)
	Application Form Dy. No / Tracking ID & date of submission	(X4M-V2R-2JP3, 2024-03-14)
	Detail of Fee Submitted	30000.0, 2024-01-25,
	The proposed proprietary name / brand name	SN Dexo 60mg Capsules
	Label Claim	Each capsule contains: Dexlansoprazole Dual Delayed release pellets eq. to Dexlansoprazole 60mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30's-As per SRO
	Shelf Life (Unit)	2 Year(s)room condition
	For generic drugs (me-too Status)	Dextol 60mg DDR Capsule Registration holder: M/s Seraph Pharmaceutical, Islamabad
	Pharmacotherapeutic Group of (API)	PPI
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. Vision Pharmaceuticals
	Detail of stability batches of drug product	Batches: T004,T005, T006 (Batch Size: 800 Cap) 06 month real time and 06 months accelerated data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Commercial invoice dated 02-10-2023 from M/s Vision Pharma is submitted 1 kg material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have conducted against Dexilent Cap 60mg by Takeda Pharma USA.

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 36 months is submitted for 03 batches is submitted according to the conditions of Zone IV-A is submitted.
	The status in reference regulatory authorities	Dexilant 60mg Capsule Takeda Pharmaceuticals America, Inc. USFD Approved
	GMP status of the firm	Inspection report dated 02-12-2021 is submitted.
	Evidence of approval of manufacturing facility	Capsule General Section is approved.
	Evaluation Remarks	
	.	
	Decision	
	Approved	
146	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Martin Dow Limited Plot No. 37, Sector 19, Korangi Industrial Area Karachi-74900, Pakistan (0639)
	Application Form Dy. No / Tracking ID & date of submission	(XHA-4VU-6HSA, 2024-08-19)
	Detail of Fee Submitted	300000.0, 2024-08-07,
	The proposed proprietary name / brand name	Cabozanib
	Label Claim	Each film coated tablet contains: Cabozantinib (S)-Malate Eq. to Cabozantinib.....60mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30s-As per SRO
	Shelf Life (Unit)	36 MonthStore below 30°C, protected from light.
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	BDR PHARMACEUTICALS INTERNATIONAL PVT. LTD-R.S. No: 578, NEAR, EFFLUENT CHANNEL ROAD, LUNA, TALUKA-PADRA. CITY: LUNA - 391 440, DIST.-VADODARA GUJARAT STATE, INDIA. -India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	BDR PHARMACEUTICALS INTERNATIONAL PVT. LTD, R.S. No: 578, NEAR, EFFLUENT CHANNEL ROAD, LUNA, TALUKA-PADRA. CITY: LUNA - 391 440, DIST.-VADODARA GUJARAT STATE, 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	CABOMETYX by EXELIXIS INC (US-FDA)
	Evaluation Remarks	
	Deferred in 347th meeting for further deliberation.	
	Decision	

	Approved	
	as per the import policy for inspection of manufacturer abroad.	
147	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(YGX-TJU-MQ2N, 2024-03-12)
	Detail of Fee Submitted	30000.0, 2024-01-26,
	The proposed proprietary name / brand name	Naprox-D 220mg/25mg Tablet
	Label Claim	Each Film Coated tablet contains: Naproxen Sodium.....220mg Diphenhydramine Hydrochloride.....25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x7's, 1x10's, 2x10'-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at cool &dry place below 30
	For generic drugs (me-too Status)	ALEVE PM (diphenhydramine hydrochloride and naproxen sodium) 25mg/220mg tablet M/s Bayer HealthCare LLC
	Pharmacotherapeutic Group of (API)	NSAID / Antihistamine
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Alcon Biosciences Private limited,,Divi's Laboratories Limited
	Detail of stability batches of drug product	Batches: TNU001,TNU002, TNU003 (Batch size: 2500 tab) 06 months real time an d06 months accelerated stability studies are submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Naproxen sodium: Clearance certificate dated 02-06-2022 is submitted for 50kg material. Diphenhydramine HCl: Loan letter dated 07-02-2023 from M/s Star Laboratories Pvt. Ltd. Lahore for 250gram of material is submitted. (Clearance certificate issued to M/s Star Labs dated 17-12-2022 is submitted)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the innovator's product i.e. Aleve PM by Bayer Healthcare.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Naproxen Sodium: 5 years real time stability and 06 months accelerated stability data is submitted according to the conditions of zone IV-A for 03 batches. Diphenhydramine HCl: 60 months real time stability and 06 months accelerated stability data is submitted according to the conditions of zone IV-A for 03 batches.
	The status in reference regulatory authorities	ALEVE PM (diphenhydramine hydrochloride and naproxen sodium) 25mg/220mg tablet M/s Bayer HealthCare
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 03-04-2023.

	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	.	
	Decision	
	Approved	
	subject to verification of loan letter.	
148	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Martin Dow Limited Plot No. 37, Sector 19, Korangi Industrial Area Karachi-74900, Pakistan (0639)
	Application Form Dy. No / Tracking ID & date of submission	(YNR-S5J-2UZU, 2024-03-13)
	Detail of Fee Submitted	150000.0, 150000.0 2023-06-07, 2024-02-01
	The proposed proprietary name / brand name	Pomalem
	Label Claim	Each Capsule contains: Pomalidomide.....4mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	21's-As per SRO
	Shelf Life (Unit)	24 Month(s)Room Temperature
	For generic drugs (me-too Status)	could not be confirmed
	Pharmacotherapeutic Group of (API)	Immunomodulatory drugs
	Name, address of Manufacturing site:	DEVA HOLDING A.S-Çerkezköy Organize Sanayi Bölgesi, Karaağaç Mah. Fatih Bulvarı No:26 Kapaklı- Tekirdağ/Türkiye-Turkey
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Innovid 4mg cap (Netherland Approved).
	Name, address of Marketing Authorization Holder:	DEVA Holding A.S, Halkalı Merkez Mah. Basın Ekspres Cad. No:1 34303 Küçükçekmece-İstanbul/TÜRKİYE, Turkey
	Details of Certificates (CoPP/FSC/cGMP):	GMP Compliant as per submitted CoPP.
	Details of Authorization Letter :	CoPP NO. 2023/4377 dated 12-10-2023 is submitted. The product is available in free sale in exporting country and the facilities and operations conform to WHO-GMP as per submitted CoPP. DSL dated 06-06-2024 valid till 16-06-2029. Product specific letter of authorization is submitted,
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Long term stability studies have been performed at 25 ± 2 for 03 batches till 60 months. accelerated stability data of 03 batches is submitted.
	The status in reference regulatory authorities	POMALYST by BRISTOL MYERS SQUIBB CO. (USFDA Approved)
	Evaluation Remarks	
	.	
	Decision	
	Approved	
	as per the import policy for inspection of manufacturer abroad.	

149	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Pacific Pharmaceuticals Ltd. Plot No.384, Sundar Industrial Estate, Raiwind Road, Lahore (000902)
	Application Form Dy. No / Tracking ID & date of submission	(YUZ-4LM-BRXM, 2024-03-05)
	Detail of Fee Submitted	75000.0, 2024-01-19,
	The proposed proprietary name / brand name	Levopraid Injection 50mg/2ml
	Label Claim	Each 2ml ampoule contains: Levosulpiride....50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5x2ml Ampoules-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Levopraid solution for Injection 50mg/2ml
	Pharmacotherapeutic Group of (API)	Psycholeptic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Taizhou Xingcheng ChemPharma Co., Ltd. Address:Yantou Industrial Park Jiaojiang District, Taizhou City, Zhejiang China.
	Detail of stability batches of drug product	Batches: GECP0012023, GECP0022023, GECP0032023 (Batch Size: 2500amp) 09 months real time and 06 months accelerated stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 21-03-2023 for 5kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the reference product i.e. Levopraid 50mg/2mL Injection by M/s Teofarma SRL, Italy.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	36 months real time and 06 month accelerated stability data is submitted according to zone IV-A.
	The status in reference regulatory authorities	Teofarma SRL, Italy-The Italian Medicines Agency - AIFA Italy
	GMP status of the firm	Inspection report dated 12-10-2023 is submitted.
	Evidence of approval of manufacturing facility	SVP General Section is approved.
150	Evaluation Remarks	
	.	
	Decision	
	Approved	
	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Martin Dow Limited Plot No. 37, Sector 19, Korangi Industrial Area Karachi-74900, Pakistan (0639)
	Application Form Dy. No / Tracking ID & date of submission	(YYW-SJ9-WV6X, 2024-04-17)
	Detail of Fee Submitted	150000.0, 2023-05-25,
	The proposed proprietary name / brand name	Oncopal

Label Claim	Each capsule contains:Palbociclib 100mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	21's HDPE Bottle 21-As per SRO
Shelf Life (Unit)	36 Month(s)stored below 30°C
For generic drugs (me-too Status)	Ibrance Capsule 100mg by Pfizer Laboratories Ltd
Pharmacotherapeutic Group of (API)	Antineoplastic agent
Name, address of Manufacturing site:	Aizant Drug Research Solutions Pvt Ltd.-Survey No 172 & 173, Apparel Park Road, Dulapally Village, Dundigal Gandimaisamma Mandal, Medchal Malkajgiri district, Telangana State-500100, India.-India
Pharmaceutical Equivalence and Comparative Dissolution Profile	submitted
Name, address of Marketing Authorization Holder:	Aizant Drug Research Solutions Pvt Ltd., Survey No 172 & 173, Apparel Park Road, Dulapally Village, Dundigal Gandimaisamma Mandal, Medchal Malkajgiri district, Telangana State-500100, India., India
Details of Certificates (CoPP/FSC/cGMP):	Submitted
Details of Authorization Letter :	Not applicable
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches; not as per Zone IVA conditions
The status in reference regulatory authorities	IBRANCE 100 mg Hard Capsules by Pfizer Manufacturing Deutschland GmbH Betriebsstätte Freiburg Mooswa
Evaluation Remarks	
Reason for deferment	Response
justification/acceptance criteria for higher % RSD values in comparative dissolution profile studies especially at 15 min time point.	The firm has provided a reference of USP General Chapter <1092> which is reproduced below: Dissolution results may be considered highly variable if the relative standard deviation (RSD) is greater than 20% at time points of 10 minutes or less and greater than 10% RSD at later. RSD is within limit at 15minute timepoint for the applied product and innovator product.
For further deliberation for whether data of commercial batches is required till shelf life or otherwise.	“Finished product manufacturer has clarified that the stability data of finished product has been generated for exhibit batches till the assigned shelf life which are representative of the full commercial scale production process”. Moreover, the batches were manufactured using the same equipment, procedure and materials as commercial production”.
For scientific justification of reported relative standard deviation of more than 10% from second time point onwards in the CDP studies of pH 6.8 medium against the recommendations of the Guidelines for Comparative Dissolution Profile.	“Palbociclib is a BCS class II drug therefore, incomplete drug release observed in buffer of pH 6.8 for both reference and test product which contributes to higher RSD values”. Moreover,the firm has submitted BE report of the applied product.
Decision	

	Deferred	
	for submission of stability data (including accelerated and real time) of finished pharmaceutical product (FPP) according to the conditions of zone IV-A for commercial batches.	
151	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	
	The case was deferred in 347th meeting for:Clarification since assay results of accelerated stability studies are well out of specifications at 6th month time points since the shelf life of 2 years is granted on the basis of stability study data of 6 months (including real time and accelerated).Reply: The firm has referred ICH Q1F guidelines. The relevant portion of the guideline is reproduced below:If significant change occurs between three and six months' testing at the accelerated storage condition, the proposed shelf life should be based on the data available from the long-term storage condition. If significant change occurs within the first three months' testing at the accelerated storage condition, a discussion should be provided addressing the effect of short-term excursions outside the label storage condition, e.g. during shipment and handling. This discussion can be supported, if appropriate, by further testing on a single batch of the FPP for a period shorter than three months but with more frequent testing than usual. It is considered unnecessary to continue to test a product throughout six months when a significant change has occurred within the first three months of accelerated studies at the specific condition chosen in accordance with the risk analysis.Evaluation by PEC:1. The firm has submitted 24 months real time stability data at 2-8oC and has claimed a shelf of 24 months.2. Significant change in assay results has been observed at 3rd month time point of accelerated stability	

data at 25oC&60%RH.3. Out of specs assay results have been observed at 6 month time point of accelerated stability studies at 25oC&60%RH.

Decision

Deferred

for clarification / submission of further studies addressing the short term excursions outside the label storage conditions on a single batch of FPP for a period shorter than three months with more frequent testing as per the ICH guidelines.

152	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Himedic Pharmaceuticals Pvt Ltd 19 KM link Multan Road Lahore (000824)
	Application Form Dy. No / Tracking ID & date of submission	(114-AT8-ZD95, 2025-01-30)
	Detail of Fee Submitted	93000.0, 2024-12-17,
	The proposed proprietary name / brand name	Esonic Capsule 20mg
	Label Claim	Each capsule contains: - Esomeprazole magnesium trihydrate enteric coated pellets eq. to Esomeprazole.....20mg (USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	2 YearStore at temperature 15 to 30 C away from sunlight
	For generic drugs (me-too Status)	Nexum Capsule 20mg (Getz Pharma) Reg. No. 033890
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	ICU Pharmaceuticals SMC Pvt. Ltd.-Khewat No. 13/13, Khatooni No. 57/66 Mouza Mirpur Kehna, Tehsil Sharkpur, District Sheikhpura.-
	The status in reference regulatory authorities	NEXIUM 20 mg CAPSULES by M/s AstraZeneca Pharmaceuticals, USFDA Approved
	Detail of previous approval	Minutes of 326th meeting of Registration Board (14th to 16th March, 2023) Page No. 963
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
153	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welmed Pharmaceutical Industries (Pvt) Ltd. Plot No. 108/1 Road No. R-2 I.E. Gadoon. (000546)

	Application Form Dy. No / Tracking ID & date of submission	(116-7WJ-YU2R, 2025-05-15)
	Detail of Fee Submitted	75000.0, 18000.0 2024-09-03, 2025-03-25
	The proposed proprietary name / brand name	Tazwel 500mg injection
	Label Claim	Each Vial contains: Ceftazidime as Ceftazidime Pentahydrate.....500mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Fortazim 500mg Injection IM/IV
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Limited.-Plot # 129, Sunder Industrial Estate Lahore.-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	Ceftazidime 500mg Injection, Meeting No. 335th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
154	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Air Pharmaceuticals(Pvt.)Ltd Plot No's 74, 75-A, Small Industrial Estate, Kasur (000977)
	Application Form Dy. No / Tracking ID & date of submission	(128-14B-E9H7, 2025-05-07)
	Detail of Fee Submitted	30000.0, 63000.0 2023-12-15, 2025-04-11
	The proposed proprietary name / brand name	Epamet
	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-As per SRO,14's-As per SRO
	Shelf Life (Unit)	2 Year(s)below 30°C in dry cool environment
	For generic drugs (me-too Status)	DIAMPA-M 12.5mg/850mg By Getz Pharma
	Pharmacotherapeutic Group of (API)	SGLT2 Inhibitor, ATC code: A10BX12. Empagliflozin is a reversible competitive inhibitor of SGLT2 with an IC50 of 1.3 nM. It has a 5000-fold selectivity over human SGLT1 (IC50 of 6278 nM), responsible for glucose absorption in the gut. ATC code: A10BA02. Metformin is a biguanide with antihyperglycaemic effects, lowering both basal and postprandial plasma glucose.

	Name, address of Manufacturing site:	Novamed Pharmaceuticals(Pvt.)Ltd-28KM Ferozepur Road Lahore-
	Name & address of API manufacturer	Aarti Drugs Ltd Plot No 211 & 213, Road -2, G.I.D.C AT & Post Sarigam. City Sarigam– 396 155 Dist. Valsad Gujarat industrial estate ,Jiangsu Yong'an Pharmacy Company Limited,No.18 ,237 Proviencial, Road ,Economic Development Zone, Huai'an Jiangsu,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	Synjardy 12.5/850mg Boehringer Ingelheim Limited USA
	GMP status of the firm	.
	Evidence of approval of manufacturing facility	NovaMed Pharmaceuticals DML (Formulation) 000590
	Evaluation Remarks	
155	The applicant had selected “yes’ in data already approved status of the application. It was checked that Empozin 12.5/850mg Tablet of M/s Novamed Pharmaceuticals has already been approved in 320 meeting of RB. The firm has submitted differential fee of Rs63,000/- vide challan number 77136835 dated 11.04.2025.	
	Decision	
	Approved	
	Case Category	Routine (Incharge Evaluation Cell)
	Name, address of Applicant.	High-Q Pharmaceuticals Plot# 224 and 225/1, sector 23, Korangi Industrial area, Karachi (000597)
	Application Form Dy. No / Tracking ID & date of submission	(13A-TE9-B1UM, 2024-03-18)
	Detail of Fee Submitted	30000.0, 2023-12-05,
	The proposed proprietary name / brand name	Trelog
	Label Claim	Each film coated tablet contains: Trelagliptin as succinate....100mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1's-As per SRO,10's-As per SRO,14's-As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO,4's-As per SRO,56'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)	Trelaget Tablet by Getz Pharma
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Fuxin Long Rui Pharma

	Detail of stability batches of drug product	3 batches: 3225 Tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	03-03-2022: Clearance certificate
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Treptin Tablet of Horizon: PE and CDP performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IV-A
	The status in reference regulatory authorities	Zafatek 100mg Tablet by Takeda Pharma, Approved in PMDA (Japan)
	GMP status of the firm	17-05-2023: GMP certificate inspection date
	Evidence of approval of manufacturing facility	17-09-2021: Tablet (General) section
	Evaluation Remarks	
	Decision	
	Approved	
156	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	TABROS PHARMA (PVT). LTD. Plot No. L-20/B, Sector 22, F.B. Industrial Area (000106)
	Application Form Dy. No / Tracking ID & date of submission	(158-9UN-QXMT, 2025-01-30)
	Detail of Fee Submitted	93000.0, 2025-01-13,
	The proposed proprietary name / brand name	Onzil Powder For Injection 600mg
	Label Claim	Each vial contains: Ceftriaxone Fosamil as Ceftriaxone Fosamil Monoacetate Monohydrate with L-arginine.....600mg Innovator's Specification
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x1's-De-Controlled, 1x10's-De-Controlled
	Shelf Life (Unit)	2 YearSTORE BELOW 30oC
	For generic drugs (me-too Status)	Zinforo powder for Concentrate for Solution for Injection Registration No.110515 Pfizer Pakistan Limited
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt). Ltd-Plot No.129, Sunder Industrial Estate Raiwind Road Lahore-
	The status in reference regulatory authorities	Teflaro for injection 600mg, M/s. Allergan USA Inc. USFDA approved
	Detail of previous approval	Teflor 600mg Sterile powder for Injection 339th DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned	

	notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
157	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Himedic Pharmaceuticals Pvt Ltd 19 KM link Multan Road Lahore (000824)
	Application Form Dy. No / Tracking ID & date of submission	(159-E6U-WTR5, 2025-04-11)
	Detail of Fee Submitted	93000.0, 2024-12-19,
	The proposed proprietary name / brand name	Inomed 250mg Tablet
	Label Claim	Each film coated tablet contains:- Levofloxacin Hemihydrate Eq. to Levofloxacin.....250mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's, 2x10's 100's-As per SRO
	Shelf Life (Unit)	2 YearStore at temperature 15 to 30 C away from sunlight
	For generic drugs (me-too Status)	Leflox 250mg Tablet (Getz Pharma (Pvt.) Ltd Karachi) Reg. No. 026164
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	ICU Pharmaceuticals SMC Pvt. Ltd.-Khewat No. 13/13, Khatooni No. 57/66 Mouza Mirpur Kehna, Tehsil Sharkpur, District Sheikhpura-
	The status in reference regulatory authorities	Levofloxacin (250mg) Film-coated Tablets M/s Accord Healthcare Limited, MHRA Approved
	Detail of previous approval	Minutes of 333rd meeting of Registration Board (19th To 20th December, 2023) Page No. 962
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
158	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	High-Q Pharmaceuticals Plot# 224 and 225/1, sector 23, Korangi Industrial area, Karachi (000597)
	Application Form Dy. No / Tracking ID & date of submission	(15L-ZT1-LXRD, 2025-03-12)
	Detail of Fee Submitted	93000.0, 2024-11-21,

	The proposed proprietary name / brand name	Elcarni 1gm/5ml Injection
	Label Claim	Each 5ml vial contains: Levocarnitine 1gm (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in a cool & dry place below 25°C
	For generic drugs (me-too Status)	Carniject 1gm/5ml Injection [MAH: RG Pharmceutica (Pvt) Ltd]
	Pharmacotherapeutic Group of (API)	Levocarnitine is an aminoacid derivative which is utilized in various pathways for oxidation of fatty acids and ketone bodies as well as glucose and some amino acids.
	Name, address of Manufacturing site:	M/s. NovaMed Pharmaceuticals (Pvt.) Ltd-28-km Ferozepur Road, Lahore – Pakistan-
	The status in reference regulatory authorities	CARNITOR (levocarnitine) Injection 1 g per 5 mL vial (US FDA Approved)
	Detail of previous approval	Kefie (Levocarnitine) Injection 1gm/5ml (Approved in DRB Meeting Minutes 320th dated 29th – 31st Aug
	Evaluation Remarks	
	Kefie Injection 1gm/5ml of M.s NovaMed Pharmaceuticals was approved in 320th meeting of the Registratoin Board.	
	Decision	
	Approved	
159	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medwell Pharmaceuticals 1 km, terbella road, lawrencepur, faqirabad Attock (000699)
	Application Form Dy. No / Tracking ID & date of submission	(15Z-LJD-ENJ7, 2025-04-03)
	Detail of Fee Submitted	93000.0, 2024-11-28,
	The proposed proprietary name / brand name	Purti 1mg Tablet
	Label Claim	Each Film coated tablet containing: Prucalopride as Succinate.....1mg
	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 YearRoom Temperature.
	For generic drugs (me-too Status)	P Pride tablet by Wilshire Laboratories Pvt Ltd
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-
	The status in reference regulatory authorities	Motegrity by Takeda Pharms USA
	Detail of previous approval	Prumark 1mg Tablet (Meeting 340th)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation,	

	specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
160	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Gray's Pharmaceuticals Plot NO2, Street No. N-3, RCCI Rawat Islamabad (000518)
	Application Form Dy. No / Tracking ID & date of submission	(182-VM9-7USR, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2025-02-22,
	The proposed proprietary name / brand name	Tazopip 2.25gm Injection
	Label Claim	Each Vial Contains: Piperacillin as Sodium (USP) 2000mg Tazobactam as Sodium (USP) 250mg (Product Complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Zosyn 2.25gm INJECTION of M/s Regent Laboratories Reg# 070759
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wallace Pharma Evolutions-Kala wala stop, 20-KM, Lahore Jaranwala Road Lahore.-
	The status in reference regulatory authorities	Usfda Approved
	Detail of previous approval	Tazocin Injection ,DRB 331
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
161	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Semos Pharmaceuticals PVT LTD Plot No.11, Sector 12-A North Karachi, Industrial Area, Karachi, Pakistan (000335)
	Application Form Dy. No / Tracking ID & date of submission	(1DG-VSN-38U5, 2025-06-04)
	Detail of Fee Submitted	93000.0, 2025-05-08,
	The proposed proprietary name / brand name	Vepra Tablet 20mg
	Label Claim	Each film coated tablet contains: Vonoprazan (as Fumarate).....20mg (As per Innovator's Specifications)

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's, 7's, 28's, 20'-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Vonozan Tablet 20mg (Getz Pharma Private Limited)
	Pharmacotherapeutic Group of (API)	Vonoprazan as Fumarate (AMI Life Sciences Private Limited)
	Name, address of Manufacturing site:	M/s Linta Pharmaceuticals (Pvt) Ltd-Plot No 3, Street No S-5, National Industrial Zone, Rawat, Islamabad-
	The status in reference regulatory authorities	PMDA Japan Approved (TAKECAB Tablet)
	Detail of previous approval	Product name: Vonopraz Tablet 20mg (121784), Meeting No: 336th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
162	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	MEDPHARM RESEARCH LAB 28 KM FEROZPUR ROAD LAHORE (000878)
	Application Form Dy. No / Tracking ID & date of submission	(1EP-15S-44HQ, 2025-01-09)
	Detail of Fee Submitted	75000.0, 18000.0 2024-04-26, 2024-11-25
	The proposed proprietary name / brand name	VANCOMED INJECTION 500MG
	Label Claim	Each vial Contains: Vancomycin Hydrochloride eq. to Vancomycin = 500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	as per DPC-As per SRO
	Shelf Life (Unit)	2 Yearbelow 24 degree
	For generic drugs (me-too Status)	Vancomycin injection 500mg
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	May & Baker Pvt Ltd-HOUSE NO 23, STREET NO 5 SECTOR B, GHORI BLOCK BAHRIA TOWN, Pakistan-
	The status in reference regulatory authorities	FDA Approved
	Detail of previous approval	vancomin 500mg Dry Powder for injection 324th meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a	

	declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. Decision Approved	
163	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Solaris Life Sciences Private Limited , Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992)
	Application Form Dy. No / Tracking ID & date of submission	(1GB-QJV-TPYS, 2025-06-02)
	Detail of Fee Submitted	93000.0, 2025-04-28,
	The proposed proprietary name / brand name	Ketriol-0.5mcg SoftGel Capsules
	Label Claim	Each soft gelatin capsule contains: Calcitriol.....0.5mcg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Rocaltrol Capsules 0.5mcg Reg. No. 015556, Martin Dow Limited,
	Pharmacotherapeutic Group of (API)	Vitamin D analogue
	Name, address of Manufacturing site:	Biogen Life Sciences-8-KM, Chakbeli Road, Rawat, Rawalpindi-PAKISTAN.-
	The status in reference regulatory authorities	FDA Approved. ROCALTROL (calcitriol)
	Detail of previous approval	DRB M-336 By the Name of CALCIGEN 0.5mcg Soft gel Capsule
	Evaluation Remarks In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. Decision Approved	
164	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Global Pharmaceuticals Pakistan Plot # 8, Street # S-8, RCCI, Industrial Estate Rawat, Islamabad-Pakistan (000724)
	Application Form Dy. No / Tracking ID & date of submission	(1GH-E2Q-6YJE, 2025-04-07)
	Detail of Fee Submitted	93000.0, 2024-12-13,
	The proposed proprietary name / brand name	Reli-Chole 7.5mg Injection

	Label Claim	Each 1ml ampoule contains; Cholecalciferol.....300,000IU
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's-As per SRO,5's -As per SRO
	Shelf Life (Unit)	2 YearStore in a cool dry place, below 30oC.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Global Pharmaceuticals (Pvt.) Ltd-Plot # 204-205 Industrial Triangle, Kahuta Road, Islamabad- Pakistan-
	The status in reference regulatory authorities	AIFA ITALY
	Detail of previous approval	CALCIFEROL 7.5mg Injection in 336 Meeting.
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
165	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Skywin Pharmaceutical Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpora road (000971)
	Application Form Dy. No / Tracking ID & date of submission	(1GT-752-U4GM, 2025-02-11)
	Detail of Fee Submitted	93000.0, 2024-12-23,
	The proposed proprietary name / brand name	Cefix 100mg/5ml Suspension
	Label Claim	Each 5ml contains: Cefixime(as trihydrate) 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO / DPC-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Cefspan 100mg/5ml Powder for Oral Suspension of M/s Barrett
	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	Suprax 100mg/5mL Powder for Paediatric Oral Suspension of M/s Merck Farma y Quimica, S.A. Poligono Merck, 08100 Mollet del Valles (Barcelona), Spain (HPRA Approved)
	Detail of previous approval	Myxim 100mg/5ml Suspension approved in 326th Meeting
	Evaluation Remarks	

	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
166	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(1L5-LSL-J6DR, 2025-04-08)
	Detail of Fee Submitted	93000/-, 19.11.2024,
	The proposed proprietary name / brand name	Austafast 20mg Soft Gel Capsule
	Label Claim	Each soft gel capsule contains: Isotretinoin.....20mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO (10s, 20s-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature, in a cool and dry place. Protect from heat and light.
	For generic drugs (me-too Status)	Oratane 20mg Soft Gel Capsule by Crystolite Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Biogen Life Sciences-8-Km, Chakbeli Road, Rawat-
	The status in reference regulatory authorities	Isotretinoin 20 mg soft capsules (MHRA Approved)
	Detail of previous approval	Biotan 20mg Capsule, 312th Meeting of RB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
167	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(1US-JGH-UZQY, 2025-03-04)
	Detail of Fee Submitted	93000.0, 2024-10-31,

	The proposed proprietary name / brand name	TEMEY PLUS Capsule
	Label Claim	Each hard gelatin capsule contains: Dutasteride (as soft gelatin capsule) 0.5 mg Tamsulosin hydrochloride (as modified release pellets) 0.4 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearAt room temperature
	For generic drugs (me-too Status)	Maxflow-D Capsule by M/s CCL Pharmaceutical (Reg. 091571)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Biogen Life Sciences - 8km Chakbeli Road Rawat Rawalpindi -
	The status in reference regulatory authorities	Medicines and Healthcare products Regulatory Agency (MHRA)
	Detail of previous approval	Product name: Dutaride-T Capsule, Meeting no: Minutes of 335th meeting of Registration Board (25th A
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
168	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winlet Pharmaceuticals (Pvt) Ltd. 30-Km, Lahore Sargodha Raod, Sargodha (000874)
	Application Form Dy. No / Tracking ID & date of submission	(1V3-ATD-7E7S, 2025-01-08)
	Detail of Fee Submitted	93000.0, 2024-12-18,
	The proposed proprietary name / brand name	snafil suspension
	Label Claim	Each ml of reconstituted suspension contains: Sildenafil (as Citrate) ----- 10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1,s-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 °C
	For generic drugs (me-too Status)	Gray,s pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/S Gray,s pharma-plot no 2, street no N-3 RCCI rawat-
	The status in reference regulatory authorities	FDA APPORVED
	Detail of previous approval	M-343
	Evaluation Remarks	

	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
169	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Allmed (Pvt.) Ltd Plot # 590 Sunder Industrial Estate Raiwind Road Lahore-Pakistan (000645)
	Application Form Dy. No / Tracking ID & date of submission	(229-D65-3ULR, 2025-04-14)
	Detail of Fee Submitted	93000.0, 2024-12-30,
	The proposed proprietary name / brand name	Meronem
	Label Claim	Each vial of powder for solution for injection or infusion contains: 1141.56 mg Meropenem Trihydrate equivalent to 1 g anhydrous Meropenem
	Reference to Finished product specifications	The International Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30 C
	For generic drugs (me-too Status)	Meropen 1g Injection by Solaris Life Sciences Private Limited Reg # 123682
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wallace Pharma Evolutions-Kala Wala Stop 20-KM, Lahore Jaranwala Road, Lahore-
	The status in reference regulatory authorities	Meropenem 1g Injection by AstraZeneca Pharmaceuticals LP Wilmington, DE 19850
	Detail of previous approval	Minutes of 323rd meeting of Registration Board (6th to 8th December, 2022)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
170	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Pasteur & Fleming Pharma Plot # 70A , Phase -3, Road No-04, Industrial Estate Hattar, K.P.K. Pakistan (000945)
	Application Form Dy. No / Tracking ID & date of submission	(241-X27-D8H3, 2025-04-11)

	Detail of Fee Submitted	93000.0, 2025-01-06,
	The proposed proprietary name / brand name	Prupred 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	10's-As per SRO,20's-As per SRO,30's-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature.
	For generic drugs (me-too Status)	P Pride tablet by Wilshire Laboratories Pvt Ltd
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-
	The status in reference regulatory authorities	Motegrity by Takeda Pharms USA
	Detail of previous approval	PruMark 1mg Tablet (Meeting 340th)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
171	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Pasteur & Fleming Pharma Plot # 70A , Phase -3, Road No-04, Industrial Estate Hattar, K.P.K. Pakistan (000945)
	Application Form Dy. No / Tracking ID & date of submission	(2AV-R6N-GLVV, 2025-04-11)
	Detail of Fee Submitted	93000.0, 2025-01-06,
	The proposed proprietary name / brand name	Biowel Capsule 3/25mg
	Label Claim	Each hard gelatin capsule contains: Olanzapine.....3mg Fluoxetine (as hydrochloride).....25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14's -As per SRO,28's-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature.
	For generic drugs (me-too Status)	Co-Depricap capsule by Nabiqasim industries pvt ltd
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-
	The status in reference regulatory authorities	SYMBYAX by Eli Lilly & Company
	Detail of previous approval	Biowel 3/25mg Capsule (Meeting 333rd)
	Evaluation Remarks	

	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
172	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winthrox Laboratories Pvt. Ltd K-219-A, SITE, Super Highway Phase II, Karachi (000807)
	Application Form Dy. No / Tracking ID & date of submission	(2JM-HNJ-QZ75, 2025-04-14)
	Detail of Fee Submitted	93000.0, 2025-01-15,
	The proposed proprietary name / brand name	Terzil Lotion
	Label Claim	Each gm contains: Terbinafine HCl....10mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Cutis Lotion by Tabros Pharma 067109
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Biogen Life Sciences-8-Km, Chkbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Lamisil Lotion 1% by GSK Netherland
	Detail of previous approval	Terbigen Lotion approved in 335 Meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
173	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Nicholas Pharmaceuticals Plot 34, Street SS-2, National Industrial Zone, Rawat (000886)
	Application Form Dy. No / Tracking ID & date of submission	(2ML-1HN-Q2S8, 2025-04-10)
	Detail of Fee Submitted	93000.0, 2025-01-21,
	The proposed proprietary name / brand name	TERVIZA 1% CUTANEOUS SOLUTION

	Label Claim	Each gram contains: Terbinafine (as hydrochloride) 10mg
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year25°C
	For generic drugs (me-too Status)	Terbiderm 1% topical solution By ATCO Limited
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt.) Ltd.-Plot 17, Special Industrial Zone, Risalpur, Kpk.-
	The status in reference regulatory authorities	Lamisil once 1% cutaneous solution By Haleon UK Trading Limited The Heights Weybridge Surrey KT13 0NY United Kingdom
	Detail of previous approval	Lamical 1% CUTANEOUS SOLUTION, 343rd Meeting.
	Evaluation Remarks	
	LAMICAL 1% Cutaneous Solution of Caliph Pharmaceuticals (Pvt.) Ltd was approved in 343rd meeting of the Registration Board. Applicant to submit undertaking that API from the same source will be used as approved in the LAMICAL.	
174	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(2NU-Z25-66VG, 2025-02-12)
	Detail of Fee Submitted	93000.0, 2024-12-20,
	The proposed proprietary name / brand name	Perocell Night 500/25mg Tablet
	Label Claim	Each Film Coated tablet contains: Paracetamol.....500mg Diphenhydramine Hydrochloride.....25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x7's, 1x10's, 2x10'-As per SRO
	Shelf Life (Unit)	2 YearStore in a cool & Dry place below 30
	For generic drugs (me-too Status)	Panadol Night of Haleon Pakistan Limited
	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	PANADOL PM, Acetaminophen and diphenhydramine hydrochloride Film coated tablet of M/s GSK consumer Healthcare (USFDA Approved)
	Detail of previous approval	Peradol-D Tablet approved in 343rd meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as	

	an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
175	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winlet Pharmaceuticals (Pvt) Ltd. 30-Km, Lahore Sargodha Raod, Sargodha (000874)
	Application Form Dy. No / Tracking ID & date of submission	(2NX-QZL-BEND, 2025-01-06)
	Detail of Fee Submitted	93000.0, 2024-10-21,
	The proposed proprietary name / brand name	Betalet G cream
	Label Claim	Each gram cream contains: Betamethasone as dipropionate 0.5mg (0.05% w/w) Gentamicin as Sulphate 1mg (0.1% w/w)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1,s-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 °C
	For generic drugs (me-too Status)	Gentanix-B Cream by Biogen Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Biogen life sciences -8-km chakbeli road rawat Rawalpindi-
	The status in reference regulatory authorities	Mibetin 1 mg/g + 0.5 mg/g Cream, MHRA approved
	Detail of previous approval	M-333
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
176	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winthrox Laboratories Pvt. Ltd K-219-A, SITE, Super Highway Phase II, Karachi (000807)
	Application Form Dy. No / Tracking ID & date of submission	(2Z7-13R-Z2MX, 2025-04-11)
	Detail of Fee Submitted	93000.0, 2025-01-15,
	The proposed proprietary name / brand name	Terzil Cream
	Label Claim	Each gm contains: Terbinafine HCl.....10.0 mg (Japanese Specifications)

	Reference to Finished product specifications	Any Other
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Lamisil Cream by GSK Reg. No. 084005
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Biogen Life Sciences-8-Km, Chkbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	FDA Approved
	Detail of previous approval	Terbigen Cream 1% in Minutes of 335th Meeting of DRAP Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
177	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Max Pharmaceuticals Plot #12, Street # N-7, National Industrial Zone, Rawat, Islamabad. 44000 (000671)
	Application Form Dy. No / Tracking ID & date of submission	(35U-DJG-UDAL, 2025-04-21)
	Detail of Fee Submitted	93000.0, 2025-04-10,
	The proposed proprietary name / brand name	Uperacid 40mg Injection
	Label Claim	Each vial contains: Omeprazole sodium equ. to Omeprazole 40mg (Swera's Specifications)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1 Injection in 1 Uni-As per SRO
	Shelf Life (Unit)	2 YearStore below 25 degree centigrade. Protect from heat, light and moisture.
	For generic drugs (me-too Status)	Product: Ruling 40mg Injection Manufacturer: HIGH-Q International Karachi
	Pharmacotherapeutic Group of (API)	Vision Pharmaceuticals
	Name, address of Manufacturing site:	Swera Pharmaceuticals-Address: Plot No. 27, Street No. S-4 National Industrial Zone, Rawat, Islamabad, Pakistan.-
	The status in reference regulatory authorities	Omeprazole 40mg powder for solution for infusion Country where sold / registered; UK Manufactured by: SANDOZ Park view, Riverside way, Watchmoor aprk, Camerley, Surrey GU153YL UK
	Detail of previous approval	MEPRA 40mg Injection I.V (Omeprazole), 322
	Evaluation Remarks	

	Mepra 40mg Injection of Swera Pharmaceuticals was approved in 322nd meeting of the Registration Board. Applicant to submit updated status of approval of DS manufacturer. Decision Approved	
178	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Akson Pharmaceuticals (Pvt) Ltd Plot No. 9-B/1&2, street No.D-1, Old Industrial estate, Mirpur, Azad Kashmir (000486)
	Application Form Dy. No / Tracking ID & date of submission	(387-N4G-JZG5, 2025-04-16)
	Detail of Fee Submitted	93000.0, 2024-12-30,
	The proposed proprietary name / brand name	S-Ralate 2G Sachet
	Label Claim	Each sachet contains: Strontium ranelate MS.....2g (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 15-25 C
	For generic drugs (me-too Status)	Osstium Powder 2 gm Sachet
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd.-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	Strontium ranelate Aristo 2g sachet
	Detail of previous approval	Strot-2g Sachet, M-343
	Evaluation Remarks	
	Strot 2g Sachet of Solaris Life Sciences (Pvt.) Ltd. was approved in the 343rd meeting of the Registration Board.	
	Decision	
	Approved	
179	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Qintar Pharmaceuticals 14-A Punjab Small Industrial Estate Lahore Road, Sargodha (000520)
	Application Form Dy. No / Tracking ID & date of submission	(38G-3VA-BLEA, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2025-01-14,
	The proposed proprietary name / brand name	Qingro 10mg/ml for oral Suspension
	Label Claim	Each ml of reconstituted suspension contains: Sildenafil (as Citrate).....10 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	120ml-De-Controlled
	Shelf Life (Unit)	2 Year Store in a cool and dry place below 30°C
	For generic drugs (me-too Status)	YES
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Gray's Pharmaceuticals-Plot No.2, Street No. 3, National Industrial Zone, Rawat -

	The status in reference regulatory authorities	MHRA, UK
	Detail of previous approval	Selden 10mg/ml for oral Suspension, DRB 343rd
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
180	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Astellas Pharmaceutical (Pvt.) Ltd 15-C Industrial Estate Hayatabad (000677)
	Application Form Dy. No / Tracking ID & date of submission	(3A1-L57-DH4G, 2025-04-21)
	Detail of Fee Submitted	93000.0, 2025-02-27,
	The proposed proprietary name / brand name	Astephenem 500mg injection
	Label Claim	Each vial contains: Meropenem (as Trihydrate) ---- - 500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 vial-As per SRO
	Shelf Life (Unit)	2 Yearstore below 30 degree centigrade
	For generic drugs (me-too Status)	penro injecton by BOSCH
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Medicraft Pharma-126-B,Industrial Estate Hayatabad,Peshawar-Pakistan-
	The status in reference regulatory authorities	www.accessdata.fda.gov/drugs
	Detail of previous approval	Astephenem 500mg inj , 336th meeting 4-6 june 2024
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
181	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medwell Pharmaceuticals 1 km, terbella road, lawrencepur, faqirabad Attock (000699)
	Application Form Dy. No / Tracking ID & date of submission	(3G9-B8U-AXPZ, 2025-04-03)

	Detail of Fee Submitted	93000.0, 2024-11-28,
	The proposed proprietary name / brand name	VONOWEL 20mg Tablet
	Label Claim	Each Film coated tablet containing: Vonoprazan as fumarate.....20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,14's -As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature.
	For generic drugs (me-too Status)	VONOZAN tablet by GETZ Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-
	The status in reference regulatory authorities	VOQUENZA tablet by Phathom Pharmaceuticals,USA
	Detail of previous approval	Vonomark 20mg Tablet (Meeting 335th)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
182	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Effort Pharmaceuticals (Pvt.) Ltd., 28-Km, Ferozepur Road (000879)
	Application Form Dy. No / Tracking ID & date of submission	(3P1-238-GSGR, 2025-03-12)
	Detail of Fee Submitted	93000.0, 2024-11-12,
	The proposed proprietary name / brand name	FANTOP 40MG INJECTION
	Label Claim	Each vial contains (Powder for injection) Pantoprazole (as sodium sesquihydrate) ...40 mg After reconstitution: 4mg/ml
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at temperature 15 to 30 C away from sunlight
	For generic drugs (me-too Status)	Brand Name: Protonix 40mg injection Manufacturer: M/s Wilshire
	Pharmacotherapeutic Group of (API)	Pantoprazole is a member of the class of benzimidazoles that is 1H-benzimidazole substituted by a difluoromethoxy group at position 5 and a [(3,4-dimethoxypyridin-2-yl)methyl]sulfinyl group at position . It has a role as an anti-ulcer drug

	Name, address of Manufacturing site:	May & Baker Pharmaceuticals (Pvt.) Ltd.-45 Km, Thokar Multan road, Lahore-
	The status in reference regulatory authorities	MHRA & EMAE approved formulation.
	Detail of previous approval	Minutes of 333rd meeting of Registration Board (19th To 20th December, 2023) Page No. 253
	Evaluation Remarks	
	Panzole Sterile Dry Powder 40 mg Vial IV of M/s May and Baker was approved in 333rd meeting of the Registration Board. Source of API is Vision Pharmaceuticals DML (Semi-Basic) 000806. Firm shall submit: 1. updated GMP of the Drug Substance Manufacturer and 2. documents for procurement of API.	
	Decision	
183	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Tovida Pharmaceuticals (Pvt) Ltd Plot No.7, Street No.S-07, RCCI Industrial Estate Islamabad (000996)
	Application Form Dy. No / Tracking ID & date of submission	(3R4-TEA-87PA, 2025-03-11)
	Detail of Fee Submitted	93000.0, 2024-10-21,
	The proposed proprietary name / brand name	Tovicarn injection 1gm
	Label Claim	Each ampoule (5ml) contains : Levocarnitine USP.....1000gm Product complies USP Specs
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO -De-Controlled
	Shelf Life (Unit)	2 Year30C+-
	For generic drugs (me-too Status)	generic product
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wnsfeild Pharmceuticals -Plot no: 122 Block-A Industrial State Hattar -
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	L- Carta Injection 1gm (meeting No:331)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
184	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	SWERA PHARMACEUTICALS PLOT# 27, STREET# S-4, INDUSTRIAL ESTATE, RAWAT (000941)

	Application Form Dy. No / Tracking ID & date of submission	(3XG-1SL-B8EH, 2025-05-08)
	Detail of Fee Submitted	93000.0, 2025-01-17,
	The proposed proprietary name / brand name	FILDENA ORAL SUSPENSION
	Label Claim	Each ml of reconstituted suspension contains: Sildenafil (as Citrate).....10mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30C
	For generic drugs (me-too Status)	Selden 10mg/ml Suspension (124748)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Gray's Pharmaceuticals, -Plot # 2, Street No # N-3, National Industrial Zone Rawat, Islamabad-Pakistan-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Selden 10mg/ml Suspension (124748)(M-343)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
185	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	M/s Daneen Pharma (Pvt) Ltd Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, (000688)
	Application Form Dy. No / Tracking ID & date of submission	(43G-GUS-2W94, 2025-05-15)
	Detail of Fee Submitted	93000.0, 2024-12-06,
	The proposed proprietary name / brand name	Tramder
	Label Claim	Each film coated tablet contains: Tramadol HCl 75mg Paracetamol 650mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	7's, 10's, 14's, 28'-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30°C. Protect from heat, light and moisture.
	For generic drugs (me-too Status)	Dol-P Forte Tablet 650mg + 75mg (Reg. # 123446), Manufactured by Genix Pharma Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Genix Pharma (Pvt.) Ltd.-44, 45-B, Korangi Creek Road, Karachi-75190, Pakistan-

	The status in reference regulatory authorities	Tramadol/ Paracetamol Cinfa 75mg + 650 mg manufactured by Laboratories Cinfa, SA
	Detail of previous approval	Dol-P Tablet 650mg/75mg, 340 DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
186	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Pacific Pharmaceuticals Ltd. Plot No.384, Sundar Industrial Estate, Raiwind Road, Lahore (000902)
	Application Form Dy. No / Tracking ID & date of submission	(463-UNX-TDQ1, 2024-12-10)
	Detail of Fee Submitted	93000.0, 2024-11-19,
	The proposed proprietary name / brand name	Tazocare Dry Powder Injection 4.5 g
	Label Claim	Each Vial Contains: Piperacillin Sodium eq. to Piperacillin 4.00 gm, Tazobactam Sodium eq. to Tazobactam 0.50 gm
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's Vial-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30oC
	For generic drugs (me-too Status)	Tanzo Iv Injection 4.5g by Bosch Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Stallion Pharmaceuticals (Pvt) Ltd.-Plot No. 581, Sunder Industrial Estate, Lahore-
	The status in reference regulatory authorities	Piperacillin/Tazobactam 4g/0.5g Powder for Solution by Wockhardt UK Ltd
	Detail of previous approval	Talzon Dry Powder Injection 4.5 gm
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
187	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Swiss Pharmaceuticals Pvt. Ltd. A/159, S.I.T.E.-II, Super Highway (000438)

	Application Form Dy. No / Tracking ID & date of submission	(4HJ-9NS-G52D, 2025-04-28)
	Detail of Fee Submitted	75000.0, 18000.0 2024-07-19, 2025-04-24
	The proposed proprietary name / brand name	Avicel 2.5g Injection
	Label Claim	Each Vial Contains: Ceftazidime as Pentahydrate.....2000mg Avibactam as Sodium Salt.....500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	ZAVICEFTA 2.5GM INJECTION, PFIZER, Regn. No. 106848
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s. WnsFeild-Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar.-
	The status in reference regulatory authorities	Zavicefta 2 g/0.5 g powder for concentrate for solution for infusion, Pfizer Limited, Ramsgate Road, Sandwich, Kent CT13 9NJ United Kingdom.
	Detail of previous approval	Cefbact 2.5gm Injection, Draft Minutes for 343rd meeting of Registration Board (3rd -5th December, 2
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
188	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	M/s Daneen Pharma (Pvt) Ltd Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, (000688)
	Application Form Dy. No / Tracking ID & date of submission	(4HJ-QEQ-291E, 2025-05-20)
	Detail of Fee Submitted	93000.0, 2024-12-06,
	The proposed proprietary name / brand name	Zuvaroz-V
	Label Claim	Each film coated tablet contains: Valsartan 160mg Rosuvastatin (as Rosuvastatin calcium) 20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's, 10's,14's,20's,-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C. Protect from heat, light & Moisture
	For generic drugs (me-too Status)	Rosca-V Tablet by Genix Pharma Pvt Ltd (123283)

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Genix Pharma Pvt Ltd -44, 45B, KORANGI CREEK ROAD, KARACHI. PAKISTAN-
	The status in reference regulatory authorities	Valsaros 20mg/160mg film coated tablets by TAD Pharma GmbH, Germany
	Detail of previous approval	Rosca-V Tablet 20mg/160mg DRB 339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
189	Case Category	Contract Manufacturing (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	(4HS-JW6-WZWQ, 2025-06-04)
	Detail of Fee Submitted	93000.0, 2025-05-19,
	The proposed proprietary name / brand name	D-Penem 500mg Injection
	Label Claim	Each vial contains: Sterile Doripenem Monohydrate eq to Anhydrous Doripenem 500 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's or as per SRO-As per SRO
	Shelf Life (Unit)	2 Year Store in a cool, dry place below 30 degrees Celsius.
	For generic drugs (me-too Status)	Ronim, 500mg Injection, by Genix Pharma (Pvt.) Ltd
	Pharmacotherapeutic Group of (API)	Carbapenems (Beta-Lactam Antibiotic)
	Name, address of Manufacturing site:	Fleming Pharmaceuticals-23-Km, Lahore-Sheikhupura Road, Lahore-
	The status in reference regulatory authorities	DORIBAX® 500mg Injection, by Janssen Pharmaceuticals NV
	Detail of previous approval	Dori-F Injection, Minutes of 323rd meeting of Registration Board (6th to 8th December, 2022)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
190	Case Category	Contract Manufacturing (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	(4N5-TVV-ZXR4, 2025-01-08)
	Detail of Fee Submitted	93000.0, 2024-09-19,
	The proposed proprietary name / brand name	Triphage
	Label Claim	Triphage XR Tablets 12.5mg+2.5mg+1000mg Each Film Coated tablet contains: Empagliflozin..... Linagliptin (as Immediate release coating) 2.5mg Metformin HCL (as Extended-release core) 1000mg (Innovator Specification).
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per DPC-De-Controlled
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Empoli Trio
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Novamed Pharmaceutical (Pvt.) Ltd.-28-km Ferozepur Road, Lahore – Pakistan-
	The status in reference regulatory authorities	USFDA- Trijardy XR
	Detail of previous approval	Exempa-Lin Met 12.5mg+2.5mg+1000mg Tablets, 336 DRB
Evaluation Remarks		
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.		
Decision		
Approved		
191	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Dyson Research Laboratories (Pvt.) Ltd 28-Km Ferozpur Road Lahore (000559)
	Application Form Dy. No / Tracking ID & date of submission	(4QV-V34-N6GY, 2025-04-03)
	Detail of Fee Submitted	93000.0, 2024-11-23,
	The proposed proprietary name / brand name	Dynazole
	Label Claim	Each vial contains: Voriconazole lyophilized powder.....200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30ml transparent typ-As per SRO

	Shelf Life (Unit)	2 YearThe un reconstituted vial does not require any special temperature storage conditions but once reconstituted, the product must be used immediately.
	For generic drugs (me-too Status)	V. Zde 200mg/vial Injection by Neutro Pharma (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Labs (Pvt.) Ltd.-Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad.-
	The status in reference regulatory authorities	VFEND (Voriconazole) 200mg/vial, approved by USFDA.
	Detail of previous approval	Voricol (Voriconazole lyophilized powder) 200mg, approved in 331st Meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
192	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	A'raf (Pvt) Ltd 23 KM Raiwind Road Lahore (000685)
	Application Form Dy. No / Tracking ID & date of submission	(4RE-PM3-QBDM, 2025-05-08)
	Detail of Fee Submitted	93000.0, 2025-04-21,
	The proposed proprietary name / brand name	Zarip 6mg Capsule
	Label Claim	Each Capsule contains: Cariprazine Hydrochloride equivalent to Cariprazine.....6mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x5's, 1x6's, 2x7's,-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Caripz 6mg Capsule of M/s Genix Pharma (approved in M-324)
	Pharmacotherapeutic Group of (API)	Atypical antipsychotics
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhpura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	VRAYLAR (cariprazine) 6mg capsules AbbVie, Inc. North Chicago, IL 60064 USA Product of Hungary (USFDA Approved)
	Detail of previous approval	Carip 6mg Capsule approved in 343rd meeting of DRB
	Evaluation Remarks	

	Carip 6mg Capsule of Skywin Pharmaceuticals was approved in 343rd meeting of the Registration Board. Applicant to submit undertaking that API from the same source will be used as approved for Carip 6mg Capsule.	
	Decision	
	Approved	
193	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Pasteur & Fleming Pharma Plot # 70A , Phase -3, Road No-04, Industrial Estate Hattar, K.P.K. Pakistan (000945)
	Application Form Dy. No / Tracking ID & date of submission	(4RM-68B-L23S, 2025-04-14)
	Detail of Fee Submitted	93000.0, 2025-01-06,
	The proposed proprietary name / brand name	Prupred 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	10's-As per SRO,20's-As per SRO,30's-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature.
	For generic drugs (me-too Status)	P Pride tablet by Wilshire Laboratories Pvt Ltd
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-
	The status in reference regulatory authorities	Motegrity by Takeda Pharms USA
	Detail of previous approval	PruMark 2mg Tablet (Meeting 340th)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
194	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Akson Pharmaceuticals (Pvt) Ltd Plot No. 9-B/1&2, street No.D-1, Old Industrial estate, Mirpur, Azad Kashmir (000486)
	Application Form Dy. No / Tracking ID & date of submission	(4SS-YBX-61TB, 2025-04-16)
	Detail of Fee Submitted	93000.0, 2024-12-30,
	The proposed proprietary name / brand name	Melazon 5mg Tablets
	Label Claim	Metolazone.....5mg (USP Spec's)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO

	Shelf Life (Unit)	2 Year15-25 C
	For generic drugs (me-too Status)	Metxone Tablets 5 mg
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd.-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	METOLAZONE 5MG TABLET
	Detail of previous approval	343rd Meeting
	Evaluation Remarks	
	Metzon 5mg Tablets of Solaris Life Sciences (Pvt.) Ltd. was approved in the 343rd meeting of the Registration Board.	
	Decision	
	Approved	
195	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Trigon Pharmaceuticals (Private) Ltd 8-k.m thokar raiwind road Lahore (000342)
	Application Form Dy. No / Tracking ID & date of submission	(4VL-Q6J-4PVZ, 2025-01-23)
	Detail of Fee Submitted	93000.0, 2024-12-19,
	The proposed proprietary name / brand name	DUM
	Label Claim	Each ml of reconstituted Suspension Contains: Sildenafil (as Citrate) ----- 10mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1's * 112 ml-As per SRO
	Shelf Life (Unit)	2 YearBelow 25
	For generic drugs (me-too Status)	Silagro (Nabi Qasim Pharma)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Gray's Pharmaceuticals -Plot No: 2, Street No: N-3, National Industrial Zone Rawat, Islamabad -
	The status in reference regulatory authorities	Sildenafil Citrate (TEVA PHARMS USA)
	Detail of previous approval	343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
196	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Regal Pharmaceuticals Plot No. 2-A, Street No. S-5 National Industrial Zone RCCI Rawat (000839)
	Application Form Dy. No / Tracking ID & date of submission	(51L-BTV-SQ25, 2025-02-11)

	Detail of Fee Submitted	75000.0, 18000.0 2024-05-21, 2025-01-22
	The proposed proprietary name / brand name	SOLD 40 MG INJ
	Label Claim	Each vial contains: Esomeprazole sodium equ. to Esomeprazole 40mg (Sweras Specifications)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1,S-De-Controlled
	Shelf Life (Unit)	2 YearSTORE BELOW 25 C0
	For generic drugs (me-too Status)	Koncept 40mg Injection
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	SWERA PHARMACEUTICALS-PLOT 27 STREET S-4 INDUSTRIAL AREA RAWAT ISLAMABAD-
	The status in reference regulatory authorities	Nexium I.V 40mg Injection USA
	Detail of previous approval	SEZRO 40 MG INJ M-322- (In minutes Emozol 40mg Injection is approved)
	Evaluation Remarks	
	Emozol 40mg Injection of M/s Sewra Pharmaceuticals is approved in 322 meeting of RB.	
	Decision	
	Approved	
197	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	MEDPHARM RESEARCH LAB 28 KM FEROZPUR ROAD LAHORE (000878)
	Application Form Dy. No / Tracking ID & date of submission	(52M-YWN-WD22, 2025-02-11)
	Detail of Fee Submitted	93000.0, 2024-11-15,
	The proposed proprietary name / brand name	Paramed 500/25mg Tablet
	Label Claim	Each Film Coated tablet contains: Paracetamol.....500mg Diphenhydramine Hydrochloride.....25mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	As per SRO / DPC-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Panadol Night of Haleon Pakistan Limited
	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	PANADOL PM, Acetaminophen and diphenhydramine hydrochloride Film coated tablet of M/s GSK consumer Healthcare (USFDA Approved)
	Detail of previous approval	Peradol-D Tablet approved in 343rd meeting of DRB
	Evaluation Remarks	

	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
198	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Tovida Pharmaceuticals (Pvt) Ltd Plot No.7, Street No.S-07, RCCI Industrial Estate Islamabad (000996)
	Application Form Dy. No / Tracking ID & date of submission	(548-W5V-YV5S, 2025-05-15)
	Detail of Fee Submitted	93000.0, 2024-11-07,
	The proposed proprietary name / brand name	TOVINEM 500mg INJECTION
	Label Claim	Each vial contains: Meropenem trihydrate eq to Meropenem... 500mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	2 Year25C - 30C+-
	For generic drugs (me-too Status)	GENERIC DRUG
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Biogen Life Sciences -8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	MEROGEN Inj 500mg
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
199	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Akson Pharmaceuticals (Pvt) Ltd Plot No. 9-B/1&2, street No.D-1, Old Industrial estate, Mirpur, Azad Kashmir (000486)
	Application Form Dy. No / Tracking ID & date of submission	(566-U3Q-E9B8, 2025-04-16)
	Detail of Fee Submitted	93000.0, 2024-12-30,
	The proposed proprietary name / brand name	Dolosyn-E 500mg/20mg Tablets

	Label Claim	Each modified release tablet contains: Naproxen.....500mg (Enteric coated Core) Esomeprazole as Magnesium Trihydrate.....20mg (Immediate Release Coat) (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year15-25 C
	For generic drugs (me-too Status)	Glomov Tablets
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd.-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	Vimovo modified release tablets
	Detail of previous approval	Esoren-20mg/500mg Tablets, M-343
	Evaluation Remarks	
	Esoren 500mg/ 20mg Tablets of Solaris Life Sciences (Pvt.) Ltd. was approved in 343rd meeting of the Registration Board.	
	Decision	
	Approved	
200	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(59L-7AY-Z1LB, 2025-04-30)
	Detail of Fee Submitted	93000.0, 2024-11-25,
	The proposed proprietary name / brand name	Gendronate 3mg/3ml INJECTION
	Label Claim	Each 3ml ampoule contains: Ibandronate sodium monohydrate eq. to ibandronic acid 3mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	24 MonthBelow 30°C
	For generic drugs (me-too Status)	Adronil Injection 3mg/3ml
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	SERAPH PHARMACEUTICAL-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
	The status in reference regulatory authorities	Ibandronate sodium 3mg/3ml injection
	Detail of previous approval	Ibelac 3mg/3ml Injection, 335th minutes of meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned	

	notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
201	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Tovida Pharmaceuticals (Pvt) Ltd Plot No.7, Street No.S-07, RCCI Industrial Estate Islamabad (000996)
	Application Form Dy. No / Tracking ID & date of submission	(5AQ-4LB-HB2E, 2025-05-15)
	Detail of Fee Submitted	93000.0, 2024-11-07,
	The proposed proprietary name / brand name	Tovizone 2g INJECTION
	Label Claim	Each Vial Contains: Cefoperazone (as sodium).....1g Sulbactam (as sodium).....1g (JP specs)
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	2 Year25C - 30C+-
	For generic drugs (me-too Status)	GENERIC DRUG
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Biogen Life Sciences -8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	PMDA Japan Approved)
	Detail of previous approval	M-316
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
202	Case Category	Contract Manufacturing (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	(5BY-HL5-3PMW, 2025-06-04)
	Detail of Fee Submitted	93000.0, 2025-05-19,
	The proposed proprietary name / brand name	Tazillin 4.5mg Injection
	Label Claim	Each vial contains: Piperacillin 4 grams (As Piperacillin Sodium) and Tazobactam 0.5 grams (As Tazobactam sodium)
	Reference to Finished product specifications	United States Pharmacopeia

	Proposed Pack Size	1's (One vial pack-As per SRO
	Shelf Life (Unit)	2 YearStore in a cool, dry place below 30 degrees Celsius.
	For generic drugs (me-too Status)	Tanzo 4gm + 500mg Injection, by Bosch Pharmaceuticals (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Penicillin and Beta-Lactam antibiotic
	Name, address of Manufacturing site:	Fleming Pharmaceuticals-23-Km, Lahore-Sheikhupura Road, Lahore-
	The status in reference regulatory authorities	ZOSYN 4.5g Injection by Wyeth Pharmaceuticals Inc.
	Detail of previous approval	Fletazo Injection 4.5g, Minutes of 323rd meeting of Registration Board (6th to 8th December, 2022)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
203	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Trigon Pharmaceuticals (Private) Ltd 8-k.m thokar raiwind road Lahore (000342)
	Application Form Dy. No / Tracking ID & date of submission	(5G4-4YG-PE1Z, 2025-04-03)
	Detail of Fee Submitted	93000.0, 2024-11-27,
	The proposed proprietary name / brand name	OSB Sachet 40/1680mg
	Label Claim	Each Sachet contains: Omeprazole.....40mg Sodium bicarbonate.....1680mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,30's-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature.
	For generic drugs (me-too Status)	Risek Insta sachet by GETZ Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-
	The status in reference regulatory authorities	Omeprazole and sodium bicarbonate sachet by STRIDES Pharma
	Detail of previous approval	S-Insta Sachet (Meeting # 337th)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned	

	notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
204	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winlet Pharmaceuticals (Pvt) Ltd. 30-Km, Lahore Sargodha Raod, Sargodha (000874)
	Application Form Dy. No / Tracking ID & date of submission	(5GT-D2J-GN4A, 2025-04-08)
	Detail of Fee Submitted	93000.0, 2024-10-22,
	The proposed proprietary name / brand name	Fusilet H
	Label Claim	Each gram cream contains: Fusidic Acid (BP).....20mg (2%w/w) Hydrocortisone Acetate.....10mg (1% w/w)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1,s-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 °C
	For generic drugs (me-too Status)	Fusimax-H BY
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Biogen life sciences -8-km chakbeli road rawat Rawalpindi-
	The status in reference regulatory authorities	Fucidin H cream MHRA approved
	Detail of previous approval	M-331
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
205	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Saibins Pharmaceuticals Plot No.316 Industrial Triangle Kahutta Road Islamabad (000773)
	Application Form Dy. No / Tracking ID & date of submission	(5HD-APS-6PA7, 2025-04-08)
	Detail of Fee Submitted	93000.0, 2024-12-16,
	The proposed proprietary name / brand name	Saixone 250mg Injection IV
	Label Claim	Each Vial Contains: Each Vial Contains: Ceftriaxone sodium Eq. to Ceftriaxone ... 250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	2 YearStore in cool and dry place below 30C

	For generic drugs (me-too Status)	Oxidil 250mg Inj IV-Sami Pharmaceuticals - Reg.No.023393
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/S Bio labs (Pvt) Ltd -PLOT#145 kahuta industrial Triangle Islamabad-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Ceftione Inj 250mg ,308th meeting
	Evaluation Remarks	
	Ceftione injection 1 gm IV of Bio Labs was approved in 308th meeting of Registratoin Board.	
	Decision	
	Approved	
206	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Evolution Pharmaceuticals (Pvt.) Ltd. Plot no. 25,26 & 27, Street S-3, National Industrial Zone, Rawat, Islamabad. (000867)
	Application Form Dy. No / Tracking ID & date of submission	(5LV-MSS-UUN3, 2025-03-20)
	Detail of Fee Submitted	93000.0, 2024-09-24,
	The proposed proprietary name / brand name	ODANEX 8mg/4ml INJECTION
	Label Claim	Each 4 ml ampoule contains: Ondansetron as HCl Dihydrate.....8 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	2 YearStore at 20° to 25° C (68° to 77°F). Keep container closed tightly. Protect from light and moisture. Store away from foodstuffs.
	For generic drugs (me-too Status)	Brand Name: Onset™. Registration holder: Pharmedic Laboratories Pvt Ltd. Status in regulatory authorities Onset 8 mg Injection is DRAP Approved.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	SERAPH PHARMACEUTICAL -Plot No 210, Industrial triangle, Kahuta road, Islamabad-Pakistan-
	The status in reference regulatory authorities	Brand Name Zofran® Marketing Authorization holder: Novartis. Regulatory Authority: Zofran® Injection is Approved in USFDA
	Detail of previous approval	No-F.5-6/2023 Reg No.118773 product Name : Onderaph 8mg/4ml Injection
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
207	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Pasteur & Fleming Pharma Plot # 70A , Phase -3, Road No-04, Industrial Estate Hattar, K.P.K. Pakistan (000945)
	Application Form Dy. No / Tracking ID & date of submission	(5N1-TER-SHN3, 2025-02-19)
	Detail of Fee Submitted	93000.0, 2024-12-18,
	The proposed proprietary name / brand name	Oxone 20mg Tablet
	Label Claim	Each film coated tablet contains: Vonoprazan as fumarate.....20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,14's -As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature.
	For generic drugs (me-too Status)	VONozan tablet by GETZ Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-
	The status in reference regulatory authorities	VOQUENZA tablet by Phathom Pharmaceuticals,USA
	Detail of previous approval	Vonomark 20mg Tablet (Meeting 335th)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
208	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	CKD Pharmaceuticals Pakistan Pvt. Ltd Plot No. 50, Sector No. 28, Korangi Industrial Area (000144)
	Application Form Dy. No / Tracking ID & date of submission	(5QR-Q3U-Y52M, 2025-05-13)
	Detail of Fee Submitted	93000.0, 2025-04-11,
	The proposed proprietary name / brand name	Revita-ORS Orange Flavour
	Label Claim	Each sachet contains; Sodium chloride 2.6gm Potassium chloride 1.5gm Tri sodium Citrate 2.9gm Glucose Anhydrous 13.5gm
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1 x 20's-As per SRO

	Shelf Life (Unit)	2 YearBelow 30oC
	For generic drugs (me-too Status)	OEM Orange Flavour by Indus Pharma
	Pharmacotherapeutic Group of (API)	Electrolytes with Carbohydrate
	Name, address of Manufacturing site:	Focus & Rulz Pharmaceuticals (Pvt) Ltd-Plot No. 44, Industrial Triangle, kahuta Road, Islamabad -
	The status in reference regulatory authorities	Oral Rehydrating Salt by AGS Brands, INC
	Detail of previous approval	Oraldrip-ORS Orange Flavour, 297th Meeting of Registration Board Dy. No. 11689 Dated: 20-05-2020
	Evaluation Remarks	
	Oraldrip-ORS Orange Flavour of Focus & Rulz Pharmaceuticals (Pvt) Ltd was approved in 297th meeting of the Registration Board. Applicant to submit quality agreement and Licene and GMP of the following DS manufacturers: Hunan Huari Pharmaceuticals Co. Ltd Economic development Aero, Er hunan East Road, Ningxiang county, Hunan Province. for tricitrate sodium, and Xiwang Pharmaceutical Co., Ltd for Glucose anhydrous	
	Decision	
	Approved	
209	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	De-Mont Research Laboratories (Pvt.) Ltd. 20 Km, Lahore-Sheikhupura Road, Sheikhupura, Pakistan (000844)
	Application Form Dy. No / Tracking ID & date of submission	(5UG-TW8-PYUE, 2025-03-11)
	Detail of Fee Submitted	93000.0, 2024-10-15,
	The proposed proprietary name / brand name	Tobria Eye Ointment
	Label Claim	Each gm contains: Tobramycin.....3 mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Yearstore below 30 degree centigrade
	For generic drugs (me-too Status)	Tobrex Eye Ointment (Novartis Pharma private Limited)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Medevo (Pvt) Ltd.-Plot No. 94, Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Tobramycin 3mg/gm Eye Ointments, USP (Novartis Pharma USA)
	Detail of previous approval	SURGITOB EYE OINTMENT (M-336)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
210	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Skywin Pharmaceutical Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road (000971)
	Application Form Dy. No / Tracking ID & date of submission	(5VN-QUP-MS25, 2025-02-11)
	Detail of Fee Submitted	93000.0, 2024-12-23,
	The proposed proprietary name / brand name	Ceftriax 1gm IV Injection
	Label Claim	Each Vial contains: Ceftriaxone Sodium(USP) eq. to Ceftriaxone.....1g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO / DPC-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Rocephin 1g IV injection of M/s Martin Dow
	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	Ceftriaxone 1g Powder for solution for injection of M/s Wockhardt UK Ltd (MHRA Approved)
	Detail of previous approval	Welcef 1gm IV Injection approved in 323rd meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
211	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	M/s Daneen Pharma (Pvt) Ltd Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, (000688)
	Application Form Dy. No / Tracking ID & date of submission	(5XD-L2X-MPMM, 2025-04-09)
	Detail of Fee Submitted	93000.0, 2024-12-06,
	The proposed proprietary name / brand name	Zuvaroz-V
	Label Claim	Each film coated tablet contains: Valsartan 80mg Rosuvastatin (as Rosuvastatin calcium) 20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's, 10's,14's,20's,-As per SRO

	Shelf Life (Unit)	2 YearStore below 30°C. Protect from heat, light & Moisture
	For generic drugs (me-too Status)	Rosca-V Tablet by Genix Pharma Pvt Ltd (123282)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Genix Pharma Pvt Ltd -44, 45B, KORANGI CREEK ROAD, KARACHI. PAKISTAN-
	The status in reference regulatory authorities	Valsaros 20mg/80mgfilm coated tablets by TAD Pharma GmbH, Germany
	Detail of previous approval	Rosca-V Tablet 20mg/80mg DRB 339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
212	Case Category	Routine (Incharge Evaluation Cell)
	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	(682-LAD-6M1L, 2024-04-17)
	Detail of Fee Submitted	75000.0, 2024-03-04,
	The proposed proprietary name / brand name	Carnital
	Label Claim	Each 10ml Contain: Levocarnitine.....1g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	118ml-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30° C
	For generic drugs (me-too Status)	None
	Pharmacotherapeutic Group of (API)	Amino acids and derivatives
	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	3 batches: 1L
	Documents for the procurement of API with approval from DRAP (in case of Import)	24-03-2021: AD attested commercial invoice submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Carnitor 1g/10ml Oral Solution: PE performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IV-A
	The status in reference regulatory authorities	CARNITOR Oral solution (USFDA Approved)

	GMP status of the firm	03-01-2023: GMP certificate
	Evidence of approval of manufacturing facility	03-01-2023: GMP certificate Oral liquid section
	Evaluation Remarks	
	Decision	
	Approved	
213	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	M/s Daneen Pharma (Pvt) Ltd Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, (000688)
	Application Form Dy. No / Tracking ID & date of submission	(6QY-UE5-343U, 2025-05-20)
	Detail of Fee Submitted	93000.0, 2024-11-12,
	The proposed proprietary name / brand name	Zuvaroz-A
	Label Claim	Each Film Coated Tablet Contains: Rosuvastatin (as Rosuvastatin calcium) 20mg Amlodipine (as Amlodipine besylate).....5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's, 10's, 14's, 20'-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C. Protect from heat, light and moisture.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Rosuvastatin is in a class of medications called HMG-CoA reductase inhibitors. Amlodipine belongs to the group of drugs called dihydropyridine calcium channel blockers.
	Name, address of Manufacturing site:	Genix Pharma (Pvt.) Ltd.-44, 45-B, Korangi Creek Road, Karachi-75190, Pakistan-
	The status in reference regulatory authorities	Rosuvastatin/amlodipine Krka 20 mg/5 mg film- coated tablets mfg. by TAD Pharma, Germany (HPRA, Ireland)
	Detail of previous approval	Rosca-A 20mg/5mg (DRB 339)
	Evaluation Remarks	
	ROSCA-A 20mg/5mg Tablet of M/s Genix Pharma is approved in 339 meeting of Registration Board.	
	Decision	
	Approved	
214	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	fleming pharmaceutical 23-KM Sheikhpura road LAhore (000936)
	Application Form Dy. No / Tracking ID & date of submission	(6QZ-WB3-22NG, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2025-01-15,
	The proposed proprietary name / brand name	Flimfil 10mg/ml Suspension
	Label Claim	Each ml of reconstituted suspension contains: Sildenafil (as Citrate) ----- 10mg

	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	112ml-De-Controlled
	Shelf Life (Unit)	2 YearRoom Temprature
	For generic drugs (me-too Status)	SILAGRO NABI QASIM KARACHI
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Gray's Pharmaceuticals-Plot No 2, Street No N-3, National Industrial Zone, Rawat, Islamabad Islamabad Urban-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Selden 10mg/ml for oral suspension 343 DRB
	Evaluation Remarks	
	Selden 10mg/ml for oral suspension of Gray's Pharmaceuticals was approved in the 343rd meeting of the Registratiton Board. Applicant to submit quality agreement between contract giver and acceptor.	
215	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	AsianContinental (Pvt.) Ltd. D-32, S.I.T.E II, Super Highway, Karachi (000643)
	Application Form Dy. No / Tracking ID & date of submission	(6TQ-YR5-28UV, 2025-05-08)
	Detail of Fee Submitted	93000.0, 2025-04-08,
	The proposed proprietary name / brand name	Vekonex ODT 8mg
	Label Claim	Each Orodispersible tablet contains: Ondansetron.....8mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4's, 1x6's, 1x10's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	N.A
	Pharmacotherapeutic Group of (API)	serotonin 5-HT3 receptor antagonists
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Limited-Plot # 129, Sunder Industrial Estate Lahore.-
	The status in reference regulatory authorities	Ondansetron Bluefish 8mg orodispersible tablets (Bluefish Pharmaceuticals AB Box 49013 100 28 Stockholm)
	Detail of previous approval	Dysit ODT 8mg Tablet (345 Meeting Minutes of Registration Board)
	Evaluation Remarks	
	Dysit ODT 8mg Tablet of Wimits Pharmaceuticals Pvt. Limited was approved in345th meeting of the Registration Board.	
	Decision	
	Approved	
216	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	AGP Limited B-23-C, S.I.T.E., Karachi (000348)
	Application Form Dy. No / Tracking ID & date of submission	(6W4-9W6-4SJ4, 2025-05-08)

	Detail of Fee Submitted	93000.0, 2025-04-23,
	The proposed proprietary name / brand name	Agchol 25mg Tablet
	Label Claim	Each Tablet contains: Bethanechol Chloride.....25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's, 2x7's, 2x10'-De-Controlled
	Shelf Life (Unit)	2 YearDo not store over 30°C. Protect from Direct sunlight & heat.
	For generic drugs (me-too Status)	Urotone 25mg Tablet by Wimits Pharmaceutical (Pvt.) Ltd
	Pharmacotherapeutic Group of (API)	Cholinergic Agonist
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Limited.-Plot # 129, Sunder Industrial Estate Lahore-
	The status in reference regulatory authorities	Bethanechol Chloride Tablet, USP 25mg of M/s Amneal Pharmaceuticals LLC, Bridgewater, NJ 08807 (USFDA Approved)
	Detail of previous approval	Urotone 25mg Tablet, DRB Meeting No. 344
	Evaluation Remarks	
	Urotone 25mg Tablet of Wimits Pharmaceuticals Pvt. Limited. was approved in 344th meeting fo the Registration Board. Applicant to submit undertaking that API from same source will be used as approved for Urotone tablet.	
	Decision	
	Approved	
217	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	M/s Daneen Pharma (Pvt) Ltd Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, (000688)
	Application Form Dy. No / Tracking ID & date of submission	(6Y3-QSD-JR3X, 2025-04-08)
	Detail of Fee Submitted	93000.0, 2024-12-06,
	The proposed proprietary name / brand name	Zuvaroz-V
	Label Claim	Each film coated tablet contains: Valsartan 80mg Rosuvastatin (as Rosuvastatin calcium) 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's, 10's,14's,20's,-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C. Protect from heat, light & Moisture
	For generic drugs (me-too Status)	Rosca-V Tablet by Genix Pharma Pvt Ltd (123280)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Genix Pharma Pvt Ltd -44, 45B, KORANGI CREEK ROAD, KARACHI. PAKISTAN-
	The status in reference regulatory authorities	Valsaros 10mg/80mgfilm coated tablets by TAD Pharma GmbH, Germany
	Detail of previous approval	Rosca-V Tablet 10mg/80mg DRB 339
	Evaluation Remarks	

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

Decision

Approved

218	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	M/s Daneen Pharma (Pvt) Ltd Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, (000688)
	Application Form Dy. No / Tracking ID & date of submission	(6YG-XQZ-58GL, 2025-05-20)
	Detail of Fee Submitted	93000.0, 2024-11-12,
	The proposed proprietary name / brand name	Zuvaroz-A
	Label Claim	Each Film Coated Tablet Contains: Rosuvastatin (as Rosuvastatin calcium) 20mg Amlodipine (as Amlodipine besylate).....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7s, 10's, 14s, 20's,-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C. Protect from heat, light and moisture.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Rosuvastatin is in a class of medications called HMG-CoA reductase inhibitors. Amlodipine belongs to the group of drugs called dihydropyridine calcium channel blockers.
	Name, address of Manufacturing site:	Genix Pharma (Pvt.) Ltd.-44, 45-B, Korangi Creek Road, Karachi-75190, Pakistan-
	Name & address of API manufacturer	
	Detail of stability batches of drug product	.
	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	Rosuvastatin/amlodipine Krka 20 mg/10 mg film-coated tablets mfg. by TAD Pharma, Germany (HPRA, Ireland)
	GMP status of the firm	.
	Evidence of approval of manufacturing facility	Genix Pharma DML (Formulation) 000351
	Evaluation Remarks	
	ROSCA-A 20mg/10mg Tablet of Genix Pharma is approved in 339 meeting of Registratiton Board.	
	Decision	

	Approved	
219	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(718-2H4-4HRM, 2025-04-30)
	Detail of Fee Submitted	93000.0, 2024-11-25,
	The proposed proprietary name / brand name	ODAPON 8mg/5ml Oral Solution
	Label Claim	Each 5ml contains: Ondansetron hydrochloride dihydrate eq. to ondansetron.....8mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 x 1-As per SRO
	Shelf Life (Unit)	24 MonthBelow 30°C
	For generic drugs (me-too Status)	Onsetron 8mg/5ml Oral Solution
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	SERAPH PHARMACEUTICAL-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
	The status in reference regulatory authorities	Ondansetron hydrochloride Oral Solution 8mg/5ml
	Detail of previous approval	RESTON 8mg/5ml Oral Solution,336th minutes of meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
220	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Dyson Research Laboratories (Pvt.) Ltd 28-Km Ferozpur Road Lahore (000559)
	Application Form Dy. No / Tracking ID & date of submission	(73J-Q8P-H38T, 2025-03-04)
	Detail of Fee Submitted	93000.0, 2024-09-27,
	The proposed proprietary name / brand name	Dydol Eye Drops
	Label Claim	Each ml contains: Loteprednol Etabonate.....5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5ml in LDPE bottle.-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C

	For generic drugs (me-too Status)	Lotepred forte Ophthalmic Suspension by Sante (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Medevo (Pvt.) Ltd.-Plot no. 94, Sunder Industrial Estate, Raiwind Road, Lahore.-
	The status in reference regulatory authorities	Letomax Ophthalmic Suspension by Bousch and Lomb approved in USFDA.
	Detail of previous approval	Surgilot Eye Drop (0.5% Loteprednol Etabonate) approved in 336 DRB Meeting of Registration Board (04
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
221	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Invictus Pharmaceuticals Plot No. 21, 26 Street No. NS.2, National Industrial Zone Rawat, Islamabad (000892)
	Application Form Dy. No / Tracking ID & date of submission	(761-PUR-P66W, 2024-08-21)
	Detail of Fee Submitted	75000.0, 2024-05-21,
	The proposed proprietary name / brand name	invilair 4mg sachet
	Label Claim	Each Sachet contains: Montelukast as Sodium.....4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	24 Month25°C
	For generic drugs (me-too Status)	MONTIGET Sachet 4mg Getz Pharma, Pvt, Ltd
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Himark Laboratories Pvt Ltd.-Plot # 37-A, sunder Industrial Estate, Lahore.-
	The status in reference regulatory authorities	Singulair Paediatric 4 mg Granules Manufactured by Organon Pharma (UK) Limited
	Detail of previous approval	Hikast 4mg Sachet
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also	

	needed as part of module-1 of Form 5F. (Data for Hikast 4mg Sachet Approved in 323rd meeting of the Registration Board)	
	Decision	
	Approved	
222	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Parkar Pharma Plot No. 0/7-A, S.I.T.E, Area Kotri, Sindh (000883)
	Application Form Dy. No / Tracking ID & date of submission	(779-556-BM9M, 2025-04-25)
	Detail of Fee Submitted	93000.0, 2024-12-24,
	The proposed proprietary name / brand name	PARKENAFIL 10mg/ml SUSPENSION
	Label Claim	Each ml of reconstituted suspension contains: Sildenafil (as Citrate) ----- 10mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	112ml-De-Controlled
	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	SILAGRO NABI QASIM KARACHI
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Gray's Pharmaceuticals-Plot No 2, Street No N-3, National Industrial Zone, Rawat, Islamabad Islamabad Urban-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Selden 10mg/ml for oral suspension
	Evaluation Remarks	
	Selden 10mg/ml for oral suspension of Gray's Pharmaceuticals was approved in 343rd meeting of the Registration Board. Applicant to submit license and GMP status of the Drug Substance Manufacturer. Quality agreement is attached.	
	Decision	
	Approved	
223	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	MEDPHARM RESEARCH LAB 28 KM FEROZPUR ROAD LAHORE (000878)
	Application Form Dy. No / Tracking ID & date of submission	(77A-HGT-HRH8, 2025-02-11)
	Detail of Fee Submitted	93000.0, 2024-11-15,
	The proposed proprietary name / brand name	Vomomed 100/10mg Tablet
	Label Claim	Each Film Coated Modified Release Tablet contains: Aspirin----- ---100mg (Enteric coated core) Vonopranzan as Fumarate-----10mg (immediate release coat)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	As per SRO / DPC-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	N/A

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Cabpirin 10mg/100mg Tablet of M/s Takeda Pharmaceutical Company Limited (PMDA Approved)
	Detail of previous approval	Vozaan-AS Tablet approved in 340th Meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
224	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(7AT-RNQ-SANE, 2025-04-30)
	Detail of Fee Submitted	93000.0, 2024-11-25,
	The proposed proprietary name / brand name	Nystin 100,000I.U Oral Suspension
	Label Claim	Each ml contains; Nystatin 100,000I.U
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 x 30mL-As per SRO
	Shelf Life (Unit)	24 MonthBelow 30°C
	For generic drugs (me-too Status)	Nystanil oral Suspension
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	SERAPH PHARMACEUTICAL -Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan -
	The status in reference regulatory authorities	Nystatin Oral Suspension 100,000I.U
	Detail of previous approval	Nyston Oral Suspension 100,000I.U, 339th minutes of meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
225	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Skywin Pharmaceutical Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road (000971)
	Application Form Dy. No / Tracking ID & date of submission	(7M7-4TE-3DXG, 2025-05-08)
	Detail of Fee Submitted	93000.0, 2025-04-25,
	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	1x10's, 2x7's, 2x10'-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Mgablin 5mg Tablet of M/s Genix Pharma
	Pharmacotherapeutic Group of (API)	Gabapentinoid class of drugs
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Tarlige Tablets 5mg of M/s Daiichi Sankyo Co., Ltd (PMDA Approved)
	Detail of previous approval	Mirogab 5mg Tablet approved in 344th Meeting of DRB
	Evaluation Remarks	
	Mirogab 5mg Tablet was approved Wimits Pharmaceuticals Pvt. Ltd. in the 344th meeting of the Registration Board. Applicant to submit updated status of approval and GMP of DM manufacturer and an undertaking stating that API from same source will be used as approved for Mirogab.	
226	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Dyson Research Laboratories (Pvt.) Ltd 28-Km Ferozpur Road Lahore (000559)
	Application Form Dy. No / Tracking ID & date of submission	(7ML-GZD-V2WB, 2025-02-12)
	Detail of Fee Submitted	93000.0, 2024-11-26,
	The proposed proprietary name / brand name	Dyplast
	Label Claim	Each vial contains: Imipenem as monohydrate 500mg Cilastatin as sodium.....500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearStore below 25C.
	For generic drugs (me-too Status)	Cilapen Injection 500mg by Bosch Pharmaceuticals (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	M/s Bio-Next Pharmaceuticals.-Plot No. 50, Street No. S-10, RCCI, Rawat.-
	The status in reference regulatory authorities	Imipenem + Cilastatin 500mg/vial by ACS Dobfar, approved by USFDA.
	Detail of previous approval	Imipen Injection 500mg approved in 323rd meeting of Registration Board held on 06th - 08th December,
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
227	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Pacific Pharmaceuticals Ltd. Plot No.384, Sundar Industrial Estate, Raiwind Road, Lahore (000902)
	Application Form Dy. No / Tracking ID & date of submission	(7RD-VPR-UXAP, 2024-12-10)
	Detail of Fee Submitted	93000.0, 2024-11-19,
	The proposed proprietary name / brand name	PenMero 500 mg Dry Powder Injection
	Label Claim	Each Vial Contains: Meropenem 500 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's Vial-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30oC
	For generic drugs (me-too Status)	Meropenem Iv Injection 500 mg by Pfizer Laboratories
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Stallion Pharmaceuticals (Pvt) Ltd.-Plot No. 581, Sunder Industrial Estate, Lahore-
	The status in reference regulatory authorities	Meropenem 500 mg by Pfizer Limited UK
	Detail of previous approval	Merostin 500 mg Dry Powder Injection
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
228	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

	Name, address of Applicant.	Wallace Pharma Evolutions Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (000951)
	Application Form Dy. No / Tracking ID & date of submission	(7WD-WNP-8BBR, 2025-04-24)
	Detail of Fee Submitted	93000.0, 2025-01-22,
	The proposed proprietary name / brand name	Tegorr 90mg Tablet
	Label Claim	Each Film Coated Tablet Contains: TICAGRELOR.....90mg (Product complies BP Specs)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Anplag 90mg Tablet Pharmevo (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK.-
	The status in reference regulatory authorities	UK MHRA
	Detail of previous approval	Tigawin 90mg Tablet, DRB 331
	Evaluation Remarks	
	Tigawin Tablet 90mg of Wnsfeild Pharmaceuticals was approved in 331st meeting of the Registratoin Board. Firm to submit License and GMP status of Manufacturer Name: Nantong Chanyoo Pharmatech Co., Ltd (named as “Nantong Chanyoo”) Manufacturing Site: No.2 Tonghai Si Road, Yangkou Chemical Industrial Park,Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province 226407, China and Quality Agreement between Wallace Pharma Evolution and Wnsfeild Pharmaceuticals.	
	Decision	
	Approved	
229	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(7YL-E9Q-V9M4, 2025-04-11)
	Detail of Fee Submitted	93000.0, 2025-02-20,
	The proposed proprietary name / brand name	Q-D3 5MG/ML
	Label Claim	Each 1ml contains: Vitamin D3.....5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO/DPC-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 degree centigrade,protect from light,moisture and heat
	For generic drugs (me-too Status)	Indrop-D Neutro pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s MISAQ PHARMACEUTICALS-7-B,Woven Garments Zone, Value Addition City,Khurrianwala-Sahianwala Road, Faisalabad.-
	The status in reference regulatory authorities	ANSM(FRANCE)
	Detail of previous approval	MIRA-D 5MG/ML, M-339

	Evaluation Remarks	
	SOL-D-Injection 5mg/ml of Misaq Pharmaceuticals was approved in 339th meeting of the Registration Board.	
	Decision	
	Approved	
230	Case Category	Contract Manufacturing (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	(7ZW-A8T-LG9D, 2025-04-08)
	Detail of Fee Submitted	93000.0, 2024-12-09,
	The proposed proprietary name / brand name	Dologab CR Tablets 82.5 mg
	Label Claim	Each Extended-Release tablet contains: Pregabalin.....82.5 mg (Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30s-As per SRO
	Shelf Life (Unit)	2 YearBelow 30
	For generic drugs (me-too Status)	Revogab
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceutical (Pvt.) Ltd-Plot # 129, Sunder Industrial Estate, Lahore – Pakistan-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Gabal 82.5mg ER tablet ,324th
	Evaluation Remarks	
	Gabal 82.5mg ER tablet of Wimits Pharmaceutical (Pvt.) Ltd was approved in the 324th meeting fo the Registration Board.	
	Decision	
	Approved	
231	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Jenner Pharmceuticals Pvt. Ltd Plot No. 03, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhpura (000823)
	Application Form Dy. No / Tracking ID & date of submission	(89V-V1L-WQ7A, 2025-01-13)
	Detail of Fee Submitted	93000.0, 2024-11-15,
	The proposed proprietary name / brand name	Nugovy Tablets 7mg
	Label Claim	EACH TABLET CONTAINS: - SEMAGLUTIDE.....7mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10s, 20s, 30s & 7s, -De-Controlled
	Shelf Life (Unit)	24 MonthStore below 30oC
	For generic drugs (me-too Status)	SEMMA 7MG TABLET by WEATHER FOLDS PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK -
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Rybelsus 7mg Tablet (M-340)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Deferred	
	Referred to Biological Evaluation & Research Division	
232	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Air Pharmaceuticals(Pvt.)Ltd Plot No's 74, 75-A, Small Industrial Estate, Kasur (000977)
	Application Form Dy. No / Tracking ID & date of submission	(8AG-MQ5-NUHP, 2024-02-29)
	Detail of Fee Submitted	30000.0, 63000.0 2023-12-15, 2025-04-11
	The proposed proprietary name / brand name	Epamet
	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-As per SRO,14's-As per SRO,20's-As per SRO,28's-As per SRO
	Shelf Life (Unit)	2 Year(s)below 30°C in dry cool environment
	For generic drugs (me-too Status)	DIAMPA-M 5mg/850mg by Getz Pharma
	Pharmacotherapeutic Group of (API)	SGLT2 Inhibitor, ATC code: A10BX12. Empagliflozin is a reversible competitive inhibitor of SGLT2 with an IC50 of 1.3 nM. It has a 5000-fold selectivity over human SGLT1 (IC50 of 6278 nM), responsible for glucose absorption in the gut. ATC code: A10BA02. Metformin is a biguanide with antihyperglycaemic effects, lowering both basal and postprandial plasma glucose.
	Name, address of Manufacturing site:	Novamed Pharmaceuticals(Pvt.)Ltd-28KM Ferozepur Road Lahore-
	Name & address of API manufacturer	Aarti Drugs Ltd Plot No 211 & 213, Road -2, G.I.D.C AT & Post Sarigam. City Sarigam– 396 155 Dist. Valsad Gujarat industrial estate ,Jiangsu Yong'an Pharmacy Company Limited,No.18 ,237 Proviancial, Road ,Economic Development Zone, Huai'an Jiangsu,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	Synjardy 5/850mg Boehringer Ingelheim Limited USA
	GMP status of the firm	.
	Evidence of approval of manufacturing facility	Novamed Pharmaceuticals DML (Formulation) 000590
	Evaluation Remarks	
	The applicant had selected “yes” in data already approved status of the application. It was checked that Empozin-M 5mg+850mg tablet of M/s Novamed Pharmaceuticals has already been approved in 322 meeting of RB. The firm has submitted differential fee of Rs63,000/- vide challan number 46607740284 dated 11.04.2025.	
	Decision	
	Approved	
233	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Horizon Healthcare (pvt.) ltd. 35-A Small Industrial Estate - Taxila (000856)
	Application Form Dy. No / Tracking ID & date of submission	(8GJ-GWG-R4WZ, 2025-04-29)
	Detail of Fee Submitted	93000.0, 2025-03-20,
	The proposed proprietary name / brand name	prosto 100mg
	Label Claim	Each Uncoated Tablet contains: Progesterone (USP).....100MG (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	AS PER SRO-As per SRO
	Shelf Life (Unit)	2 Yearnormal
	For generic drugs (me-too Status)	weather fold pharmaceuticals plot no 69/2 phase II, Industrial estate hattar
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	weather fold pharmaceuticals-plot no 69/2,phase II, industrial estate hattar kpk-
	The status in reference regulatory authorities	https://www.accessdata.fda.gov/drugsatfda_docs/lab
	Detail of previous approval	344M
	Evaluation Remarks	
	Prostone 100mg Tablet of Weather fold Pharmaceuticals was approved in the 344th meeting of the Registration Board. Applicant to submit License and GMP status of the Drug Substance Manufacturer and quality agreement between contract giver and acceptor.	
	Decision	
	Approved	
234	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(8M4-5PA-JZTJ, 2025-03-27)
	Detail of Fee Submitted	93000.0, 2024-11-22,
	The proposed proprietary name / brand name	ZANXIM 200mg Capsule
	Label Claim	Each capsule contains: Cefixime trihydrate eq. to cefixime 200mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	As per SRO -As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Trispan 200mg Capsule(Seraph Pharmaceutical, Islamabad)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	SERAPH PHARMACEUTICAL-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
	The status in reference regulatory authorities	M/s Laboratorios Normon, S.A., (Cefixima 200mg Capsule)Spain approved
	Detail of previous approval	316th meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
235	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Skywin Pharmaceutical Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpora road (000971)
	Application Form Dy. No / Tracking ID & date of submission	(8T8-HH4-8SB2, 2025-05-08)
	Detail of Fee Submitted	93000.0, 2025-04-25,
	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	1x10's, 2x7's, 2x10'-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Mgablin 2.5mg Tablet of M/s Genix Pharma

	Pharmacotherapeutic Group of (API)	Gabapentinoid class of drugs
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Tarlige Tablets 2.5mg of M/s Daiichi Sankyo Co., Ltd (PMDA Approved)
	Detail of previous approval	Mirogab 2.5mg Tablet approved in 344th Meeting of DRB
	Evaluation Remarks	
	Mirogab 2.5mg Tablet of Wimits Pharmaceuticals Pvt. Ltd. was approved in the 344th meeting of the Registration Board. Firm to submit undertaking that API from same source will be used as approved for Mirogab 2.5 mg tablet.	
	Decision	
	Approved	
236	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winlet Pharmaceuticals (Pvt) Ltd. 30-Km, Lahore Sargodha Raod, Sargodha (000874)
	Application Form Dy. No / Tracking ID & date of submission	(8UW-GUS-QQD5, 2025-01-13)
	Detail of Fee Submitted	93000.0, 2024-10-22,
	The proposed proprietary name / brand name	Betalet
	Label Claim	Each ml of lotion Contains: Betamethasone as valerate.....0.1% w/v
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1,s-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 °C
	For generic drugs (me-too Status)	Betnovate lotion
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Biogen life sciences -8-km chakbeli road rawat Rawalpindi-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	M-313
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
237	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(8V8-QS8-AH93, 2025-04-11)

	Detail of Fee Submitted	93000.0, 2025-02-20,
	The proposed proprietary name / brand name	K-PER 10MG/ML
	Label Claim	Each 1ml contains: Phytonadione.....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO/DPC-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 degree centigrade,protect from light,moisture and heat
	For generic drugs (me-too Status)	K-Lot 10mg/ml injection, M/s GT Pharma-Lahore
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s MISAQ PHARMACEUTICALS-7-B,Woven Garments Zone, Value Addition City,Khurrianwala-Sahianwala Road, Faisalabad.-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	K-SAQ 10MG/ML Injection, M-339
	Evaluation Remarks	
	K-Saq injection of Misaq Pharmaceuticals was approved in 339th meeting of the registration Board. The API manufacturer is Anhui Wanhe Pharmaceutical Co. Ltd, located in China. The facility holds a Certificate of Good Manufacturing Practices (GMP) valid until May 20, 2025. The vendor qualification is document-based, ensuring compliance with quality standards. Contract Manufacturing Agreement document outlines a toll manufacturing agreement between Quaper Private Limited and Misaq Pharmaceuticals for the production of injections and infusions. Inspection conducted by a panel of experts on 09-06-2023. Facility rated as satisfactory with functional HVAC systems. Separate areas for raw materials, packaging, and finished goods established. Liquid Ampoules Section includes machines for washing, filling, sealing, and autoclaving with capacities ranging from 10,200 vials/hour to 100,000 ampoules/hour.	
	Decision	
	Approved	
238	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Dyson Research Laboratories (Pvt.) Ltd 28-Km Ferozpur Road Lahore (000559)
	Application Form Dy. No / Tracking ID & date of submission	(8Y6-W1Y-5UNU, 2025-04-15)
	Detail of Fee Submitted	93000.0, 2025-01-06,
	The proposed proprietary name / brand name	Dypant
	Label Claim	Each vial contains: Pantoprazole sodium eq. to Pantoprazole (lyophilized powder).....40mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearStore below 25C.
	For generic drugs (me-too Status)	Toprzole Injection by Morgan Technologies Services (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Labs (Pvt.) Ltd.-Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad.-
	The status in reference regulatory authorities	Pantoprazole Sodium Injection by TEVA PARENTERAL, approved by US-FDA.

	Detail of previous approval	Panazole IV Injection 40mg, approved in 339 DRB meeting held on 06 - 08 August, 2024.
	Evaluation Remarks	
	Panazole 40mg IV Injection of Nio-Labs was approved in the 339th meeting of the Registration Board. Applicant shall submit: i. Applicant shall submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure. ii. 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.	
	Decision	
	Approved	
239	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Dyson Research Laboratories (Pvt.) Ltd 28-Km Ferozpur Road Lahore (000559)
	Application Form Dy. No / Tracking ID & date of submission	(91M-M7W-HQQW, 2025-04-08)
	Detail of Fee Submitted	93000.0, 2024-11-26,
	The proposed proprietary name / brand name	Dyket
	Label Claim	Each gram contains: Ketoconazole.....20mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	30mL, 60mL, 100mL an-As per SRO
	Shelf Life (Unit)	2 YearStore below 25° C.
	For generic drugs (me-too Status)	Ketowin Lotion by Shaigan Pharmaceuticals (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Labs (Pvt.) Ltd.-Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad.-
	The status in reference regulatory authorities	Nizoral Shampoo 2% by Thornton & Ross Ltd., approved by MHRA.
	Detail of previous approval	KT-Zole Lotion (Ketoconazole) 20mg, approved in Minutes of 336th meeting of Registration Board held
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
240	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Ameer Pharma Pvt Ltd 23 km sheikhupura road lahore (000604)

	Application Form Dy. No / Tracking ID & date of submission	(94J-QXR-4Y1U, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2025-01-14,
	The proposed proprietary name / brand name	Amefil 10mg/ml Suspension
	Label Claim	Each ml of reconstituted suspension contains: Sildenafil (as Citrate) ----- 10mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	112ml-De-Controlled
	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	SILAGRO NABI QASIM KARACHI
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Gray's Pharmaceuticals-Plot No 2, Street No N-3, National Industrial Zone, Rawat, Islamabad Islamabad Urban-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Selden 10mg/ml for oral suspension 343 DRB
	Evaluation Remarks	
	Selden 10mg/ml for oral suspension of Gray's Pharmaceuticals was approved in the 343rd meeting of the Registration Board. Applicant to submit quality agreement between contract giver and contract acceptor.	
241	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(94L-474-96QL, 2025-05-02)
	Detail of Fee Submitted	93000.0, 2024-11-25,
	The proposed proprietary name / brand name	MEMGIN 10MG/5ML ORAL SOLUTION
	Label Claim	Each 5ml contains: Memantine hydrochloride Eq. to Memantine 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 x 1-As per SRO
	Shelf Life (Unit)	24 MonthBelow 30°C
	For generic drugs (me-too Status)	Afdol 10mg/5ml oral solution
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	SERAPH PHARMACEUTICAL -Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
	The status in reference regulatory authorities	Memantine hydrochloride Oral Solution
	Detail of previous approval	MEMXIO 10mg/5ml oral solution, 336th minutes of meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as	

	an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
242	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winthrox Laboratories Pvt. Ltd K-219-A, SITE, Super Highway Phase II, Karachi (000807)
	Application Form Dy. No / Tracking ID & date of submission	(953-1YL-S387, 2025-04-15)
	Detail of Fee Submitted	93000.0, 2025-01-15,
	The proposed proprietary name / brand name	Deecal Soft Gelatin Capsule
	Label Claim	Each soft gel capsule contains: Cholecalciferol.....50,000 IU (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Solar-D Soft Gelatin Capsule 50,000 IU
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Biogen Life Sciences-8-Km, Chkbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	In Vita D3 50,000 Soft Capsule (MHRA approved)
	Detail of previous approval	3-D Capsule in 312th Meeting of Drug Registration Board Approved for Biogen Life Science
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
243	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Tovida Pharmaceuticals (Pvt) Ltd Plot No.7, Street No.S-07, RCCI Industrial Estate Islamabad (000996)
	Application Form Dy. No / Tracking ID & date of submission	(95G-8YS-E7TA, 2025-05-15)
	Detail of Fee Submitted	93000.0, 2024-11-07,
	The proposed proprietary name / brand name	TOVINEM 1GM INJECTION
	Label Claim	Each vial contains: Meropenem trihydrate eq to Meropenem 1g (USP Specifications))

	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	2 Year25C - 30C+-
	For generic drugs (me-too Status)	GENERIC DRUG
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Biogen Life Sciences -8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	MEROGEN Inj 1gm, M-312
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
244	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Himedic Pharmaceuticals Pvt Ltd 19 KM link Multan Road Lahore (000824)
	Application Form Dy. No / Tracking ID & date of submission	(997-L5J-JDER, 2025-04-15)
	Detail of Fee Submitted	93000.0, 2024-12-19,
	The proposed proprietary name / brand name	Inomed 500mg Tablet
	Label Claim	Each film coated tablet contains:- Levofloxacin Hemihydrate Eq. to Levofloxacin.....500mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's, 2x10's 100's-As per SRO
	Shelf Life (Unit)	2 YearStore at temperature 15 to 30 C away from sunlight
	For generic drugs (me-too Status)	Leflox 500mg Tablet (Getz Pharma (Pvt.) Ltd Karachi) Reg. No. 026163
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	ICU Pharmaceuticals SMC Pvt. Ltd.-Khewat No. 13/13, Khatooni No. 57/66 Mouza Mirpur Kehna, Tehsil Sharkpur, District Sheikhpura-
	The status in reference regulatory authorities	Levofloxacin (500mg) Film-coated Tablets M/s Accord Healthcare Limited, MHRA Approved
	Detail of previous approval	Minutes of 333rd meeting of Registration Board (19th To 20th December, 2023) Page No. 967
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as	

	an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
245	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winlet Pharmaceuticals (Pvt) Ltd. 30-Km, Lahore Sargodha Raod, Sargodha (000874)
	Application Form Dy. No / Tracking ID & date of submission	(9SE-793-DPXD, 2025-01-13)
	Detail of Fee Submitted	93000.0, 2024-10-22,
	The proposed proprietary name / brand name	Fibi 1%
	Label Claim	Each gm contains: Terbinafine hydrochloride 10.0mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1,s-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 °C
	For generic drugs (me-too Status)	Cutis Lotion by Tabros Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Biogen life sciences -8-km chakbeli road rawat Rawalpindi-
	The status in reference regulatory authorities	Lamisil Lotion 1% by M/s GSK of Netherland approved.
	Detail of previous approval	M-335
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
246	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medwell Pharmaceuticals 1 km, terbella road, lawrencepur, faqirabad Attock (000699)
	Application Form Dy. No / Tracking ID & date of submission	(9V2-DP8-DL5Z, 2025-04-04)
	Detail of Fee Submitted	93000.0, 2024-09-09,
	The proposed proprietary name / brand name	ESOME 20mg Capsule
	Label Claim	Each capsule contains: Esomeprazole magnesium Trihydrate equivalent to Esomeprazole (as enteric coated pellets) 20mg

	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14's -As per SRO,28's-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature.
	For generic drugs (me-too Status)	S-ZOLE capsule by NOVAMED Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-
	The status in reference regulatory authorities	Nexium Capsules by ASTRAZENECA
	Detail of previous approval	Staesso 20mg capsule (Meeting no. 329th)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
247	Decision	
	Approved	
	Case Category	Routine (Incharge Evaluation Cell)
	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	(9W4-T8Q-QENT, 2024-03-18)
	Detail of Fee Submitted	75000.0, 2024-01-03,
	The proposed proprietary name / brand name	Roxutopic
	Label Claim	Each gram contains: Ruxolitinib (as Ruxolitinib Phosphate).....15mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g-As per SRO,60g-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C in a cool and dry place.
	For generic drugs (me-too Status)	Nil
	Pharmacotherapeutic Group of (API)	Other dermatological preparations, agents for dermatitis, excluding corticosteroids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CHANGZHOU PHARMACEUTICAL FACTORY
	Detail of stability batches of drug product	3 batches: 1000g
	Documents for the procurement of API with approval from DRAP (in case of Import)	06-11-2022: Drug Import License submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Opzelura 1.5% Cream: PE performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IV-A
	The status in reference regulatory authorities	Opzelura 1.5% Cream (MHRA Approved)
	GMP status of the firm	03-01-2023: GMP certificate

	Evidence of approval of manufacturing facility	03-01-2023: GMP certificate Semi solid section (Cream / ointment / gel)
	Evaluation Remarks	
	Decision	
	Approved	
248	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Evolution Pharmaceuticals (Pvt.) Ltd. Plot no. 25,26 & 27, Street S-3, National Industrial Zone, Rawat, Islamabad. (000867)
	Application Form Dy. No / Tracking ID & date of submission	(9WU-9X6-QB3R, 2025-03-21)
	Detail of Fee Submitted	93000.0, 2024-10-08,
	The proposed proprietary name / brand name	Evozan tablet 20mg
	Label Claim	Each film coated tablet contains: Vonoprazan fumarate eq to vonoprazan 20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	2 Yeartore below 30°C. Protect from light. Reconstituted solution may be stored at 25°C for 24 hours or between 2-8°C for 7 days.
	For generic drugs (me-too Status)	Brand Name: Vonozan Tablet 20mg Registration holder: M/s Getz Pharma (Pvt.) Ltd
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Seraph Pharmaceutical.-Plot No. 210, Industrial Triangle Kahuta Road, Islamabad, -
	The status in reference regulatory authorities	Brand Name Takecab Tablet 20mg Marketing Authorization holder: Takeda Pharmaceutical Regulatory Authority: Japan (PMDA)
	Detail of previous approval	Vonocel 20mg Tablet,NO.F.6-5/2017-Reg-III(M-322)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
249	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Dyson Research Laboratories (Pvt.) Ltd 28-Km Ferozpur Road Lahore (000559)
	Application Form Dy. No / Tracking ID & date of submission	(9X4-ZTN-1N88, 2025-04-03)

	Detail of Fee Submitted	93000.0, 2024-11-26,
	The proposed proprietary name / brand name	Dyfrin
	Label Claim	Each ml contains: Iron as Ferric Carboxymaltose.....50mg.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10ml Vial.-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 30°C.
	For generic drugs (me-too Status)	FCM Injection by Genix Pharma.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Labs (Pvt.) Ltd.-Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad.-
	The status in reference regulatory authorities	Injectafer Solution IV by AM Regents, approved in USFDA.
	Detail of previous approval	MaltEvo 50mg/ml Solution for Injection approved in 331st Meeting of Registration Board held on 02nd
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
250	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Sarco Chemicals Industries 17-Km. Lahore Road Multan (000203)
	Application Form Dy. No / Tracking ID & date of submission	(9YX-Q9S-9U6T, 2025-05-08)
	Detail of Fee Submitted	93000.0, 2025-04-25,
	The proposed proprietary name / brand name	Medifer 30mg Capsule
	Label Claim	Each Capsule contains: Iron (as Ferric Maltol).....30mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x6's, 2x7's, 1 x 10-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Ferric maltol is a complexed iron supplement used to treat iron deficiency in adults.
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhpura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	ACCRUFER (Ferric Maltol) 30mg capsules of M/s Shield TX (UK) Ltd (USFDA Approved)

	Detail of previous approval	Maltofer 30mg Capsules approved in 343rd Meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
251	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welmed Pharmaceutical Industries (Pvt) Ltd. Plot No. 108/1 Road No. R-2 I.E. Gadoon. (000546)
	Application Form Dy. No / Tracking ID & date of submission	(A5N-Z5Z-H1DV, 2025-04-30)
	Detail of Fee Submitted	75000.0, 18000.0 2024-09-03, 2025-03-25
	The proposed proprietary name / brand name	Tazwel 1000mg Injection
	Label Claim	each Vial contains: Ceftazidime as Ceftazidime Pentahydrate 1g (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Fortazim 1000mg Injection IM/IV
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Limited.-Plot # 129, Sunder Industrial Estate Lahore.-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	Ceftazidime 1000mg Injection, Meeting No. 335th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
252	Case Category	Routine (Incharge Evaluation Cell)
	Name, address of Applicant.	Platinum Pharmaceuticals A-20,North Western Industrial Zone Bin Qasim,Karachi (000415)
	Application Form Dy. No / Tracking ID & date of submission	(A9A-2EW-Y3DS, 2024-04-17)

	Detail of Fee Submitted	75000.0, 2023-11-29,
	The proposed proprietary name / brand name	Elagolix 150mg Tablet
	Label Claim	Each film coated tablet contains: Elagolix (Elagolix as Sodium).....150mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's,14's,20's,30's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30C in a dry place and protect from su
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	(GnRH) receptor antagonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Kehui Pharmaceutical Co., Ltd
	Detail of stability batches of drug product	3 batches: 1000 tablet
	Documents for the procurement of API with approval from DRAP (in case of Import)	25-08-2023: Drug Import License submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Orilisa 150 mg Tablet: PE & CDP performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IV-A
	The status in reference regulatory authorities	Orilissa 150mg Tablet (AbbVie Pharmaceuticals) US FDA
	GMP status of the firm	14-06-2023: GMP Certificate
	Evidence of approval of manufacturing facility	14-06-2023: GMP Certificate specifies Tablet General Section
	Evaluation Remarks	
	Decision	
	Approved	
253	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Gray's Pharmaceuticals Plot NO2, Street No. N-3, RCCI Rawat Islamabad (000518)
	Application Form Dy. No / Tracking ID & date of submission	(AAG-BH3-G8VU, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2025-02-22,
	The proposed proprietary name / brand name	Tazopip 4.5gm Injection
	Label Claim	Each Vial Contains: Piperacillin as Sodium (USP) 4000mg Tazobactam as Sodium (USP) 500mg (Product Complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Zosyn 4.5gm INJECTION of M/s Regent Laboratories Reg# 070759
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	Wallace Pharma Evolutions-Kala wala stop, 20-KM, Lahore Jaranwala Road Lahore.-
	The status in reference regulatory authorities	Usfda Approved
	Detail of previous approval	Tazocin Injection ,DRB 331
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
254	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Q. Track Pharma Plot No. D-90-91, Sector-D H.I.T.E Lasbella, Hub, Balochistan. (000982)
	Application Form Dy. No / Tracking ID & date of submission	(ABP-EL3-N6A2, 2025-02-11)
	Detail of Fee Submitted	75000.0, 18000.0 2024-06-25, 2024-12-18
	The proposed proprietary name / brand name	OPENIUM Q
	Label Claim	Each vial contains Meropenem as trihydrate.....1g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	vial 1x1's-As per SRO
	Shelf Life (Unit)	2 Year20° to 25°C (68° to 77°F)
	For generic drugs (me-too Status)	Merem 1 g injection by Global Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Nicholas Pharmaceuticals, -plot # 34, St # SS-02 National industrial Zone Rawat Islamabad-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Ronem 1 g Injection) in its 307th meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
255	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Neutro Pharma (Pvt.) Ltd., 9.5-Km, Sheikhpura Road, Lahore (000576)

	Application Form Dy. No / Tracking ID & date of submission	(AEV-VZA-GJAV, 2025-01-08)
	Detail of Fee Submitted	93000.0, 207000.0 2024-09-24, 2024-11-28
	The proposed proprietary name / brand name	Dutamsin Soft Gelatin Capsule.
	Label Claim	Each hard gelatin capsule contains: Dutasteride (as soft gelatin capsule) 0.5 mg Tamsulosin hydrochloride (as modified release pellets).....0.4 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 20's, 30's -As per SRO
	Shelf Life (Unit)	2 Yearstore at 25C
	For generic drugs (me-too Status)	Maxflow-D Capsule by M/s CCL Pharmaceutical (Reg. 091571)Dutasteride/Tamsulosin hydrochloride 0.5 mg / 0.4 mg hard capsules (MHRA)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Biogen Life Sciences -8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Dutasteride/Tamsulosin hydrochloride 0.5 mg / 0.4 mg hard capsules (MHRA)
	Detail of previous approval	Dutaride-T Capsule in 335th meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
256	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Q. Track Pharma Plot No. D-90-91, Sector-D H.I.T.E Lasbella, Hub, Balochistan. (000982)
	Application Form Dy. No / Tracking ID & date of submission	(AHT-DHY-9D5Y, 2025-02-11)
	Detail of Fee Submitted	75000.0, 18000.0 2024-06-25, 2024-12-18
	The proposed proprietary name / brand name	OPENIUM Q
	Label Claim	Each vial contains Meropenem as trihydrate.....500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	vial 1x1's-As per SRO
	Shelf Life (Unit)	2 Year20° to 25°C (68° to 77°F)
	For generic drugs (me-too Status)	Merem 500mg injection by Global Pharma
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	M/s Nicholas Pharmaceuticals, -plot # 34, St # SS-02 National industrial Zone Rawat Islamabad-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Ronem 500mg Injection) in its 307th meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
257	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	De-Mont Research Laboratories (Pvt.) Ltd. 20 Km, Lahore-Sheikhupura Road, Sheikhupura, Pakistan (000844)
	Application Form Dy. No / Tracking ID & date of submission	(AQJ-ZUL-TL4M, 2025-03-11)
	Detail of Fee Submitted	75000.0, 18000.0 2024-06-27, 2025-03-05
	The proposed proprietary name / brand name	Dorzo-T Eye Drops
	Label Claim	Each ml contains: Dorzolamide HCL (USP) equivalent to Dorzolamide.....20 mg Timolol Maleate(USP) equivalent to Timolol.....5 mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Yearstore below 30 degree centigrade
	For generic drugs (me-too Status)	COSOPT ophthalmic Solution (SANTEN PHARMA CO.,LTD. JAPAN)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Medevo (Pvt) Ltd.-Plot No. 94, Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Dorzolamide/Timolol 20mg/ml + 5mg/ml Eye Drops, Solution USP (Accord-UK Ltd) UK
	Detail of previous approval	SURGIDOR-T EYE DROP (M-336)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	

258	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	McOlson Research Laboratories Pvt. Ltd Plot No. 02, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhupura Pakistan (000664)
	Application Form Dy. No / Tracking ID & date of submission	(ASD-Y9L-Z3JP, 2025-06-04)
	Detail of Fee Submitted	93000.0, 2025-05-13,
	The proposed proprietary name / brand name	Zygogest 100 mg Vaginal Tablets
	Label Claim	Each Vaginal Tablet Contains : Progesterone..... 100 mg (as per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearBelow 30C
	For generic drugs (me-too Status)	Prostone 100 mg Tablets
	Pharmacotherapeutic Group of (API)	Progestin
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot # 69/2. Phase-II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	https://www.accessdata.fda.gov/drugsatfda_docs/lab
	Detail of previous approval	Prostone 100mg Tablet Approved in DRB 344th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
259	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	MEDPHARM RESEARCH LAB 28 KM FEROZPUR ROAD LAHORE (000878)
	Application Form Dy. No / Tracking ID & date of submission	(AUU-SZN-PAA8, 2025-01-09)
	Detail of Fee Submitted	75000.0, 18000.0 2024-04-26, 2024-11-25
	The proposed proprietary name / brand name	ASECTOR DRY POWDER INJECTION 40MG
	Label Claim	Each vial Contains: Esomeprazole Sodium eq. to Esomeprazole = 40mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	as per DPC-As per SRO
	Shelf Life (Unit)	2 Yearbelow 24 degree
	For generic drugs (me-too Status)	Nexum 40mg vial
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	May & Baker Pvt Ltd-HOUSE NO 23, STREET NO 5 SECTOR B, GHORI BLOCK BAHRIA TOWN, Pakistan-

	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Esozium 40mg dry powder vial 327th meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
260	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Kanel Pharma Plot No. 6, Street No. SS-3, National Industrial Zone, Rawat (000758)
	Application Form Dy. No / Tracking ID & date of submission	(AWG-UBT-WHMX, 2025-04-09)
	Detail of Fee Submitted	93000.0, 2025-03-11,
	The proposed proprietary name / brand name	Vancobin
	Label Claim	Each vial contains: Vancomycin HCl eq. to Vancomycin.....500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30c
	For generic drugs (me-too Status)	Vancomycin 500mg Injection by Abbott
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/S BIO-LABS PVT LTD-Plot No. 145, Industrial Triangle Kahuta Road Islamabad-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	Vanconext 500mg Injection, 343rd Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
261	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medwell Pharmaceuticals 1 km, terbella road, lawrencepur, faqirabad Attock (000699)
	Application Form Dy. No / Tracking ID & date of submission	(AXY-T2Z-DM5N, 2025-04-07)

	Detail of Fee Submitted	75000.0, 18000.0 2024-05-23, 2024-11-28
	The proposed proprietary name / brand name	DESWELL Syrup 0.5mg/ml
	Label Claim	Each ml contains: Desloratadine.....0.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	120ml-As per SRO,60ml-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature.
	For generic drugs (me-too Status)	Neo-Antial Syrup by SAMI Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-
	The status in reference regulatory authorities	Clarinex Syrup by SCHERING, USA
	Detail of previous approval	Varidine 0.5mg/ml Syrup (Meeting 297th)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
262	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Albro Pharmaceuticals 340/s Quiad-e-Azam Industrial Estate Kotlakhpat Lahore (000175)
	Application Form Dy. No / Tracking ID & date of submission	(B35-JEL-E6BT, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2025-01-16,
	The proposed proprietary name / brand name	Vifil Suspension 10mg/ml
	Label Claim	Each ml of reconstituted Suspension Contains: Sildenafil (as Citrate) ----- 10mg/ml
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	112-As per SRO
	Shelf Life (Unit)	2 YearStore at temperature below 25C. Keep away from sunlight, heat and moisture.
	For generic drugs (me-too Status)	LIQREV (CMP Pharma U.S.A)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/S Gray's Pharmaceuticals -Plot No: 2, Street No: N-3, National Industrial Zone Rawat, Islamabad-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Selden Suspension
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation,	

	specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
263	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Kanel Pharma Plot No. 6, Street No. SS-3, National Industrial Zone, Rawat (000758)
	Application Form Dy. No / Tracking ID & date of submission	(BAH-SAY-HV57, 2025-04-09)
	Detail of Fee Submitted	93000.0, 2025-03-11,
	The proposed proprietary name / brand name	Keloside
	Label Claim	Each 2ml ampoule contains: Thiocolchicoside 4mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2ml x 5's-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30c
	For generic drugs (me-too Status)	Muscoril injection by Searle pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/S SERAPH PHARMACEUTICAL-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
	The status in reference regulatory authorities	ANSM France approved
	Detail of previous approval	Tiofrel, 335th Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
264	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Delux Chemical Industries LT, 26 A-1, Landhi Industrial Area, Karachi (000033)
	Application Form Dy. No / Tracking ID & date of submission	(BB8-W3A-XBMA, 2025-05-19)
	Detail of Fee Submitted	93000.0, 2025-02-03,
	The proposed proprietary name / brand name	Duvalra 10mg/ml Suspension
	Label Claim	Each ml of Reconstituted Suspension Contains: Sildenafil (as Citrate) ----- 10mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	112ml-As per SRO

	Shelf Life (Unit)	2 YearAt room Temperature
	For generic drugs (me-too Status)	Nabi Qasim Karachi
	Pharmacotherapeutic Group of (API)	Rakshit Pharma, India
	Name, address of Manufacturing site:	Gray's Pharmaceuticals-Plot No: 2, Street No: N-3, National Industrial Zone Rawat, Islamabad-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	M-343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
265	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	PERFECT PHARMA (PVT) LTD 5Km, Manga Road, Raiwind, Lahore (000469)
	Application Form Dy. No / Tracking ID & date of submission	(BEG-BHP-L5V6, 2025-06-04)
	Detail of Fee Submitted	93000.0, 2025-05-12,
	The proposed proprietary name / brand name	Haemofect 100mg/5ml Injection
	Label Claim	Each 5ml ampoule contains: Iron (III) hydroxide sucrose complex eq. to elemental Iron 100mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	5's Ampoules-As per SRO
	Shelf Life (Unit)	2 Year25
	For generic drugs (me-too Status)	Venofer 100 mg/5ml by M/s OBS Reg. No. 085031
	Pharmacotherapeutic Group of (API)	Anti Anemic Drug
	Name, address of Manufacturing site:	May & Baker (Pvt) Ltd-45 Km Dina Nath Multan Road Lahore-
	The status in reference regulatory authorities	Venofer 100mg/5ml by M/s Vifor Pharma, approved by TGA Australia
	Detail of previous approval	Bakrofor 100mg/5ml Injection by Minutes of 323rd meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
266	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Pasteur & Fleming Pharma Plot # 70A , Phase -3, Road No-04, Industrial Estate Hattar, K.P.K. Pakistan (000945)
	Application Form Dy. No / Tracking ID & date of submission	(BGH-7AX-XBNJ, 2025-02-19)
	Detail of Fee Submitted	93000.0, 2024-12-18,
	The proposed proprietary name / brand name	Pentazole 40mg Tablet
	Label Claim	Each film coated tablet contains: Pantoprazole as sodium sesquihydrate.....40mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO,14's -As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature.
	For generic drugs (me-too Status)	Neege tablet 40mg by SAMI Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-
	The status in reference regulatory authorities	Protonix 40mg tablet by Wyeth Ayerst Laboratories
	Detail of previous approval	Pantostal 40mg Tablet (Meeting 331st)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
267	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Pak Risen Pharmaceuticals Plot No. 3, Block B, Phase I-II, Industrial Estate, Hattar (000573)
	Application Form Dy. No / Tracking ID & date of submission	(BGH-8T5-EDQV, 2025-01-20)
	Detail of Fee Submitted	75000.0, 18000.0 2024-07-08, 2024-12-23
	The proposed proprietary name / brand name	Danzo 2.25gm Injection
	Label Claim	Each Vial Contains: Piperacillin as Sodium (USP) 2000mg Tazobactam as Sodium (USP) 250mg (Product Complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C

	For generic drugs (me-too Status)	Zosyn 2.25gm INJECTION of M/s Regent Laboratories Reg# 070759
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wallace Pharma Evolutions-Kala wala stop, 20-KM, Lahore Jaranwala Road Lahore.-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Tazocin Injection ,DRB 331
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
268	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(BH5-NDZ-H7HQ, 2025-04-16)
	Detail of Fee Submitted	93000.0, 2024-11-29,
	The proposed proprietary name / brand name	Limpa 5mg/2.5mg/1000mg XR Tablet
	Label Claim	Each Film Coated Extended Release tablet contains: Empagliflozin.....5mg Linagliptin.....2.5mg (Immediate release coat) Metformin HCl.....1000mg (Extended release core)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
	Shelf Life (Unit)	2 YearStore 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	TRIJARDY XR- empagliflozin, linagliptin, metformin hydrochloride tablet, extended release of M/s BOEHRINGER INGELHEIM PHARMACEUTICALS, INC. (USFDA Approved)
	Detail of previous approval	Limpa-Met 5/2.5/1000mg XR Tablet approved in 340th meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation,	

	specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
269	Case Category	Routine (Incharge Evaluation Cell)
	Name, address of Applicant.	High-Q Pharmaceuticals Plot# 224 and 225/1, sector 23, Korangi Industrial area, Karachi (000597)
	Application Form Dy. No / Tracking ID & date of submission	(BHD-Q68-YADN, 2024-03-21)
	Detail of Fee Submitted	30000.0, 2023-12-05,
	The proposed proprietary name / brand name	Trelog
	Label Claim	Each film coated tablet contains: Trelagliptin as succinate....50mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	10s-As per SRO, 14s-As per SRO, 1s-As per SRO, 20s-As per SRO, 28s-As per SRO, 30s-As per SRO, 4s-As per SRO, 56s-As per SRO, 7s-As per SRO
	Shelf Life (Unit)	24 Month(s) Store below 30°C
	For generic drugs (me-too Status)	Trelaget Tablet by Getz Pharma
	Pharmaceutical Group of (API)	Antidiabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Fuxin Long Rui Pharma
	Detail of stability batches of drug product	3 batches: 4347 Tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	03-03-2022: Clearance certificate
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Treptin Tablet of Horizon: PE and CDP performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IV-A
	The status in reference regulatory authorities	Zafatek 50mg Tablet by Takeda Pharma, Approved in PMDA (Japan)
	GMP status of the firm	17-05-2023: GMP certificate inspection date
	Evidence of approval of manufacturing facility	17-09-2021: Tablet (General) section
	Evaluation Remarks	
	Decision	
	Approved	
270	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	INVENTOR PHARMA PVT LTD Plot No. K-196 S.I.T.E, Super Highway Phase-II (000866)
	Application Form Dy. No / Tracking ID & date of submission	(BHE-RW3-7BHH, 2025-04-25)

	Detail of Fee Submitted	93000.0, 2024-12-24,
	The proposed proprietary name / brand name	INVENAFIL 10mg/ml SUSPENSION
	Label Claim	Each ml of reconstituted suspension contains: Sildenafil (as Citrate) ----- 10mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	112ml-De-Controlled
	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	SILAGRO NABI QASIM KARACHI
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Gray's Pharmaceuticals-Plot No 2, Street No N-3, National Industrial Zone, Rawat, Islamabad Islamabad Urban-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Selden 10mg/ml for oral suspension, 343
	Evaluation Remarks	
	Selden 10mg/ml for oral suspension of Gray's Pharmaceuticals was approved in 343rd meeting of the Registration Board. Applicant to submit License and GMP certificate of Drug Substance manufacturer,	
	Decision	
	Approved	
271	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Rogen Pharmaceuticals Plot No. 30, S-4, National Industrial Zone Rawat, Islamabad. (000692)
	Application Form Dy. No / Tracking ID & date of submission	(BHP-48H-9HZQ, 2025-04-30)
	Detail of Fee Submitted	93000.0, 2025-01-03,
	The proposed proprietary name / brand name	Rogzone
	Label Claim	Each vial contains: Sterile Powder of Ceftriaxone Sodium USP eq. to Ceftriaxone.....500mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1,s-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	Oxidil
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Shawan pharmaceuticals-Plot # 37, Road NS-1, RCCI Rawat-
	The status in reference regulatory authorities	Approved by US FDA USFDA approves Alembic's Ketorolac tromethamine injection USP
	Detail of previous approval	Axon 500mg Injection, 333th meeting of Registration Board (19th to 20th December, 2023)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a	

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

Decision

Approved

272	Case Category	Routine (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	(BHW-7WH-5EYW, 2024-04-30)
	Detail of Fee Submitted	30000.0, 2024-04-17,
	The proposed proprietary name / brand name	M-Tor 5mg/10mg Tablet
	Label Claim	Each film coated tablet contains: Amlodipine (as Amlodipine Besylate) 5mg Atorvastatin (as Atorvastatin Calcium).....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO,14's-As per SRO,15's-As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO,50's-As per SRO,7's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 25°C (Excursions permitted between 15°C to 30°C). Protect from sunlight & moisture.
	For generic drugs (me-too Status)	VASTOR-AM Tablet by ATCO
	Pharmacotherapeutic Group of (API)	Calcium channel blocker with lipid modifying agent
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	JPR Labs Pvt Ltd India,Prudence pharma chem India
	Detail of stability batches of drug product	3 batches: 5000 Tablet
	Documents for the procurement of API with approval from DRAP (in case of Import)	Amlodipine: 04-04-2023 Clearance certificate, Atorvastatin: 11-05-2023 clerance certificate
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Caduet Tablet: PE and CDP performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IV-A
	The status in reference regulatory authorities	CADUET TABLET 5 MG/10 MG (USFDA Approved)
	GMP status of the firm	22-02-2023: GMP certificate inspection date
	Evidence of approval of manufacturing facility	22-02-2023: GMP certificate Tablet (General) section
	Evaluation Remarks	
	Decision	
	Deferred	

	The application will be considered on its own turn.	
273	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Skywin Pharmaceutical Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road (000971)
	Application Form Dy. No / Tracking ID & date of submission	(BJL-S8V-5NLS, 2025-05-08)
	Detail of Fee Submitted	93000.0, 2025-04-25,
	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	1x10's, 2x7's, 2x10'-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Mgablin 15mg Tablet of M/s Genix Pharma
	Pharmacotherapeutic Group of (API)	Gabapentinoid class of drugs
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Tarlige Tablets 15mg of M/s Daiichi Sankyo Co., Ltd (PMDA Approved)
	Detail of previous approval	Mirogab 15mg Tablet approved in 344th Meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
274	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(BP7-XZU-VEV5, 2025-04-30)
	Detail of Fee Submitted	93000.0, 2024-11-25,
	The proposed proprietary name / brand name	Deslop 2.5 mg/ 5 ml Syrup
	Label Claim	Each ml of Syrup contains: Desloratidine... 0.5 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 x 1-As per SRO
	Shelf Life (Unit)	24 MonthBelow 30°C
	For generic drugs (me-too Status)	Neo-Antial

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	SERAPH PHARMACEUTICAL -Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
	The status in reference regulatory authorities	AERIUS FOR CHILDREN SYRUP
	Detail of previous approval	DESENT 2.5mg/5ml Syrup, 336th Minutes of Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
275	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Davis Pharmaceutical Laboratories Plot No. 121, Industrial Triangle Area, Kahuta Road (000432)
	Application Form Dy. No / Tracking ID & date of submission	(BR9-JEG-8YQR, 2025-03-04)
	Detail of Fee Submitted	93000.0, 2024-10-30,
	The proposed proprietary name / brand name	Zonacid 10mg Tablet
	Label Claim	Each Film coated Tablet Contains Vonoprazan Fumarate equivalent to Vonoprazan 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	2 YearBelow 30c
	For generic drugs (me-too Status)	Vonozan 10mg Tablet
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/S Linta Pharmaceutical Pvt Ltd-Plot No. 03, Street No. S-5 National Industrial Zone, Rawat, Islamabad-
	The status in reference regulatory authorities	Tekeda, Japan
	Detail of previous approval	Vonopraz 10mg Tablet, DRB No. 336
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	

276	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Tovida Pharmaceuticals (Pvt) Ltd Plot No.7, Street No.S-07, RCCI Industrial Estate Islamabad (000996)
	Application Form Dy. No / Tracking ID & date of submission	(BRL-BWP-9D46, 2025-05-15)
	Detail of Fee Submitted	93000.0, 2024-11-07,
	The proposed proprietary name / brand name	Taf-acno 20mg
	Label Claim	Each Soft Gel capsule Contains Isotretinoin 20mg BP Specs
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO -De-Controlled
	Shelf Life (Unit)	2 Year(s)30C+-
	For generic drugs (me-too Status)	generic product
	Pharmacotherapeutic Group of (API)	A retinoid used for treating severe acne.
	Name, address of Manufacturing site:	Biogen Pharmaceuticals -8-km Chakbeli Road Rawat-Rawalpindi -
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Biotan Capsule 20mg (approved in 312th meeting
	Evaluation Remarks	
	Biotan 20mg Capsule of Biogen Pharmaceuticals was approved in 312th meeting of the Registration Board. Firm shall submit1. approval of Drug Substance Manufacturer2. API procurement documents	
	Decision	
	Approved	
277	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	STANDARD DRUG COMPANY Plot No. E-6-A, S.I.T.E (000118)
	Application Form Dy. No / Tracking ID & date of submission	(BRS-X9Q-MNJD, 2025-04-25)
	Detail of Fee Submitted	93000.0, 2024-12-24,
	The proposed proprietary name / brand name	STANDENAFIL 10mg/ml SUSPENSION
	Label Claim	EACH ml OF RECONSTITUTED SUSPENSION CONTAINS SILDENAFIL (as Citerate)....10mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	112ml-De-Controlled
	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	SILAGRO NABI QASIM KARACHI
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Gray's Pharmaceuticals-Plot No 2, Street No N-3, National Industrial Zone, Rawat, Islamabad Islamabad Urban-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Selden 10mg/ml for oral suspension
	Evaluation Remarks	

	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
278	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Jinnah Pharmaceuticals Pvt Ltd 13 Km Lahore Road Multan (000578)
	Application Form Dy. No / Tracking ID & date of submission	(BRZ-LAX-U12W, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2025-01-25,
	The proposed proprietary name / brand name	J.Agra
	Label Claim	Each ml of reconstituted suspension contains Sildenafil (as Citrate).....10mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	112ml-De-Controlled
	Shelf Life (Unit)	2 YearBelow 30%
	For generic drugs (me-too Status)	Selden 10mg/ml (Grays Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/S Grays Pharmaceuticals -Plot No 2, Street No N-3, National Industrial Zone Rawat-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Selden 10mg/ml (M-343)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
279	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Pine Pharmaceuticals Plot No, 40, S-4, Rawat Industrial Estate, Islamabad (000955)
	Application Form Dy. No / Tracking ID & date of submission	(BT9-EL1-VTT8, 2024-09-20)
	Detail of Fee Submitted	75000.0, 18000.0 2024-08-09, 2024-09-12
	The proposed proprietary name / brand name	Pritam 100mg/ml oral solution
	Label Claim	Each ml contains: Levetiracetam 100mg

	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30 ° C
	For generic drugs (me-too Status)	Epian 100mg/ml Oral Solution, Pharmasol (Pvt) Ltd Plot No. 549, Sundar Industrial Estate, Lahore, Pakistan,Reg#093124
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	SERAPH PHARMACEUTICAL-Plot no 210 Seraph pharma Model Town Kahuta Road Islamabad-
	The status in reference regulatory authorities	KEPPRA 100mg/ml Oral Solution,UCB Pharma Limited 208 Bath Road Slough Berkshire SL1 3WE United Kingdom, approved in FDA.
	Detail of previous approval	339th Meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
280	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(D2X-LY9-QEQR, 2025-04-16)
	Detail of Fee Submitted	93000.0, 2024-11-29,
	The proposed proprietary name / brand name	Limpa 25mg/5mg/1000mg XR Tablet
	Label Claim	Empagliflozin.....25mg Linagliptin.....5mg (Immediate release coat) Metformin HCl.....1000mg (Extended release core)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
	Shelf Life (Unit)	2 YearStore 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	TRIJARDY XR- empagliflozin, linagliptin, metformin hydrochloride tablet, extended release of M/s BOEHRINGER INGELHEIM PHARMACEUTICALS, INC. (USFDA Approved)

	Detail of previous approval	Limpa-Met 25/5/1000mg XR Tablet approved in 340th meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
281	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Skywin Pharmaceutical Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road (000971)
	Application Form Dy. No / Tracking ID & date of submission	(D3U-ZYE-4YUA, 2025-02-11)
	Detail of Fee Submitted	93000.0, 2024-12-23,
	The proposed proprietary name / brand name	Ceftriax 250mg IM Injection
	Label Claim	Each Vial contains: Ceftriaxone Sodium(USP) eq. to Ceftriaxone.....250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO / DPC-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Oxidil 250mg IM Injection of M/s SAMI
	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	Ceftriaxone 250mg powder for solution for injection vials (USFDA Approved)
	Detail of previous approval	Welcef 250mg IM Injection approved in 326th meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
282	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	M/s Daneen Pharma (Pvt) Ltd Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, (000688)

	Application Form Dy. No / Tracking ID & date of submission	(D7T-D1G-78BQ, 2025-04-08)
	Detail of Fee Submitted	93000.0, 2024-12-06,
	The proposed proprietary name / brand name	Vomiset
	Label Claim	Each film coated tablet contains: Granisetron (as the hydrochloride) 2mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's,2's,5's,7's,10's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C. Protect from heat, light & Moisture
	For generic drugs (me-too Status)	Sitensa 2mg Tablet by Genix Pharma Pvt Ltd
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Genix Pharma Pvt Ltd -44, 45B, KORANGI CREEK ROAD, KARACHI. PAKISTAN-
	The status in reference regulatory authorities	Kytril by Atnahs Pharma Netherlands B.V.
	Detail of previous approval	Sitensa 2mg Tablet DRB 339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
283	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(DDW-L93-ZYD1, 2025-06-04)
	Detail of Fee Submitted	93000.0, 2025-05-27,
	The proposed proprietary name / brand name	Capileo 2% Topical Solution
	Label Claim	Each ml contains: Minoxidil 20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	60ml-As per SRO
	Shelf Life (Unit)	2 YearStore at Room Temperature
	For generic drugs (me-too Status)	REGRO 2% W/V Topical Solution (Reg. No. 038386) Manufacturer: Seatlte Pvt. Ltd
	Pharmacotherapeutic Group of (API)	Antihypertansive
	Name, address of Manufacturing site:	Wimits Pharmaceuticals (Pvt)Ltd-Plot No 129 Sundar Indusrial Estate, Raiwind Road Lahore-
	The status in reference regulatory authorities	Bosley Woman 2 Minoxidil Topical Solution of M/s Bosley Inc. (USFDA Approved)
	Detail of previous approval	343 DRB Meeting ; REGAIN 2% Topical Solution

	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
284	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	M/s Daneen Pharma (Pvt) Ltd Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, (000688)
	Application Form Dy. No / Tracking ID & date of submission	(DH5-4LY-18A9, 2025-04-15)
	Detail of Fee Submitted	93000.0, 2025-01-21,
	The proposed proprietary name / brand name	Qinglif-M XR
	Label Claim	Each film coated tablet contains: Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin.....5mg Metformin HCl.....1000mg (as extended Release)
	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 YearStore below 30°C. Protect from heat, light & Moisture
	For generic drugs (me-too Status)	Daglozin-M XR Tablet by Genix Pharma Pvt Ltd (123455)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Genix Pharma Pvt Ltd -44, 45B, KORANGI CREEK ROAD, KARACHI. PAKISTAN-
	The status in reference regulatory authorities	Xigduo®XR by AstraZeneca Pharmaceuticals LP
	Detail of previous approval	Daglozin-M XR Tablet 5mg/1000mg DRB 343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
285	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	M/s Daneen Pharma (Pvt) Ltd Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, (000688)

	Application Form Dy. No / Tracking ID & date of submission	(DHB-N55-L66J, 2025-05-20)
	Detail of Fee Submitted	93000.0, 2024-11-12,
	The proposed proprietary name / brand name	Zuvaroz-A
	Label Claim	Each Film Coated Tablet Contains: Rosuvastatin (as Rosuvastatin calcium) 10mg Amlodipine (as Amlodipine besylate).....5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's, 10's, 14's, 20'-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C. Protect from heat, light and moisture.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Rosuvastatin is in a class of medications called HMG-CoA reductase inhibitors. Amolodipine belongs to the group of drugs called dihydropyridine calcium channel blockers.
	Name, address of Manufacturing site:	Genix Pharma (Pvt.) Ltd.-44, 45-B, Korangi Creek Road, Karachi-75190, Pakistan-
	The status in reference regulatory authorities	Rosuvastatin/amlodipine Krka 10 mg/5 mg film-coated tablets mfg. by TAD Pharma, Germany (HPRA, Ireland)
	Detail of previous approval	Rosca-A 10mg/5mg (DRB 339)
	Evaluation Remarks	
	ROSCA-A 10mg/5mg Tablet of M/s Genix Pharma is approved in 339 meeting of Registration Board.	
286	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medwell Pharmaceuticals 1 km, terbella road, lawrencepur, faqirabad Attock (000699)
	Application Form Dy. No / Tracking ID & date of submission	(DLR-WNG-74H3, 2025-04-04)
	Detail of Fee Submitted	93000.0, 2024-11-28,
	The proposed proprietary name / brand name	TAPENO Tablet 75mg
	Label Claim	Each Immediate release Film-coated Tablet containing: Tapentadol (as HCl) 75 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 x 10's-As per SRO,10's-As per SRO,20's-As per SRO,30's-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature.
	For generic drugs (me-too Status)	Tapento IR Tablet by Sami Pharma.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-
	The status in reference regulatory authorities	Nucynta by Ortho McNeil Janssen
	Detail of previous approval	Tapent IR 75mg Tablet (Meeting 340th)
	Evaluation Remarks	

	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
287	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(DMW-4HX-RXMT, 2025-05-08)
	Detail of Fee Submitted	93000.0, 2025-04-15,
	The proposed proprietary name / brand name	Amoxi 156.25mg/5ml Dry Suspension
	Label Claim	Each 5ml of reconstituted suspension contains: Amoxicillin trihydrate eq. to Amoxicillin.....125mg Potassium clavulanate eq. to Clavulanic acid....31.25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	90mls/ As per SRO / -As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Augmentin 156.25mg/5ml Dry suspension of M/s GSK Pakistan
	Pharmacotherapeutic Group of (API)	penicillin combinations, including beta-lactamase inhibitors
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhpura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	Augmentin 156.25mg/5ml Dry Suspension of M/s GlaxoSmithKline Research Triangle Park, NC 27709 (USFDA Approved)
	Detail of previous approval	Amoxi 156.25mg/5ml Dry Suspension approved in 344th Meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
288	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

	Name, address of Applicant.	Solaris Life Sciences Private Limited , Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992)
	Application Form Dy. No / Tracking ID & date of submission	(DX3-42P-9LY5, 2025-06-02)
	Detail of Fee Submitted	93000.0, 2025-04-28,
	The proposed proprietary name / brand name	Procetrol-4mcg Soft gel Capsules
	Label Claim	Each soft gelatin capsule contains: Paricalcitol.....4mcg
	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)	Parical 4mcg Soft gelatin Capsule Reg. No. 124504
	Pharmacotherapeutic Group of (API)	Vitamin D2 and Vitamin D analogs
	Name, address of Manufacturing site:	Biogen Life Sciences-8-KM, Chakbeli Road, Rawat, Rawalpindi-PAKISTAN.-
	The status in reference regulatory authorities	FDA Approved. Zemplar (Paricalcitol) 4mcg Soft Gel Capsule
	Detail of previous approval	DRB M-339 By the Name of Parical 4mcg Soft gelatin Capsule
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
289	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welcome Pakistan Trading Pharma (Pvt) Ltd Chakri Interchange, Gangawala (000987)
	Application Form Dy. No / Tracking ID & date of submission	(DZS-VNY-H755, 2025-02-11)
	Detail of Fee Submitted	75000.0, 18000.0 2024-06-27, 2024-12-07
	The proposed proprietary name / brand name	Ettirox 120mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Etoricoxib.....120mg (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)	Starcox Tablet by Getz 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	UK MHRA
	Detail of previous approval	339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
290	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	MEDPHARM RESEARCH LAB 28 KM FEROPUR ROAD LAHORE (000878)
	Application Form Dy. No / Tracking ID & date of submission	(E59-Y3Q-6ZAH, 2025-02-11)
	Detail of Fee Submitted	93000.0, 2024-11-15,
	The proposed proprietary name / brand name	Tanzomed 2.25gm Injection
	Label Claim	Each Vial contains: Piperacillin (as Piperacillin Sodium) 2.0 g Tazobactam (as Tazobactam Sodium) 0.25 g (as lyophilized powder for IV injection)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO / DPC-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Tanzo 2.25gm Injection of M/s Bosch Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhpura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	Zosyn Injection of M/s Wyeth (USFDA Approved)
	Detail of previous approval	Tazopip 2.25gm Injection approved in 335th Meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	

291	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medwell Pharmaceuticals 1 km, terbella road, lawrencepur, faqirabad Attock (000699)
	Application Form Dy. No / Tracking ID & date of submission	(EP3-PEN-8Z7B, 2025-04-04)
	Detail of Fee Submitted	93000.0, 2024-09-09,
	The proposed proprietary name / brand name	ESOME 40mg Capsule
	Label Claim	Each capsule contains: Esomeprazole magnesium Trihydrate equivalent to Esomeprazole (as enteric coated pellets) 40mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14's -As per SRO,28's-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature.
	For generic drugs (me-too Status)	S-ZOLE capsule by NOVAMED Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-
	The status in reference regulatory authorities	Nexium Capsules by ASTRAZENECA
	Detail of previous approval	Staesso 40mg Capsule (Meeting no. 329th)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
292	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Jenner Pharmceuticals Pvt. Ltd Plot No. 03, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhupura (000823)
	Application Form Dy. No / Tracking ID & date of submission	(ERX-UV7-B2R3, 2025-01-23)
	Detail of Fee Submitted	93000.0, 2024-11-15,
	The proposed proprietary name / brand name	Nugovy Tablets 14mg
	Label Claim	EACH TABLET CONTAINS: - SEMAGLUTIDE.....14mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10s, 20s, 30s & 7s, -De-Controlled
	Shelf Life (Unit)	24 MonthStore below 30oC
	For generic drugs (me-too Status)	SEMMA 14MG TABLET by WEATHER FOLDS PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK -
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Rybelsus 14mg Tablet (M-340)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Deferred	
	Referred to Biological Evaluation & Research Division	
293	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	wellbornpharmachem&biologicals Plot No.51/1,52/2 Phase I & II Industrial Estate, Hattar-Pakistan (000657)
	Application Form Dy. No / Tracking ID & date of submission	(G2D-EBH-ZJ2Q, 2025-01-15)
	Detail of Fee Submitted	93000.0, 2024-12-30,
	The proposed proprietary name / brand name	Seldiborn
	Label Claim	10MG/ML
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	112ml-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 C
	For generic drugs (me-too Status)	Selden 10mg/5ml
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Grays Pharmaceuticals-plot No 2 ,street no 3 national industrial zone Rawat-
	The status in reference regulatory authorities	Liqrev
	Detail of previous approval	Selden 10mg/ml Reg #124748
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
294	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Air Pharmaceuticals(Pvt.)Ltd Plot No's 74, 75-A, Small Industrial Estate, Kasur (000977)

Application Form Dy. No / Tracking ID & date of submission	(G6B-JPV-6461, 2025-05-07)
Detail of Fee Submitted	30000.0, 63000.0 2023-12-15, 2025-04-11
The proposed proprietary name / brand name	Epamet
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	14's-As per SRO,28's-As per SRO
Shelf Life (Unit)	2 Year(s)below 30°C in dry cool environment
For generic drugs (me-too Status)	DIAMPA-M by Getz Pharma Reg no. 093084
Pharmacotherapeutic Group of (API)	. Empagliflozin: SGLT2 Inhibitor, ATC code: A10BX12. Empagliflozin is a reversible competitive inhibitor of SGLT2 with an IC50 of 1.3 nM. It has a 5000-fold selectivity over human SGLT1 (IC50 of 6278 nM), responsible for glucose absorption in the gut. Metformin: ATC code: A10BA02. Metformin is a biguanide with antihyperglycaemic effects, lowering both basal and postprandial plasma glucose.
Name, address of Manufacturing site:	Novamed Pharmaceuticals(Pvt.)Ltd-28KM Ferozepur Road Lahore-
Name & address of API manufacturer	Aarti Drugs Ltd Plot No 211 & 213, Road -2, G.I.D.C AT & Post Sarigam. City Sarigam– 396 155 Dist. Valsad Gujarat industrial estate India,Jiangsu Yong'an Pharmacy Company Limited,No.18 ,237 Proviancial, Road ,Economic Development Zone, Huai'an Jiangsu,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	Synjardy 12.5/500mg by Boehringer Ingelheim Limited USA
GMP status of the firm	.
Evidence of approval of manufacturing facility	Novamed Pharmaceuticals DML (Formulation) 000590.
Evaluation Remarks	
The applicant selected "yes" in data approved category for corss reference. It was checked that Empozin-M 12.5mg+500mg tablet was approved in 322 RB meeting.	
Decision	
Approved	
295	Case Category Contract Manufacturing (Incharge Evaluation Cell)

	Name, address of Applicant.	Effort Pharmaceuticals (Pvt.) Ltd., 28-Km, Ferozepur Road (000879)
	Application Form Dy. No / Tracking ID & date of submission	(G6V-Z6A-BYPN, 2025-03-08)
	Detail of Fee Submitted	93000.0, 2024-11-12,
	The proposed proprietary name / brand name	Eftor 30mg/1ml Injection
	Label Claim	Each ml contains: Ketorolac Tromethamine.....30mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at temperature 15 to 30 C away from sunlight
	For generic drugs (me-too Status)	Toradol injection 30mg/ml by M/s Martin Dow
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	May & Baker Pharmaceuticals (Pvt.) Ltd.-45 Km, Thokar Multan road, Lahore-
	The status in reference regulatory authorities	Ketorolac Trometamol injection 30mg/ml MHRA approved
	Detail of previous approval	Minutes of 323rd meeting of Registration Board (6th to 8th December, 2022) Page No. 2207
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
296	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Jenner Pharmceuticals Pvt. Ltd Plot No. 03, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhpura (000823)
	Application Form Dy. No / Tracking ID & date of submission	(G7U-LMZ-YA8T, 2025-01-23)
	Detail of Fee Submitted	93000.0, 2024-12-20,
	The proposed proprietary name / brand name	Jenlac Injection 30mg
	Label Claim	Each 1ml ampoule contains: Ketorolac tromethamine 30mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30C
	For generic drugs (me-too Status)	TALKEE Injection By GT Pharma PVT.LTD
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	GT Pharma (Pvt.) Ltd.-Plot # 713 Sundar Industrial Estate, Lahore-
	The status in reference regulatory authorities	Toradol Injection by Martin Dow Pharmaceuticals (Pak) Ltd
	Detail of previous approval	Kelac 30mg/ml Injection is registered for M/S Stallion Pharma in M-336
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
297	Case Category	Contract Manufacturing (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	(GE5-NTB-PBZ3, 2025-06-04)
	Detail of Fee Submitted	93000.0, 2025-05-19,
	The proposed proprietary name / brand name	D-Penem 250mg Injection
	Label Claim	Each vial contains: Sterile Doripenem Monohydrate eq to Anhydrous Doripenem 250 mg.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's or as per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore in a cool, dry place below 30 degrees Celsius.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Carbapenems (Beta-Lactam Antibiotic)
	Name, address of Manufacturing site:	Fleming Pharmaceuticals-23-Km, Lahore-Sheikhupura Road, Lahore-
	The status in reference regulatory authorities	DORIBAX® 250mg Injection, by Janssen Pharmaceuticals NV
	Detail of previous approval	Dori-F Injection, Minutes of 323rd meeting of Registration Board (6th to 8th December, 2022)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	

298	Case Category	Routine (Incharge Evaluation Cell)
	Name, address of Applicant.	Caliph Pharmaceuticals Plot 17, Special Industrial Zone Risalpur, KPK (000748)
	Application Form Dy. No / Tracking ID & date of submission	(GN8-28R-Q7PQ, 2024-04-30)
	Detail of Fee Submitted	30000.0, 2024-04-02,
	The proposed proprietary name / brand name	CALTRIM-B CREAM
	Label Claim	Each gram of cream contains: Clotrimazole.....10mg Betamethasone (as Dipropionate).....0.5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)25°C
	For generic drugs (me-too Status)	Lotricort Cream By M/s Dermagen Pharma Pakistan
	Pharmacotherapeutic Group of (API)	Antifungal with glucocorticoid
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	ENVEE DRUGS PVT.LTD. N. H. No. 8, Dumral-387 355, Ta. Nadiad, Dist: Kheda, Gujarat, India,HALCYON LABS PVT. LTD., Plot No. 409, Phase – IV, GIDC Industrial estate, Naroda, Ahmedadad –382 330, Gujarat, INDIA
	Detail of stability batches of drug product	3 batches: 500 tubes
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clotrimazole: 02-08-2021: AD attested invoice submitted, Betamethasone: 08-06-2023 Clearance certificate
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Loticort cream by Dermagen: PE studies performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IV-A
	The status in reference regulatory authorities	LOTRIDERM 0.05% w/w/1.0% w/w Cream (MHRA Approved)
	GMP status of the firm	13-03-2023: GMP certificate inspection date
	Evidence of approval of manufacturing facility	17-01-2019: letter for grant of additional section specifies cream / ointment / lotion section.
299	Evaluation Remarks	
	Decision	
	Deferred	
299	The application will be considered on its own turn.	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	CIBA Pharmaceuticals (Pvt) Ltd. A-371, Nooriabad S.I.T.E., Karachi, Hyderabad Super Highway, District Jamshoro (000825)
	Application Form Dy. No / Tracking ID & date of submission	(GNS-DT6-W64T, 2025-02-12)

	Detail of Fee Submitted	75000.0, 18000.0 2024-08-08, 2024-11-05
	The proposed proprietary name / brand name	CHOLECIB
	Label Claim	Each ml ampoule contains: Cholecalciferol 5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's, 5's or and As p-As per SRO
	Shelf Life (Unit)	2 YearBELOW 30 DEGREE
	For generic drugs (me-too Status)	Novel-D injection
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/S. Biogen Life Sciences-8-KM, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Cholecalciferol (5mg) injection (IM/ Oral) by M/s Bouchara Recordate Laboratories DE GAULLE GAL IMMEUBLE LE WILSON GAULLE 70 AVENUE DU GENERAL DE GAULLE.92800, PUTEAUX, ILE-DE-FRANCE
	Detail of previous approval	Gen-D3 Injection 5mg/ml (DRB Meeting 323)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
300	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Swiss Pharmaceuticals Pvt. Ltd. A/159, S.I.T.E.- II, Super Highway (000438)
	Application Form Dy. No / Tracking ID & date of submission	(GR3-9G2-E88J, 2025-04-18)
	Detail of Fee Submitted	93000.0, 2024-11-21,
	The proposed proprietary name / brand name	Zoledon 5mg/100ml infusion
	Label Claim	Each 100ml vial contains: Zoledronic acid as monohydrate.....5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Zometa Infusion by Novartis Pharma Karachi (072551)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Biogen Life Sciences-8-KM, Chak Beli Road, Rawat, Islamabad-Pakistan-
	The status in reference regulatory authorities	ZOLEDRONIC ACID 5MG/100ML SOLUTION FOR INFUSION MHRA Approved.

	Detail of previous approval	Gen-Zole 5mg/100ml infusion, Minutes of 333rd meeting of Registration Board (19th To 20th December)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
301	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	M/s Daneen Pharma (Pvt) Ltd Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, (000688)
	Application Form Dy. No / Tracking ID & date of submission	(GS3-X7M-SDR8, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2025-01-21,
	The proposed proprietary name / brand name	Qinglif-M XR
	Label Claim	Each film coated tablet contains: Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin.....10mg Metformin HCl.....500mg(as Extended Release)
	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 YearStore below 30°C. Protect from heat, light & Moisture
	For generic drugs (me-too Status)	Daglozin-M XR Tablet by Genix Pharma Pvt Ltd (123455)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Genix Pharma Pvt Ltd -44, 45B, KORANGI CREEK ROAD, KARACHI. PAKISTAN-
	The status in reference regulatory authorities	Xigduo®XR by AstraZeneca Pharmaceuticals LP
	Detail of previous approval	Daglozin-M XR Tablet 10mg/500mg DRB 343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
302	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

	Name, address of Applicant.	Kanel Pharma Plot No. 6, Street No. SS-3, National Industrial Zone, Rawat (000758)
	Application Form Dy. No / Tracking ID & date of submission	(GV6-4WL-3EBD, 2025-05-20)
	Detail of Fee Submitted	93000.0, 2025-04-15,
	The proposed proprietary name / brand name	NELANDO
	Label Claim	Each 4ml ampoule contains: Ondansetron as HCl Dihydrate.....8 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4ml-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30c
	For generic drugs (me-too Status)	Zofran Injection by Novartis
	Pharmacotherapeutic Group of (API)	Selective 5-HT ₃ serotonin- receptor antagonist
	Name, address of Manufacturing site:	M/S SERAPH PHARMACEUTICAL-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Reston Injection, 330th Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
303	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Aulton Pharmaceuticals Plot # 84/1,Block A, Phase 5 , Industrial Estate Hattar, KPK, (000828)
	Application Form Dy. No / Tracking ID & date of submission	(GVR-AUJ-PYQ5, 2025-02-11)
	Detail of Fee Submitted	75000.0, 18000.0 2024-06-26, 2024-12-24
	The proposed proprietary name / brand name	Zonst Syrup
	Label Claim	Each 5ml contains: Ondansetron (as Hydrochloride Dihydrate).....4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO / DPC-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Zofran Syrup by M/s GSK
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s BioMark Pharmaceuticals-Plot No. 527, Sundar Industrial Estate,Lahore-
	The status in reference regulatory authorities	Zofran Oral Solution by GSK (USFDA approved)
	Detail of previous approval	“APTRON 4mg/5ml Syrup” 316th meeting of DRB

	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
304	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(GVW-M8P-ETUY, 2025-05-08)
	Detail of Fee Submitted	93000.0, 2025-04-15,
	The proposed proprietary name / brand name	Caripz 1.5mg Capsule
	Label Claim	Each Capsule contains: Cariprazine Hydrochloride equivalent to Cariprazine.....1.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x5's, 1x6's, 2x7's,-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Caripz 1.5mg Capsule of M/s Genix Pharma (approved in M-324)
	Pharmacotherapeutic Group of (API)	Atypical antipsychotics
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhpura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	VRAYLAR (cariprazine) 1.5mg capsules AbbVie, Inc. North Chicago, IL 60064 USA Product of Hungary (USFDA Approved)
	Detail of previous approval	Carip 1.5mg Capsule approved in 343rd meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
305	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wallace Pharma Evolutions Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (000951)

	Application Form Dy. No / Tracking ID & date of submission	(H1R-P6V-51TX, 2025-05-14)
	Detail of Fee Submitted	93000.0, 2025-01-22,
	The proposed proprietary name / brand name	Emzaa-ML Tablet
	Label Claim	Each Film Coated Extended Release Tablet contains: Empagliflozin.....10mg Linagliptin.....5mg (As immediate release core) Metformin Hydrochloride*.....1000MG (As extended release core) (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	DIAMPA LXR Tablet by Getz Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Welmark Pharmaceuticals-Plot No. 122, Phase-V, Block-B, Industrial Estate, Hattar.-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Empeg-ML XR Tablet, DRB 340
	Evaluation Remarks	
	EMPEG-ML XR TABLET of Welmark Pharmaceuticals was approved in 340th meeting of the Registration Board. Applicant to submit quality agreement and License and GMP status of the following DS manufacturers: Fuxin Long Rui Pharmaceutical CO., Ltd for EmpagliflozinAnhui Haikang Pharmaceutical Co., Ltd for LinagliptinAARTI DRUGS LIMITED for Metformin	
	Decision	
	Approved	
306	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winbrains Research Laboratories Plot No. 69/1 Block B, Phase I-II Industrial Estate, Hattar, Pakistan (000725)
	Application Form Dy. No / Tracking ID & date of submission	(H3G-EG1-SATX, 2024-08-20)
	Detail of Fee Submitted	75000.0, 2024-06-25,
	The proposed proprietary name / brand name	Ferrina 500mg Injection
	Label Claim	Each 10ml Vial Contains: Iron as Ferric Carboxymaltose.....500mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C.
	For generic drugs (me-too Status)	FERINJECT 500mg/10ml INJECTION by RG Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK. -
	The status in reference regulatory authorities	USFDA Approved

	Detail of previous approval	FERRINA 500mg/10ml Injection approved in M-343 DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
307	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Swiss Pharmaceuticals Pvt. Ltd. A/159, S.I.T.E.-II, Super Highway (000438)
	Application Form Dy. No / Tracking ID & date of submission	(H3R-YTW-85XG, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2025-02-17,
	The proposed proprietary name / brand name	MIROGAB Tablet 15mg
	Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to Mirogabalin.....15mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Brand Name: Mirogab 15mg Tablet., Manufacturer/ Brand Holder: Wimits Pharmaceuticals Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt.) Ltd. -Plot No. 129, Sundar Industrial Estate Raiwind Road Lahore Pakistan-
	The status in reference regulatory authorities	Manufacturer Name: Daiichi Sankyo Co., Ltd., Brand Name & Strength: Tarlige Tablets 10mg., Reference Regulatory Authority: PMDA Approved.
	Detail of previous approval	Mirogab 15mg Tablet, M-344
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
308	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Swiss Pharmaceuticals Pvt. Ltd. A/159, S.I.T.E.-II, Super Highway (000438)

	Application Form Dy. No / Tracking ID & date of submission	(H53-XP5-EDPL, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2025-02-17,
	The proposed proprietary name / brand name	MIROGAB Tablet 2.5mg
	Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to Mirogabalin.....2.5mg.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Brand Name: Mirogab 2.5mg Tablet, Manufacturer/ Brand Holder: Wimits Pharmaceuticals Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt.) Ltd. -Plot No. 129, Sundar Industrial Estate Raiwind Road Lahore Pakistan-
	The status in reference regulatory authorities	Manufacturer Name: Daiichi Sankyo Co., Ltd, Brand Name & Strength: Tarlige Tablets 2.5mg, Reference Regulatory Authority: PMDA Approved.
	Detail of previous approval	Mirogab 2.5mg Tablet, M-344
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
309	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Hicon Pharmaceuticals 131- Industrial estate Hayatabad (000583)
	Application Form Dy. No / Tracking ID & date of submission	(H5J-4YJ-359U, 2025-01-13)
	Detail of Fee Submitted	93000.0, 2024-10-25,
	The proposed proprietary name / brand name	DEXCON 60MG CAPSULE
	Label Claim	Each capsule contains: Dexlansoprazole (as dual delayed release pellets).....60mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30's-As per SRO
	Shelf Life (Unit)	3 YearRoom Temperature
	For generic drugs (me-too Status)	Razodex Capsule by Getz Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Biogen Life Sciences-8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan-
	The status in reference regulatory authorities	Dexilant capsule USFDA Approved

	Detail of previous approval	Minutes of 335th meeting of Registration Board, with brand name of LANSOGEN 60 mg Capsule.
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
310	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(H9V-YSD-M4QW, 2025-05-13)
	Detail of Fee Submitted	93000.0, 2024-12-30,
	The proposed proprietary name / brand name	Revogest 10mg Tablet
	Label Claim	Each film coated tablet Contains: Dydrogesterone..... 10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO,20's-As per SRO,30's-As per SRO,40's-As per SRO
	Shelf Life (Unit)	2 YearStore in a cool and dry place below 30°C
	For generic drugs (me-too Status)	Dirogest 10mg tablet manufactured by Zafa pharmaceutical laboratories Ltd.,
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Platinum Pharmaceuticals (Pvt) Ltd.,-Plot no. A-20, North Western Industrial Zone, Bin Qasim Authority, Karachi-75020, Pakistan.-
	The status in reference regulatory authorities	Medicines Evaluation Board (MEB)
	Detail of previous approval	Dydrogesterone 10mg tablet (Approved in M-343)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
311	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Kanel Pharma Plot No. 6, Street No. SS-3, National Industrial Zone, Rawat (000758)

	Application Form Dy. No / Tracking ID & date of submission	(HDX-7HY-A1UN, 2025-05-14)
	Detail of Fee Submitted	93000.0, 2025-03-11,
	The proposed proprietary name / brand name	Vancobin
	Label Claim	Each vial contains: Vancomycin HCl eq. to Vancomycin...1gm
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30c
	For generic drugs (me-too Status)	Vancomycin Injection by Abbott
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/S BIO-LABS PVT LTD-Plot No. 145, Industrial Triangle Kahuta Road Islamabad-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	Vanconext 1gm Injection, 343rd Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
312	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Synchro Pharmaceuticals 77-Industrial Estate, Kot Lakhpat (000575)
	Application Form Dy. No / Tracking ID & date of submission	(HGM-SL3-X4H5, 2025-04-28)
	Detail of Fee Submitted	93000.0, 2025-01-21,
	The proposed proprietary name / brand name	Synagra
	Label Claim	Each ml of reconstituted suspension contains: Sildenafil (as Citrate) 10mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	112ml-De-Controlled
	Shelf Life (Unit)	2 Yearstore at room temperature
	For generic drugs (me-too Status)	Silagro 10mg/ml for Oral Suspension-Nabi Qasim, Karachi
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Gray's Pharmaceuticals-Plot # 2, Street No # N-3, National Industrial Zone Rawat, Islamabad-Pakistan.-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Selden, M-343

	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
313	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winthrox Laboratories Pvt. Ltd K-219-A, SITE, Super Highway Phase II, Karachi (000807)
	Application Form Dy. No / Tracking ID & date of submission	(HJ8-DAR-3SX5, 2025-05-14)
	Detail of Fee Submitted	93000.0, 2025-01-15,
	The proposed proprietary name / brand name	Wonozan Tablet 20mg
	Label Claim	Each Film Coated Tablet Contains: Vonoprazan as Fumarate.....20mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Vonnp 20mg Tablet by Weather Folds Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s WnsFeild Pharmaceuticals-Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	PMDA Japan Approved
	Detail of previous approval	Verozen Tablet 20mg approved in Meeting of 322 Drug Registration Board for Wnsfeild Pharmaceuticals
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
314	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	M/s Daneen Pharma (Pvt) Ltd Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, (000688)

	Application Form Dy. No / Tracking ID & date of submission	(HLW-UYT-9GYG, 2025-02-12)
	Detail of Fee Submitted	75000.0, 18000.0 2024-08-01, 2024-12-17
	The proposed proprietary name / brand name	Zuvaroz Plus
	Label Claim	Each film coated tablet contains: Rosuvastatin calcium equivalent to Rosuvastatin 10mg Ezetimibe 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's, 9's, 10's, 14's-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30°C. Protect from heat, light and moisture.
	For generic drugs (me-too Status)	Rolip EZE 10mg/10mg Mfg. by Hilton Pharma Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Genix Pharma (Pvt.) Ltd.-44, 45-B, Korangi Creek Road, Karachi-75190, Pakistan-
	The status in reference regulatory authorities	Alzil plus 10 mg/10 mg filmcoated tablets mfg. by Ferrer International, SA, Spain
	Detail of previous approval	Rosca Plus 10mg/10mg, DRB 336
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
315	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Allmed (Pvt.) Ltd Plot # 590 Sunder Industrial Estate Raiwind Road Lahore-Pakistan (000645)
	Application Form Dy. No / Tracking ID & date of submission	(HPL-AD3-DQHW, 2025-04-14)
	Detail of Fee Submitted	93000.0, 2024-12-30,
	The proposed proprietary name / brand name	Merone
	Label Claim	Each vial of powder for solution for injection or infusion contains: 570.78 mg Meropenem Trihydrate equivalent to 500 anhydrous Meropenem.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30 C
	For generic drugs (me-too Status)	Meropen 500mg Injection by Solaris Life Sciences Private Limited Reg # 123681
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	Wallace Pharma Evolutions-Kala Wala Stop 20-KM, Lahore Jaranwala Road, Lahore-
	The status in reference regulatory authorities	Meropenem 500mg Injection by AstraZeneca Pharmaceuticals LP Wilmington, DE 19850
	Detail of previous approval	Minutes of 323rd meeting of Registration Board (6th to 8th December, 2022)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
316	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Variant Pharmaceuticals (Pvt.) Ltd Plot # 5 M2-Pharmazone, 26KM lahore-sharaqpur road, sheikhupura (000914)
	Application Form Dy. No / Tracking ID & date of submission	(HPS-398-R34T, 2025-01-15)
	Detail of Fee Submitted	93000.0, 2025-01-02,
	The proposed proprietary name / brand name	SELDEN 10MG/ML FOR SUSPENSION
	Label Claim	Each ml of reconstituted suspension contains: Sildenafil (as Citrate).....10mg (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	112ML-De-Controlled
	Shelf Life (Unit)	2 YearStore below 25 degree centigrade, away from sunlight and heat
	For generic drugs (me-too Status)	Sildenafil for oral suspension, 10mg/ml Suspension,Amneal Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Gray's Pharmaceuticals-lot # 2, Street No # N-3, National Industrial Zone Rawat, Islamabad-Pakistan-
	The status in reference regulatory authorities	Sildenafil for oral suspension, 10mg/ml Suspension,Amneal Pharmaceuticals , USFDA APPROVED
	Detail of previous approval	REG NO. 124748, SELDIN 10MG/ML FOR ORAL SUSPENSION
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned	

	notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
317	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	CIBA Pharmaceuticals (Pvt) Ltd. A-371, Nooriabad S.I.T.E., Karachi, Hyderabad Super Highway, District Jamshoro (000825)
	Application Form Dy. No / Tracking ID & date of submission	(HQZ-375-91UL, 2025-04-18)
	Detail of Fee Submitted	93000.0, 2024-12-05,
	The proposed proprietary name / brand name	Cibacef 2g IV Injection
	Label Claim	Each vial contains: Ceftriaxone Sodium eq. to Ceftriaxone.....2g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Oxidil 2g IV Injection Reg No. 086609 M/s SAMI Pharmaceuticals Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s. Swiss Pharmaceutiucals Pvt. Ltd.-A/159, S.I.T.E. II Super Highway, Karachi – Pakistan-
	The status in reference regulatory authorities	Ceftriaxone 2g Powder for Solution for Injection or Infusion CP Pharmaceuticals Ltd Ash Road North Wrexham LL13 9UF UK MHRA Approved
	Detail of previous approval	STRACEF 2g IV Injection, Minutes of 336th meeting of Registration Board (4th to 6th June, 2024)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
318	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	CUREXA HEALTH (PVT.) LIMITED 517 SUNDER INDUSTRIAL ESTSTE (000864)
	Application Form Dy. No / Tracking ID & date of submission	(HRH-EJE-VWN3, 2025-03-17)
	Detail of Fee Submitted	93000.0, 2024-11-22,
	The proposed proprietary name / brand name	Merzel 500mg Injection IV

	Label Claim	Each vial contains: Meropenem (as Trihydrate) 500mg (Blended with sterile sodium carbonate)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 30°C. Keep in a dry place. Protect from light.
	For generic drugs (me-too Status)	Romero Injection
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Next Pharmaceuticals-Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad-
	The status in reference regulatory authorities	MERREM Injection (by Pfizer) USFDA Approved
	Detail of previous approval	MENEPOR 500 mg Injection IV, 296
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
319	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Himedic Pharmaceuticals Pvt Ltd 19 KM link Multan Road Lahore (000824)
	Application Form Dy. No / Tracking ID & date of submission	(HT9-BBN-4NBT, 2025-05-12)
	Detail of Fee Submitted	93000.0, 2024-12-31,
	The proposed proprietary name / brand name	Trapra Tablet
	Label Claim	Each Film Coated Tablet Contains: Paracetamol.....325mg Tramadol Hydrochloride....37.5mg (USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's, 2x10's, 3x10-As per SRO
	Shelf Life (Unit)	2 YearStore at temperature 15 to 30 C away from sunlight
	For generic drugs (me-too Status)	Tonoflex-P Tablet (Sami Pharmaceuticals (Pvt.) Ltd. Karachi) Reg. No. 067163
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	ICU Pharmaceuticals SMC Pvt. Ltd.-Khewat No. 13/13, Khatooni No. 57/66 Mouza Mirpur Kehna, Tehsil Sharkpur, District Sheikhpura-
	The status in reference regulatory authorities	Tramadol hydrochloride and Paracetamol 37.5 mg/325 mg Film-coated Tablets (tramadol hydrochloride and Paracetamol) - PL 30684/0222 (MHRA Approved)
	Detail of previous approval	Minutes of 333rd meeting of Registration Board (19th To 20th December, 2023) Page No.967

	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
320	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Well Care Pharmaceuticals A/7 PSIE (000465)
	Application Form Dy. No / Tracking ID & date of submission	(HXZ-764-28VY, 2025-06-02)
	Detail of Fee Submitted	93000.0, 2024-11-08,
	The proposed proprietary name / brand name	D-Let injection
	Label Claim	Each ampoule contains: Cholecalciferol (Vitamin D3)..5mg (eq 200,000IU of Vitamin D)
	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)	By. scotman pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/S BIO LAB-PLOT NO 145 KAHUTA INDUSTRIAL TRIANGLE ISLAMABAD-
	The status in reference regulatory authorities	https://recordati.com/wp-content/uploads/2023/06/brochure-2022-1-en.pdf
	Detail of previous approval	M-323
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
321	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Evolution Pharmaceuticals (Pvt.) Ltd. Plot no. 25,26 & 27, Street S-3, National Industrial Zone, Rawat, Islamabad. (000867)
	Application Form Dy. No / Tracking ID & date of submission	(HY6-53R-64PB, 2025-01-06)
	Detail of Fee Submitted	93000.0, 2024-10-08,

	The proposed proprietary name / brand name	Evomalt Injection/Infusion 50 mg Iron/ml; 10 ml
	Label Claim	Each 10 ml ampoule contains: Ferric carboxymaltose corresponding to elemental iron.....500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	2 Yeartore below 30°C. Protect from light. Reconstituted solution may be stored at 25°C for 24 hours or between 2-8°C for 7 days.
	For generic drugs (me-too Status)	Brand Name: Fercari Registration holder: Hilton Pharma. Status in regulatory authorities Fercari Dispersion for Injection/Infusion 50 mg Iron/ml; 10 ml is DRAP Approved.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Seraph Pharmaceutical. -Plot No. 210, Industrial Triangle Kahuta Road, Islamabad, -
	The status in reference regulatory authorities	Brand Name Ferinject. Marketing Authorization holder: Vifor Pharma UK Limited. Regulatory Authority: Ferinject ® Dispersion for Injection/Infusion is Approved in USFDA
	Detail of previous approval	Altom, No.F-119-PRVC/2024(PR-II)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
322	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	CIBA Pharmaceuticals (Pvt) Ltd. A-371, Nooriabad S.I.T.E., Karachi, Hyderabad Super Highway, District Jamshoro (000825)
	Application Form Dy. No / Tracking ID & date of submission	(HYU-Z7W-7R1J, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2025-01-23,
	The proposed proprietary name / brand name	ORGID
	Label Claim	Each Vial Contains: Omeprazole as Sodium.....40
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearBELOW 30 DEGREE
	For generic drugs (me-too Status)	RISEK 40mg INJECTION (GETZ PHARMA)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Biogen Life Sciences-8-KM, Chakbeli Road, Rawat, Rawalpindi-

	The status in reference regulatory authorities	USFDA APPROVED
	Detail of previous approval	Reflex Injection 40mg IV (312 DRB Meeting)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
323	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Regal Pharmaceuticals Plot No. 2-A, Street No. S-5 National Industrial Zone RCCI Rawat (000839)
	Application Form Dy. No / Tracking ID & date of submission	(HZD-S3L-T5BE, 2025-02-11)
	Detail of Fee Submitted	75000.0, 2024-05-21,
	The proposed proprietary name / brand name	REXOZ 40 MG INJECTION
	Label Claim	Each vial contains: Omeprazole sodium equ. to Omeprazole 40mg (Sweras's Specifications)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1,S-Controlled
	Shelf Life (Unit)	2 YearStore below 250c
	For generic drugs (me-too Status)	Ruling 40mg Injection Manufacturer: HIGH-Q International Karachi
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	SWERA PHARMACEUTICALS-PLOT 27 STREET S-4 INDUTRIAL AREA RAWAT ISLAMABAD-
	The status in reference regulatory authorities	yeOmeprazole 40mg powder for solution for infusion Country where sold / registered; UK Manufactured by: SANDOZ Park view.
	Detail of previous approval	SWEpra 40 MG INJ M-322
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
324	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	M/s Daneen Pharma (Pvt) Ltd Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road,

		(000688)
	Application Form Dy. No / Tracking ID & date of submission	(J8H-NBH-XUWN, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2025-01-21,
	The proposed proprietary name / brand name	Qinglif-M XR
	Label Claim	Each film coated tablet contains: Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin.....5mg Metformin HCl.....500mg(as Extended Release)
	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 YearStore below 30°C. Protect from heat, light & Moisture
	For generic drugs (me-too Status)	Daglozin-M XR Tablet by Genix Pharma Pvt Ltd (123455)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Genix Pharma Pvt Ltd -44, 45B, KORANGI CREEK ROAD, KARACHI. PAKISTAN-
	The status in reference regulatory authorities	Xigduo®XR by AstraZeneca Pharmaceuticals LP
	Detail of previous approval	Daglozin-M XR Tablet 5mg/500mg DRB 343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
325	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Martin Dow Marker Limited 7, Jail Road Quetta. (000028)
	Application Form Dy. No / Tracking ID & date of submission	(JEW-WH5-WJ8N, 2025-04-08)
	Detail of Fee Submitted	93000.0, 2024-12-09,
	The proposed proprietary name / brand name	Dologab CR Tablets 330mg
	Label Claim	Each Extended-Release tablet contains: Pregabalin.....330 mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30s-As per SRO
	Shelf Life (Unit)	2 YearBelow 30
	For generic drugs (me-too Status)	Revogab
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	Wimits Pharmaceutical (Pvt.) Ltd-Plot # 129, Sunder Industrial Estate, Lahore – Pakistan-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Pregabalin 330mg ER Tablet ,335
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
326	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Tovida Pharmaceuticals (Pvt) Ltd Plot No.7, Street No.S-07, RCCI Industrial Estate Islamabad (000996)
	Application Form Dy. No / Tracking ID & date of submission	(JGE-PDY-JAA3, 2025-05-15)
	Detail of Fee Submitted	93000.0, 2024-11-07,
	The proposed proprietary name / brand name	TOVIDART
	Label Claim	Each hard gelatin capsule contains: Dutasteride (as soft gelatin capsule) 0.5 mg Tamsulosin hydrochloride (as modified release pellets) 0.4 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO -De-Controlled
	Shelf Life (Unit)	2 Year(s)30C+-
	For generic drugs (me-too Status)	generic product
	Pharmacotherapeutic Group of (API)	Dutasteride is testosterone-5-alpha-reductase inhibitors. ATC code: G04C B02. It reduces circulating levels of dihydrotestosterone (DHT) by inhibiting both type 1 and type 2, 5 α -reductase isoenzymes which are responsible for the conversion of testosterone to DHT. Tamsulosin is an alpha-1A and alpha-1B adrenergic receptor antagonist used to treat benign prostatic hyperplasia, ureteral stones, prostatitis.
	Name, address of Manufacturing site:	Biogen Life Sciences Pharmaceuticals -8-km Chakbeli Road Rawat-Rawalpindi -
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Dutaride-T Capsule
	Evaluation Remarks	
	Dutaride-T Capsule of M/s Biogen was approved in 335th meeting of Registration Board. Firm shall submit: 1. approval of Drug Substances Manufacturers2. API procurement documents	
	Decision	

	Approved	
327	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Kanel Pharma Plot No. 6, Street No. SS-3, National Industrial Zone, Rawat (000758)
	Application Form Dy. No / Tracking ID & date of submission	(JH5-VHZ-AJQD, 2025-05-14)
	Detail of Fee Submitted	93000.0, 2025-03-11,
	The proposed proprietary name / brand name	Kadisdin
	Label Claim	Each 5ml of syrup contains; Desloratadine 2.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30c
	For generic drugs (me-too Status)	Neo-Antial Syrup by Sami Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/S SERAPH PHARMACEUTICAL-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	DESENT, 336th Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
328	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Jinnah Pharmaceuticals Pvt Ltd 13 Km Lahore Road Multan (000578)
	Application Form Dy. No / Tracking ID & date of submission	(JMG-ANT-NQG4, 2025-05-15)
	Detail of Fee Submitted	93000.0, 2025-01-25,
	The proposed proprietary name / brand name	Vonoprajin
	Label Claim	Each Film Coated Tablet Contain:- Vonoprazan as fumarate 20mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year15-30C
	For generic drugs (me-too Status)	: VPN-20 Tablet Reg No. 110204 by Helix Pharma Karachi
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	World Biz Pharmaceuticals Company-340, Phase-II, Industrial Estate, Multan -
	The status in reference regulatory authorities	PMDA Japan Approved
	Detail of previous approval	M-339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
329	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Onyx Pharmaceuticals 30-A small Industrial Estate mansehra (000440)
	Application Form Dy. No / Tracking ID & date of submission	(JQ2-YLZ-TPN4, 2025-05-19)
	Detail of Fee Submitted	93000.0, 2025-01-24,
	The proposed proprietary name / brand name	Dynox
	Label Claim	Each ml of reconstituted suspension contains: Sildenafil (as Citrate) ----- 10mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	112ml-De-Controlled
	Shelf Life (Unit)	2 YearAt room temperature
	For generic drugs (me-too Status)	Silagro 10mg/ml for oral suspension by Nabi Qasim-Karachi
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Gray's Pharmaceuticals-Plot#2- Street No: N-3, National Industrial Zone Rawat, Islamabad-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Selden 10mg/ml for oral suspension, M-434
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
330	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	MEDPHARM RESEARCH LAB 28 KM FEROZPUR ROAD LAHORE (000878)

	Application Form Dy. No / Tracking ID & date of submission	(JQU-E4W-PY8Q, 2025-02-11)
	Detail of Fee Submitted	75000.0, 18000.0 2024-04-25, 2024-11-26
	The proposed proprietary name / brand name	SERMED INJECTION 8MG/4ML
	Label Claim	Each 4ml Contains: Ondansetron as Hydrochloride dihydrate = 8MG
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	as per DPC-As per SRO
	Shelf Life (Unit)	2 Yearbelow 24 degree
	For generic drugs (me-too Status)	onset 8mg/4ml injection
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	May & Baker Pvt Ltd-HOUSE NO 23, STREET NO 5 SECTOR B, GHORI BLOCK BAHRIA TOWN, Pakistan-
	The status in reference regulatory authorities	FDA Approved
	Detail of previous approval	Baktron 8mg/4ml Injection approved in 321st meeting of RB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
331	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Gray's Pharmaceuticals Plot NO2, Street No. N-3, RCCI Rawat Islamabad (000518)
	Application Form Dy. No / Tracking ID & date of submission	(JS5-VHS-83W6, 2025-04-25)
	Detail of Fee Submitted	93000.0, 2025-02-22,
	The proposed proprietary name / brand name	Vonipa Tablet 10mg 100mg
	Label Claim	Each Tablet Contains: Aspirin as Enteric Coated Tablet (USP).....100mg Vonoprazan as fumarate as Immediate Release Layer.....10mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Venospa Tablet by Wnsfeild Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Estate, Hattar.-
	The status in reference regulatory authorities	Usfda Approved

	Detail of previous approval	Vonp-AS 10/100 Tablet, DRB 335
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
332	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	MEDPHARM RESEARCH LAB 28 KM FEROZPUR ROAD LAHORE (000878)
	Application Form Dy. No / Tracking ID & date of submission	(JST-H7X-HVT5, 2025-01-09)
	Detail of Fee Submitted	75000.0, 18000.0 2024-05-08, 2024-11-25
	The proposed proprietary name / brand name	VANCOMED 1G
	Label Claim	Each vial Contains: Vancomycin Hydrochloride eq. to Vancomycin = 1 G
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	as per DPC-As per SRO
	Shelf Life (Unit)	2 Yearbelow 24 degree
	For generic drugs (me-too Status)	Vancomycin injection 1gm
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	May & Baker Pvt Ltd-HOUSE NO 23, STREET NO 5 SECTOR B, GHORI BLOCK BAHRIA TOWN, Pakistan-
	The status in reference regulatory authorities	FDA Approved
	Detail of previous approval	vancomin 1g Dry Powder for injection 324th meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
333	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Saaaf Pharmaceuticals Risalpur, Nowshera, Khyber Pakhtunkhwa 23200 (000637)
	Application Form Dy. No / Tracking ID & date of submission	(JT1-SYN-VTTA, 2025-05-09)

	Detail of Fee Submitted	93000.0, 2025-01-24,
	The proposed proprietary name / brand name	Tablet Sildifin 50mg
	Label Claim	Each Tablet contains Sildinafil as citrate 50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's-As per SRO
	Shelf Life (Unit)	2 YearBelow 25c
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Gray's Pharmaceuticals-Plot No2, street No. N-3,National Industrial Zone, Rawat.-
	The status in reference regulatory authorities	NA
	Detail of previous approval	Selden, 343rd DRB meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Deferred	
334	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Scilife Pharma Private Limited FD-57/58-A2, Korangi Creek Industrial Park (KCIP) (000837)
	Application Form Dy. No / Tracking ID & date of submission	(JTA-55X-Q96T, 2024-04-02)
	Detail of Fee Submitted	75000.0, 2024-02-14,
	The proposed proprietary name / brand name	Doara 0.5mg/ml Syrup
	Label Claim	Each ml contains: Desloratidine.....0.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x120ml-As per SRO,1x60ml-As per SRO,1x90ml-As per SRO
	Shelf Life (Unit)	24 Month(s)Keep the packs below 30 °C. Remove bottle from unit carton and break its seal and shake it immediately before use.
	For generic drugs (me-too Status)	Desora syrup of continental pharma
	Pharmacotherapeutic Group of (API)	H1 antagonist
	Name, address of Manufacturing site:	Wimits Pharmaceuticals (Pvt) Ltd-Plot No. 129, Sunder Industrial Estate Raiwind Road, Lahore-
	Name & address of API manufacturer	Morepen Laborateries Limited
	Detail of stability batches of drug product	3 batches: 1500L, 1200L, 2000L
	Documents for the procurement of API with approval from DRAP (in case of Import)	03-11-2021: AD attested invoice

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Desora syrup of continental pharma: PE performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IV-A
	The status in reference regulatory authorities	MHRA Approved
	GMP status of the firm	03-04-2023: GMP certificate inspection date
	Evidence of approval of manufacturing facility	03-04-2023: GMP certificate Oral liquid section
	Evaluation Remarks	
	Decision	
335	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Kanel Pharma Plot No. 6, Street No. SS-3, National Industrial Zone, Rawat (000758)
	Application Form Dy. No / Tracking ID & date of submission	(JUS-YUT-8718, 2025-05-20)
	Detail of Fee Submitted	93000.0, 2025-04-15,
	The proposed proprietary name / brand name	NELANDO
	Label Claim	Each 5ml Contains: Ondansetron Hydrochloride Dihydrate eq. to Ondansetron.....4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30c
	For generic drugs (me-too Status)	Onserton 4mg/5ml Oral Solution by Dyson
	Pharmacotherapeutic Group of (API)	Selective 5-HT3 serotonin- receptor antagonist
	Name, address of Manufacturing site:	M/S SERAPH PHARMACEUTICAL-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	Reston 4mg/5ml Oral Solution, 336th Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
336	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(L13-X5D-NY82, 2025-05-02)

Detail of Fee Submitted	93000.0, 2024-11-25,
The proposed proprietary name / brand name	ODAPON 4mg/5ml Oral Solution
Label Claim	Each 5ml contains: Ondansetron hydrochloride dihydrate eq. to ondansetron.....4mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	1 x 1-As per SRO
Shelf Life (Unit)	24 MonthBelow 30°C
For generic drugs (me-too Status)	Onsetron 4mg/5ml Oral Solution
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	SERAPH PHARMACEUTICAL -Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
The status in reference regulatory authorities	Ondansetron hydrochloride Oral Solution 4mg/5ml
Detail of previous approval	RESTON 4mg/5ml Oral Solution, 336th minutes of meeting

Evaluation Remarks

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

Decision

Approved

337	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	AGP Limited B-23-C, S.I.T.E., Karachi (000348)
	Application Form Dy. No / Tracking ID & date of submission	(L5V-13B-M5XL, 2025-05-08)
	Detail of Fee Submitted	93000.0, 2025-04-23,
	The proposed proprietary name / brand name	Agchol 10mg Tablet
	Label Claim	Each Tablet contains: Bethanechol Chloride.....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's, 2x7's, 2x10'-De-Controlled
	Shelf Life (Unit)	2 YearDo not store over 30°C. Protect from Direct sunlight & heat.
	For generic drugs (me-too Status)	Urotone 10mg Tablet by Wimits Pharmaceutical (Pvt.) Ltd
	Pharmacotherapeutic Group of (API)	Cholinergic Agonist
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Limited.-Plot # 129, Sunder Industrial Estate Lahore-
	The status in reference regulatory authorities	Bethanechol Chloride Tablet, USP 10mg of M/s Amneal Pharmaceuticals LLC, Bridgewater, NJ 08807 (USFDA Approved)
	Detail of previous approval	Urotone 10mg Tablet, DRB Meeting No. 344

	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
338	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	CIBA Pharmaceuticals (Pvt) Ltd. A-371, Nooriabad S.I.T.E., Karachi, Hyderabad Super Highway, District Jamshoro (000825)
	Application Form Dy. No / Tracking ID & date of submission	(LBX-P2Y-LRPV, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2025-01-23,
	The proposed proprietary name / brand name	ESOLE
	Label Claim	Each Vial Contains: Esomeprazole as Sodium.....40mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearBELOW 30 DEGREE
	For generic drugs (me-too Status)	Nexum 40mg Injection (Getz Pharma)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Biogen Life Sciences-8-KM, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Approved in USFDA
	Detail of previous approval	ESOGEN 40mg IV INJECTION (312 DRB Meeting)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
339	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Misaq Pharmaceuticals Pvt Ltd. Plot no.7-B, Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad. (000985)
	Application Form Dy. No / Tracking ID & date of submission	(LDG-GBD-THMN, 2024-09-12)

	Detail of Fee Submitted	75000.0, 18000.0 2024-04-23, 2024-09-10
	The proposed proprietary name / brand name	Mixime
	Label Claim	Each capsule contains: Cefixime trihydrate eq. to cefixime 400mg
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 Year15-30 degree Celsius
	For generic drugs (me-too Status)	Brand Name: Trispan 400mg Capsule Registration holder: Seraph Pharmaceutical, Islamabad
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	SERAPH PHARMACEUTICAL-Plot No 210, Industrial triangle, Kahuta road, Islamabad-Pakistan-
	The status in reference regulatory authorities	US-FDA Approved
	Detail of previous approval	Trispan 400mg Capsule,317th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
340	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	A'raf (Pvt) Ltd 23 KM Raiwind Road Lahore (000685)
	Application Form Dy. No / Tracking ID & date of submission	(LGG-PWY-DS4Z, 2025-05-08)
	Detail of Fee Submitted	93000.0, 2025-04-21,
	The proposed proprietary name / brand name	Zarip 3mg Capsule
	Label Claim	Each Capsule contains: Cariprazine Hydrochloride equivalent to Cariprazine.....3mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x5's, 1x6's, 2x7's,-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Caripz 3mg Capsule of M/s Genix Pharma (approved in M-324)
	Pharmacotherapeutic Group of (API)	Atypical antipsychotics
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhpura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	VRAYLAR (cariprazine) 3mg capsules AbbVie, Inc. North Chicago, IL 60064 USA Product of Hungary (USFDA Approved)

	Detail of previous approval	Carip 3mg Capsule approved in 343rd meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
341	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Searle Pakistan Limited C-14, Manghopir Road, SITE, Karachi (000012)
	Application Form Dy. No / Tracking ID & date of submission	(LH3-4NT-7VAV, 2025-06-03)
	Detail of Fee Submitted	93000.0, 2025-05-15,
	The proposed proprietary name / brand name	MEROKYT (Meropenem) Injection 1 gm
	Label Claim	Each vial contains: Meropenem as Trihydrate Blended with Anhydrous Sodium Carbonate..... 500 mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30°C.
	For generic drugs (me-too Status)	Penro 500 mg Injection (Bosch Pharma)
	Pharmacotherapeutic Group of (API)	Carbapenem
	Name, address of Manufacturing site:	M/s. High-Q Pharmaceuticals -Plot No. 224 & 225/1, Sector 23, Korangi Industrial Area, Karachi, Pakistan.-
	The status in reference regulatory authorities	Merrem Injection (USFDA Approved)
	Detail of previous approval	The product, Meropenem Injection 500 mg & 1 gm has already been approved by the Registration Board i
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
342	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Pasteur & Fleming Pharma Plot # 70A , Phase -3, Road No-04, Industrial Estate Hattar, K.P.K.

		Pakistan (000945)
	Application Form Dy. No / Tracking ID & date of submission	(LNA-UUS-P98W, 2025-02-19)
	Detail of Fee Submitted	93000.0, 2024-12-18,
	The proposed proprietary name / brand name	Oxone 10mg Tablet
	Label Claim	Each film coated tablet contains: Vonoprazan as fumarate.....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
	Shelf Life (Unit)	2 YearRoom Temperature.
	For generic drugs (me-too Status)	VONozan tablet by GETZ Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-
	The status in reference regulatory authorities	VOQUENZA tablet by Phathom Pharmaceuticals,USA
	Detail of previous approval	Vonomark 10mg Tablet (Meeting 335th)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
343	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Akson Pharmaceuticals (Pvt) Ltd Plot No. 9-B/1&2, street No.D-1, Old Industrial estate, Mirpur, Azad Kashmir (000486)
	Application Form Dy. No / Tracking ID & date of submission	(LPH-TU3-8SVH, 2025-04-16)
	Detail of Fee Submitted	93000.0, 2024-12-30,
	The proposed proprietary name / brand name	Dolosyn-E 375mg/20mg Tablets
	Label Claim	Each modified release tablet contains: Naproxen.....375mg (Enteric coated Core) Esomeprazole as Magnesium Trihydrate.....20mg (Immediate Release Coat) (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 Year15- 25°C
	For generic drugs (me-too Status)	Glomov Tablets (Global Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd,-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	Vimovo modified release tablets
	Detail of previous approval	Esoren-20mg/375mg Tablets, M-343
	Evaluation Remarks	
	Esoren 375mg/ 20mg Tablets of Solaris Life Sciences (Pvt.) Ltd, was approved in the 343rd meeting of the Registration Board.	
	Decision	
	Approved	
344	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	UNISON CHEMICAL WORKS POST OFFICE ARAIAN 15-km RAIWIND ROAD LAHORE (000174)
	Application Form Dy. No / Tracking ID & date of submission	(LRP-QRP-4UZ3, 2025-01-06)
	Detail of Fee Submitted	93000.0, 2024-12-19,
	The proposed proprietary name / brand name	Actisip 10mg Suspension
	Label Claim	Each ml of reconstituted suspension contains
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1 x 112ml-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Silagro (Nabi Qasim)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Gray's Pharmaceuticals-Plot#2, Street#N3, National Industrial Zone Rawat Islamabad-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Seldon 10mg/ml (Reg. No 124748) Meeting No. 343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
345	Case Category	New Section (Incharge Evaluation Cell)
	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	(LSE-SZN-GVP3, 2025-04-09)

	Detail of Fee Submitted	75000.0, 2025-02-14,
	The proposed proprietary name / brand name	Tucatin 150 mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Tucatinib 150mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,120's-As per SRO,30's-As per SRO,60's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a cool and dry place below 30°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Antineoplastic agents, protein kinase inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	GANSU HAOTIAN PHARMATECH CO., LTD. Address:No.11 Chongqing Road,Baiyin District, Baiyin City, Gansu Province
	Detail of stability batches of drug product	3 batches: 1000 tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	01-10-2024: Drug Import License, along with Commercial invoice and Fedex receipt is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Tukysa 150mg Tablet of Seattle Genetics Inc: PE and CDP submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches as per zone IV-A
	The status in reference regulatory authorities	TUKYSA 150mg Tablet (USFDA Approved)
	GMP status of the firm	20-11-2024: GMP report concludes satisfactory compliance to GMP
	Evidence of approval of manufacturing facility	10-05-2024: Tablet (Cytotoxic) New Section
	Evaluation Remarks	
	Decision	
	Approved	
346	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(LT7-QT8-7EEN, 2025-04-16)
	Detail of Fee Submitted	93000.0, 2024-11-29,
	The proposed proprietary name / brand name	Limpa 12.5mg/2.5mg/1000mg XR Tablet
	Label Claim	Each Film Coated Extended Release tablet contains: Empagliflozin.....12.5mg Linagliptin.....2.5mg (Immediate release coat) Metformin HCl.....1000mg (Extended release core)
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
	Shelf Life (Unit)	2 YearStore 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	TRIJARDY XR- empagliflozin, linagliptin, metformin hydrochloride tablet, extended release of M/s BOEHRINGER INGELHEIM PHARMACEUTICALS, INC. (USFDA Approved)
	Detail of previous approval	Limpa-Met 12.5/2.5/1000mg XR Tablet approved in 340th meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
347	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Evolution Pharmaceuticals (Pvt.) Ltd. Plot no. 25,26 & 27, Street S-3, National Industrial Zone, Rawat, Islamabad. (000867)
	Application Form Dy. No / Tracking ID & date of submission	(LTE-LV7-AMTQ, 2025-03-21)
	Detail of Fee Submitted	93000.0, 2024-09-24,
	The proposed proprietary name / brand name	RELMUS 4MG/2ML INJECTION
	Label Claim	Each 2ml ampoule contains: Thiocolchicoside 4mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	2 YearStore at 20° to 25° C (68° to 77°F). Keep container closed tightly. Protect from light and moisture. Store away from foodstuffs.
	For generic drugs (me-too Status)	Brand Name: Muscoril Injection 4mg/2ml Registration holder: Searle Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	SERAPH PHARMACEUTICAL Plot # 210, Industrial Trian-Plot # 210, Industrial Triangle, Kahuta Road, Islamabad, Pakistan-
	The status in reference regulatory authorities	Brand Name Myorel 4mg/2ml injection Marketing Authorization holder: LABORATORIO FARMACEUTICO SIT Srl Regulatory Authority: ANSM FRANCE

	Detail of previous approval	123584 Tiofrel4mg/2mlInjection, No.F.5-2/2024-RF,G-II(M-335)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
348	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Evolution Pharmaceuticals (Pvt.) Ltd. Plot no. 25,26 & 27, Street S-3, National Industrial Zone, Rawat, Islamabad. (000867)
	Application Form Dy. No / Tracking ID & date of submission	(LVG-QJN-73SH, 2025-03-20)
	Detail of Fee Submitted	93000.0, 2024-09-24,
	The proposed proprietary name / brand name	ALESTIN 5MG/5ML SYRUP
	Label Claim	Each 5ml of Syrup contains: Ebastine 5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	2 Yeartore below 30°C. Protect from light. Reconstituted solution may be stored at 25°C for 24 hours or between 2-8°C for 7 days.
	For generic drugs (me-too Status)	Simstine 5mg/5ml Syrup, Simz Pharmaceuticals (Pvt) Ltd. Plot No. 574-575 Punjab Industrial Estate Sundar Lahore, Lahore
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	SERAPH PHARMACEUTICAL Plot # 210, Industrial Trian-Plot # 210, Industrial Triangle, Kahuta Road, Islamabad, Pakistan-
	The status in reference regulatory authorities	EBASTEL 1mg/1ml oral solution Spain Approved.
	Detail of previous approval	121871, EBESTOL 5mg/5ml Syrup, No F,5-3/2024-REG-II(M-336)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	

349	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(M3W-DE7-TYAD, 2025-05-08)
	Detail of Fee Submitted	93000.0, 2025-04-15,
	The proposed proprietary name / brand name	Caripz 3mg Capsule
	Label Claim	Each Capsule contains: Cariprazine Hydrochloride equivalent to Cariprazine.....3mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x5's, 1x6's, 2x7's,-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Caripz 3mg Capsule of M/s Genix Pharma (approved in M-324)
	Pharmacotherapeutic Group of (API)	Atypical antipsychotics
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhpura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	VRAYLAR (cariprazine) 3mg capsules AbbVie, Inc. North chicago, IL 60064 USA Product of Hungary (USFDA Approved)
	Detail of previous approval	Carip 3mg Capsule approved in 343rd meeting of DRB
Evaluation Remarks		
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.		
Decision		
Approved		
350	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Steris Pharmaceuticals Plot No 9 Near Synpac Hattar Private Industrial Estate Haripur Road Hattar (000995)
	Application Form Dy. No / Tracking ID & date of submission	(M4U-47Y-WVUD, 2025-04-24)
	Detail of Fee Submitted	93000.0, 2025-02-25,
	The proposed proprietary name / brand name	Azaset
	Label Claim	Each reconstituted 5ml contains: Azithromycin.....200mg (as dihydrate) (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 25°C

	For generic drugs (me-too Status)	Yes
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd-Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, Rawalpindi-Pakistan-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Minutes of 343rd meeting of Registration Board, with brand name of Azysol Suspension 200mg/5ml
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
351	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Swiss Pharmaceuticals Pvt. Ltd. A/159, S.I.T.E.-II, Super Highway (000438)
	Application Form Dy. No / Tracking ID & date of submission	(M51-Q73-8LBV, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2025-02-17,
	The proposed proprietary name / brand name	ELLA Tablet 200mg
	Label Claim	Each Film coated tablet contains: Elagolix sodium Equivalent to Elagolix.....200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x10's, 2x7'-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Brand name: Elagolixin 200mg Tablet, Manufacturer/Registration holder: Kaizan Pharmaceutical Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt.) Ltd. -Plot No. 129, Sundar Industrial Estate Raiwind Road Lahore Pakistan-
	The status in reference regulatory authorities	Brand Name: Orilissa(Elagolix) 200mg tablet, Manufacturer AbbVie Inc. North Chicago, IL 60064 03-B517, Reference Regulatory Authority: USFDA approved.
	Detail of previous approval	Orlix 200mg Tablet, M-343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned	

	notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
352	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Steris Pharmaceuticals Plot No 9 Near Synpac Hattar Private Industrial Estate Haripur Road Hattar (000995)
	Application Form Dy. No / Tracking ID & date of submission	(M5G-E94-UQXV, 2025-02-12)
	Detail of Fee Submitted	75000.0, 18000.0 2024-09-02, 2024-10-18
	The proposed proprietary name / brand name	Monoram
	Label Claim	Each vial contains: Meropenem Trihydrate 500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30
	For generic drugs (me-too Status)	Yes
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bogen Life Science-8-km, ChakbeliRoad, Rawat, Rawalpindi-
	The status in reference regulatory authorities	UK – MHRA
	Detail of previous approval	merogen Injection 500mg, Approved at 312th meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
353	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	CCL Pharmaceuticals (Pvt.) Ltd. 62-Quaid-e-Azam Industrial Estate, Kot Lakhpat (000052)
	Application Form Dy. No / Tracking ID & date of submission	(M91-NN7-YDB2, 2025-04-22)
	Detail of Fee Submitted	93000.0, 2025-02-13,
	The proposed proprietary name / brand name	Eifil Oral Suspension 10ng/ml
	Label Claim	Each ml contains; Sildenafil as citrate..... 10mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled,112ml-De-Controlled,50ml-De-Controlled,90ml-De-Controlled
	Shelf Life (Unit)	2 YearDo not store above 30C.

	For generic drugs (me-too Status)	Brand Name: Silagro Powder for Oral Suspension Company Name: Nabiqasim
	Pharmacotherapeutic Group of (API)	Century Pharmaceuticals Limited.
	Name, address of Manufacturing site:	Focus & Rulz Pharmaceuticals Pvt. Ltd.-Plot no.44-Industrial Triangle, Kahuta Road, Islamabad.-
	The status in reference regulatory authorities	Name: Revatio 10mg/ml Powder for Oral Suspension. Manufacturer: Upjohn UK Limited.
	Detail of previous approval	Proposed Name: Silpah 10mg/ml Oral Suspension Minutes for 340th meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
354	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Skywin Pharmaceutical Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road (000971)
	Application Form Dy. No / Tracking ID & date of submission	(MAZ-8ME-WG9G, 2025-02-11)
	Detail of Fee Submitted	93000.0, 2024-12-23,
	The proposed proprietary name / brand name	Skyset 4mg/5ml Syrup
	Label Claim	Each 5ml contains: Ondansetron as (hydrochloride dihydrate) 4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO / DPC-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Onseron Syrup of M/s Indus Pharma
	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	Zofran 4mg/5ml syrup of M/s Novartis Pharmaceuticals UK Ltd. (MHRA Approved)
	Detail of previous approval	Stawia 4mg/5ml Syrup approved in 326th Meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned	

	notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
355	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Skywin Pharmaceutical Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpora road (000971)
	Application Form Dy. No / Tracking ID & date of submission	(ME1-YN8-2HXX, 2025-02-11)
	Detail of Fee Submitted	93000.0, 2024-12-23,
	The proposed proprietary name / brand name	Ceftriax 500mg IM Injection
	Label Claim	Each Vial contains: Ceftriaxone Sodium(USP) eq. to Ceftriaxone.....500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO / DPC-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Rocephin 500mg IM injection of M/s Martin Dow
	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	Ceftriaxone For injection USP 500mg of M/s Lupin Pharmaceutical, Inc. (USFDA Approved)
	Detail of previous approval	Welcef 500mg IM Injection approved in 326th meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
356	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Seraph Pharmaceutical Plot No 210, Industrial Triangle Kahuta Road, Islamabad. (000860)
	Application Form Dy. No / Tracking ID & date of submission	(MHV-DT7-TRUJ, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2025-02-04,
	The proposed proprietary name / brand name	Montes 4mg sachet
	Label Claim	Each sachet contains. Montelukast Sodium (equivalent to Montelukast).....4mg (USP Spec's)

	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Brand Name: Myteka 4mg Sachet Manufacturer: Hilton Pharma (Private) Limited Address: Plot No.13-14,sector 15,Korangi Industrial Area.Karachi,Pakistan.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd.-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	FDA approved
	Detail of previous approval	Solkast 4mg Sachet, Meeting No. M-339th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
357	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Effort Pharmaceuticals (Pvt.) Ltd., 28-Km, Ferozepur Road (000879)
	Application Form Dy. No / Tracking ID & date of submission	(MJ4-9JA-XVBY, 2025-03-08)
	Detail of Fee Submitted	93000.0, 2024-11-12,
	The proposed proprietary name / brand name	Esolite 40mg Injection
	Label Claim	Each vial Contains: Esomeprazole Sodium eq. to Esomeprazole ...40mg
	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)	Nexum IV 40mg Injection (Getz Pharma (Pvt) Limited) Reg. No. 050651
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	May & Baker Pharmaceuticals (Pvt.) Ltd.-45 Km, Thokar Multan road, Lahore-
	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	Approved by MHRA of UK
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The product Ezole 40mg Dry powder Vial of M/s May & Baker was approved in 327 meeting of RB.	
	Decision	
	Approved	
358	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Jinnah Pharmaceuticals Pvt Ltd 13 Km Lahore Road Multan (000578)
	Application Form Dy. No / Tracking ID & date of submission	(MJ7-JYJ-M2R7, 2025-04-25)
	Detail of Fee Submitted	93000.0, 2024-12-11,
	The proposed proprietary name / brand name	Cefiderm Capsule 200mg
	Label Claim	Each capsule contains: Cefixime (as tri-hydrate)..... 200 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5's-Controlled
	Shelf Life (Unit)	2 Year15-30C
	For generic drugs (me-too Status)	Icef ICI Pakistan
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/S.High-Cure Research Laboratories -19-KM Tayyaba industrial zone Sheikhpura Road Lahore-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Hixime Capsule 200mg (M-331)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
359	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	INVENTOR PHARMA PVT LTD Plot No. K-196 S.I.T.E, Super Highway Phase-II (000866)
	Application Form Dy. No / Tracking ID & date of submission	(MLY-DJE-7785, 2025-05-15)
	Detail of Fee Submitted	93000.0, 2025-02-12,

	The proposed proprietary name / brand name	Invenzo 4.50 g Injection
	Label Claim	Each Vial Contains: Piperacillin Sodium USP eq. to 4.0 gm Piperacillin & Tazobactam Sodium MS eq. to 500 mg Tazobactam
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1,s-As per SRO
	Shelf Life (Unit)	2 Year15C-25 C
	For generic drugs (me-too Status)	Tanzo 4.50 g injection
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Fleming Pharmaceuticals-23- Km Lahore-Sheikhupura Road, Lahore.-
	The status in reference regulatory authorities	Zosyn injection
	Detail of previous approval	Fletazo Injection 4.50 g , 323rd meeting
	Evaluation Remarks	
	Fletazo Injection 4.5g of Fleming Pharmaceuticals was approved in 323rd meeting of the Registration Board. Applicant to submit quality agreement between contract manufacturer and acceptor.	
	Decision	
	Approved	
360	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	A'raf (Pvt) Ltd 23 KM Raiwind Road Lahore (000685)
	Application Form Dy. No / Tracking ID & date of submission	(MMP-326-79Q2, 2025-05-08)
	Detail of Fee Submitted	93000.0, 2025-04-21,
	The proposed proprietary name / brand name	Zarip 1.5mg Capsule
	Label Claim	Each Capsule contains: Cariprazine Hydrochloride equivalent to Cariprazine.....1.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x5's, 1x6's, 2x7's,-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Caripz 1.5mg Capsule of M/s Genix Pharma (approved in M-324)
	Pharmacotherapeutic Group of (API)	Atypical antipsychotics
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	VRAYLAR (cariprazine) 1.5mg capsules AbbVie, Inc. North Chicago, IL 60064 USA Product of Hungary (USFDA Approved)
	Detail of previous approval	Carip 1.5mg Capsule approved in 343rd meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned	

	notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
361	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	MEDPHARM RESEARCH LAB 28 KM FEROZPUR ROAD LAHORE (000878)
	Application Form Dy. No / Tracking ID & date of submission	(MNP-P4R-64EM, 2025-02-11)
	Detail of Fee Submitted	93000.0, 2024-11-15,
	The proposed proprietary name / brand name	Tanzomed 4.5gm Injection
	Label Claim	Each Vial contains: Piperacillin (as Piperacillin Sodium) : 4.0 g Tazobactam (as Tazobactam Sodium) : 0.5 g (as lyophilized powder for IV injection)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO / DPC-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Tanzo 4.5gm Injection of M/s Bosch Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhpura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	Zosyn Injection of M/s Wyeth (USFDA Approved)
	Detail of previous approval	Tazopip 4.5gm Injection approved in 335th Meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
362	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Dyson Research Laboratories (Pvt.) Ltd 28-Km Ferozpur Road Lahore (000559)
	Application Form Dy. No / Tracking ID & date of submission	(MP5-1DT-UND3, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2025-01-06,
	The proposed proprietary name / brand name	Vbacin
	Label Claim	Each vial contains: Vancomycin HCL eq. to vancomycin.....500mg

	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearStore below 25C.
	For generic drugs (me-too Status)	Vancorin Injection 500mg by CJ Corporation Korea and imported by Hoffmann Human Health (Pak.) Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Labs (Pvt.) Ltd.-Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad.-
	The status in reference regulatory authorities	Vancomycin Hydrochloride 500mg by FRESENIUS KABI USA, approved by US-FDA.
	Detail of previous approval	Vanconext Powder for Solution for Infusion 500mg, approved in Minutes of 343 meeting of Registration
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
363	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Saibins Pharmaceuticals Plot No.316 Industrial Triangle Kahutta Road Islamabad (000773)
	Application Form Dy. No / Tracking ID & date of submission	(MPV-Y7Y-PH6G, 2025-04-08)
	Detail of Fee Submitted	93000.0, 2024-12-16,
	The proposed proprietary name / brand name	Saipenem Injection 1g IV
	Label Claim	Each Vial Contains: Each Vial Contains: Meropenem (as Trihydrate) blended with sodium carbonate----- 1g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	2 YearStore in cool and dry place below 30C
	For generic drugs (me-too Status)	Meropam1g Inj IV (Munawar Pharma Lahore)Reg.No.107176
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio Next Pharmaceuticals -Plot # 50 Street # S10 RCCI Rawat-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Meropen 1g Injection, 333rd
	Evaluation Remarks	
	MENEPOR 1gm Injection IV of Bio Next was approved in 296th meeting of the registration Board.	
	Decision	

	Approved	
364	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Well Care Pharmaceuticals A/7 PSIE (000465)
	Application Form Dy. No / Tracking ID & date of submission	(MPX-MXN-T39E, 2025-01-08)
	Detail of Fee Submitted	93000.0, 2024-12-18,
	The proposed proprietary name / brand name	sildiwel suspemsion
	Label Claim	Each ml of reconstituted suspension contains: Sildenafil (as Citrate) ----- 10mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1,s-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 °C
	For generic drugs (me-too Status)	M/s Gray,s pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/S Gray,s pharma-plot no 2, street no N-3 RCCI rawat-
	The status in reference regulatory authorities	FDA APPORVED
	Detail of previous approval	M-343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
365	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Biogen PHarma 8-KM, Chak Beli Road, Rawat, (000639)
	Application Form Dy. No / Tracking ID & date of submission	(MPY-DQH-GVAR, 2025-03-20)
	Detail of Fee Submitted	93000.0, 2024-11-15,
	The proposed proprietary name / brand name	Leside-100mg/ 5ml Suspension (60ml)
	Label Claim	Each 5ml contains; Linezolid 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearroom condition
	For generic drugs (me-too Status)	Brand Name: Nezolid Suspension 100mg/5ml Manufacturer: M/s Searle Pakistan Limited
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan-

	The status in reference regulatory authorities	Brand Name: Zyvox 100mg/ 5ml Suspension Manufacturer: Pfizer Service Company Address: BVBA, Hoge Wei 10, 1930 Zaventem, Belgium
	Detail of previous approval	Liznisol 100mg/ 5ml Suspension Minutes for 339th meeting of Registration Board (6th August to 8th A
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
366	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Pasteur & Fleming Pharma Plot # 70A , Phase -3, Road No-04, Industrial Estate Hattar, K.P.K. Pakistan (000945)
	Application Form Dy. No / Tracking ID & date of submission	(MQW-L83-9J3B, 2025-05-12)
	Detail of Fee Submitted	93000.0, 2025-01-08,
	The proposed proprietary name / brand name	EMFIN 10/5mg Tablet
	Label Claim	Each film coated tablet contains: Linagliptin.....5mg Empagliflozin.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's -As per SRO,28's-As per SRO,30's-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature.
	For generic drugs (me-too Status)	LinJardy tablet by CCL Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-
	The status in reference regulatory authorities	GLYXAMBI by Boehringer Ingelheim Pharmaceuticals, Inc
	Detail of previous approval	Glulina-E 10/5mg Tablet (Meeting no. 339th)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
367	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

	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	(MSP-RR7-4BG4, 2025-04-21)
	Detail of Fee Submitted	93000.0, 2025-02-20,
	The proposed proprietary name / brand name	PERAMOL1000mg/100ml
	Label Claim	Each 100ml contains: Paracetamol.....1000mg
	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 30 degree centigrade,protect from light,moisture and heat,Donot freeze.
	For generic drugs (me-too Status)	PROVAS 1000MG/100ML, M/s Sami pharmaceuticals-Karachi
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s MISAQ PHARMACEUTICALS-7-B,Woven Garments Zone, Value Addition City,Khurrianwala- Sahianwala Road, Faisalabad.-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	PARASAQ 1000MG/100ML INFUSION, M-336
	Evaluation Remarks	
	Metamol Infusion of M/s MISAQ PHARMACEUTICALS was approved in the 336th meeting of the Registration Board.	
	Decision	
	Approved	
368	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(MVR-6NH-31B8, 2024-08-23)
	Detail of Fee Submitted	75000.0, 2024-07-25,
	The proposed proprietary name / brand name	Altrizan 50mg/5ml Injection
	Label Claim	Each 5ml Ampoule contains: Atracurium besylate.....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's x 5ml-As per SRO,5's x 5ml Ampoule-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Zoledronic acid Normon 4mg/5ml Injection Reg No. 082059 M/s Merixil Pharma Islamabad (Importer)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	MHRA Approved.

	Detail of previous approval	331 st meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
369	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winthrox Laboratories Pvt. Ltd K-219-A, SITE, Super Highway Phase II, Karachi (000807)
	Application Form Dy. No / Tracking ID & date of submission	(MWL-R26-A1BH, 2025-01-15)
	Detail of Fee Submitted	93000.0, 2024-12-23,
	The proposed proprietary name / brand name	Virexo Powder for Oral Suspension
	Label Claim	Each ml of reconstituted suspension contains: Sildenafil (as Citrate) ----- 10mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	112ml-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Selden 10mg/ml Powder for Oral Suspension by Gray's Pharmaceuticalls Reg. No. 124748
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Gray's Pharmaceuticals-Plot No 2, Street No. N-3, National Industrial Zone Rawat-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Selden 10mg/ml Powder for Oral Suspension by Gray's Pharmaceuticalls Reg. No. 124748 approved in 34
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
370	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Hudson Pharma (Pvt) Ltd D-93, North Western Industrial Zone, Port Qasim Authority (000842)
	Application Form Dy. No / Tracking ID & date of submission	(MYR-LWL-DM97, 2025-05-12)

	Detail of Fee Submitted	93000.0, 2025-01-08,
	The proposed proprietary name / brand name	Minoxgro 5% Topical Spray
	Label Claim	Each ml contains: Minoxidil.....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x60ml-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Hair max 5%w/v Topical solution
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Private Limited-Plot No. 129 – Sunder Industrial Estate Raiwind Road, Lahore, Pakistan-
	The status in reference regulatory authorities	Bosley man 5 Minoxidil Topical Solution
	Detail of previous approval	M-343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
371	Case Category	Routine (Incharge Evaluation Cell)
	Name, address of Applicant.	Caliph Pharmaceuticals Plot 17, Special Industrial Zone Risalpur, KPK (000748)
	Application Form Dy. No / Tracking ID & date of submission	(N12-J1R-SQ67, 2024-03-27)
	Detail of Fee Submitted	30000.0, 2024-03-13,
	The proposed proprietary name / brand name	CALTRIM 500MG VAGINAL TABLET
	Label Claim	Each vaginal tablet contains: Clotrimazole 500mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)25°C
	For generic drugs (me-too Status)	Canesten 500mg Vaginal Tablet M/s Bayer Health Care
	Pharmacotherapeutic Group of (API)	Antifungals
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	HALCYON LABS PVT. LTD., Plot No. 409, Phase – IV, GIDC Industrial estate, Naroda, Ahmedabad – 382 330, Gujarat, INDIA.
	Detail of stability batches of drug product	3 batches: 400 Tablet
	Documents for the procurement of API with approval from DRAP (in case of Import)	30-07-2021: AD attested invoice is submitted

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Canesten 500mg vaginal tablet: PE and CDP studies performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IV-B
	The status in reference regulatory authorities	Clotrimazole 500mg Vaginal Tablet (MHRA Approved)
	GMP status of the firm	13-03-2023: GMP certificate inspection date
	Evidence of approval of manufacturing facility	17-01-2019: DML grant of additional section & regularization of layout plan letter specifies Tablet (General) section
	Evaluation Remarks	
	Decision	
	Approved	
372	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Athan Pharmaceuticals Plot # 84/2,Block A, Phase 5 , Industrial Estate Hattar, KPK, (000900)
	Application Form Dy. No / Tracking ID & date of submission	(N3Y-W7J-ALEV, 2025-01-15)
	Detail of Fee Submitted	93000.0, 2024-12-24,
	The proposed proprietary name / brand name	Athden 10mg/ml for Oral Suspension
	Label Claim	Each ml of reconstituted suspension contains: Sildenafil as Citrate.....10mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's (112ml)-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Selden 10mg/ml for Oral Suspension by M/s Grays Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Sildenafil is a phosphodiesterase-5 (PDE5) inhibitor that is predominantly employed for two primary indications: (1) the treatment of erectile dysfunction, (2) pulmonary arterial hypertension
	Name, address of Manufacturing site:	M/s Gray's Pharmaceuticals-Plot No 2, Street # N-3, National Industrial Zone, Rawat-
	The status in reference regulatory authorities	SILDENA FIL CITRATE FOR SUSPENSION; ORAL by TEVA PHARMS USA
	Detail of previous approval	(Reg No. 124748) Selden 10mg/ml for Oral Suspension
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
373	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	M/s Daneen Pharma (Pvt) Ltd Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, (000688)
	Application Form Dy. No / Tracking ID & date of submission	(N4R-YW2-X31J, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2025-01-21,
	The proposed proprietary name / brand name	Qinglif-M XR
	Label Claim	Each film coated tablet contains: Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin.....10mg Metformin HCl.....1000mg(as Extended Release)
	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 YearStore below 30°C. Protect from heat, light & Moisture
	For generic drugs (me-too Status)	Daglozin-M XR Tablet by Genix Pharma Pvt Ltd (123455)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Genix Pharma Pvt Ltd -44, 45B, KORANGI CREEK ROAD, KARACHI. PAKISTAN-
	The status in reference regulatory authorities	Xigduo®XR by AstraZeneca Pharmaceuticals LP
	Detail of previous approval	Daglozin-M XR Tablet 10mg/1000mg DRB 343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
374	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Skywin Pharmaceutical Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road (000971)
	Application Form Dy. No / Tracking ID & date of submission	(N95-2BD-9YAM, 2025-02-11)
	Detail of Fee Submitted	93000.0, 2024-12-23,
	The proposed proprietary name / brand name	Cefix DS 200mg/5ml Suspension
	Label Claim	Each 5ml contains: Cefixime(as trihydrate) 200mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO / DPC-As per SRO

	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Cefspan DS 200mg/5ml Powder for Oral Suspension of M/s Barrett
	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	Suprax 200mg/5mL Powder for Paediatric Oral Suspension of M/s Merck Farma y Quimica, S.A. Poligono Merck, 08100 Mollet del Valles (Barcelona), Spain (HPRA Approved)
	Detail of previous approval	Myxim DS 200mg/5ml Suspension
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
375	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Cell Health Sciences , Plot No 217, Industrial Triangle, Kahuta Road, Islamabad (000711)
	Application Form Dy. No / Tracking ID & date of submission	(ND4-MNT-VDBN, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2025-02-25,
	The proposed proprietary name / brand name	Edic 180mg tablet
	Label Claim	Each Film Coated Tablet Contains: Bempedoic Acid.....180mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO / DPC -As per SRO
	Shelf Life (Unit)	2 YearAt room temperature
	For generic drugs (me-too Status)	Not Available Since this is a New Product
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Weather folds Pharmaceuticals -Plot No 69/2, Phase II, Industrial Estate Hattar-
	The status in reference regulatory authorities	MHRA approved
	Detail of previous approval	PDM 180 mg Tablet , Minutes of 331st Meeting of Registration Board held on 31st Oct – 2nd Nov, 2023
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned	

	notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
376	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	TABROS PHARMA (PVT). LTD. Plot No. L-20/B, Sector 22, F.B. Industrial Area (000106)
	Application Form Dy. No / Tracking ID & date of submission	(NG4-EZG-MD37, 2025-05-14)
	Detail of Fee Submitted	93000.0, 2025-01-14,
	The proposed proprietary name / brand name	Elatab 200mg Tablet
	Label Claim	Each tablet contains: Elagolix sodium Equivalent to Elagolix.....200mg Innovator's Specification
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's-De-Controlled,2x10's-De-Controlled,2x7's-De-Controlled,3x10's-De-Controlled,4x7's-De-Controlled
	Shelf Life (Unit)	2 YearSTORE BELOW 30oC
	For generic drugs (me-too Status)	Eladiol 200mg Tablet Registration No. 120223 Nabiqasim Industries (Pvt).Ltd
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt). Ltd-Plot No.129, Sunder Industrial Estate Raiwind Road Lahore-
	The status in reference regulatory authorities	Onlissa (Elagolix) 200mg tablet, AbbVie Inc North Chicago IL 60064 USFDA approved
	Detail of previous approval	Orlix 200mg Tablet 343rd DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
377	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Jinnah Pharmaceuticals Pvt Ltd 13 Km Lahore Road Multan (000578)
	Application Form Dy. No / Tracking ID & date of submission	(NG9-5DR-DAQ1, 2025-05-15)
	Detail of Fee Submitted	93000.0, 2025-01-25,
	The proposed proprietary name / brand name	Flucojin
	Label Claim	Each Capsule Contain:- Fluconazole.... 150mg (B.P Specifications)

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-Controlled
	Shelf Life (Unit)	2 Year15-30C
	For generic drugs (me-too Status)	: Zolanix Capsule 150mg (GlaxoSmithKline Pakistan Ltd.) Reg No. 084720
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	World Biz Pharmaceuticals Company, -340, Phase-II, Industrial Estate, Multan -
	The status in reference regulatory authorities	Azocan 150mg Capsule (MHRA Approved)
	Detail of previous approval	M-339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
378	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Tovida Pharmaceuticals (Pvt) Ltd Plot No.7, Street No.S-07, RCCI Industrial Estate Islamabad (000996)
	Application Form Dy. No / Tracking ID & date of submission	(NLE-ULV-7XPR, 2025-05-14)
	Detail of Fee Submitted	93000.0, 2025-02-24,
	The proposed proprietary name / brand name	TOXOMET
	Label Claim	Each Tablet Contains; Metolazone.....5mg (USP specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO -De-Controlled
	Shelf Life (Unit)	2 Year30C+-
	For generic drugs (me-too Status)	METXONE TABLETS 5MG
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Solaris Life Sciences -8-km Chakbeli Road Rawat-Rawalpindi -
	The status in reference regulatory authorities	USFDA (METOLAZONE TABLETS)
	Detail of previous approval	343 MINUTES OF MEETING
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	

	Decision	
	Approved	
379	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Astellas Pharmaceutical (Pvt.) Ltd 15-C Industrial Estate Hayatabad (000677)
	Application Form Dy. No / Tracking ID & date of submission	(NN6-3XH-QEEN, 2025-04-21)
	Detail of Fee Submitted	93000.0, 2025-02-27,
	The proposed proprietary name / brand name	Astephenem 1g injection
	Label Claim	Each vial contains: Meropenem (as trihydrate) ----- - 1 gram
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 vial-As per SRO
	Shelf Life (Unit)	2 Yearstore below 30 degree centigrade
	For generic drugs (me-too Status)	penro injecton by BOSCH
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Medicraft Pharma-126-B,Industrial Estate Hayatabad,Peshawar-Pakistan-
	The status in reference regulatory authorities	www.accessdata.fda.gov/drugs
	Detail of previous approval	Astephenem 1g inj , 336th meeting 4-6 june 2024
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
380	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Skywin Pharmaceutical Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpora road (000971)
	Application Form Dy. No / Tracking ID & date of submission	(NUZ-1WE-4VMH, 2025-05-08)
	Detail of Fee Submitted	93000.0, 2025-04-25,
	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	1x10's, 2x7's, 2x10'-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Mgablin 10mg Tablet of M/s Genix Pharma

	Pharmacotherapeutic Group of (API)	Gabapentinoid class of drugs
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Tarlige Tablets 10mg of M/s Daiichi Sankyo Co., Ltd (PMDA Approved)
	Detail of previous approval	Mirogab 10mg Tablet approved in 344th Meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
381	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Benson Pharmaceuticals Plot No.03, Main Road, National Industrial Zone, RCCI, Rawat, Rawalpindi (000447)
	Application Form Dy. No / Tracking ID & date of submission	(NXQ-J91-94GJ, 2025-01-15)
	Detail of Fee Submitted	93000.0, 2025-01-07,
	The proposed proprietary name / brand name	Seldoben 10mg Suspension
	Label Claim	10mg/ml
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	2 Yearroom temperature
	For generic drugs (me-too Status)	Silagro by Nabi Qasim
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Gray's Pharmaceuticals-Plot 2, Street N-3, National Industrial Zone, RCCI, Rawat, Islamabad-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Selden 10mg/ml for oral suspension M-343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
382		

	Name, address of Applicant.	Pacific Pharmaceuticals Ltd. Plot No.384, Sundar Industrial Estate, Raiwind Road, Lahore (000902)
	Application Form Dy. No / Tracking ID & date of submission	(NYR-ES7-LHMS, 2024-12-10)
	Detail of Fee Submitted	93000.0, 2024-11-19,
	The proposed proprietary name / brand name	PenMero 1 g Dry Powder Injection
	Label Claim	Each Vial Contains: Meropenem 1 gm
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's Vial-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30oC
	For generic drugs (me-too Status)	Meropenem Iv Injection 1 g by Pfizer Laboratories
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Stallion Pharmaceuticals (Pvt) Ltd.-Plot No. 581, Sunder Industrial Estate, Lahore-
	The status in reference regulatory authorities	Meropenem 1 g by Pfizer Limited UK
	Detail of previous approval	Merostin 1 gm Dry Powder Injection
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
383	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Kanel Pharma Plot No. 6, Street No. SS-3, National Industrial Zone, Rawat (000758)
	Application Form Dy. No / Tracking ID & date of submission	(P46-TQ2-LXWN, 2025-05-14)
	Detail of Fee Submitted	93000.0, 2025-03-11,
	The proposed proprietary name / brand name	L-Zole
	Label Claim	Each 300ml vial contains: Linezolid.....600mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30c
	For generic drugs (me-too Status)	Nezkil Infusion by SG J pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/S BIO-LABS PVT LTD-Plot No. 145, Industrial Triangle Kahuta Road Islamabad-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Linzid Infusion 600mg/300ml, 308th Meeting
	Evaluation Remarks	

	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
384	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Swiss Pharmaceuticals Pvt. Ltd. A/159, S.I.T.E.-II, Super Highway (000438)
	Application Form Dy. No / Tracking ID & date of submission	(P49-YWV-HEU4, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2025-02-17,
	The proposed proprietary name / brand name	MIROGAB Tablet 10mg
	Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to Mirogabalin.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Brand Name: Mirogab 10mg Tablet., Manufacturer/ Brand Holder: Wimits Pharmaceuticals Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt.) Ltd. -Plot No. 129, Sundar Industrial Estate Raiwind Road Lahore Pakistan-
	The status in reference regulatory authorities	Manufacturer Name: Daiichi Sankyo Co., Ltd., Brand Name & Strength: Tarlige Tablets 10mg , Reference Regulatory Authority: PMDA Approved.
	Detail of previous approval	Mirogab 10mg Tablet, M-344.
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
385	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Saibins Pharmaceuticals Plot No.316 Industrial Triangle Kahutta Road Islamabad (000773)
	Application Form Dy. No / Tracking ID & date of submission	(P6R-QUT-565Z, 2025-04-08)

	Detail of Fee Submitted	93000.0, 2024-12-16,
	The proposed proprietary name / brand name	Saipenem Injection 500mg IV
	Label Claim	Each Vial Contains: Each Vial Contains: Meropenem (as Trihydrate) blended with sodium carbonate----- 500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	2 YearStore in cool and dry place below 30C
	For generic drugs (me-too Status)	Meropam 500mg Inj IV (Munawar Pharma Lahore)Reg.No.107175
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio Next Pharmaceuticals -Plot#50 Street -S10 RCCI, Rawat-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Meropen 500mg Injection, 333rd
	Evaluation Remarks	
	MENEPOR 500 mg Injection IV of Bio Next was approved in 296th meeting of the Registration Board.	
	Decision	
	Approved	
386	Case Category	Routine (Incharge Evaluation Cell)
	Name, address of Applicant.	Caliph Pharmaceuticals Plot 17, Special Industrial Zone Risalpur, KPK (000748)
	Application Form Dy. No / Tracking ID & date of submission	(P8N-29J-47RT, 2024-04-17)
	Detail of Fee Submitted	30000.0, 2024-03-13,
	The proposed proprietary name / brand name	CALTRIM 1% W/W CREAM
	Label Claim	Each gram of cream contains: Clotrimazole 10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)25°C
	For generic drugs (me-too Status)	Canesten 1% w/w Cream M/s Bayer Health Care
	Pharmacotherapeutic Group of (API)	Antifungals
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	HALCYON LABS PVT. LTD., Plot No. 409, Phase – IV, GIDC Industrial estate, Naroda, Ahmedabad – 382 330, Gujarat, INDIA
	Detail of stability batches of drug product	3 batches: 500 tubes
	Documents for the procurement of API with approval from DRAP (in case of Import)	02-08-2021: AD attested invoice submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Canesten Cream: PE studies performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IV-A
	The status in reference regulatory authorities	Canesten Cream (MHRA Approved)

	GMP status of the firm	13-03-2023: GMP certificate inspection date
	Evidence of approval of manufacturing facility	17-01-2019: letter for grant of additional section specifies cream / ointment / lotion section.
	Evaluation Remarks	
	Decision	
	Approved	
387	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Hudson Pharma (Pvt) Ltd D-93, North Western Industrial Zone, Port Qasim Authority (000842)
	Application Form Dy. No / Tracking ID & date of submission	(PB7-W9W-XHY1, 2025-05-12)
	Detail of Fee Submitted	93000.0, 2025-01-08,
	The proposed proprietary name / brand name	Minoxgro 2% Topical Spray
	Label Claim	Each ml contains: Minoxidil.....20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	60ml-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Regro 2%w/v Topical solution
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Private Limited-Plot No. 129 – Sunder Industrial Estate Raiwind Road, Lahore, Pakistan-
	The status in reference regulatory authorities	Bosley Woman 2 Minoxidil Topical Solution-USFDA
	Detail of previous approval	M-343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
388	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Saaaf Pharmaceuticals Risalpur, Nowshera, Khyber Pakhtunkhwa 23200 (000637)
	Application Form Dy. No / Tracking ID & date of submission	(PQU-9HQ-SGE4, 2025-04-25)
	Detail of Fee Submitted	93000.0, 2025-01-13,
	The proposed proprietary name / brand name	Suspension Sildifil
	Label Claim	Each ml contains Sildenafil as Citrate 10mg/ml
	Reference to Finished product specifications	British Pharmacopeia

	Proposed Pack Size	112 ml-As per SRO
	Shelf Life (Unit)	2 YearBelow 25c
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Gray's Pharmaceuticals-Plot No2, street No. N-3,National Industrial Zone, Rawat.-
	The status in reference regulatory authorities	NA
	Detail of previous approval	Selden10mg/ml, 343rd DRB meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
389	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	McOlson Research Laboratories Pvt. Ltd Plot No. 02, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhpura Pakistan (000664)
	Application Form Dy. No / Tracking ID & date of submission	(PUJ-Y5Q-AYTD, 2025-01-23)
	Detail of Fee Submitted	93000.0, 2024-11-12,
	The proposed proprietary name / brand name	Emalgo 3 mg Tablets
	Label Claim	Each Tablet Contains: Semaglutide: 3 mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 20's, 30's-As per SRO
	Shelf Life (Unit)	2 YearBelow 30C
	For generic drugs (me-too Status)	Sematide 3mg Tablets By Ferozsons Laboratories
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot # 69/2. Phase-II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	https://www.medicines.org.uk/emc/product/11507/s
	Detail of previous approval	Rybelsus 3 mg Tablet approved in 340th DRB Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Deferred	
	Referred to Biological Evaluation & Research Division	
390	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	M/s Daneen Pharma (Pvt) Ltd Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, (000688)
	Application Form Dy. No / Tracking ID & date of submission	(PVW-1W6-W187, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2025-01-21,
	The proposed proprietary name / brand name	Ansidap
	Label Claim	Each ml contains: Escitalopram oxalate, equivalent to Escitalopram.....1 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	30ml,60ml,120ml-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C. Protect from heat, light & Moisture
	For generic drugs (me-too Status)	Depsit Oral solution 1mg/ml by Genix Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Genix Pharma Pvt Ltd -44, 45B, KORANGI CREEK ROAD, KARACHI. PAKISTAN-
	The status in reference regulatory authorities	Escitalopram Oxalate 1mg/ml by Macleods Pharma Ltd
	Detail of previous approval	Depsit 1mg/ml oral solution. DRB # 343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
391	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	CIBA Pharmaceuticals (Pvt) Ltd. A-371, Nooriabad S.I.T.E., Karachi, Hyderabad Super Highway, District Jamshoro (000825)
	Application Form Dy. No / Tracking ID & date of submission	(PXA-U64-RTQM, 2025-04-21)
	Detail of Fee Submitted	93000.0, 2024-12-05,
	The proposed proprietary name / brand name	Abilo 5mg/5ml Oral Solution
	Label Claim	Each 5ml contains: Ebastine.....5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO

	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Kestine 5mg/5ml Liquid (Regn. No. 028369) Highnoon Laboratories Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s. Swiss Pharmaceutiucals Pvt. Ltd.-A/159, S.I.T.E. II Super Highway, Karachi – Pakistan-
	The status in reference regulatory authorities	Ebastel 1 mg/ml oral solution, Manufacturer: Industrias Farmacéuticas Almirall, S.A., Crta. de Martorell 41-61, 08740 Sant Andreu de la Barca, Barcelona - Spain, MAH: Almirall S.A. General Mitre 151, 08022 Barcelona, Spain
	Detail of previous approval	EBAT 5mg/5ml Liquid, 345
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
392	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Pasteur & Fleming Pharma Plot # 70A , Phase -3, Road No-04, Industrial Estate Hattar, K.P.K. Pakistan (000945)
	Application Form Dy. No / Tracking ID & date of submission	(Q1B-HAD-J2PH, 2025-05-12)
	Detail of Fee Submitted	93000.0, 2025-01-08,
	The proposed proprietary name / brand name	EMFIN 25/5mg Tablet
	Label Claim	Each film coated tablet contains: Empagliflozin.....25 mg Linagliptin.....5 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's -As per SRO,28's-As per SRO,30's-As per SRO,7's-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature.
	For generic drugs (me-too Status)	LinJardy tablet by CCL Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-
	The status in reference regulatory authorities	GLYXAMBI by Boehringer Ingelheim Pharmaceuticals, Inc
	Detail of previous approval	Glulina-E 25/5mg Tablet (Meeting no. 343rd)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a	

	declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
393	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Tovida Pharmaceuticals (Pvt) Ltd Plot No.7, Street No.S-07, RCCI Industrial Estate Islamabad (000996)
	Application Form Dy. No / Tracking ID & date of submission	(Q2Q-35J-NWHS, 2025-05-15)
	Detail of Fee Submitted	93000.0, 2024-11-07,
	The proposed proprietary name / brand name	Tovizone 1g INJECTION
	Label Claim	Each Vial Contains: Cefoperazone (as sodium).....500mg Sulbactam (as sodium).....500mg (JP specs)
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	2 Year25C - 30C+-
	For generic drugs (me-too Status)	GENERIC DRUG
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Biogen Life Sciences -8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	PMDA Japan Approved)
	Detail of previous approval	SULGEN 1g Injection, M-316
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
394	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	De-Mont Research Laboratories (Pvt.) Ltd. 20 Km, Lahore-Sheikhupura Road, Sheikhupura, Pakistan (000844)
	Application Form Dy. No / Tracking ID & date of submission	(Q2Q-L9E-SAUY, 2025-03-11)
	Detail of Fee Submitted	93000.0, 2024-10-15,
	The proposed proprietary name / brand name	Clio Eye Ointment
	Label Claim	Each gm contains: Ciprofloxacin HCl eq. to Ciprofloxacin.....3 mg (USP Specifications)

	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Yearstore below 30 degree centigrade
	For generic drugs (me-too Status)	ROCIP (Remington Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Medevo (Pvt) Ltd.-Plot No. 94, Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	C i p r o f l o x a c i n 3 m g / g m E y e O i n t m e n t s (ALCON Laboratories USA)
	Detail of previous approval	SURGICIP EYE OINTMENT (M-331)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
395	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Dyson Research Laboratories (Pvt.) Ltd 28-Km Ferozpur Road Lahore (000559)
	Application Form Dy. No / Tracking ID & date of submission	(Q49-MSX-DLL4, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2025-01-06,
	The proposed proprietary name / brand name	Dubin
	Label Claim	Each 1ml ampoule contains: Nalbuphine HCl.....10 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	2 YearStore at 25°C.
	For generic drugs (me-too Status)	Nubin Injection by Searle Company (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Labs (Pvt.) Ltd.-Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad.-
	The status in reference regulatory authorities	Nalbuphine Hydrochloride Injection by Hospira, approved by US-FDA.
	Detail of previous approval	Nalcin Injection 10mg approved in 336 DRB meeting of Registration Board held on 04 - 06 June, 2024.
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned	

	notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
396	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Jenner Pharmaceuticals Pvt. Ltd Plot No. 03, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhpura (000823)
	Application Form Dy. No / Tracking ID & date of submission	(Q5E-QTD-HHHX, 2025-01-23)
	Detail of Fee Submitted	93000.0, 2024-11-15,
	The proposed proprietary name / brand name	Nugovy Tablets 3mg
	Label Claim	EACH TABLET CONTAINS: - SEMAGLUTIDE.....3MG
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10s, 20s, 30s & 7s, -De-Controlled
	Shelf Life (Unit)	24 MonthStore below 30C
	For generic drugs (me-too Status)	SEMMA 3MG TABLET by WEATHER FOLDS PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK -
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Rybelsus 14mg Tablet (M-340)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Deferred	
	Referred to Biological Evaluation & Research Division	
397	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	linear pharma plot # 18 street # s-4 national industrial zone (rcci) rawat islamabad (000670)
	Application Form Dy. No / Tracking ID & date of submission	(Q69-U53-QPNE, 2025-04-06)
	Detail of Fee Submitted	75000.0, 18000.0 2024-08-29, 2024-10-22
	The proposed proprietary name / brand name	Citicholin
	Label Claim	Each ml contains: Citicholine as sodium.....100mg
	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 YearRoom Temperature.
	For generic drugs (me-too Status)	Citolin Oral solution by Global Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-
	The status in reference regulatory authorities	Citicolina Normon 100 mg/ml oral solution EFG by LABORATORIOUS NORMON, S.A
	Detail of previous approval	Strocit Oral Solution 100mg/ml (Meeting # 331st)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
398	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Steris Pharmaceuticals Plot No 9 Near Synpac Hattar Private Industrial Estate Haripur Road Hattar (000995)
	Application Form Dy. No / Tracking ID & date of submission	(Q6D-5E6-7UZM, 2025-04-18)
	Detail of Fee Submitted	93000.0, 2025-03-13,
	The proposed proprietary name / brand name	Rebone
	Label Claim	Each sachet contains: Strontium ranelate MS.....2g (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 25
	For generic drugs (me-too Status)	Yes
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd-Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, Rawalpindi-Pakistan-
	The status in reference regulatory authorities	Registered in UK Brand Name: Strontium ranelate Aristo 2g sachet
	Detail of previous approval	Strot 2g Sachet,Minutes of 343th meeting of Registration Board, Registered with Brand Name as "Maqsa
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation,	

	specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
399	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	M/s Daneen Pharma (Pvt) Ltd Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, (000688)
	Application Form Dy. No / Tracking ID & date of submission	(QAB-J7Q-Q5ZN, 2025-02-12)
	Detail of Fee Submitted	75000.0, 18000.0 2024-08-06, 2024-12-17
	The proposed proprietary name / brand name	Emlif ML XR
	Label Claim	Each Film coated tablet contains: Metformin HCl (As extended release core)...1000mg (Core) Empagliflozin (As immediate release) 5mg Linagliptin (As immediate release)..... 2.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7, 10, 14's, 20, 28'-As per SRO
	Shelf Life (Unit)	24 YearStore below 30°C. Protect from heat, light and moisture.
	For generic drugs (me-too Status)	Emglif LM XR Tablet 5mg/2.5mg/1000mg by Genix Pharma (Reg. No. 120303)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Genix Pharma (Pvt.) Ltd.-44, 45-B, Korangi Creek Road, Karachi-75190, Pakistan-
	The status in reference regulatory authorities	TRIJARDY XR 2.5mg/5mg/1000mg (Boehringer Ingelheim International)
	Detail of previous approval	Emlimet XR Tablet 2.5mg/5mg/1000mg, DRB 336
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
400	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Trigon Pharmaceuticals (Private) Ltd 8-k.m thokar raiwind road Lahore (000342)
	Application Form Dy. No / Tracking ID & date of submission	(QAL-3ER-DWLD, 2025-05-14)
	Detail of Fee Submitted	93000.0, 2024-10-15,

	The proposed proprietary name / brand name	MPA
	Label Claim	Each Film Coated Tablet contains: Empagliflozin.....10mg Metformin Hydrochloride.....1000mg (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1*14's-As per SRO
	Shelf Life (Unit)	2 YearBelow 25
	For generic drugs (me-too Status)	Erli Plus XR TABLET (PHARMEVO)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Winbrains Research Laboratories, -PLOT #69-1, BLOCK-B, PHASE I-II, HATTAR INDUSTRIAL ESTATE, HATTAR KPK -
	The status in reference regulatory authorities	EMPAGLIFLOZIN + METFORMIN 10mg + 1000mg XR TABLET USFDA Reference: https://www.accessdata.fda.gov/drugsatfda_docs/lab
	Detail of previous approval	343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
401	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	M/s Daneen Pharma (Pvt) Ltd Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, (000688)
	Application Form Dy. No / Tracking ID & date of submission	(QM8-SHN-7PWP, 2025-05-26)
	Detail of Fee Submitted	75000.0, 18000.0 2024-08-06, 2025-05-20
	The proposed proprietary name / brand name	Emlif ML XR
	Label Claim	Each Film coated tablet contains: Empagliflozin (As immediate release) 12.5mg Linagliptin (As immediate release) 2.5mg Metformin HCl (As extended release Core) 1000mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's, 28's & 30's-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30°C. Protect from heat, light and moisture.
	For generic drugs (me-too Status)	Emglif LM XR Tablet 12.5mg/2.5mg/1000mg by Genix Pharma (Reg. No. 120305)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Genix Pharma (Pvt.) Ltd.-44, 45-B, Korangi Creek Road, Karachi-75190, Pakistan-

	The status in reference regulatory authorities	Trijardy XR Tablet (USFDA Approved)
	Detail of previous approval	EMLIMET XR 2.5mg/12.5mg/1000 mg Tablet , DRB 336
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision Approved	
402	Case Category	Contract Manufacturing (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	(QNU-54G-J556, 2025-04-08)
	Detail of Fee Submitted	93000.0, 2024-12-09,
	The proposed proprietary name / brand name	Dologab CR Tablets 165mg
	Label Claim	Each Extended-Release tablet contains: Pregabalin.....165 mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30s-As per SRO
	Shelf Life (Unit)	2 YearBelow 30
	For generic drugs (me-too Status)	Revogab
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceutical (Pvt.) Ltd-Plot # 129, Sunder Industrial Estate, Lahore – Pakistan-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Gabal 165mg ER tablet,324th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision Approved	
403	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Trigon Pharmaceuticals (Private) Ltd 8-k.m thokar raiwind road Lahore (000342)
	Application Form Dy. No / Tracking ID & date of submission	(QR1-5MM-VWM2, 2025-04-03)

	Detail of Fee Submitted	93000.0, 2024-11-27,
	The proposed proprietary name / brand name	SRS Sachet 2gm
	Label Claim	Each Sachet contains: Strontium Ranelate.....2gm
	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 YearRoom Temperature.
	For generic drugs (me-too Status)	Onita Sachet by Pharmevo Pvt. Ltd
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-
	The status in reference regulatory authorities	Aristo Sachet by Aristo Pharma, Germany
	Detail of previous approval	Dairo 2g Sachet (Meeting # 336th)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
404	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Jinnah Pharmaceuticals Pvt Ltd 13 Km Lahore Road Multan (000578)
	Application Form Dy. No / Tracking ID & date of submission	(QYQ-VEY-X2BD, 2025-04-25)
	Detail of Fee Submitted	93000.0, 2024-12-12,
	The proposed proprietary name / brand name	Jcef 2g IV Dry Powder Injection
	Label Claim	Each Vial Contains ceftriaxone Sodium Equivalent to Ceftriaxone 2g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1`s-Controlled
	Shelf Life (Unit)	2 YearBelow 30%
	For generic drugs (me-too Status)	Sami Pharmaceuticals (Oxidil 2g)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/S.High-Cure Research Laboratories -19-KM Tayyaba industrial zone Sheikhpura Road Lahore-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	HIXONE INJ 2g IV (M-331)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned	

	notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
405	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winthrox Laboratories Pvt. Ltd K-219-A, SITE, Super Highway Phase II, Karachi (000807)
	Application Form Dy. No / Tracking ID & date of submission	(R24-TL4-ERQJ, 2025-01-15)
	Detail of Fee Submitted	75000.0, 18000.0 2024-08-08, 2024-10-08
	The proposed proprietary name / brand name	Colisto 2MIU Injection
	Label Claim	Each vial contains: Colistimethate Sodium 2 million International Units (IU) eq. to 160mg of Colistimethate Sodium (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25 Degree Centigrade
	For generic drugs (me-too Status)	Genthane Injection 2MIU IV Registration Number 108055
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Biogen Life Sciences-8-Km, Chakbeli Road, Rawat-
	The status in reference regulatory authorities	Colistimethate Sodium Injection USFDA Approved
	Detail of previous approval	Genthane Injection 2MIU in 297 Meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
406	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Dyson Research Laboratories (Pvt.) Ltd 28-Km Ferozpur Road Lahore (000559)
	Application Form Dy. No / Tracking ID & date of submission	(R33-MUE-9EZY, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2025-01-06,
	The proposed proprietary name / brand name	Vbacin
	Label Claim	Each vial contains: Vancomycin HCL eq. to vancomycin.....1gm.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO

	Shelf Life (Unit)	2 YearStore below 25C.
	For generic drugs (me-too Status)	Vancorin Injection 1gm by CJ Corporation Korea and imported by Hoffmann Human Health (Pak.) Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Labs (Pvt.) Ltd.-Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad.-
	The status in reference regulatory authorities	Vancomycin Hydrochloride 1gm by FRESENIUS KABI USA, approved by US-FDA.
	Detail of previous approval	Vanconext Powder for Solution for Infusion 1gm, approved in Minutes of 343 meeting of Registration B
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
407	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	MEDPHARM RESEARCH LAB 28 KM FEROZPUR ROAD LAHORE (000878)
	Application Form Dy. No / Tracking ID & date of submission	(R4U-98Z-V9GD, 2025-01-20)
	Detail of Fee Submitted	75000.0, 18000.0 2024-04-26, 2024-11-25
	The proposed proprietary name / brand name	MED-JECT 100MG/5ML
	Label Claim	Each 5ml Contains: IRON (III) HYDROXIDE SUCROSE COMPLEX Eq. to ELEMENTAL IRON.= 100mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	as per DPC-As per SRO
	Shelf Life (Unit)	2 Yearbelow 24 degree
	For generic drugs (me-too Status)	venofer
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	May & Baker Pvt Ltd-HOUSE NO 23, STREET NO 5 SECTOR B, GHORI BLOCK BAHRIA TOWN, Pakistan-
	The status in reference regulatory authorities	FDA Approved
	Detail of previous approval	Bakrofor 100mg/5ml Injection Meeting # 323
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned	

	notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
408	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Med Asia Pharmaceuticals (Pvt) Ltd Plot No. 7, Nowshera Industrial Estate (SIZ) Risalpur (000690)
	Application Form Dy. No / Tracking ID & date of submission	(R5A-NH6-V12E, 2025-04-24)
	Detail of Fee Submitted	75000.0, 2024-07-24,
	The proposed proprietary name / brand name	Tofamed 5mg tablet
	Label Claim	Each film coted tablet contains: Tofacitinib citrate eq. to tofacitinib 5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearstore below 30 C.
	For generic drugs (me-too Status)	Brand Name: Tofab 5mg Tablet Registration holder: Genome Pharmaceuticals (Pvt.) Ltd Plot No. 16/1, Industrial Estate Hattar,, Haripur, Pakistan
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Seraph Pharmaceutical-Plot # 210, Industrial Triangle, Kahuta Road, Islamabad, Pakistan-
	The status in reference regulatory authorities	FDA approved drug
	Detail of previous approval	Toproz 5mg Tablet , Meeting No :336th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
409	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(R66-WWR-V1WM, 2024-09-09)
	Detail of Fee Submitted	75000.0, 2024-08-19,
	The proposed proprietary name / brand name	LEVENUE 100MG/ML ORAL SOLUTION
	Label Claim	Each ml contains: Levetiracetam 100mg
	Reference to Finished product specifications	United States Pharmacopeia

	Proposed Pack Size	As per SRO -As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Epian 100mg/ml Oral Solution(Pharmasol (Pvt) Ltd Plot No. 549, Sundar Industrial Estate, Lahore, Pakistan) 093124
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	SERAPH PHARMACEUTICAL-Plot No 210, Industrial triangle, Kahuta road, Islamabad-Pakistan-
	The status in reference regulatory authorities	KEPPRA 100mg/ml Oral Solution(UCB Pharma Limited 208 Bath Road Slough Berkshire SL1 3WE United Kingdom, approved in FDA.)
	Detail of previous approval	339th meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
410	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Trigon Pharmaceuticals (Private) Ltd 8-k.m thokar raiwind road Lahore (000342)
	Application Form Dy. No / Tracking ID & date of submission	(RD9-ET1-QW5D, 2025-05-14)
	Detail of Fee Submitted	93000.0, 2024-11-27,
	The proposed proprietary name / brand name	Nuroclub Tablet 330mg
	Label Claim	Each film coated extended release tablet contains: Pregabalin.....330mg
	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 YearRoom Temperature.
	For generic drugs (me-too Status)	Gablin CR 330mg Tablet by CCL Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-
	The status in reference regulatory authorities	Lyrica CR 330mg Tablet by Pfizer
	Detail of previous approval	Nepco 330mg Tablet (Meeting 343rd)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned	

	notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
411	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Skywin Pharmaceutical Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road (000971)
	Application Form Dy. No / Tracking ID & date of submission	(REQ-WDE-RPPN, 2025-02-11)
	Detail of Fee Submitted	93000.0, 2024-12-23,
	The proposed proprietary name / brand name	Ceftriax 2gm IV Injection
	Label Claim	Each Vial contains: Ceftriaxone Sodium (USP) eq. to Ceftriaxone.....2g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO / DPC-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Oxidil 2gm Injection of M/s SAMI
	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	Ceftriaxone 2g Powder for solution for injection of M/s Wockhardt UK Ltd (MHRA Approved)
	Detail of previous approval	Welcef 2gm IV Injection approved in 330th meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
412	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	FAAS Pharmaceuticals (Pvt)Ltd F-748 L, S.I.T.E, Karachi (000767)
	Application Form Dy. No / Tracking ID & date of submission	(RGM-RY8-2T4T, 2024-08-29)
	Detail of Fee Submitted	75000.0, 2024-07-04,
	The proposed proprietary name / brand name	Fastam 100mg/ml Injection
	Label Claim	Each ml contains; Levetiracetam 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO

	Shelf Life (Unit)	2 Yearstore below 30 C.
	For generic drugs (me-too Status)	Brand Name: Lerace 100mg/ml injection Registration holder: Hilton pharma Lahore Pakistan.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Seraph Pharmaceutical-Plot # 210, Industrial Triangle, Kahuta Road, Islamabad, Pakistan-
	The status in reference regulatory authorities	FDA approved drug
	Detail of previous approval	Levace , PRVC 119th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
413	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Solaris Life Sciences Private Limited , Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992)
	Application Form Dy. No / Tracking ID & date of submission	(RH1-DQX-ER8Y, 2025-06-02)
	Detail of Fee Submitted	93000.0, 2025-04-28,
	The proposed proprietary name / brand name	Procetrol-2mcg Soft gel Capsules
	Label Claim	Each soft gelatin capsule contains: Paricalcitol.....2mcg
	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)	Parical 2mcg Soft gelatin Capsule Reg. No. 124503
	Pharmacotherapeutic Group of (API)	Vitamin D2 and Vitamin D analogs
	Name, address of Manufacturing site:	Biogen Life Sciences-8-KM, Chakbeli Road, Rawat, Rawalpindi-PAKISTAN.-
	The status in reference regulatory authorities	FDA Approved. Zemplar (Paricalcitol) 2mcg Soft Gel Capsule
	Detail of previous approval	DRB M-339 By the Name of Parical 2mcg Soft gelatin Capsule
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	

	Decision	
	Approved	
414	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	The Searle Company Limited Karachi (000016)
	Application Form Dy. No / Tracking ID & date of submission	(RHP-Y4A-GGQV, 2025-01-16)
	Detail of Fee Submitted	93000.0, 2024-12-06,
	The proposed proprietary name / brand name	NMP 200mg Capsule
	Label Claim	Each soft gel capsule contains: Micronized Progesterone.....200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's, 14's, 15's, 28'-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 °C.
	For generic drugs (me-too Status)	U-Progest Capsules 200mg by Aspin Pharma (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Searle Pakistan Limited-C-14, Manghopir Road, S.I.T.E, Karachi - 75700, Sindh, Pakistan-
	The status in reference regulatory authorities	PROMETRIUM 200mg Capsule by BESINS MANUFACTURING BELGIUM - Groot-Bijgaardenstraat, 128 - 1620 Drogenbos (Belgium)
	Detail of previous approval	Ogestron 200mg Capsule in 335th Minutes of meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
415	Case Category	New Section (Incharge Evaluation Cell)
	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	(RMM-UE7-MMX1, 2025-04-09)
	Detail of Fee Submitted	75000.0, 2025-02-14,
	The proposed proprietary name / brand name	Tucatin 50mg Tablet
	Label Claim	Each Film Coated Tablet Contains Tucatinib 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,30's-As per SRO,60's-As per SRO

	Shelf Life (Unit)	2 Year(s)store below 30°C in a cool and dry place
	For generic drugs (me-too Status)	Not applicable as it is a new drug product
	Pharmacotherapeutic Group of (API)	Antineoplastic agents, protein kinase inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	GANSU HAOTIAN PHARMATECH CO., LTD. address: No.11 Chongqing Road,Baiyin District, Baiyin City, Gansu Province
	Detail of stability batches of drug product	3 batches: 1000 tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	01-10-2024: Drug Import License, along with Commercial invoice and Fedex receipt is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Tukysa 50mg Tablet of Seattle Genetics Inc: PE and CDP submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches as per zone IV-A
	The status in reference regulatory authorities	TUKYSA 50mg Tablet (USFDA Approved)
	GMP status of the firm	20-11-2024: GMP report concludes satisfactory compliance to GMP
	Evidence of approval of manufacturing facility	10-05-2024: Tablet (Cytotoxic) New Section
	Evaluation Remarks	
	Decision	
	Approved	
416	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	M/s Daneen Pharma (Pvt) Ltd Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, (000688)
	Application Form Dy. No / Tracking ID & date of submission	(RRD-27R-MW3N, 2025-04-08)
	Detail of Fee Submitted	93000.0, 2024-12-06,
	The proposed proprietary name / brand name	Zuvaroz-V
	Label Claim	Each film coated tablet contains: Valsartan 160mg Rosuvastatin (as Rosuvastatin calcium) 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's, 10's,14's,20's,-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C. Protect from heat, light & Moisture
	For generic drugs (me-too Status)	Rosca-V Tablet by Genix Pharma Pvt Ltd (123281)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Genix Pharma Pvt Ltd -44, 45B, KORANGI CREEK ROAD, KARACHI. PAKISTAN-
	The status in reference regulatory authorities	Valsaros 10mg/160mgfilm coated tablets by TAD Pharma GmbH, Germany
	Detail of previous approval	Rosca-V Tablet 10mg/160mg DRB 339
	Evaluation Remarks	

	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
417	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winthrox Laboratories Pvt. Ltd K-219-A, SITE, Super Highway Phase II, Karachi (000807)
	Application Form Dy. No / Tracking ID & date of submission	(RSX-41P-GUEL, 2025-05-14)
	Detail of Fee Submitted	93000.0, 2025-01-15,
	The proposed proprietary name / brand name	Wonozan Tablet 10mg
	Label Claim	Each film coated tablet contains:: Vonoprazan as Fumarate.....10mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Vonnp 10mg Tablet by Weather Folds Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s WnsFeild Pharmaceuticals-Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	PMDA Japan Approved
	Detail of previous approval	Verozen Tablet 10mg approved in Meeting of 322 Drug Registration Board for Wnsfeild Pharmaceuticals
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
418	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Swiss Pharmaceuticals Pvt. Ltd. A/159, S.I.T.E.-II, Super Highway (000438)
	Application Form Dy. No / Tracking ID & date of submission	(RVJ-6HA-2ZJL, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2025-02-14,

	The proposed proprietary name / brand name	Ceftar Powder For Injection 400mg
	Label Claim	Each Vial contains: Ceftaroline Fosamil as Ceftaroline Fosamil Monoacetate Monohydrate with L-arginine.....400mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x1's, 1x10's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Brand name: Daytef 400mg Injection, Manufacturer/Registration holder: M/S High-Q Pharmaceuticals, Approved by DRAP in 329th meeting.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt.) Ltd. -Plot No. 129, Sundar Industrial Estate Raiwind Road Lahore Pakistan-
	The status in reference regulatory authorities	Manufacturer Name: M/S Allergan USA, Inc.Madison, NJ 07940 Brand Name & Strength: Teflaro (ceftaroline Fosamil) for Injection 400mg/vial, NDC 0456-0400-10 Packing: 10single-use vial Dosage Form: Powder for Injection, Reference Regulatory Authority: USFDA approved.
	Detail of previous approval	Teflor 400mg Injection, M-339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
419	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(RZ1-TJB-493Y, 2025-05-08)
	Detail of Fee Submitted	93000.0, 2025-04-15,
	The proposed proprietary name / brand name	Golix 120mg Tablet
	Label Claim	Each Film Coated Tablet contains: Relugolix.....120mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO / DPC-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	gonadotropin-releasing hormone (GnRH) receptor antagonists

	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhpura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	ORGOVYX (relugolix) tablets 120mg of M/s Sumitomo Pharma America, Inc., Marlborough, MA 01752 (USFDA Approved)
	Detail of previous approval	Rexilo 120mg Tablet approved in 344th Meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
420	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Effort Pharmaceuticals (Pvt.) Ltd., 28-Km, Ferozepur Road (000879)
	Application Form Dy. No / Tracking ID & date of submission	(S2E-69X-98GD, 2025-03-08)
	Detail of Fee Submitted	93000.0, 2024-11-12,
	The proposed proprietary name / brand name	Fit-D Injection 5mg
	Label Claim	Each 1ml ampoule contains: Vitamin D3 5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearStore at temperature 15 to 30 C away from sunlight
	For generic drugs (me-too Status)	Indrop-D Injection by M/s Neutro Pharma (Reg#023170)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	May & Baker Pharmaceuticals (Pvt.) Ltd.-45 Km, Thokar Multan road, Lahore-
	The status in reference regulatory authorities	Approved by ANSM of France.
	Detail of previous approval	V-Drop 5mg/ml Injection Approved In (Minutes of 323rd meeting of Registration Board (6th to 8th Dece
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
421	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Air Pharmaceuticals(Pvt.)Ltd Plot No's 74, 75-A, Small Industrial Estate, Kasur (000977)
	Application Form Dy. No / Tracking ID & date of submission	(S6W-ZLY-WATV, 2025-05-07)
	Detail of Fee Submitted	30000.0, 63000.0 2023-12-15, 2025-04-11
	The proposed proprietary name / brand name	Epa
	Label Claim	Each Film coated Tablet Contains: Empagliflozin.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	2 Year(s)below 30°C in dry cool environment
	For generic drugs (me-too Status)	Empator 10mg by Horizon Pharma Reg no. 098822
	Pharmacotherapeutic Group of (API)	SGLT2 Inhibitor, ATC code: A10BX12. Empagliflozin is a reversible competitive inhibitor of SGLT2 with an IC50 of 1.3 nM. It has a 5000-fold selectivity over human SGLT1 (IC50 of 6278 nM), responsible for glucose absorption in the gut.
	Name, address of Manufacturing site:	Novamed Pharmaceuticals(Pvt.)Ltd-28KM Ferozepur Road Lahore-
	Name & address of API manufacturer	Jiangsu Yong'an Pharmacy Company Limited,No.18 ,237 Proviencial, Road ,Economic Development Zone, Huai'an Jiangsu,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	Jardiance 10mg tablet Boehringer Ingelheim Limited USA
	GMP status of the firm	.
	Evidence of approval of manufacturing facility	Novamed Pharmaceuticals(Pvt.)Ltd, DML (Formulation) 000590
	Evaluation Remarks	
	The applicant had selected "yes" for data already approved in the contract manufacturing application. It was checked that Tablet Empozin 10 mg of M/s Novamed Pharmaceuticals was approved in the 324th Meeting of Registratoin Board. Applicant also paid differential fee of Rs63,000/- vide challan number 64380624469 dated 11/04/2025.	
	Decision	
	Approved	
422	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winthrox Laboratories Pvt. Ltd K-219-A, SITE, Super Highway Phase II, Karachi (000807)

	Application Form Dy. No / Tracking ID & date of submission	(SEN-UME-ZZNU, 2025-05-14)
	Detail of Fee Submitted	93000.0, 2025-01-15,
	The proposed proprietary name / brand name	Isowin Soft Gel Capsule 20mg
	Label Claim	Each Soft Gel Capsule Contains: Isotretinoin.....20mg (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Oratane 20mg Capsule by Crystolite Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Biogen Life Sciences-8-Km, Chkbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Isotretinoin 20mg Capsule MHRA Approved
	Detail of previous approval	Biotan Capsule in 312th Meeting of Drug Registration Board Approved for Biogen Life Science
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
423	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Kanel Pharma Plot No. 6, Street No. SS-3, National Industrial Zone, Rawat (000758)
	Application Form Dy. No / Tracking ID & date of submission	(SH6-MBL-MBNX, 2025-04-24)
	Detail of Fee Submitted	93000.0, 2025-04-17,
	The proposed proprietary name / brand name	Kanasil Suspension
	Label Claim	Each ml of reconstituted Suspension Contains: Sildenafil as Citrate (BP).....10mg(BP Specs)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30c
	For generic drugs (me-too Status)	Silagro by Nabi Qasim
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 inhibitor (PDE5-I)
	Name, address of Manufacturing site:	M/S Welcome Pakistan Trading Pharma (Pvt) Ltd- Chakri Interchange, Ganganwala, Rawalpindi -
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Defsil Suspension, 344th Meeting
	Evaluation Remarks	

	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
424	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(SLH-EEU-13PT, 2025-06-17)
	Detail of Fee Submitted	93000.0, 2025-05-21,
	The proposed proprietary name / brand name	Baclin 5 mg/5 ml Oral Solution
	Label Claim	Each 5ml contains: Baclofen..... 5mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per Sro-As per SRO
	Shelf Life (Unit)	2 YearBelow 25 C
	For generic drugs (me-too Status)	Liorex 5mg/5ml Oral Solution
	Pharmacotherapeutic Group of (API)	AntiSpasmodic agent
	Name, address of Manufacturing site:	SERAPH PHARMACEUTICAL -Plot # 210, Industrial Triangle, Kahuta road, Islamabad.-
	The status in reference regulatory authorities	Baclofen Oral solution 5mg/5ml
	Detail of previous approval	LIOREX 5mg/5ml Oral Solution, M-336
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
425	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	MEDPHARM RESEARCH LAB 28 KM FEROZPUR ROAD LAHORE (000878)
	Application Form Dy. No / Tracking ID & date of submission	(SPD-H84-PAVL, 2025-03-12)
	Detail of Fee Submitted	93000.0, 2024-11-15,
	The proposed proprietary name / brand name	Vorast 4mg/5ml Syrup
	Label Claim	Each 5ml contains: Ondansetron as (hydrochloride dihydrate) 4mg

	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO / DPC-As per SRO
	Shelf Life (Unit)	2 MonthStore at room temperature below 30
	For generic drugs (me-too Status)	Onseron Syrup of M/s Indus Pharma
	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	Zofran 4mg/5ml syrup of M/s Novartis Pharmaceuticals UK Ltd. (MHRA Approved)
	Detail of previous approval	Stawia 4mg/5ml Syrup approved in 326th Meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
426	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wallace Pharma Evolutions Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (000951)
	Application Form Dy. No / Tracking ID & date of submission	(SSL-RP9-B4TE, 2025-05-14)
	Detail of Fee Submitted	93000.0, 2025-01-22,
	The proposed proprietary name / brand name	Emzaa-ML Tablet
	Label Claim	Each Film Coated Extended Release Tablet contains: Empagliflozin.....25mg Linagliptin.....5mg (As immediate release core) Metformin Hydrochloride*.....1000MG (As extended release core) (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	DIAMPA LXR Tablet by Getz Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Welmark Pharmaceuticals-Plot No. 122, Phase-V, Block-B, Industrial Estate, Hattar.-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Empeg-ML XR Tablet, DRB 340
	Evaluation Remarks	
	EMPEG-ML XR TABLET of Welmark Pharmaceuticals was approved in 340th meeting of the Registration Board. Applicant to submit quality agreement and License and GMP status of the	

	following DS manufacturers: Fuxin Long Rui Pharmaceutical CO., Ltd for Empagliflozin Anhui Haikang Pharmaceutical Co., Ltd for Linagliptin AARTI DRUGS LIMITED for Metformin	
	Decision	
	Approved	
427	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Solaris Life Sciences Private Limited , Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992)
	Application Form Dy. No / Tracking ID & date of submission	(SX1-E29-ZV1U, 2025-06-02)
	Detail of Fee Submitted	93000.0, 2025-04-28,
	The proposed proprietary name / brand name	Ketriol-0.25mg SoftGel Capsules
	Label Claim	Each soft gelatin capsule contains: Calcitriol.....0.25mcg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year Below 30°C
	For generic drugs (me-too Status)	Rocaltrol Capsules 0.25mcg Reg. No. 015557 By: Martin Dow Limited,
	Pharmacotherapeutic Group of (API)	Vitamin D analogue
	Name, address of Manufacturing site:	Biogen Life Sciences-8-KM, Chakbeli Road, Rawat, Rawalpindi-PAKISTAN.-
	The status in reference regulatory authorities	FDA Approved. ROCALTROL (calcitriol)
	Detail of previous approval	DRB M-336 By the Name of CALCIGEN 0.25mcg Soft gel Capsule
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
428	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Himedic Pharmaceuticals Pvt Ltd 19 KM link Multan Road Lahore (000824)
	Application Form Dy. No / Tracking ID & date of submission	(SY9-PVA-NDX6, 2025-04-08)
	Detail of Fee Submitted	93000.0, 2024-12-17,
	The proposed proprietary name / brand name	Esonic Capsule 40mg
	Label Claim	Each capsule contains: - Esomeprazole magnesium trihydrate enteric coated pellets eq. to Esomeprazole...40mg USP Specifications

	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	2 YearStore at temperature 15 to 30 C away from sunlight
	For generic drugs (me-too Status)	Nexum Capsule 40mg (Getz Pharma) Reg. No. 033891
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	ICU Pharmaceuticals SMC Pvt. Ltd.-Khewat No. 13/13, Khatooni No. 57/66 Mouza Mirpur Kehna, Tehsil Sharkpur, District Sheikhpura -
	The status in reference regulatory authorities	USFDA approved Nexium capsule
	Detail of previous approval	Minutes of 326th meeting of Registration Board (14th to 16th March, 2023) Page No 967
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
429	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	MEDPHARM RESEARCH LAB 28 KM FEROZPUR ROAD LAHORE (000878)
	Application Form Dy. No / Tracking ID & date of submission	(T2H-85G-HEHS, 2025-03-12)
	Detail of Fee Submitted	93000.0, 2024-11-15,
	The proposed proprietary name / brand name	Dexlo 30mg Capsule
	Label Claim	Each Capsule contains: Dexlansoprazole.....30mg (as dual Delayed released Pellets)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO / DPC-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Dextop 30mg Capsule of M/s Searle
	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	Dexilant 30mg capsule of M/s Takeda Pharmaceuticals America, Inc. Deerfield, IL 60015 (USFDA Approved)
	Detail of previous approval	Dexin 30mg Capsule approved in 331st meeting of DRB
	Evaluation Remarks	

	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
430	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Skywin Pharmaceutical Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhupura road (000971)
	Application Form Dy. No / Tracking ID & date of submission	(T3U-MQN-LWX2, 2025-02-11)
	Detail of Fee Submitted	93000.0, 2024-12-23,
	The proposed proprietary name / brand name	Cefix 400mg Capsule
	Label Claim	Each Capsule contains: Cefixime(as trihydrate).....400mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x4's, 1x5's, 1x10's-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Cebosh 400mg Capsule of M/s Bosch Pharma
	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	SUPRAX 400mg capsule of M/s Lupin Limited (USFDA Approved)
	Detail of previous approval	Myxim 400mg Capsule approved in 326th Meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
431	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Seraph Pharmaceutical Plot No 210, Industrial Triangle Kahuta Road, Islamabad. (000860)
	Application Form Dy. No / Tracking ID & date of submission	(T5Q-JW2-YQZA, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2025-02-04,

	The proposed proprietary name / brand name	Strot 2gm sachet
	Label Claim	Each sachet contains. Strontium Ranelate MS.....2g (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 YearStore below 30C
	For generic drugs (me-too Status)	Brand Name: Osstium Powder 2 gm Sachet Manufacturer: Atco Laboratories Ltd. Address: Manghopir Rd, B-18 Sindh Industrial Trading Estate, Karachi, Sindh, Pakistan
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd.-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	Maqsa 2gm Sachet, Meeting No. M-343rd
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
432	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Max Pharmaceuticals Plot #12, Street # N-7, National Industrial Zone, Rawat, Islamabad. 44000 (000671)
	Application Form Dy. No / Tracking ID & date of submission	(TB1-TMH-MJ7V, 2025-04-21)
	Detail of Fee Submitted	93000.0, 2025-04-10,
	The proposed proprietary name / brand name	FerEso 40mg Injection
	Label Claim	Each vial contains: Esomeprazole sodium equ. to Esomeprazole 40mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Injection in 1 Uni-As per SRO
	Shelf Life (Unit)	2 YearStore below 25 degree centigrade. Protect from heat, light and moisture.
	For generic drugs (me-too Status)	Product: Konzept 40mg Injection Manufacturer: Mcolson Reseach Lab. Rawat Pack size:1's Registration No.: 060700
	Pharmacotherapeutic Group of (API)	Vision Pharmaceuticals
	Name, address of Manufacturing site:	Swera Pharmaceuticals-Address: Plot No. 27, Street No. S-4 National Industrial Zone, Rawat, Islamabad, Pakistan.-

	The status in reference regulatory authorities	Nexium I.V 40mg Injection Country where sold / registered; USA Manufactured by: AstraZeneca Pharmaceuticals LP, Wilmington, DE 19850
	Detail of previous approval	EMOZOL 40mg Injection I.V (Esomeprazole), 322 RB Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision Approved	
433	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Pasteur & Fleming Pharma Plot # 70A , Phase -3, Road No-04, Industrial Estate Hattar, K.P.K. Pakistan (000945)
	Application Form Dy. No / Tracking ID & date of submission	(TBH-PPR-215A, 2025-02-19)
	Detail of Fee Submitted	93000.0, 2024-12-18,
	The proposed proprietary name / brand name	Esomep 40mg Capsule
	Label Claim	Each capsule contains: Esomeprazole magnesium Trihydrate equivalent to Esomeprazole (as enteric coated pellets) 40mg.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14's -As per SRO,28's-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature.
	For generic drugs (me-too Status)	S-ZOLE capsule by NOVAMED Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-
	The status in reference regulatory authorities	Nexium Capsules by ASTRAZENECA
	Detail of previous approval	Staesso 40mg Capsule (Meeting no. 329)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision Approved	
434	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

Name, address of Applicant.	Invictus Pharmaceuticals Plot No. 21, 26 Street No. NS.2, National Industrial Zone Rawat, Islamabad (000892)
Application Form Dy. No / Tracking ID & date of submission	(TDN-ZM3-24P2, 2025-03-08)
Detail of Fee Submitted	93000.0, 2024-11-13,
The proposed proprietary name / brand name	T-bon 3mg/3mL Injection
Label Claim	Each 3ml contains: Ibandronate sodium monohydrate eq. to ibandronic acid 3mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per SRO -As per SRO
Shelf Life (Unit)	24 Month25°C
For generic drugs (me-too Status)	Adronil Injection 3mg/3ml of Searle Company Limited,Pakistan
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	SERAPH PHARMACEUTICAL-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
The status in reference regulatory authorities	Ibandronate sodium 3mg/3ml injection of ACCORD HEALTHCARE
Detail of previous approval	Ibelac 3mg/3ml Injection Minutes of 335th meeting of Registration Board Page No. 112-114

Evaluation Remarks

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

Decision

Approved

435	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Gray's Pharmaceuticals Plot NO2, Street No. N-3, RCCI Rawat Islamabad (000518)
	Application Form Dy. No / Tracking ID & date of submission	(TG5-AEW-ZZTN, 2025-04-25)
	Detail of Fee Submitted	93000.0, 2025-02-22,
	The proposed proprietary name / brand name	Esoren 20mg 375mg Tablet
	Label Claim	Each Modified release Tablet contains: Naproxen 375mg (as Enteric Coated Core) Esomeprazole as Magnesium Trihydrate 20mg (as Immediate Release Coat) (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C

	For generic drugs (me-too Status)	Eznepo Tablet by Wnsfeild Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	Usfda Approved
	Detail of previous approval	Esonyp Tablet, DRB 324
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
436	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	TABROS PHARMA (PVT). LTD. Plot No. L-20/B, Sector 22, F.B. Industrial Area (000106)
	Application Form Dy. No / Tracking ID & date of submission	(TGE-G3P-PBX5, 2025-05-14)
	Detail of Fee Submitted	93000.0, 2025-01-14,
	The proposed proprietary name / brand name	Elatab 150mg Tablet
	Label Claim	Each film coated tablet contains: Elagolix sodium Equivalent to Elagolix.....150mg Innovator's Specification
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's-De-Controlled,2x10's-De-Controlled,2x7's-De-Controlled,3x10's-De-Controlled,4x7's-De-Controlled
	Shelf Life (Unit)	2 YearSTORE BELOW 30oC
	For generic drugs (me-too Status)	Eladiol 150mg Tablet Registration No. 120222 Nabiqasin Industries (Pvt)Ltd
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt). Ltd-Plot No.129, Sunder Industrial Estate Raiwind Road Lahore-
	The status in reference regulatory authorities	Orilissa (Elagolix) 150mg tablet AbbVie Inc. North Chicago IL 60064 USFDA approved
	Detail of previous approval	Orlix 150mg Tablet 343rd DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	

	Decision	
	Approved	
437	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	CUREXA HEALTH (PVT.) LIMITED 517 SUNDER INDUSTRIAL ESTSTE (000864)
	Application Form Dy. No / Tracking ID & date of submission	(THV-JXG-WGBM, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2025-02-11,
	The proposed proprietary name / brand name	Colixa Injection 34mg IV (1MIU)
	Label Claim	Each vial Contains: Colistimethate sodium (1MIU) eq. to 34mg Colistin Base Activity
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 30°C. Keep in a dry place. Protect from light.
	For generic drugs (me-too Status)	Colistim Injection (1MIU) by Pharmasol Pvt. Ltd. (Reg. No.089922)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Labs (Pvt.) Ltd.-Plot # 145, Industrial Triangle, Kahuta Road, Islamabad-
	The status in reference regulatory authorities	MHRA Approved - Product Name: Colomycin 1 million International Units (IU) Powder for solution for injection, infusion - Manufacturer: Teva UK Limited
	Detail of previous approval	Nextcraft 1MIU Injection IV, 330th DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
438	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Pacific Pharmaceuticals Ltd. Plot No.384, Sundar Industrial Estate, Raiwind Road, Lahore (000902)
	Application Form Dy. No / Tracking ID & date of submission	(TJJ-94W-Z449, 2024-12-10)
	Detail of Fee Submitted	93000.0, 2024-11-19,
	The proposed proprietary name / brand name	Tazocare Dry Powder Injection 2.25 g
	Label Claim	Each Vial Contains: Piperacillin Sodium eq. to Piperacillin 2.00 gm, Tazobactam Sodium eq. to Tazobactam 0.250 gm

	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's Vial-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30oC
	For generic drugs (me-too Status)	Tanzo Iv Injection 2.25G by Bosch Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Stallion Pharmaceuticals (Pvt) Ltd.-Plot No. 581, Sunder Industrial Estate, Lahore-
	The status in reference regulatory authorities	Piperacillin/Tazobactam 2g/0.25g Powder for Solution for Infusion by Aurobindo Pharma Milpharm Ltd.
	Detail of previous approval	Talzon Dry Powder Injection 2.25 gm
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
439	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Trigon Pharmaceuticals (Private) Ltd 8-k.m thokar raiwind road Lahore (000342)
	Application Form Dy. No / Tracking ID & date of submission	(TNN-SZY-QYVT, 2025-04-04)
	Detail of Fee Submitted	93000.0, 2024-11-27,
	The proposed proprietary name / brand name	MOUNTEEZ PLUS Sachet 4mg
	Label Claim	Each Sachet contains: Montelukast (as Sodium).....4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14's -As per SRO,2x14's-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature.
	For generic drugs (me-too Status)	Aerokast Sachet 4mg by Barrette Hodgson Pakistan Limited
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-
	The status in reference regulatory authorities	Singulair Sachet by Merck Research Laboratories
	Detail of previous approval	Josef Sachet 4mg (Meeting No 331st)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned	

	notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
440	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Invictus Pharmaceuticals Plot No. 21, 26 Street No. NS.2, National Industrial Zone Rawat, Islamabad (000892)
	Application Form Dy. No / Tracking ID & date of submission	(TSZ-4EZ-GH79, 2024-08-19)
	Detail of Fee Submitted	75000.0, 2024-05-21,
	The proposed proprietary name / brand name	Invid 100mg Suspension
	Label Claim	Each 5 ml (after reconstitution) contains: Linezolid = 100 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	60mL -As per SRO
	Shelf Life (Unit)	24 Month25°C
	For generic drugs (me-too Status)	Barizold 100mg /5ml oral dry suspension of Barret Hodgson Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Himark Laboratories Pvt Ltd-Plot # 37-A, sunder Industrial Estate, Lahore-
	The status in reference regulatory authorities	Zyvox 100 mg/5ml Granules for Oral Suspension of Pharmacia Limited
	Detail of previous approval	Hiline-D 100mg for suspension
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
441	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Evolution Pharmaceuticals (Pvt.) Ltd. Plot no. 25,26 & 27, Street S-3, National Industrial Zone, Rawat, Islamabad. (000867)
	Application Form Dy. No / Tracking ID & date of submission	(TTH-V8A-E8PR, 2025-05-15)
	Detail of Fee Submitted	93000.0, 2024-10-08,
	The proposed proprietary name / brand name	EVOZAN 10MG
	Label Claim	Each film coated tablet contains: Vonoprazan fumarate eq to vonoprazan 10mg

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	2 Yeartore below 30°C. Protect from light. Reconstituted solution may be stored at 25°C for 24 hours or between 2-8°C for 7 days.
	For generic drugs (me-too Status)	Brand Name: Vonozan Tablet 10mg Registration holder: M/s Getz Pharma (Pvt.) Ltd
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	SERAPH PHARMACEUTICAL -000860 Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
	The status in reference regulatory authorities	Brand Name Takecab Tablet 10mg Marketing Authorization holder: Takeda Pharmaceutical Regulatory Authority: Japan (PMDA)
	Detail of previous approval	Vonocel 10mg Tablet, No-F.5-6/2022-REG-II(M-322)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
442	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	CUREXA HEALTH (PVT.) LIMITED 517 SUNDER INDUSTRIAL ESTSTE (000864)
	Application Form Dy. No / Tracking ID & date of submission	(TUY-PUA-H5X8, 2025-03-17)
	Detail of Fee Submitted	93000.0, 2024-11-22,
	The proposed proprietary name / brand name	Merzel 1g Injection IV
	Label Claim	Each vial contains: Meropenem (as Trihydrate) 1g (Blended with sterile sodium carbonate)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 30°C. Keep in a dry place. Protect from light.
	For generic drugs (me-too Status)	Romero Injection
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Next Pharmaceuticals-Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad. -
	The status in reference regulatory authorities	MERREM Injection (by Pfizer) USFDA Approved
	Detail of previous approval	MENEPOR 1g Injection IV, 296
	Evaluation Remarks	

	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
443	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Effort Pharmaceuticals (Pvt.) Ltd., 28-Km, Ferozepur Road (000879)
	Application Form Dy. No / Tracking ID & date of submission	(TW3-PBG-HDNT, 2025-03-08)
	Detail of Fee Submitted	93000.0, 2024-11-12,
	The proposed proprietary name / brand name	OPTOC 40MG INJECTION
	Label Claim	Each vial contains: Omeprazole as sodium.....40mg
	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)	Risek 40mg Injection (M/s Getz Pharma)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	May & Baker Pharmaceuticals (Pvt.) Ltd.-45 Km, Thokar Multan road, Lahore-
	The status in reference regulatory authorities	Approved by EMA of Sandoz Limited, UK
	Detail of previous approval	Minutes of 322nd meeting of Registration Board (8th & 10th November,2022) Page No. 92
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
444	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Trigon Pharmaceuticals (Private) Ltd 8-k.m thokar raiwind road Lahore (000342)
	Application Form Dy. No / Tracking ID & date of submission	(TXD-2X5-4QTD, 2025-05-14)
	Detail of Fee Submitted	93000.0, 2024-10-10,
	The proposed proprietary name / brand name	LEO

	Label Claim	Each Ampoule (5mL) Contains:- Levocarnitine (USP) 1000mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's * 5 ml-As per SRO
	Shelf Life (Unit)	2 YearBelow 25
	For generic drugs (me-too Status)	KEFEI INJECTION,R.G. PHARMACEUTICA (PVT) LTD., KARACHI
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wnsfeild Pharmaceuticals -Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK Pakistan-
	The status in reference regulatory authorities	LEVOCARNITINE 1gm INJECTION,Alfasigma S.p.A. Viale Sarca, n. 223 20126 Milan Italy.
	Detail of previous approval	331
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
445	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Biogen Life Sciences 8-KM, Chak Beli Road, Rawat, (000911)
	Application Form Dy. No / Tracking ID & date of submission	(TYN-VVT-2G21, 2025-03-08)
	Detail of Fee Submitted	93000.0, 2024-11-11,
	The proposed proprietary name / brand name	BI-SET 4mg/5ml Syrup
	Label Claim	Each 5ml contains: Ondansetron as hydrochloride Dihydrate 4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	30ml & 50ml-As per SRO
	Shelf Life (Unit)	2 YearRoom Condition
	For generic drugs (me-too Status)	Manufacturer Name Wimits Pharmaceuticals Brand Name Dysit 4mg/5ml Syrup
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore, Pakistan-
	The status in reference regulatory authorities	dansetron Hydrochloride syrup (USFDA Approved)
	Detail of previous approval	APTRON 4mg/5ml Syrup Minutes of 316th meeting of Registration Board (15-18 March, 2022)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as	

	an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
446	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welmed Pharmaceutical Industries (Pvt) Ltd. Plot No. 108/1 Road No. R-2 I.E. Gadoon. (000546)
	Application Form Dy. No / Tracking ID & date of submission	(U9L-3UA-ARAE, 2025-05-02)
	Detail of Fee Submitted	75000.0, 18000.0 2024-09-03, 2025-03-25
	The proposed proprietary name / brand name	DYWEL 10MG TABLET
	Label Claim	Each film coated tablet contains 10mg of Dydrogesterone
	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)	Dydrogest 10mg Tablet
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore- Pakistan-Pakistan. -
	The status in reference regulatory authorities	HPRA Approved
	Detail of previous approval	D-Gest 10mg Tablet, Meeting no. 336th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
447	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	MEDPHARM RESEARCH LAB 28 KM FEROZPUR ROAD LAHORE (000878)
	Application Form Dy. No / Tracking ID & date of submission	(UGJ-SBJ-GN8P, 2025-01-20)
	Detail of Fee Submitted	75000.0, 18000.0 2024-04-25, 2024-11-26
	The proposed proprietary name / brand name	M-CURE INJECTION 5MG/ML
	Label Claim	Each ml contains: Vitamin D3=5mg

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5's*5ml, 1's-As per SRO
	Shelf Life (Unit)	2 Yearbelow 24 degree
	For generic drugs (me-too Status)	D-Trees
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	May & Baker Pvt Ltd-HOUSE NO 23, STREET NO 5 SECTOR B, GHORI BLOCK BAHRIA TOWN, Pakistan-
	The status in reference regulatory authorities	ANSM of france
	Detail of previous approval	May D3 , 323 meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
448	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	MEDPHARM RESEARCH LAB 28 KM FEROZPUR ROAD LAHORE (000878)
	Application Form Dy. No / Tracking ID & date of submission	(UP9-MYJ-6EMR, 2025-03-12)
	Detail of Fee Submitted	93000.0, 2024-11-15,
	The proposed proprietary name / brand name	Eso-N 500/20mg Tablet
	Label Claim	Each Modified release tablet contains: Naproxen.....500mg (Enteric coated core) Esomeprazole as magnesium trihydrate 20mg (Immediate released coat)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO / DPC-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Glomov Tablet of M/s Global Pharma
	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	Vimovo 500/20mg modified-release tablet of M/s Grunenthal Ltd (USFDA Approved)
	Detail of previous approval	Napsom Tablet 500/20mg approved in 331st meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation,	

	specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
449	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Tovida Pharmaceuticals (Pvt) Ltd Plot No.7, Street No.S-07, RCCI Industrial Estate Islamabad (000996)
	Application Form Dy. No / Tracking ID & date of submission	(URV-LQG-E6PG, 2025-05-14)
	Detail of Fee Submitted	93000.0, 2025-02-24,
	The proposed proprietary name / brand name	Ketovril tablet
	Label Claim	Each film coated tablet contains; α -Ketoanalogue to isoleucine (Calcium-salt)... 67 mg α -Ketoanalogue to leucine (Calcium-salt)... 101 mg α -Ketoanalogue to phenylalanine (Calcium-Salt) 68 mg α -Ketoanalogue to valine (Calcium-Salt)..... 86 mg α -hydroxyanalogue to DL-methionine (Calcium-Salt)....59 mg L-lysine acetate...105mg corresponding to L-lysine 75 mg L-threonine 53 mg L-tryptophan 23 mg L-histidine 38 mg L-tyrosine 30 mg Total nitrogen content per tablet 36 mg Calcium content per tablet.....1.25mmol = 50 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO -De-Controlled
	Shelf Life (Unit)	2 Year30C+-
	For generic drugs (me-too Status)	generic product
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Solaris Life Sciences -Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, Rawalpindi-PAKISTAN.-
	The status in reference regulatory authorities	Bfarm Approved (Fresenius Kabi, Germany)
	Detail of previous approval	Ketorein Tablets
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned	

	notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
450	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Evolution Pharmaceuticals (Pvt.) Ltd. Plot no. 25,26 & 27, Street S-3, National Industrial Zone, Rawat, Islamabad. (000867)
	Application Form Dy. No / Tracking ID & date of submission	(URX-RJG-7ZP6, 2024-10-17)
	Detail of Fee Submitted	93000.0, 2024-09-24,
	The proposed proprietary name / brand name	LEVEPIL
	Label Claim	Each ml contains; Levetiracetam 100mg USP SPECS
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	2 YearStore at 20° to 25° C (68° to 77°F). Keep container closed tightly. Protect from light and moisture. Store away from foodstuffs.
	For generic drugs (me-too Status)	Brand Name: Lerace 100mg/ml injection Registration holder: Hilton pharma Lahore Pakistan.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Seraph Pharmaceutical -Address: Plot # 210, Industrial Triangle Kahuta Road, Islamabad. Pakistan-
	The status in reference regulatory authorities	Brand Name: KEPPRA Injection.....100mg/ml Registration holder: UCB Pharma Limited 208 Bath Road Slough Berkshire SL1 3WE UK, Approved in FDA.
	Detail of previous approval	110934 Product Name: Cevisto 100mg/mlInjection, Meeting No: No.F-119-PRVC/2024(PR-II)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
451	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	De-Mont Research Laboratories (Pvt.) Ltd. 20 Km, Lahore-Sheikhupura Road, Sheikhupura, Pakistan (000844)

	Application Form Dy. No / Tracking ID & date of submission	(USR-SQE-X3NW, 2025-03-11)
	Detail of Fee Submitted	93000.0, 2024-10-15,
	The proposed proprietary name / brand name	Acovir 3% Eye Ointment
	Label Claim	Each gm contains: Acyclovir.....30 mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Yearstore below 30 degree centigrade
	For generic drugs (me-too Status)	LOVIR EYE OINTMENT (Remington Pharmaceutical Industries)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Medevo (Pvt) Ltd.-Plot No. 94, Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Avaclyr 30mg/gm Eye Ointments (Fera Pharmaceuticals LLC USA)
	Detail of previous approval	Surgivir Eye Ointment (M-335)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
452	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Searle Pakistan Limited C-14, Manghopir Road, SITE, Karachi (000012)
	Application Form Dy. No / Tracking ID & date of submission	(UWJ-PS4-3MYU, 2025-06-03)
	Detail of Fee Submitted	93000.0, 2025-05-15,
	The proposed proprietary name / brand name	MEROKYT (Meropenem) Injection 1 gm
	Label Claim	Each vial contains: Meropenem as Trihydrate Blended with Anhydrous Sodium Carbonate..... 1 gm (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30°C.
	For generic drugs (me-too Status)	Penro 1 gm Injection (Bosch Pharma)
	Pharmacotherapeutic Group of (API)	Carbapenem
	Name, address of Manufacturing site:	M/s. High-Q Pharmaceuticals -Plot No. 224 & 225/1, Sector 23, Korangi Industrial Area, Karachi, Pakistan.-
	The status in reference regulatory authorities	Merrem Injection (USFDA Approved)

	Detail of previous approval	The product, Meropenem Injection 500 mg & 1 gm has already been approved by the Registration Board i
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
453	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winlet Pharmaceuticals (Pvt) Ltd. 30-Km, Lahore Sargodha Raod, Sargodha (000874)
	Application Form Dy. No / Tracking ID & date of submission	(V48-82A-MNAT, 2025-01-13)
	Detail of Fee Submitted	93000.0, 2024-11-08,
	The proposed proprietary name / brand name	ricolet 200mg injection
	Label Claim	Each lyophilized vial contains: Voriconazole.....200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1,s-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 °C
	For generic drugs (me-too Status)	v.zde by neutro pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/S BIO LAB-PLOT NO 145 KAHUTA INDUSTRIAL TRIANGLE ISLAMABAD-
	The status in reference regulatory authorities	USFDA approved
	Detail of previous approval	M-331
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
454	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Aulton Pharmaceuticals Plot # 84/1,Block A, Phase 5 , Industrial Estate Hattar, KPK, (000828)
	Application Form Dy. No / Tracking ID & date of submission	(V6J-D2G-HVMM, 2025-01-15)

	Detail of Fee Submitted	93000.0, 2024-12-24,
	The proposed proprietary name / brand name	Aulden 10mg/ml for Oral Suspension
	Label Claim	Each ml of reconstituted suspension contains: Sildenafil (as Citrate).....10mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's (112ml)-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Selden 10mg/ml for Oral Suspension by M/s Grays Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Gray's Pharmaceuticals-Plot No 2, Street # N-3, National Industrial Zone, Rawat-
	The status in reference regulatory authorities	SILDENA FIL CITRATE FOR SUSPENSION; ORAL by TEVA PHARMS USA
	Detail of previous approval	(Reg No. 124748) Selden 10mg/ml for Oral Suspension
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
455	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Candid Pharmaceuticals Opp. Pasrur Sugar Mills, Sialkot Road, Pasrur (000450)
	Application Form Dy. No / Tracking ID & date of submission	(V7Q-5S5-YXQB, 2025-05-20)
	Detail of Fee Submitted	93000.0, 2025-01-16,
	The proposed proprietary name / brand name	Erexon
	Label Claim	Sildenafil (as Citrate)....10mg/ml
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	112ml-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30 C
	For generic drugs (me-too Status)	Selden 10mg/ml
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Gray's Pharmaceuticals-Plot No.2, Street No. N-3, National Industrial Zone, Rawat, Islamabad- Pakistan.-
	The status in reference regulatory authorities	US FDA Approved
	Detail of previous approval	Selden 10mg/ml. M-343
	Evaluation Remarks	

	Selden 10mg/ml for oral suspension of Gray's Pharmaceuticals was approved in 343rd meeting of the Registratiton Board. Applicant to submit approval and GMP status of DS manufacturer (Rakshit Drugs Private Limited, India).	
	Decision	
	Approved	
456	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	CUREXA HEALTH (PVT.) LIMITED 517 SUNDER INDUSTRIAL ESTSTE (000864)
	Application Form Dy. No / Tracking ID & date of submission	(V8Y-J9E-9ZP5, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2025-02-11,
	The proposed proprietary name / brand name	Colixa Injection 100mg IV (3MIU)
	Label Claim	Each vial Contains: Colistimethate sodium (3MIU) eq. to 100mg Colistin Base Activity
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 30°C. Keep in a dry place. Protect from light.
	For generic drugs (me-too Status)	Colistimethate Sodium 3MIU, Manufactured by: TABROS PHARMA (PVT). LTD (Reg. No. 108905)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Labs (Pvt.) Ltd.-Plot # 145, Industrial Triangle, Kahuta Road, Islamabad. -
	The status in reference regulatory authorities	Colistimethate sodium 3 MIU, powder for solution for injection - (colistin methasulfonate sodium salt) - PL 34328/0016; UK/H/6255/003/DC MHRA Approved.
	Detail of previous approval	Colicraft 100mg Injection 3MIU, 331st DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
457	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Effort Pharmaceuticals (Pvt.) Ltd., 28-Km, Ferozepur Road (000879)
	Application Form Dy. No / Tracking ID & date of submission	(VAH-QQG-XYGU, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2025-04-08,
	The proposed proprietary name / brand name	Hilook 600mg Vial

	Label Claim	Each Vial Contains:- Glutathione as Sodium.....600mg (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's, 5's-As per SRO
	Shelf Life (Unit)	2 YearStore at temperature 15 to 30 C away from sunlight
	For generic drugs (me-too Status)	Gluto 600mg injection of M/s MTI Medical (Pvt.) Ltd
	Pharmacotherapeutic Group of (API)	Antidote
	Name, address of Manufacturing site:	M/s Friends Pharma Pvt Ltd. -31-km, Ferozepur Road, Lahore, Pakistan-
	The status in reference regulatory authorities	Approved by AIFA of Italy
	Detail of previous approval	Minutes of 343rd meeting of Registration Board (3rd-5th December, 2024) Page No. 68
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
458	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wallace Pharma Evolutions Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (000951)
	Application Form Dy. No / Tracking ID & date of submission	(VAZ-UHG-WB3G, 2025-05-14)
	Detail of Fee Submitted	93000.0, 2025-01-22,
	The proposed proprietary name / brand name	Emzaa-ML Tablet
	Label Claim	Each Film Coated Extended Release Tablet contains: Empagliflozin.....5MG Linagliptin.....2.5MG (As immediate release core) Metformin Hydrochloride*.....1000MG (As extended release core) (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	DIAMPA LXR Tablet by Getz Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Welmark Pharmaceuticals-Plot No. 122, Phase-V, Block-B, Industrial Estate, Hattar.-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Empeg-ML XR Tablet, DRB 340

	Evaluation Remarks	
	EMPEG-ML XR TABLET of Welmark Pharmaceuticals was approved in 340th meeting of the Registration Board. Applicant to submit quality agreement and License and GMP status of the following DS manufacturers: Fuxin Long Rui Pharmaceutical CO., Ltd for Empagliflozin Anhui Haikang Pharmaceutical Co., Ltd for Linagliptin AARTI DRUGS LIMITED for Metformin	
	Decision	
	Approved	
459	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(VH6-1W1-NJZB, 2025-04-21)
	Detail of Fee Submitted	93000.0, 2025-02-20,
	The proposed proprietary name / brand name	K-PER 2MG/ML
	Label Claim	Each 1ml contains: Phytonadione.....2mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO/DPC-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 degree centigrade,protect from light,moisture and heat
	For generic drugs (me-too Status)	K-Lot 2mg/ml injection, M/s GT Pharma-Lahore
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s MISAQ PHARMACEUTICALS-7-B,Woven Garments Zone, Value Addition City,Khurrianwala-Sahianwala Road, Faisalabad.-
	The status in reference regulatory authorities	HEALTH CANADA
	Detail of previous approval	K-SAQ 2MG/ML Injection, M-339
	Evaluation Remarks	
	K-SAQ of M/s MISAQ PHARMACEUTICALS was approved in the 339th meeting of the Registration Board.	
	Decision	
	Approved	
460	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Pharmedic Laboratories (Pvt.) Ltd Lahore 16-Km Multan Road, Lahore (000228)
	Application Form Dy. No / Tracking ID & date of submission	(VNE-RVD-GYQP, 2025-05-20)
	Detail of Fee Submitted	93000.0, 2025-04-15,
	The proposed proprietary name / brand name	FECMA
	Label Claim	Each ml contains: Iron as Ferric carboxymaltose....50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearDon't store above 30C
	For generic drugs (me-too Status)	Fercari by Hilton Pharma
	Pharmacotherapeutic Group of (API)	Anti-Anemic

	Name, address of Manufacturing site:	Cunningham Pharmaceuticals (Pvt.) Ltd.-Plot No. 81, Sundar Industrial Estate, Lahore. -
	The status in reference regulatory authorities	FERINJECT (by Vifor France)
	Detail of previous approval	Ferrova 500mg/10ml Injection in Minutes of 336th meeting of Registration Board (4th to 6th June, 2024)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
461	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Obsons Pharmaceuticals 209-S Quaid-e-Azam industrial estate, (000416)
	Application Form Dy. No / Tracking ID & date of submission	(VP6-US1-M8YN, 2025-04-25)
	Detail of Fee Submitted	93000.0, 2025-01-16,
	The proposed proprietary name / brand name	Obenafil 10 mg/mL Suspension
	Label Claim	Each mL reconstituted suspension contains: Sildenafil (as Citrate) ----- 10 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	112 mL-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature.
	For generic drugs (me-too Status)	Selden Suspension, Gray's Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Gray's Pharmaceuticals-Plot No. 2, Street No. N-3, National Industrial Zone, Rawat, Pakistan.-
	The status in reference regulatory authorities	Sildenafil Suspension, Ajanta Pharma, USA (USFDA Approved)
	Detail of previous approval	Selden Suspension, M-343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
462	Case Category	Routine (Incharge Evaluation Cell)

	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	(VSW-ZXR-VYPE, 2024-03-19)
	Detail of Fee Submitted	75000.0, 2024-03-04,
	The proposed proprietary name / brand name	Carnital
	Label Claim	Each 3.3ml contains: Levocarnitine.....1g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30° C
	For generic drugs (me-too Status)	None
	Pharmacotherapeutic Group of (API)	Amino acids and derivatives
	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	3 batches: 1L
	Documents for the procurement of API with approval from DRAP (in case of Import)	24-03-2021: AD attested commercial invoice submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Biocarn 1 g/3.3 ml Syrup: PE performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IV-A
	The status in reference regulatory authorities	Biocarn 1 g/3.3 ml Syrup (Germany approved)
	GMP status of the firm	03-01-2023: GMP certificate
	Evidence of approval of manufacturing facility	03-01-2023: GMP certificate Oral liquid section
	Evaluation Remarks	
	Decision	
	Approved	
463	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	M/s Daneen Pharma (Pvt) Ltd Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, (000688)
	Application Form Dy. No / Tracking ID & date of submission	(VUZ-2TG-VTNN, 2025-04-08)
	Detail of Fee Submitted	93000.0, 2024-12-06,
	The proposed proprietary name / brand name	Vomiset
	Label Claim	Each ml Contains: 1.12 mg Granisetron hydrochloride equivalent to Granisetron 1mg OR Each 3ml Contains: 3.351 mg Granisetron hydrochloride equivalent to Granisetron 3mg
	Reference to Finished product specifications	United States Pharmacopeia

	Proposed Pack Size	1's, 5's & 10's.-As per SRO
	Shelf Life (Unit)	2 Yearstore between 20°C to 25°C
	For generic drugs (me-too Status)	Vomitron by Helix pharma private limited (086056)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Genix Pharma Pvt Ltd -44, 45B, KORANGI CREEK ROAD, KARACHI. PAKISTAN-
	The status in reference regulatory authorities	Granisetron concentrate solution for injection 3mg/3ml by Martindale Pharma® Pvt Ltd
	Detail of previous approval	Sitensa 3mg/3ml Injection DRB 339th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
464	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	MEDPHARM RESEARCH LAB 28 KM FEROZPUR ROAD LAHORE (000878)
	Application Form Dy. No / Tracking ID & date of submission	(VVB-YQ5-MTGB, 2025-01-20)
	Detail of Fee Submitted	75000.0, 18000.0 2024-04-26, 2024-11-25
	The proposed proprietary name / brand name	OLIT DRY POWDER INJECTION 40MG
	Label Claim	Each Vial Contains: Omeprazole as sodium = 40mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	as per DPC-As per SRO
	Shelf Life (Unit)	2 Yearbelow 24 degree
	For generic drugs (me-too Status)	Risek 40mg vial
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	May & Baker Pvt Ltd-HOUSE NO 23, STREET NO 5 SECTOR B, GHORI BLOCK BAHRIA TOWN, Pakistan-
	The status in reference regulatory authorities	FDA Approved
	Detail of previous approval	omebak 40mg vial 322
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
465	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	The Searle Company Limited Karachi (000016)
	Application Form Dy. No / Tracking ID & date of submission	(VW3-272-NG2S, 2025-01-23)
	Detail of Fee Submitted	93000.0, 2024-12-06,
	The proposed proprietary name / brand name	NMP 100mg Capsule
	Label Claim	Each soft gel capsule contains: Micronized Progesterone..... 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's, 14's, 15's, 28'-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 °C.
	For generic drugs (me-too Status)	U-Progest Capsules 100mg by Aspin Pharma (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Searle Pakistan Limited-C-14, Manghopir Road, S.I.T.E, Karachi - 75700, Sindh, Pakistan-
	The status in reference regulatory authorities	UTROGESTAN 100MG CAPSULES by Besins Healthcare Rue Washington, 80 1050 Ixelles Belgium
	Detail of previous approval	Ogestron 100mg Capsule in 335th Minutes of meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
466	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	M/s Daneen Pharma (Pvt) Ltd Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, (000688)
	Application Form Dy. No / Tracking ID & date of submission	(VW4-AU1-9YME, 2025-05-20)
	Detail of Fee Submitted	93000.0, 2024-12-06,
	The proposed proprietary name / brand name	Qinglif-M
	Label Claim	Each film coated bilayered tablet contains: Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin..... 2.5mg (ImmediateRelease) Metformin HCl (as extended release)..... 1000mg

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's, 10's,14's,20's,-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C. Protect from heat, light & Moisture
	For generic drugs (me-too Status)	Daglozin-M XR Tablet by Genix Pharma Pvt Ltd (123455)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Genix Pharma Pvt Ltd -44, 45B, KORANGI CREEK ROAD, KARACHI. PAKISTAN-
	The status in reference regulatory authorities	Xigduo®XR by AstraZeneca Pharmaceuticals LP
	Detail of previous approval	Daglozin-M XR Tablet 2.5mg/1000mg DRB 340
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
467	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Trigon Pharmaceuticals (Private) Ltd 8-k.m thokar raiwind road Lahore (000342)
	Application Form Dy. No / Tracking ID & date of submission	(W2T-MED-ULJY, 2025-04-04)
	Detail of Fee Submitted	93000.0, 2024-11-27,
	The proposed proprietary name / brand name	OSB Sachet 20/1680mg
	Label Claim	Each Sachet contains: Omeprazole.....20mg Sodium bicarbonate.....1680mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,30's-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature.
	For generic drugs (me-too Status)	Risek Insta sachet by GETZ Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-
	The status in reference regulatory authorities	Omeprazole and sodium bicarbonate sachet by STRIDES Pharma
	Detail of previous approval	S-Insta Sachet (Meeting # 337th)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned	

	notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
468	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	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	(W2V-9RW-NB8U, 2025-06-02)
	Detail of Fee Submitted	93000.0, 2025-04-28,
	The proposed proprietary name / brand name	Procetrol-1mcg Soft gel Capsules
	Label Claim	Each soft gelatin capsule contains: Paricalcitol.....1 mcg
	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)	Parical 1mcg Soft gelatin Capsule Reg. No. 124502
	Pharmacotherapeutic Group of (API)	Vitamin D2 and Vitamin D analogs
	Name, address of Manufacturing site:	Biogen Life Sciences-8-KM, Chakbeli Road, Rawat, Rawalpindi-PAKISTAN.-
	The status in reference regulatory authorities	FDA Approved. Zemplar (Paricalcitol) 1mcg Soft Gel Capsule
	Detail of previous approval	DRB M-339 By the Name of Parical 1mcg Soft gelatin Capsule
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
469	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winlet Pharmaceuticals (Pvt) Ltd. 30-Km, Lahore Sargodha Raod, Sargodha (000874)
	Application Form Dy. No / Tracking ID & date of submission	(WEZ-TR4-ZJS8, 2025-01-13)
	Detail of Fee Submitted	93000.0, 2024-10-21,
	The proposed proprietary name / brand name	Fusilet B
	Label Claim	Each Gram Fusilet B Cream Contains: Fusidic Acid.....20mg Betamethasone (as Valerate) 1 mg

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1,s-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 °C
	For generic drugs (me-too Status)	FUDIC B Cream
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Biogen life sciences -8-km chakbeli road rawat Rawalpindi-
	The status in reference regulatory authorities	Fusidic acid/Betamethasone 20 mg/g + 1 mg/g cream MHRA approved.
	Detail of previous approval	M-331
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
470	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Neutro Pharma (Pvt.) Ltd., 9.5-Km, Sheikhpura Road, Lahore (000576)
	Application Form Dy. No / Tracking ID & date of submission	(WGQ-5YD-7WQM, 2025-06-04)
	Detail of Fee Submitted	93000.0, 2025-05-07,
	The proposed proprietary name / brand name	Isonoin 20mg Sg Capsules
	Label Claim	Each soft gel capsule contains: Isotretinoin... 20mg (BP Specs)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	30-As per SRO
	Shelf Life (Unit)	2 Yearstore at 25c
	For generic drugs (me-too Status)	Oratane capsule
	Pharmacotherapeutic Group of (API)	Retinoids
	Name, address of Manufacturing site:	M/S Biogen Pharmaceuticals-8-Km chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	MHRA approved
	Detail of previous approval	Biotan 10mg Capsule approved in 312 meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
471	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Invictus Pharmaceuticals Plot No. 21, 26 Street No. NS.2, National Industrial Zone Rawat, Islamabad (000892)
	Application Form Dy. No / Tracking ID & date of submission	(WP9-LUW-VBEJ, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2025-02-14,
	The proposed proprietary name / brand name	Nakzen Plus Tablets
	Label Claim	Each modified release tablet contains: Naproxen.....500mg (Enteric coated Core) Esomeprazole as Magnesium Trihydrate.....20mg (Immediate Release Coat)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO -As per SRO
	Shelf Life (Unit)	24 Month25°C
	For generic drugs (me-too Status)	Glomov Tablets of Global Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd.-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan-
	The status in reference regulatory authorities	Vimovo modified release tablets of AstraZeneca Pharmaceutical UK
	Detail of previous approval	Esoren 500mg/20mg Tablets Meeting 343rd (3-5 December 2025) Page No. 1201
Evaluation Remarks		
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.		
Decision		
Approved		
472	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	De-Mont Research Laboratories (Pvt.) Ltd. 20 Km, Lahore-Sheikhupura Road, Sheikhupura, Pakistan (000844)
	Application Form Dy. No / Tracking ID & date of submission	(WPS-3L7-55HL, 2025-03-12)
	Detail of Fee Submitted	93000.0, 2024-10-15,
	The proposed proprietary name / brand name	Tobria-D Eye Ointment
	Label Claim	Each gm contains: Tobramycin.....3 mg Dexamethasone.....1 mg (USP Specifications)

	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Yearstore below 30 degree centigrade
	For generic drugs (me-too Status)	Santodex Eye Ointment (Sante Private Limited)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Medevo (Pvt) Ltd.-Plot No. 94, Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Tobramycin/Dexamethasone 3mg/gm + 1mg/gm Eye Ointments, USP (Novartis Pharma US-FDA)
	Detail of previous approval	SURGITOB-D EYE OINTMENT (M-335)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
473	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Neutro Pharma (Pvt.) Ltd., 9.5-Km, Sheikhpura Road, Lahore (000576)
	Application Form Dy. No / Tracking ID & date of submission	(WQB-6Y4-248A, 2025-06-04)
	Detail of Fee Submitted	93000.0, 2025-05-07,
	The proposed proprietary name / brand name	Isonoin 10mg Sg Capsules
	Label Claim	Each soft gel capsule contains: Isotretinoin... 10mg (BP Specs)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	30-As per SRO
	Shelf Life (Unit)	2 Yearstore at 25c
	For generic drugs (me-too Status)	Oratane capsule
	Pharmacotherapeutic Group of (API)	Retinoids
	Name, address of Manufacturing site:	M/S Biogen Pharmaceuticals-8-Km chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	MHRA approved
	Detail of previous approval	Biotan 10mg Capsule approved in 312 meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
474	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Dyson Research Laboratories (Pvt.) Ltd 28-Km Ferozpur Road Lahore (000559)
	Application Form Dy. No / Tracking ID & date of submission	(WR3-X9S-WZ1W, 2025-03-12)
	Detail of Fee Submitted	93000.0, 2024-11-22,
	The proposed proprietary name / brand name	Dysotig
	Label Claim	Each vial contains: Tigecycline (Lyophilized Powder).....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearStore below 25C.
	For generic drugs (me-too Status)	Tygacil injection by Wyeth Pakistan Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Labs (Pvt.) Ltd.-Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad.-
	The status in reference regulatory authorities	Tigecycline injection 50mg by Sandoz Pharma, approved by USFDA.
	Detail of previous approval	Bactilil Injection 50mg (Tigecycline), approved in 330 meeting of registration board held on 24 - 26
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
475	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Invictus Pharmaceuticals Plot No. 21, 26 Street No. NS.2, National Industrial Zone Rawat, Islamabad (000892)
	Application Form Dy. No / Tracking ID & date of submission	(WRP-MZQ-XBQX, 2025-05-12)
	Detail of Fee Submitted	75000.0, 18000.0 2024-08-28, 2024-10-01
	The proposed proprietary name / brand name	Vrochi 40mg Plus Sachet
	Label Claim	Each Sachet contains: Omeprazole 40 mg & Sodium Bicarbonate 1680mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	24 Month25°C
	For generic drugs (me-too Status)	Omirin Insta Sachet (40 mg / 1680 mg)

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Himark Laboratories (Pvt)Ltd-Plot#37-A,Sunder Industrial Estate Lahore-
	The status in reference regulatory authorities	Zegerid 40/1680 oral packet of Salix Pharmaceuticals
	Detail of previous approval	Omirin Insta Sachet (40 mg / 1680 mg) minutes of 333th meeting of Registration Board from page No. 5
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
476	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Dyson Research Laboratories (Pvt.) Ltd 28-Km Ferozpur Road Lahore (000559)
	Application Form Dy. No / Tracking ID & date of submission	(WWH-7X3-4JL, 2025-04-08)
	Detail of Fee Submitted	93000.0, 2024-11-26,
	The proposed proprietary name / brand name	Dyplast
	Label Claim	Each vial contains: Imipenem as monohydrate.....250mg Cilastatin as sodium.....250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearKeep vials in the outer carton in order to protect from light.
	For generic drugs (me-too Status)	Cilapen Injection 250mg by Bosch Pharmaceuticals (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Bio-Next Pharmaceuticals.-Plot No. 50, Street No. S-10, RCCI, Rawat.-
	The status in reference regulatory authorities	Imipenem + Cilastatin 250mg/vial by ACS Dobfar, approved by USFDA.
	Detail of previous approval	Imipen Injection 250mg approved in 323rd meeting of Registration Board held on 06th - 08th December,
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned	

	notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
477	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welmed Pharmaceutical Industries (Pvt) Ltd. Plot No. 108/1 Road No. R-2 I.E. Gadoon. (000546)
	Application Form Dy. No / Tracking ID & date of submission	(WYW-VBG-ZZRY, 2025-05-07)
	Detail of Fee Submitted	75000.0, 18000.0 2024-09-03, 2025-03-25
	The proposed proprietary name / brand name	Tazwel 250mg Injection
	Label Claim	Each Vial contains: Ceftazidime as Ceftazidime Pentahydrate.....250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Fortazim 250mg Injection IM/IV
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Limited-Plot # 129, Sunder Industrial Estate Lahore.-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	Ceftazidime 250mg Injection, Meeting No. 335th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
478	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(WZ5-5ZA-YBM8, 2025-04-30)
	Detail of Fee Submitted	93000.0, 2024-11-25,
	The proposed proprietary name / brand name	LEVOTIN 1G INJECTION
	Label Claim	Each 5ml ampoule contains: Levocarnitine 1g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 x 5mL-As per SRO

Shelf Life (Unit)	24 MonthBelow 30°C
For generic drugs (me-too Status)	Lekarnitin Injection 1g/5ml
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	SERAPH PHARMACEUTICAL-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
The status in reference regulatory authorities	Carnitor injection
Detail of previous approval	CARNIT 1G INJECTION, 331st minutes of meeting

Evaluation Remarks

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

Decision

Approved

479	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Crown Pharmaceuticals Plot 286, Kahuta industrial Triangle, Kahota Road, Islamabad (000456)
	Application Form Dy. No / Tracking ID & date of submission	(X29-4N9-D33B, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2025-01-27,
	The proposed proprietary name / brand name	C-Eso 40mg Dry Powder Vial
	Label Claim	Each vial contain Esomeprazole as Sodium (BP) 40mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30 centi grade
	For generic drugs (me-too Status)	Acireg of Barret hodgson Pakistan
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s May & Baker Pharmaceuticals (Pvt.) Ltd.-45 Km, Thokar Multan road, Lahore-
	The status in reference regulatory authorities	Approved by MHRA of UK
	Detail of previous approval	Ezole 40mg Dry powder Vial, Minutes of 327th meeting of Registration Board (13th April, 2023)

Evaluation Remarks

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

Decision

	Approved	
480	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Saaaf Pharmaceuticals Risalpur, Nowshera, Khyber Pakhtunkhwa 23200 (000637)
	Application Form Dy. No / Tracking ID & date of submission	(X2R-769-WA15, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2025-01-24,
	The proposed proprietary name / brand name	Tablet Sildifin 100mg
	Label Claim	Each Tab contains Sildinafil as Citrate 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's-As per SRO
	Shelf Life (Unit)	2 YearBelow 25c
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Gray's Pharmaceuticals-Plot No2, street No. N-3,National Industrial Zone, Rawat.-
	The status in reference regulatory authorities	NA
	Detail of previous approval	Selden100mg, 343rd DRB meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Deferred	
481	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	M/s Daneen Pharma (Pvt) Ltd Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, (000688)
	Application Form Dy. No / Tracking ID & date of submission	(X48-WG5-6THY, 2025-05-26)
	Detail of Fee Submitted	75000.0, 18000.0 2024-08-06, 2025-05-20
	The proposed proprietary name / brand name	Emlif ML XR
	Label Claim	Each Film coated tablet contains: Empagliflozin (As immediate release) 25mg Linagliptin (As immediate release) 5mg Metformin HCl (As extended release Core) 1000mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's, 28's & 30's-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30°C. Protect from heat, light and moisture.

	For generic drugs (me-too Status)	Emglif LM XR Tablet 25mg/5mg/1000mg by Genix Pharma (Reg. No. 120306)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Genix Pharma (Pvt.) Ltd.-44, 45-B, Korangi Creek Road, Karachi-75190, Pakistan-
	The status in reference regulatory authorities	Trijardy XR Tablet 5mg/25mg/ 1000mg (USFDA Approved)
	Detail of previous approval	EMLIMET XR 5mg/25mg/1000 mg Tablet, DRb 336
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
482	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Hygeia Pharmaceuticals Plot NO 295, Industrial Triangles Kahuta Road Islamabad (000523)
	Application Form Dy. No / Tracking ID & date of submission	(X4B-ZAU-13MZ, 2025-04-25)
	Detail of Fee Submitted	93000.0, 2025-01-22,
	The proposed proprietary name / brand name	HYDEN 10mg/ml SUSPENSION
	Label Claim	Each ml of reconstituted suspension contains: Sildenafil (as Citrate) ----- 10mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	112ml-De-Controlled
	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	SILAGRO NABI QASIM KARACHI
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Gray's Pharmaceuticals-Plot No 2, Street No N-3, National Industrial Zone, Rawat, Islamabad Islamabad Urban-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Selden 10mg/ml for oral suspension 343 DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
483	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Gray's Pharmaceuticals Plot NO2, Street No. N-3, RCCI Rawat Islamabad (000518)
	Application Form Dy. No / Tracking ID & date of submission	(X5X-8TS-ULDG, 2025-04-25)
	Detail of Fee Submitted	93000.0, 2025-02-22,
	The proposed proprietary name / brand name	Esoren 20mg 500mg Tablet
	Label Claim	Each Modified release Tablet contains: Naproxen 500mg (as Enteric Coated Core) Esomeprazole as Magnesium Trihydrate 20mg (as Immediate Release Coat) (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Enzepo MR Tablet by Wnsfeild Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	Usfda Approved
	Detail of previous approval	Esonyp Tablet, DRB 324
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
484	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	McOlson Research Laboratories Pvt. Ltd Plot No. 02, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhpura Pakistan (000664)
	Application Form Dy. No / Tracking ID & date of submission	(XEX-E8P-YZ97, 2025-01-13)
	Detail of Fee Submitted	93000.0, 2024-11-12,
	The proposed proprietary name / brand name	Emalgo 7 mg Tablets
	Label Claim	Each Tablet Contains: Semaglutide: 7 mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 20's, 30's-As per SRO
	Shelf Life (Unit)	2 YearBelow 30C

	For generic drugs (me-too Status)	Sematide 7 mg Tablets By Ferozsans Laboratories
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot # 69/2. Phase-II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	https://www.medicines.org.uk/emc/product/11507/s
	Detail of previous approval	Rybelsus 7 mg Tablet approved in 340th DRB Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Deferred	
	Referred to Biological Evaluation & Research Division	
485	Case Category	Routine (Incharge Evaluation Cell)
	Name, address of Applicant.	Caliph Pharmaceuticals Plot 17, Special Industrial Zone Risalpur, KPK (000748)
	Application Form Dy. No / Tracking ID & date of submission	(XG1-4NJ-4BWT, 2024-03-26)
	Detail of Fee Submitted	30000.0, 2024-03-13,
	The proposed proprietary name / brand name	CALTRIM 10% W/W VAGINAL CREAM
	Label Claim	Each gram of cream contains: Clotrimazole 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)25°C
	For generic drugs (me-too Status)	Canesten 10%w/w vaginal Cream M/s Bayer Health Care
	Pharmacotherapeutic Group of (API)	Antifungal
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches: 500 tubes
	Documents for the procurement of API with approval from DRAP (in case of Import)	30-07-2021: AD attested invoice is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CANESTEN 10% W/W VAGINAL CREAM: PE studies performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IV-B
	The status in reference regulatory authorities	Canesten Thrush Internal Cream 10% w/w vaginal cream (MHRA Approved)
	GMP status of the firm	13-03-2023: GMP certificate inspection date
	Evidence of approval of manufacturing facility	17-01-2019: DML grant of additional section specifies cream/ointment/lotion section
	Evaluation Remarks	

	Decision	
	Approved	
486	Case Category	Routine (Incharge Evaluation Cell)
	Name, address of Applicant.	Platinum Pharmaceuticals A-20,North Western Industrial Zone Bin Qasim,Karachi (000415)
	Application Form Dy. No / Tracking ID & date of submission	(XJP-N5L-1LTV, 2024-04-17)
	Detail of Fee Submitted	75000.0, 2023-11-29,
	The proposed proprietary name / brand name	Elagolix 200mg Tablet
	Label Claim	Each film coated tablet contains: Elagolix (Elagolix as Sodium).....200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-14's-20's-30's-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30C in a dry place and protect from su
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	(GnRH) receptor antagonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Kehui Pharmaceutical Co., Ltd
	Detail of stability batches of drug product	3 batches: 1000 tablet
	Documents for the procurement of API with approval from DRAP (in case of Import)	25-08-2023: Drug Import License submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Orilisa 200 mg Tablet: PE & CDP performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IV-A
	The status in reference regulatory authorities	Orilissa Tablet 200mg (AbbVie Pharmaceuticals) USFDA
	GMP status of the firm	14-06-2023: GMP Certificate
	Evidence of approval of manufacturing facility	14-06-2023: GMP Certificate specifies Tablet General Section
	Evaluation Remarks	
	Decision	
	Approved	
487	Case Category	Routine (Incharge Evaluation Cell)
	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	(XN4-A2Q-7PHZ, 2024-03-12)

	Detail of Fee Submitted	75000.0, 2024-02-12,
	The proposed proprietary name / brand name	Alendro 70mg Effervescent tablet
	Label Claim	Each effervescent tablet contains: Sodium alendronate trihydrate.....91.37mg eq. to 70mg of alendronic acid
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	12's-As per SRO,24's-As per SRO,4's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C in a cool and dry place
	For generic drugs (me-too Status)	Nil
	Pharmacotherapeutic Group of (API)	Bisphosphonates
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Ultra Tech India Ltd. Address: Plot No. 24, 25 & 26, New chemical zone, Taloja Midc, New Mubai, Maharashtra, India- 410208, Dist- Raigad
	Detail of stability batches of drug product	3 batches: 1200 tablet
	Documents for the procurement of API with approval from DRAP (in case of Import)	03-11-2022: Drug import license submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Binosto 70 mg effervescent tablets: PE and CDP performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IV-A
	The status in reference regulatory authorities	Binosto 70 mg effervescent tablets (MHRA Approved)
	GMP status of the firm	03-01-2023: GMP certificate
	Evidence of approval of manufacturing facility	03-01-2023: GMP certificate Tablet (general) section
	Evaluation Remarks	
	Decision	
	Approved	
488	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	jupiter Pharma Plot No 25 Street S-6 RCCI Rawat Rawalpindi (000838)
	Application Form Dy. No / Tracking ID & date of submission	(XQS-58Y-LX7Y, 2025-02-07)
	Detail of Fee Submitted	75000.0, 18000.0 2024-06-25, 2025-01-10
	The proposed proprietary name / brand name	Monexi 0.5% Eye Drops
	Label Claim	Each ml contains: Moxifloxacin HCl as Moxifloxacin 5mg (0.5%)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Azlox ophthalmic solution 2900 Minutes of 331st Meeting of Registration Board held on 31st Oct – 2nd Nov, 2023 Alza Pharmaceuticals 081625

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	winbrains Research Laboratories-Plot No. 69/1, Phase I-II, Industrial Estate, Hattar.-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Monexi Eye Drops, DRB 331
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
489	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Pasteur & Fleming Pharma Plot # 70A , Phase -3, Road No-04, Industrial Estate Hattar, K.P.K. Pakistan (000945)
	Application Form Dy. No / Tracking ID & date of submission	(XTP-DZL-WMWV, 2025-02-19)
	Detail of Fee Submitted	93000.0, 2024-12-18,
	The proposed proprietary name / brand name	Esomep 20mg Capsule
	Label Claim	Each capsule contains: Esomeprazole magnesium Trihydrate equivalent to Esomeprazole (as enteric coated pellets) 20mg.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14's -As per SRO,28's-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature.
	For generic drugs (me-too Status)	S-ZOLE capsule by NOVAMED Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-
	The status in reference regulatory authorities	Nexium Capsules by ASTRAZENECA
	Detail of previous approval	Staesso 20mg capsule (Meeting no. 329)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
490	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

	Name, address of Applicant.	Bio-Next Pharmaceuticals plot no 50 street no S-10 RCCI Rawat (000910)
	Application Form Dy. No / Tracking ID & date of submission	(XV2-35E-DBPQ, 2025-01-15)
	Detail of Fee Submitted	93000.0, 2025-01-02,
	The proposed proprietary name / brand name	Sednext
	Label Claim	Each ml suspension contains: Sildenafil (as Citrate) 10mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1 vial-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Nabiqasim Industries
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Labs (Pvt) Ltd.-Plot 145, Industrial Trangle, Kahuta Road Is;a,abad-
	The status in reference regulatory authorities	MHRA UK
	Detail of previous approval	Silargo Susp DRB 340
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
491	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(XWA-UXT-BJHT, 2025-05-08)
	Detail of Fee Submitted	93000.0, 2025-04-15,
	The proposed proprietary name / brand name	Amoxi 625mg Tablet
	Label Claim	Each film coated tablet contains: Amoxicillin trihydrate eq. to Amoxicillin.....500mg Potassium clavulanate eq. to Clavulanic acid....125mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	12's/ As per SRO / D-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Augmentin 625mg Tablets of M/s GSK Pakistan
	Pharmacotherapeutic Group of (API)	penicillin combinations, including beta-lactamase inhibitors
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhpura Road, Lahore-Pakistan-

	The status in reference regulatory authorities	Augmentin 625mg Tablet of M/s AUGMENTIN is a registered trademark of GlaxoSmithKline and is licensed to Dr. Reddy's Laboratories Inc, Distributed by: Dr. Reddy's Laboratories Inc. Bridgewater, NJ 08807 USFDA Approved
	Detail of previous approval	Amoxi 625mg Tablet approved in 344th Meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
492	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	MEDPHARM RESEARCH LAB 28 KM FEROZPUR ROAD LAHORE (000878)
	Application Form Dy. No / Tracking ID & date of submission	(XZL-E9S-3MPJ, 2025-03-12)
	Detail of Fee Submitted	93000.0, 2024-11-15,
	The proposed proprietary name / brand name	D-Med 75mg/200mcg Tablet
	Label Claim	Each Film Coated Modified Release Tablet contains: Diclofenac sodium-----75mg (Enteric coated core) Misoprostol ----- -200mcg (immediate release coat)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO / DPC-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Rotec Tablet of M/s Searle
	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	Arthrotec 75mg/200mcg Tablet of M/s Pfizer (USFDA Approved)
	Detail of previous approval	Artec Tablet approved in 343rd meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
493	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	VENUS PHARMA 23-KM MULTAN ROAD, LAHORE (000300)
	Application Form Dy. No / Tracking ID & date of submission	(Y4M-TW6-9LZG, 2025-05-27)
	Detail of Fee Submitted	93000.0, 2025-01-24,
	The proposed proprietary name / brand name	Hitra 100mg capsule
	Label Claim	Each Capsule contains: Itraconazole (as IR Pellets)....100mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4,s,As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30 degree celsius temperature
	For generic drugs (me-too Status)	Fewnol 100mg capsule by M/S Dew Max, Pharma ,Islamabad
	Pharmacotherapeutic Group of (API)	Anti-mycotic agent
	Name, address of Manufacturing site:	M/S Kohinoor Industries,Sahiwal-160-B Small Industrial Estate Sahiwal.-
	The status in reference regulatory authorities	Itraconazole 100mg capsule by M/S Mint Pharmaceuticals Inc.6575 Davand Drive, Ontario. (USFDA Approved)
	Detail of previous approval	Itcan 100mg capsule,336th Meetings of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
494	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	McOlson Research Laboratories Pvt. Ltd Plot No. 02, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhpura Pakistan (000664)
	Application Form Dy. No / Tracking ID & date of submission	(Y98-5RY-MES1, 2025-01-13)
	Detail of Fee Submitted	93000.0, 2024-11-12,
	The proposed proprietary name / brand name	Emalgo 14 mg Tablets
	Label Claim	Each Tablet Contains: Semaglutide: 14 mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 20's, 30's-As per SRO

	Shelf Life (Unit)	2 YearBelow 30C
	For generic drugs (me-too Status)	Sematide 14 mg Tablets By Ferozsons Laboratories
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot # 69/2. Phase-II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	https://www.medicines.org.uk/emc/product/11507/s
	Detail of previous approval	Rybelsus 14 mg Tablet approved in 340th DRB Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Deferred	
495	Referred to Biological Evaluation & Research Division	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Crown Pharmaceuticals Plot 286, Kahuta industrial Triangle, Kahota Road, Islamabad (000456)
	Application Form Dy. No / Tracking ID & date of submission	(YEH-4LZ-U7SP, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2025-02-24,
	The proposed proprietary name / brand name	CR-D3 5mg/ml Injection
	Label Claim	Each 1ml ampoule contains: Cholecalciferol (BP).....5mg (200000IU) The product complies Innovator's Specifications
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30 centi grade
	For generic drugs (me-too Status)	Indrop-D 5mg/ml by M/s Neutro Pharma (Pvt) Ltd. Reg. No. 023170
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Islam Pharmaceuticals-7KM Pasrur Road Sialkot-
	The status in reference regulatory authorities	Vitamin D3 Good 200000 IU/ml (5mg/ml) by M/s Bouchara-Recordati, ANSM France Approved.
	Detail of previous approval	Care-D 5mg/ml Injection, Minutes of 316th meeting of Registration Board (15th-18th March, 2022)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned	

	notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
496	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medwell Pharmaceuticals 1 km, terbella road, lawrencepur, faqirabad Attock (000699)
	Application Form Dy. No / Tracking ID & date of submission	(YEL-UGP-ZD46, 2025-02-13)
	Detail of Fee Submitted	93000.0, 2024-12-18,
	The proposed proprietary name / brand name	Selden 10mg/ml for oral suspension
	Label Claim	Each ml of reconstituted suspension contains: Sildenafil (as Citrate) ----- 10mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	112ml-De-Controlled
	Shelf Life (Unit)	2 YearAt Room Temperature
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Gray's Pharmaceuticals-Plot No: 2, Street No: N-3, National Industrial Zone Rawat, Islamabad, Pakistan-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Selden 10mg Suspension, 343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
497	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Air Pharmaceuticals(Pvt.)Ltd Plot No's 74, 75-A, Small Industrial Estate, Kasur (000977)
	Application Form Dy. No / Tracking ID & date of submission	(YHW-H2Y-X8XW, 2025-04-11)
	Detail of Fee Submitted	75000.0, 2024-08-19,
	The proposed proprietary name / brand name	Cefiair Capsule
	Label Claim	Each Capsule contain: Cefixime (as Trihydrate) 400mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	5's-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30°C in dry cool environment

	For generic drugs (me-too Status)	TYSEN 400mg Himont Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Novamed Pharmaceuticals(Pvt.)Ltd-28-KM, FEROZEPUR ROAD, NEAR GRAND AVENUE, Lahore Nishter Town-
	The status in reference regulatory authorities	Suprax Capsule 400mg, approved in FDA USA
	Detail of previous approval	ICEF Capsule ,316th DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
498	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Gray's Pharmaceuticals Plot NO2, Street No. N-3, RCCI Rawat Islamabad (000518)
	Application Form Dy. No / Tracking ID & date of submission	(YMT-6N3-9U1Q, 2025-04-25)
	Detail of Fee Submitted	93000.0, 2025-02-22,
	The proposed proprietary name / brand name	ICOZOL 100MG CAPSULE
	Label Claim	Each Capsule contains: Itraconazole as IR Pellets 22%..... 100mg (Product Complies USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	ICOnyx 100mg Capsule by Wnsfeild Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Welcome Pakistan Trading Pharma (Pvt) Ltd-Chakri Interchange, Gangawala, Rawalpindi-
	The status in reference regulatory authorities	UK Mhra Approved
	Detail of previous approval	Icon 100mg Capsule, DRB 339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	

499	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medwell Pharmaceuticals 1 km, terbella road, lawrencepur, faqirabad Attock (000699)
	Application Form Dy. No / Tracking ID & date of submission	(YQ3-D3X-XVPJ, 2025-04-03)
	Detail of Fee Submitted	93000.0, 2024-11-28,
	The proposed proprietary name / brand name	Purti 2mg Tablet
	Label Claim	Each Film coated tablet containing: Prucalopride as Succinate.....2mg
	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 YearRoom Temperature.
	For generic drugs (me-too Status)	P Pride tablet by Wilshire Laboratories Pvt Ltd
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-
	The status in reference regulatory authorities	Motegrity by Takeda Pharms USA
	Detail of previous approval	PruMark 2mg Tablet (Meeting 340th)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
500	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	M/s Daneen Pharma (Pvt) Ltd Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, (000688)
	Application Form Dy. No / Tracking ID & date of submission	(YR5-M3P-L62U, 2025-05-26)
	Detail of Fee Submitted	75000.0, 18000.0 2024-08-06, 2025-05-20
	The proposed proprietary name / brand name	Emlif ML XR
	Label Claim	Each Film coated tablet contains: Empagliflozin (As immediate release) 10mg Linagliptin (As immediate release) 5mg Metformin HCl (As extended release Core) 1000mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's, 28's & 30's-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30°C. Protect from heat, light and moisture.
	For generic drugs (me-too Status)	Emglif-LM XR Tablet 10mg/5mg/1000mg by Genix Pharma (Reg. No. 120304)

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Genix Pharma (Pvt.) Ltd.-44, 45-B, Korangi Creek Road, Karachi-75190, Pakistan-
	The status in reference regulatory authorities	Trijardy XR Tablet (USFDA Approved)
	Detail of previous approval	EMLIMET XR 5mg/10mg/1000 mg Tablet , DRB 336
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
501	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winbrains Research Laboratories Plot No. 69/1 Block B, Phase I-II Industrial Estate, Hattar, Pakistan (000725)
	Application Form Dy. No / Tracking ID & date of submission	(YSG-JP5-UDNS, 2025-03-10)
	Detail of Fee Submitted	75000.0, 18000.0 2024-06-25, 2025-02-21
	The proposed proprietary name / brand name	Azchlo 40mg/12.5mg Tablet
	Label Claim	Each Film Coated Tablet contains: Azilsartan Medoxomil Potassium eq. to Azilsartan Medoxomil 40MG Chlorthalidone 12.5MG (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK. -
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	AZCHLO 40mg/12.5mg Tablet approved in 343 DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
502	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Davis Pharmaceutical Laboratories Plot No. 121, Industrial Triangle Area, Kahuta Road (000432)
	Application Form Dy. No / Tracking ID & date of submission	(YTG-WT2-QV7D, 2025-03-04)
	Detail of Fee Submitted	93000.0, 2024-10-30,
	The proposed proprietary name / brand name	Zonacid 20mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Vonoprazan Fumarate equivalent to Vonoprazan 20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	2 YearBelow 30c
	For generic drugs (me-too Status)	Vonozan 20mg Tablet
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/S Linta Pharmaceutical Pvt Ltd-Plot No. 03, Street No. S-5 National Industrial Zone, Rawat, Islamabad-
	The status in reference regulatory authorities	Tekeda, Japan
	Detail of previous approval	Vonopraz 20mg Tablet, DRB No. 336
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
503	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Effort Pharmaceuticals (Pvt.) Ltd., 28-Km, Ferozepur Road (000879)
	Application Form Dy. No / Tracking ID & date of submission	(YTV-EQY-RUUG, 2025-03-08)
	Detail of Fee Submitted	93000.0, 2024-11-12,
	The proposed proprietary name / brand name	Fanset 8mg/4ml Injection
	Label Claim	Each 4ml Contains: Ondansetron as Hydrochloride dihydrate ...8mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at temperature 15 to 30 C away from sunlight

	For generic drugs (me-too Status)	ONSET Injection 4mg/2ml by M/s Pharmedic Laboratories (Pvt) Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	May & Baker Pharmaceuticals (Pvt.) Ltd.-45 Km, Thokar Multan road, Lahore-
	The status in reference regulatory authorities	MHRA Approved.
	Detail of previous approval	Minutes for 321st meeting of Registration Board (20th – 22nd September, 2022) Page No.1983
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
504	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	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	(YVW-88Q-QBMV, 2025-06-04)
	Detail of Fee Submitted	93000.0, 2025-05-27,
	The proposed proprietary name / brand name	Capileo 5% Topical Solution
	Label Claim	Each ml contains: Minoxidil ...50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	60ml-As per SRO
	Shelf Life (Unit)	2 YearStore at Room Temperature
	For generic drugs (me-too Status)	Hair Max 5% w/v Topical Solution of M/s Elko Organization Pvt. Ltd..(Reg. No. 027592)
	Pharmacotherapeutic Group of (API)	Antihypertansive
	Name, address of Manufacturing site:	Wimits Pharmaceuticals (Pvt)Ltd-Plot No 129 Sundar Indusrial Estate, Raiwind Road Lahore-
	The status in reference regulatory authorities	Bosley Woman 2 Minoxidil Topical Solution of M/s Bosley Inc. (USFDA Approved)
	Detail of previous approval	343 DRB Meeting ; REGAIN 5% Topical Solution
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
505	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	MEDPHARM RESEARCH LAB 28 KM FEROZPUR ROAD LAHORE (000878)
	Application Form Dy. No / Tracking ID & date of submission	(YXQ-6UQ-DUM6, 2025-03-12)
	Detail of Fee Submitted	93000.0, 2024-11-15,
	The proposed proprietary name / brand name	Dexlo 60mg Capsule
	Label Claim	Each Capsule contains: Dexlansoprazole.....60mg (as dual Delayed released Pellets)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO / DPC-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Dextop 60mg Capsule of M/s Searle
	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	Dexilant 60mg capsule of M/s Takeda Pharmaceuticals America, Inc. Deerfield, IL 60015 (USFDA Approved)
	Detail of previous approval	Dexin 60mg Capsule approved in 331st meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
506	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Steris Pharmaceuticals Plot No 9 Near Synpac Hattar Private Industrial Estate Haripur Road Hattar (000995)
	Application Form Dy. No / Tracking ID & date of submission	(YZM-J88-11P8, 2025-04-18)
	Detail of Fee Submitted	93000.0, 2025-02-25,
	The proposed proprietary name / brand name	Cinoderm -C
	Label Claim	Each gram contains: Fluocinolone Acetonide..... (0.25mg) (USP Spec's)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO

	Shelf Life (Unit)	2 Year(s)BELOW 25
	For generic drugs (me-too Status)	Yes
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd, -Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, Rawalpindi-Pakistan-
	The status in reference regulatory authorities	SRA, Registered in United State
	Detail of previous approval	Minutes of 339th meeting of Registration Board, with brand name of Flocinol 0.025% Cream.
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
507	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Cell Health Sciences , Plot No 217, Industrial Triangle, Kahuta Road, Islamabad (000711)
	Application Form Dy. No / Tracking ID & date of submission	(Z6D-9BQ-YSES, 2025-02-12)
	Detail of Fee Submitted	93000.0, 2024-12-20,
	The proposed proprietary name / brand name	Perocell Extend 665mg Tablet
	Label Claim	Each Film coated Modified Released tablet contains: Paracetamol 665mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
	Shelf Life (Unit)	2 YearStore in a cool & Dry place below 30
	For generic drugs (me-too Status)	Panadol 665mg Extend tablet of M/s GSK
	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	Panadol 665mg Extend tablet of M/s Glaxo Wellcome, S.A.Avenida.Extewmadura,3 09400 Aranda De Duero Burgos-Espana/Spain (USFDA Approved)
	Detail of previous approval	Peradol Extend Tablet Approved in 343rd meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned	

	notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
508	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Jenner Pharmceuticals Pvt. Ltd Plot No. 03, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhupura (000823)
	Application Form Dy. No / Tracking ID & date of submission	(Z7W-X8A-6UAG, 2025-01-13)
	Detail of Fee Submitted	93000.0, 2024-12-20,
	The proposed proprietary name / brand name	Fluocijen Cream
	Label Claim	Each gram contains: Fluocinolone Acetonide..... (0.25mg)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30C
	For generic drugs (me-too Status)	Synalar cream 0.025% by Mass pharma (pvt). ltd
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd,-Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, Rawalpindi-PAKISTAN-
	The status in reference regulatory authorities	Fluocinolone Acetonide cream 0.025% USP by Cosette pharmaceuticals,inc USA
	Detail of previous approval	Flocinol Cream 0.025%, approved in M-339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
509	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Dyson Research Laboratories (Pvt.) Ltd 28-Km Ferozpur Road Lahore (000559)
	Application Form Dy. No / Tracking ID & date of submission	(ZDJ-SVN-ZXBL, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2024-12-13,
	The proposed proprietary name / brand name	Dydic
	Label Claim	Each gram cream contains: Fusidic acid 20 mg.
	Reference to Finished product specifications	British Pharmacopeia

	Proposed Pack Size	As per S.R.O-As per SRO
	Shelf Life (Unit)	2 YearStore below 25C.
	For generic drugs (me-too Status)	Fudic Cream by Shaigan Pharmaceuticals (Pvt) Limited.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Solaris Life Sciences (Pvt.) Ltd.-Plot No.08, Street No S-1, RCCI, Industrial Estate, Rawat.-
	The status in reference regulatory authorities	Fucidin Cream by Leo laboratories limited UK, approved in Medicines and Healthcare products Regulatory Agency (UK).
	Detail of previous approval	Albet 2% Cream (Fusidic Acid) 20mg, approved in Minutes of 344th meeting of Registration Board held
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
510	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Cell Health Sciences , Plot No 217, Industrial Triangle, Kahuta Road, Islamabad (000711)
	Application Form Dy. No / Tracking ID & date of submission	(ZGL-RU9-L7X1, 2025-01-23)
	Detail of Fee Submitted	93000.0, 2024-11-29,
	The proposed proprietary name / brand name	Limpa 10mg/5mg/1000mg XR Tablet
	Label Claim	Each Film Coated Extended Release tablet contains: Empagliflozin.....10mg Linagliptin.....5mg (Immediate release coat) Metformin HCl.....1000mg (Extended release core)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
	Shelf Life (Unit)	2 YearStore 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	TRIJARDY XR- empagliflozin, linagliptin, metformin hydrochloride tablet, extended release of M/s BOEHRINGER INGELHEIM PHARMACEUTICALS, INC. (USFDA Approved)

	Detail of previous approval	Limpa-Met 10/5/1000mg XR Tablet approved in 340th meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
511	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	SHAWAN PHARMACEUTICALS PLOT # 37, NS-1. NATIONAL INDUSTRIAL ZONE. RAWAT (000627)
	Application Form Dy. No / Tracking ID & date of submission	(ZGR-LJW-ABX6, 2024-10-24)
	Detail of Fee Submitted	93000.0, 2024-10-10,
	The proposed proprietary name / brand name	P-Seq
	Label Claim	Each vial contains (Sterile powder for reconstitution): Pantoprazole as (sodium sesquihydrate)..... 40mg)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1,s-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	PANPAK, Rasco pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Biogen Life Sciences -Biogen Life Sciences: 8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Protonix 40mg Injection (I.V) approved By US FDA.
	Detail of previous approval	Pentazole 40mg Injection IV Each vial contains (Sterile powder for reconstitution): Pantoprazole as
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
512	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medwell Pharmaceuticals 1 km, terbella road, lawrencepur, faqirabad Attock (000699)

	Application Form Dy. No / Tracking ID & date of submission	(ZLA-QEP-8T4P, 2025-01-13)
	Detail of Fee Submitted	93000.0, 2024-12-31,
	The proposed proprietary name / brand name	TIO-MED 18MCG Rota Capsule
	Label Claim	Each RotaCapsule contains: Tiotropium as Bromide Monohydrate.....18 Mcg (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Apollo-F Capsule Nexus Pharma Karachi. (Reg# 076149)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	winbrains Research Laboratories-Plot No. 69/1, Phase I-II, Industrial Estate, Hattar.-
	The status in reference regulatory authorities	Usfda Approved
	Detail of previous approval	Tybro 18mcg Rota capsule, DRB 336
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
513	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Misaq Pharmaceuticals Pvt Ltd. Plot no.7-B, Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad. (000985)
	Application Form Dy. No / Tracking ID & date of submission	(ZNN-4QY-A9LN, 2024-08-31)
	Detail of Fee Submitted	75000.0, 2024-04-23,
	The proposed proprietary name / brand name	Mizone
	Label Claim	Each vial contains: Ceftriaxone sodium equivalent to Ceftriaxone 2000mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 Year15-30 degree Celsius
	For generic drugs (me-too Status)	Brand Name: Droncef Injection 2g IV Registration holder: Seraph Pharmaceutical, Islamabad
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	SERAPH PHARMACEUTICAL-Plot No 210, Industrial triangle, Kahuta road, Islamabad-

		Pakistan-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	Droncef Injection 2g IV, 293rd
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
514	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	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	(ZNQ-45H-4E99, 2025-05-14)
	Detail of Fee Submitted	93000.0, 2025-02-20,
	The proposed proprietary name / brand name	Barinib 2mg Tablets
	Label Claim	Each Film coated Tablet Contains: Baricitinib.....2mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	10's-As per SRO,14's-As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	NovaMed Pharmaceuticals Pvt.Ltd-28 KM, Ferozepur Road, Lahore -
	The status in reference regulatory authorities	USFDA Approved - https://www.accessdata.fda.gov/drugsatfda_docs/lab
	Detail of previous approval	Baricit Tablet 2 mg ; 336 DRB Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
515	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medwell Pharmaceuticals 1 km, terbella road, lawrencepur, faqirabad Attock (000699)

	Application Form Dy. No / Tracking ID & date of submission	(ZQZ-Y84-HN1X, 2025-01-13)
	Detail of Fee Submitted	93000.0, 2024-11-28,
	The proposed proprietary name / brand name	VONOWEL 10mg Tablet
	Label Claim	Each Film coated tablet containing: Vonoprazan as fumarate.....10 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,14's -As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature.
	For generic drugs (me-too Status)	VONOZAN tablet by GETZ Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-
	The status in reference regulatory authorities	VOQUENZA tablet by Phathom Pharmaceuticals,USA
	Detail of previous approval	Vonomark 10mg Tablet (Meeting 335th)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
516	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Air Pharmaceuticals(Pvt.)Ltd Plot No's 74, 75-A, Small Industrial Estate, Kasur (000977)
	Application Form Dy. No / Tracking ID & date of submission	(ZS3-B5W-JXA3, 2025-05-02)
	Detail of Fee Submitted	75000.0, 18000.0 2024-08-19, 2025-04-30
	The proposed proprietary name / brand name	Cefiair
	Label Claim	Each 5ml contains:Cefixime (as trihydrate).....200mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's(30ml)-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30°C in dry cool environment
	For generic drugs (me-too Status)	TYSEN Dry Suspension by Himont Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Novamed Pharmaceuticals(Pvt.)Ltd-28-KM, FEROZEPUR ROAD, NEAR GRAND AVENUE, Lahore Nishter Town-

	The status in reference regulatory authorities	Cefixime Capsule 200mg/5ml approved in FDA USA
	Detail of previous approval	Product Name, Meeting No Icef (M-308th DRB Approved)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
517	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Magns Pharmaceuticals Plot # 7B Value Addition City Sahianwala Road Khurrianwala (000849)
	Application Form Dy. No / Tracking ID & date of submission	(ZSX-71Y-NHDB, 2025-05-15)
	Detail of Fee Submitted	93000.0, 2025-03-25,
	The proposed proprietary name / brand name	Magsum
	Label Claim	Each Vial Contains: Cefoperazone as Sodium...1000mg Sulbactam as Sodium...1000mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 x1,s -As per SRO
	Shelf Life (Unit)	2 Yearstore below 30 oC
	For generic drugs (me-too Status)	Cebac Injection by Bosch pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Nicholas Pharmaceuticals-Plot # 34, Street No. SS-2, National Industrial Zone, Rawat, Islamabad.-
	The status in reference regulatory authorities	Sulperazone Intravenous Injection 2g by pfizer PMDA Japan
	Detail of previous approval	Wincef 2 gm injection 333rd meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
518	Case Category	New License (Maham Misbah)
	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	(8YD-GM5-DV4N, 2024-08-26)	
Detail of Fee Submitted	30000.0, 9000.0 2024-07-30, 2025-06-26	
The proposed proprietary name / brand name	Finen 10mg Tablets	
Label Claim	Each film coated tablet contains; Finerenone.....10mg (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)	Kerendia 10mg Tablet, Company:BAYER HLTHCARE, (NDA): 215341 (USFDA Approved)	
Pharmacotherapeutic Group of (API)	Finerenone: C03DA05: Aldosterone antagonists	
Name, address of Manufacturing site:	Self Manufacturing	
Name & address of API manufacturer		
Detail of stability batches of drug product	Solaris: Finerenone: 3 batches, 1500 tablets each	
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate issued to M/s Novamed is submitted. Loan letter is submitted.	
Pharmaceutical Equivalence and Comparative Dissolution Profile	Solaris: Finerenone: PE & CDP perfomed against Finone Tablet by M/s Getz	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Solaris: Submitted as per Zone IV	
The status in reference regulatory authorities	Kerendia 10mg Tablet, Company:BAYER HEALTHCARE, (NDA): 215341 (USFDA Approved)	
GMP status of the firm	Solaris: Section approval letter dated 17-01-2024 specifies Tablet (General) section	
Evidence of approval of manufacturing facility	Solaris: Section approval letter dated 17-01-2024 specifies Tablet (General) section	
Evaluation Remarks		
Sr. No	Observations	Response of applicant
1	3.2.S.4.2: Drug substance manufacturer has given following conditions for assay testing:Mobile phase: 0.1percent formic acid aqueous solution: acetonitrile (70:30)Sample dilution: 0.05mg/ml However, drug product manufacturer has given different mobile phase and sample concentration for assay testing. Justification shall be submitted for difference in assay test parameters. Method verification studies shall be submitted accordingly.	Method of analysis is developed and validated for analysis of Drug substance from the analytical method provided by API manufacturer. The condition for assay determination is same i.e. Buffer: acetonitrile (70:30). The preparation of buffer mentioned in CTD is dipotassium hydrogen phosphate aqueous solution instead of 0.1percent formic acid in aqueous solution mistakenly. The Assay conditions are corrected in revised Module-III and the method validatedstudies are already submitted according to the API manufacturer Method

		in Module-III for your consideration.
2	3.2.P.2.2.1: Pictorial evidence of the innovator product, against which PE & CDP studies are performed, with visible information of batch number, manufacturing date etc. shall be submitted.	Submitted
3	3.2.P.51: Justify the disintegration limit of NMT 30minutes whereas the limit for dissolution is NLT Q in 15 minutes.	Specifications revised and fee submitted for revision of the finished product specifications. Fee slip attached having Challan number 0442106593
4	3.2.P.8: Stability studies data for 6 month time point shall be submitted.	Submitted
5	3.2.R: Executed BMRs of stability batches shall be submitted.	Submitted
Decision		
Approved		
519	Case Category	Routine (Maham Misbah)
	Name, address of Applicant.	NovaMed Pharmaceuticals(Pvt.)Ltd 28-KM Ferozepur Road Lahore (000590)
	Application Form Dy. No / Tracking ID & date of submission	(AV5-QXX-5YGS, 2024-03-12)
	Detail of Fee Submitted	30000.0, 2024-02-13,
	The proposed proprietary name / brand name	Excitor
	Label Claim	Each film-coated tablet contains: Etoricoxib.....60mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	7's, 10's ,14's 20's-De-Controlled
	Shelf Life (Unit)	2 Year(s)store below 30C
	For generic drugs (me-too Status)	Dowcoxia tablet by M/s Martin Dow 110308
	Pharmacotherapeutic Group of (API)	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Prudence Pharma Chem
	Detail of stability batches of drug product	3 batches 2000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP submitted against Arcox tablet by M/s Genome

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		As per Zone Iva
	The status in reference regulatory authorities		MHRA Approved (PL 04569/1465)
	GMP status of the firm		GMP certificate issued on the basis of inspection conducted on 07-11-23 specifies Tablet general section.
	Evidence of approval of manufacturing facility		Letter No. F.1-9/2003-Lic (Vol-II) dated 14-09-2021 for regularization/renewal of DML wef 08-04-2021 specifies Tablet general (revised) section.
	Evaluation Remarks		
	Sr. No.	Observation	Response of applicant
	1	1.6.5: Valid GMP/DML of API manufacturer issued by the regulatory body of country of origin shall be submitted.	GMP Certificate valid till 23-05-2026 is submitted
	Decision		
	Approved		
	520	Case Category	Routine (Maham Misbah)
	Name, address of Applicant.	Islam Pharmaceuticals 7km Pasrur Road Sialkot (000885)	
	Application Form Dy. No / Tracking ID & date of submission	(BTQ-RAG-YGXT, 2024-03-18)	
	Detail of Fee Submitted	30000.0, 2023-12-27,	
	The proposed proprietary name / brand name	Tizid 2mg	
	Label Claim	Each Tablet Contains: Tizanidine as Hydrochloride 2mg	
	Reference to Finished product specifications	United States Pharmacopeia	
	Proposed Pack Size	10's-As per SRO	
	Shelf Life (Unit)	2 Year(s)Below 30 Celsius	
	For generic drugs (me-too Status)	Musidin 2mg tablet, Reg. No. 027218, Martin Dow	
	Pharmacotherapeutic Group of (API)	WHO ATC Code: M03BX02 : MUSCLE RELAXANTS	
	Name, address of Manufacturing site:	Self Manufacturing	
	Name & address of API manufacturer	Viswa Laboratories Pvt.LTD. Plot No. D-35, M.I.D.C., kurkumbh, Tal, Daund, Dist. Pune 413 802, Maharashtra (India).	
	Detail of stability batches of drug product	3 batches; 2000 tablets each	
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate submitted	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Islam: Tizanidine: PE and CDP conducted against Musidin tablet of M/s Martin Dow.	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	As per Zone Iva	
	The status in reference regulatory authorities	MHRA Approved	

	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 08-02-2023 specifies the following sections Tablet (General), Capsule(General), sachet(General), Dry suspension(General), Liquid Ampule (SVP) (General)
	Evidence of approval of manufacturing facility	Section approval letter No.F.1-19/2014-Lic dt 29-08-2018 specifies the following sections: Tablet (General), Capsule(General), sachet(General), Dry suspension(General)
	Evaluation Remarks	
	Decision	
	Approved	
521	Case Category	Priority As Per 257-M of RB (Maham Misbah)
	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	(DA2-697-D3JX, 2025-04-18)
	Detail of Fee Submitted	37000.0, 9000.0 2025-02-14, 2025-06-27
	The proposed proprietary name / brand name	palbolib125mg Tablet
	Label Claim	Each Film coated Tablet Contains: palbociclib 125mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,20's-As per SRO,21's-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30°C in a cool and dry place
	For generic drugs (me-too Status)	Ibralib Tablet 125mg, Manufactured by M/s Oncogen Pharma (Private) Limited
	Pharmacotherapeutic Group of (API)	cyclin-dependent kinase (CDK) inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Kaifeng Pharmaceutical (Group) Company Limited . ADDRESS: No.1, Yunan Street, Kaifeng,Henan Prov- ince, China
	Detail of stability batches of drug product	03 batches; batch size 1000units
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 and invoice are submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence and CDP have been provided against Ibrance tablet by M/s Pfizer
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	As per Zone IVa
	The status in reference regulatory authorities	Ibrance USFDA Approved
	GMP status of the firm	GMP inspection report generated on the basis of inspection conducted on 20-11-24 concluded “satisfactory” GMP conformance.
	Evidence of approval of manufacturing facility	Letter for grant of additional sections dated 10-05-2024 specifies Tablet (Cytotoxic) and Capsule (Cytotoxic) Sections

Evaluation Remarks

Serial No.	Observations	Response of applicant
1	3.2.S.4.2 & 3.2.S.4.4: Test for palladium and water content are included in drug substance testing specifications, according to reference drug product literature. These tests are not included in API specifications and CoA provided with your application. Justify.	he drug substance manufacturer has performed heavy metal testing in accordance with applicable guidelines, and the results comply with the specified limit of less than 20 ppm. However, this test was inadvertently omitted from our laboratory's analytical method. We acknowledge this oversight and confirm that heavy metal testing will be incorporated into our routine analytical procedure to ensure alignment with regulatory expectations and comprehensive quality assessment. Both the drug substance and drug product manufacturers, including Kaizen, have employed the Loss on Drying (LOD) method instead of a specific water content test. Since palbociclib does not possess water of hydration in its molecular structure, a Karl Fischer titration is not appropriate. The LOD method is more appropriate in this case, as it effectively captures both adsorbed moisture and any residual organic solvents that may be present, providing a more relevant estimation of volatile content. Therefore, our current approach is scientifically justified and consistent with the drug substance manufacturer's practice.
2	3.2.P.2.2.1 & 3.2.P.5.1: Test for water content is included in finished product specifications of innovator. However, this test is not included in pharmaceutical equivalence report and finished product specifications. Justify. Submit prescribed fee in case of revision of specifications.	During the development of the finished product testing stage, it was observed that there was no significant source of water contribution from either the active pharmaceutical ingredient or the excipients. Additionally, the granules were adequately dried using a tray dryer to achieve a moisture content below the desired threshold to ensure smooth tablet compression. Based on these findings, the decision

		was made not to include water content as a test parameter at the finished product stage. However, in light of your recommendation and in alignment with the reference product literature, we confirm that the water content test will be incorporated into the finished product specification to ensure regulatory compliance and product quality assurance. Specifications have been revised along with submission of requisite fee (PKR9000/-)
3	3.2.P.8: Accelerated and real time stability studies data is submitted for three months only. Stability studies data of 6-month time point shall be submitted.	Submitted
Decision		
Approved		
522	Case Category	Routine (Maham Misbah)
	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	(DZJ-L8R-W82X, 2024-03-01)
	Detail of Fee Submitted	75000.0, 2024-01-16,
	The proposed proprietary name / brand name	Vomeron Oral Solution 4mg/5ml
	Label Claim	Each 5ml contains: Ondansetron 4mg. (as Ondansetron Hydrochloride Dihydrate)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	15mL, 25mL, 50mL, an-As per SRO
	Shelf Life (Unit)	24 Month(s) Store below 30°C. Protect from heat, light and moisture.
	For generic drugs (me-too Status)	Onseron 4mg/5ml Oral Solution (Indus Pharma)
	Pharmacotherapeutic Group of (API)	Serotonin (5HT3) antagonists WHO ATC Code: A04AA01
	Name, address of Manufacturing site:	Martin Dow Marker Limited -7- Jail Road, Quetta, Pakistan-
	Name & address of API manufacturer	CTX LIFESCIENCES PVT. LTD
	Detail of stability batches of drug product	3 batches; Batch size 100 bottles of 50ml
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted against Onseron Oral Solution 4mg/5ml by M/s Indus Pharma

Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per Zona IV
The status in reference regulatory authorities	ZOFRAN Oral Solution (US FDA)
GMP status of the firm	Martin Dow Marker Ltd, Quetta: GMP certificate No. 015/2021-DRAP (Q)/K issued against inspection conducted on 27-02-2021 is submitted specifying Oral Liquid Syrup (general) section.
Evidence of approval of manufacturing facility	Martin Dow Marker Ltd, Quetta: Letter No. 4-2/86-Lic(Vol-VII) dt 31-05-21 on the subject "Regularization of sections" from Licensing Division, DRAP is submitted specifying Liquid Syrup (general) section.

Evaluation Remarks

Serial no.	Observations	Response of applicant
1	3.2.P: Sorbitol is included in the applied formulation as sweetener. Clarify the batch details and source of sorbitol used in the formulation and submit tests results of EG and DEG impurity testing of the relevant batch.	Batch detail of used sorbitol Manufacturer Batch Name: 0823 Mfg. Date: 15.09.2023 Expiry Date: 14.09.2026 Source of Sorbitol: Habib Rice Products Ltd. Karachi Testing of EG and DEG: The results were taken from the Manufacturer COA. Limit of EG and DEG (NMT 0.1%: Complies) Note: Copy of Manufacturer COA is attached. Justification and Undertaking: Sorbitol was not tested for EG and DEG earlier at the time of product development as it was a new material at site. However, now we have full testing facility for EG and DEG. We undertake that we shall perform EG and DEG parameters along with all other parameters as specified in the official monograph, now an onward all incoming supply of sorbitol that will be procured for manufacturing of commercial batches of finished products.

Decision

Approved

Approved. With reference to DRAP's Letter No. F.3-41/2023-QC dated 01-12-2023, applicant shall perform proper testing to verify that DEG and EG impurities are within limits in the batch of Sorbitol used for the manufacturing of stability batches and submit the in-house CoA of the relevant batch to Registration section, prior to issuance of registration letter.

523	Case Category	Routine (Maham Misbah)
	Name, address of Applicant.	BF Biosciences Limited 5-KM Sundar Raiwind Road, Raiwind, Lahore (000655)
	Application Form Dy. No / Tracking ID & date of submission	(HZR-EMG-Q3GA, 2024-03-06)
	Detail of Fee Submitted	30000.0, 2023-08-01,
	The proposed proprietary name / brand name	Vancin 500mg Injection
	Label Claim	Each 30mL vial contains Vancomycin (as HCl) 500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's -As per SRO

Shelf Life (Unit)	2 Year(s)Store at 15°C to 30°C	
For generic drugs (me-too Status)	Vancomycin 500mg Injection(Abbot Laboratories)	
Pharmacotherapeutic Group of (API)	J01XA01: Anti-infectives for systemic use	
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	1 batch of 250 vials and 2 batches of 500 vials each	
Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is submitted	
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE submitted against Vancomycin injection of M/s Abbot	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per Zone Iv	
The status in reference regulatory authorities	Vancocin HCl Injectiion (Abbot Laboratories) FDA Approved	
GMP status of the firm	GMP certificate No. 176/2024-DRAP (AD-788058753) issued on the basis on inspection conducted on 01-03-2024 specifies following sections: Parenteral (Liquid Lyophilized) Biotech Section, Injection Pre-Filled Syringes (Biotech), Injectable (Ampoule/Vial) SV	
Evidence of approval of manufacturing facility	Copy of Letter No. F.1-29/2004-Lic (Vol-II) dated 07-05-2024 on the subject RENEWAL OF DRUG MANUFACTURING LICENSE & GRANT OF ADDITIONAL SECTION UNDER THE DRUGS ACT, 1976 specifies following sections: Parenteral (Liquid Lyophilized) Biotech Section, Injection Pre-Filled Syringes (Biotech), Product Development Section, Injectable (Ampoule/Vial) SVP (Lyophilized/Liquid) (General) Section	
Evaluation Remarks		
Serial No.	Observations	Response of applicant
1	DML renewal due in 2024 shall be submitted.	submitted.
2	Name the section in which the applied product shall be manufactured and submit its section approval letter issued by Licensing Division of DRAP.	Copy of Letter No. F.1-29/2004-Lic (Vol-II) dated 07-05-2024 on the subject RENEWAL OF DRUG MANUFACTURING LICENSE & GRANT OF ADDITIONAL SECTION UNDER THE DRUGS ACT, 1976 specifies Injectable (Ampoule/Vial) SVP (Lyophilized/Liquid) (General) Section.
3	1.6.5: Submit valid DML/GMP of API manufacturer issued by the regulatory authority of the country of origin.	Submitted
Decision		

	Approved							
524	Case Category	Priority As Per 257-M of RB (Maham Misbah)						
	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	(MAJ-73M-2P32, 2025-04-18)						
	Detail of Fee Submitted	37000.0, 9000.0 2025-02-14, 2025-06-27						
	The proposed proprietary name / brand name	Palbolib (Palbociclib) 100mg Tablet						
	Label Claim	Each film-coated tablet contains Palbociclib 100mg						
	Reference to Finished product specifications	As per Innovators Specification						
	Proposed Pack Size	10's-As per SRO, 20's-As per SRO, 21'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)	Ibralis Tablet 100mg, Manufacturer: M/s Oncogen Pharma (Private) Limited						
	Pharmacotherapeutic Group of (API)	Antineoplastic agents, protein kinase inhibitors						
	Name, address of Manufacturing site:	Self Manufacturing						
	Name & address of API manufacturer	Kaifeng Pharmaceutical (Group) Company Limited. Address: No.1, Yunan Street, Kaifeng, Henan Province, China						
	Detail of stability batches of drug product	03 batches; batch size 1000units						
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 and invoice are submitted						
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence and CDP have been provided against Ibrance tablet by M/s Pfizer						
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	As per Zone IVa						
	The status in reference regulatory authorities	Ibrance FC tablet 100mg Approved in Medicines and Healthcare Regulatory Agency (MHRA)						
	GMP status of the firm	GMP inspection report generated on the basis of inspection conducted on 20-11-24 concluded “satisfactory” GMP conformance.						
	Evidence of approval of manufacturing facility	Letter for grant of additional sections dated 10-05-2024 specifies Tablet (Cytotoxic) and Capsule (Cytotoxic) Sections						
Evaluation Remarks								
<table border="1"> <thead> <tr> <th>Serial No.</th><th>Observations</th><th>Response of applicant</th></tr> </thead> <tbody> <tr> <td>1</td><td>3.2.S.4.2 & 3.2.S.4.4: Test for palladium and water content are included in drug substance testing specifications, according to reference drug product literature. These tests are not included in API specifications and CoA</td><td>The drug substance manufacturer has performed heavy metal testing in accordance with applicable guidelines, and the results comply with the specified limit of less than 20 ppm. However, this test was</td></tr> </tbody> </table>			Serial No.	Observations	Response of applicant	1	3.2.S.4.2 & 3.2.S.4.4: Test for palladium and water content are included in drug substance testing specifications, according to reference drug product literature. These tests are not included in API specifications and CoA	The drug substance manufacturer has performed heavy metal testing in accordance with applicable guidelines, and the results comply with the specified limit of less than 20 ppm. However, this test was
Serial No.	Observations	Response of applicant						
1	3.2.S.4.2 & 3.2.S.4.4: Test for palladium and water content are included in drug substance testing specifications, according to reference drug product literature. These tests are not included in API specifications and CoA	The drug substance manufacturer has performed heavy metal testing in accordance with applicable guidelines, and the results comply with the specified limit of less than 20 ppm. However, this test was						

	provided with your application. Justify.	inadvertently omitted from our laboratory's analytical method. We acknowledge this oversight and confirm that heavy metal testing will be incorporated into our routine analytical procedure to ensure alignment with regulatory expectations and comprehensive quality assessment. Both the drug substance and drug product manufacturers, including Kaizen, have employed the Loss on Drying (LOD) method instead of a specific water content test. Since palbociclib does not possess water of hydration in its molecular structure, a Karl Fischer titration is not appropriate. The LOD method is more appropriate in this case, as it effectively captures both adsorbed moisture and any residual organic solvents that may be present, providing a more relevant estimation of volatile content. Therefore, our current approach is scientifically justified and consistent with the drug substance manufacturer's practice.
2	3.2.P.2.2.1 & 3.2.P.5.1: Test for water content is included in finished product specifications of innovator. However, this test is not included in pharmaceutical equivalence report and finished product specifications. Justify. Submit prescribed fee in case of revision of specifications.	During the development of the finished product testing stage, it was observed that there was no significant source of water contribution from either the active pharmaceutical ingredient or the excipients. Additionally, the granules were adequately dried using a tray dryer to achieve a moisture content below the desired threshold to ensure smooth tablet compression. Based on these findings, the decision was made not to include water content as a test parameter at the finished product stage. However, in light of your recommendation and in alignment with the reference product literature, we confirm that the water content test will be incorporated into the finished product specification to ensure regulatory compliance and

			product quality assurance. Specifications have been revised along with submission of requisite fee (PKR9000/-)
	3	3.2.P.8: Accelerated and real time stability studies data is submitted for three months only. Stability studies data of 6-month time point shall be submitted.	Submitted
	Decision		
	Approved		
525	Case Category		Routine (Maham Misbah)
	Name, address of Applicant.		NovaMed Pharmaceuticals(Pvt.)Ltd 28-KM Ferozepur Road Lahore (000590)
	Application Form Dy. No / Tracking ID & date of submission		(ML1-1JL-EJ13, 2024-03-08)
	Detail of Fee Submitted		30000.0, 2024-02-13,
	The proposed proprietary name / brand name		Prilid
	Label Claim		Each 1gm of the cream contains : Prilocaine 25mg and Lidocaine 25mg
	Reference to Finished product specifications		United States Pharmacopeia
	Proposed Pack Size		5g tube(1's) , 5g tu-As per SRO
	Shelf Life (Unit)		2 Year(s)store at controlled room temperature below 30C
	For generic drugs (me-too Status)		Epinum cream by M/s ATCO (DRN 110359)
	Pharmacotherapeutic Group of (API)		Local anaesthetic
	Name, address of Manufacturing site:		Self Manufacturing
	Name & address of API manufacturer		Alcon Biosciences (Pvt.)Ltd (lidocaine) and Sawati spentose (Pvt)Ltd (Prilocaine)
	Detail of stability batches of drug product		3 batches Batch size: 500tubes of 5 grams each
	Documents for the procurement of API with approval from DRAP (in case of Import)		Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile		PE is performed against EMLA cream by M/s Aspen. CDP is not applicable
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		Zone Iva
	The status in reference regulatory authorities		Emla cream USFDA Approved
	GMP status of the firm		GMP certificate issued on the basis of inspection conducted on 07-11-23 specifies Cream/ointment/gel section
	Evidence of approval of manufacturing facility		GMP certificate issued on the basis of inspection conducted on 07-11-23 specifies Cream/ointment/gel section
	Evaluation Remarks		
	Serial no.	Observations	Response of applicant

1	1.6.5: Valid GMP certificate/ DML of M/s Alcon Biosciences Pvt ltd, India shall be submitted.	Submitted
2	3.2.P.5.1: Specifications of finished product are not as per USP monograph. e.g test for specific microorganisms does not state the absence of Staph. aureus. Submit revised drug product specifications and submit prescribed pre-registration fee.	Revised drug product specifications and prescribed pre-registration fee is submitted (PKR 9000/- DS No. 65235536531)
3	3.2.P.5.2: Analytical procedure does not cover all tests given in USP monograph. e.g, procedure for system suitability testing is not included in assay testing. Submit revised procedure, test results and associated chromatograms for system suitability testing. Moreover, system suitability procedure given in 3.2.P.5.3 is not as per USP monograph. Clarify your testing method.	The analytical method has been revised to align fully with the USP specification, the assay method has been amended to incorporate the USP-specified system suitability criteria. Updated analytical method and associated chromatograms for system suitability testing are submitted.

Decision

Approved

526	Case Category	New Section (Maham Misbah)
	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	(MYU-DAP-BZHD, 2025-01-21)
	Detail of Fee Submitted	37000.0, 2025-01-09,
	The proposed proprietary name / brand name	Ora-D 50000IU Capsule
	Label Claim	Each soft capsule contains: Cholecalciferol..... 50000IU
	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)	Dee 50k Soft Gelatin Capsule (093452) by Mass Pharma
	Pharmacotherapeutic Group of (API)	Vitamin
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	-
	Detail of stability batches of drug product	3 batches of 8000 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE submitted against DX3 50000IU soft gelatin capsule by M/s Zestech Sciences.

Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	as per zone Iv
The status in reference regulatory authorities	InVita D3 50,000 IU Soft capsules (MHRA Approved)
GMP status of the firm	GMP certificate issued on the basis of evaluation conducted on 25-09-2024 is submitted which specifies Soft Gelatin Capsule Section.
Evidence of approval of manufacturing facility	Additional section approval letter No.F.1-17/2005-Lic(Vol-I) dt 18-02-2020 specifies grant of Soft Gelatin Capsule Section.

Evaluation Remarks

Serial No	Observations	Response of applicant
1	Valid DML/GMP certificate of API manufacturer shall be submitted.	The API Manufacturer Sichuan Province Yuxin Pharmaceutical Co Ltd holds valid DML till 18-10-2025.

Decision

Approved

527	Case Category	Priority As Per 257-M of RB (Maham Misbah)
	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	(NPS-X23-HV2J, 2025-04-18)
	Detail of Fee Submitted	37000.0, 9000.0 2025-02-14, 2025-06-27
	The proposed proprietary name / brand name	palbolib 75mg Tablet
	Label Claim	Each Film coated Tablet Contains: palbociclib 75mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,20's-As per SRO,21's-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30°C in a cool and dry place
	For generic drugs (me-too Status)	Ibralib Tablet 75mg, Manufactured by M/s Oncogen Pharma (Private) Limited
	Pharmacotherapeutic Group of (API)	cyclin-dependent kinase (CDK) inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Kaifeng Pharmaceutical (Group) Company Limited . ADDRESS:No.1, Yunan Street, Kaifeng,Henan Prov- ince, China
	Detail of stability batches of drug product	3 batches, 1000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Drug Import License submitted for import of 2kg API
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence and CDP has been provided against Ibrance tablet by M/s Pfizer Ltd
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	As per Zone IVa

The status in reference regulatory authorities		Ibrance USFDA Approved
GMP status of the firm		GMP inspection report generated on the basis of inspection conducted on 20-11-24 concluded “satisfactory” GMP conformance.
Evidence of approval of manufacturing facility		Letter for grant of additional sections dated 10-05-2024 specifies Tablet (Cytotoxic) and Capsule (Cytotoxic) Sections
Evaluation Remarks		
Serial No.	Observation	Response of applicant
1	3.2.S.4.2 & 3.2.S.4.4: Test for palladium and water content are included in drug substance testing specifications, according to reference drug product literature. These tests are not included in API specifications and CoA provided with your application. Justify.	The drug substance manufacturer has performed heavy metal testing in accordance with applicable guidelines, and the results comply with the specified limit of less than 20 ppm. However, this test was inadvertently omitted from our laboratory’s analytical method. We acknowledge this oversight and confirm that heavy metal testing will be incorporated into our routine analytical procedure to ensure alignment with regulatory expectations and comprehensive quality assessment. Both the drug substance and drug product manufacturers, including Kaizen, have employed the Loss on Drying (LOD) method instead of a specific water content test. Since palbociclib does not possess water of hydration in its molecular structure, a Karl Fischer titration is not appropriate. The LOD method is more appropriate in this case, as it effectively captures both adsorbed moisture and any residual organic solvents that may be present, providing a more relevant estimation of volatile content. Therefore, our current approach is scientifically justified and consistent with the drug substance manufacturer’s practice.
2	3.2.P.2.2.1 & 3.2.P.5.1: Test for water content is included in finished product specifications of innovator. However, this test is not included in pharmaceutical equivalence report and finished product specifications. Justify. Submit prescribed fee in case of revision of specifications.	During the development of the finished product testing stage, it was observed that there was no significant source of water contribution from either the active pharmaceutical ingredient or the excipients. Additionally, the granules were adequately dried using a tray dryer to achieve a moisture content below the desired threshold to ensure smooth tablet compression. Based on these findings, the decision was made not to include water content as a test parameter at the finished product stage. However, in light of your recommendation and in alignment with the reference product literature, we confirm that the water content test will be incorporated into the finished product specification to ensure regulatory compliance and product quality assurance. Specifications have been revised along with submission of requisite fee (PKR9000/-)
3	3.2.P.8: Accelerated and real time stability studies data is submitted for three months only. Stability	Submitted

	studies data of 6-month time point shall be submitted.	
Decision		
Approved		
528	Case Category	Routine (Maham Misbah)
	Name, address of Applicant.	Nabiqasim Industries (Pvt) Ltd., 17/24, Korangi Industrial Area, Karachi. (000105)
	Application Form Dy. No / Tracking ID & date of submission	(NQQ-W6A-LJNR, 2024-03-12)
	Detail of Fee Submitted	30000.0, 2024-02-19,
	The proposed proprietary name / brand name	RELIEFAL DUO
	Label Claim	Each film coated tablet contains: Ibuprofen 200mg & Paracetamol 500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 20's, 30's-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 degree
	For generic drugs (me-too Status)	Provas Duo tablet 200mg/500mg DRN: 108579 by M/s SAMI
	Pharmacotherapeutic Group of (API)	ATC Code: N02BE51 (paracetamol, combinations excl. psycholeptics)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Citi Pharma Private Limited, Lahore,Hubei Biocause Heilen Pharmaceuticals
	Detail of stability batches of drug product	2 batches of 5000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Ibuprofen-Drug Import License is submitted Paracetamol- Local procurement documents submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP submitted against Provas Duo tablet 200mg/500mg DRN: 108579 by M/s SAMI
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per Zone Iv
	The status in reference regulatory authorities	MHRA Approved - Neuromol pain relief tablet 200mg/500mg- Reckitt Benckiser, UK
	GMP status of the firm	Nabi Qasim: GMP certificate No. 512/2023-DRAP (K) issued on the basis of evaluation conducted on 22-05-2023 is submitted which specifies the following sections: Tablet (general/Cephalosporin/hormone)
	Evidence of approval of manufacturing facility	Nabi Qasim: Copy of DML renewal letter No.F.2-20/85-Lic(Vol V) dated 27-04-2020 specifies the following sections: Capsule (general/Cephalosporin), Dry powder for suspension (general/antibiotic/Cephalosporin), lyophilized vial (general), Tablet (general/hormone), sachet (general), Liquid syrup(General), cream/ointment (general), ear

		drops/topical solution, eye drops, enema, vaginal (gel & tablet) (hormones).
	Evaluation Remarks	
	Decision	
	Approved	
529	Case Category	New License (Maham Misbah)
	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	(NQB-RUL-UN53, 2024-08-26)
	Detail of Fee Submitted	30000.0, 9000.0 2024-07-30, 2025-06-26
	The proposed proprietary name / brand name	Finen 20mg Tablets
	Label Claim	Each film coated tablet contains; Finerenone.....20mg (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)	Kerendia 20mg Tablet, Company:BAYER HLTHCARE, (NDA): 215341 (USFDA Approved)
	Pharmaceutical Group of (API)	Solaris: Finerenone:
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Solaris: Finerenone: 3 batches, 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate issued to M/s Novamed is submitted. Loan letter is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Solaris: Finerenone: PE & CDP performed against Finone 20mg Tablets by M/s Getz
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Solaris: Submitted as per Zone IV
	The status in reference regulatory authorities	Kerendia 20mg Tablet, Company:BAYER HLTHCARE, (NDA): 215341 (USFDA Approved)
	GMP status of the firm	Solaris: Section approval letter dated 17-01-2024 specifies Tablet (General) section
	Evidence of approval of manufacturing facility	Solaris: Section approval letter dated 17-01-2024 specifies Tablet (General) section
	Evaluation Remarks	
	Sr. No	Observations
	1	3.2.S.4.2: Drug substance manufacturer has given following conditions for assay testing:Mobile phase: 0.1percent formic acid aqueous solution: acetonitrile (70:30)Sample dilution: 0.05mg/ml However, drug product
		Response of applicant
		Method of analysis is developed validated for analysis of Drug su from the analytical method prov API manufacturer. The condition determination is same i.e. Buffer acetonitrile (70:30). The prepara

		manufacturer has given different mobile phase and sample concentration for assay testing. Justification shall be submitted for difference in assay test parameters. Method verification studies shall be submitted accordingly.	buffer mentioned in CTD is dipotassium hydrogen phosphate aqueous solution instead of 0.1 percent formic acid aqueous solution mistakenly. The conditions are corrected in revised Module-III and the method validated studies are already submitted according to the API manufacturer Method in Module-III for your consideration.
2		3.2.P.2.2.1: Pictorial evidence of the innovator product, against which PE & CDP studies are performed, with visible information of batch number, manufacturing date etc. shall be submitted.	Submitted
3		3.2.P.51: Justify the disintegration limit of NMT 30 minutes whereas the limit for dissolution is NLT Q in 15 minutes.	Specifications revised and fee submitted for revision of the finished product specifications.
4		3.2.P.8: Stability studies data for 6 month time point shall be submitted.	Submitted
5		3.2.R: Executed BMRs of stability batches shall be submitted.	Submitted
Decision			
Approved			
530	Case Category	Priority As Per 257-M of RB (Maham Misbah)	
	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	(TNL-2EU-AP5V, 2025-04-25)	
	Detail of Fee Submitted	37000.0, 9000.0 2025-02-14, 2025-06-27	
	The proposed proprietary name / brand name	Palbolib 125mg Capsule	
	Label Claim	Each Hard Capsule Contains: Palbociclib 125mg	
	Reference to Finished product specifications	As per Innovators Specification	
	Proposed Pack Size	10's-As per SRO, 20's-As per SRO, 21'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)	Brand Name: Ibrance Manufacturer: Pfizer Registration No: 103788	
	Pharmacotherapeutic Group of (API)	ATC Code: L01EF01 Cyclin-dependent kinase (CDK) inhibitor	
	Name, address of Manufacturing site:	Self Manufacturing	
	Name & address of API manufacturer	No.1, Yunan Street, Kaifeng, Henan Province, China.	
	Detail of stability batches of drug product	03 batches; batch size 1000 units	
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 and invoice are submitted	

Pharmaceutical Equivalence and Comparative Dissolution Profile		Pharmaceutical equivalence and CDP have been provided against Ibrance capsule by M/s Pfizer Ltd
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		Provided a per Zone IVa
The status in reference regulatory authorities		Ibrance USFDA Approved
GMP status of the firm		GMP inspection report generated on the basis of inspection conducted on 20-11-24 concluded "satisfactory" GMP conformance.
Evidence of approval of manufacturing facility		Letter for grant of additional sections dated 10-05-2024 specifies Tablet (Cytotoxic) and Capsule (Cytotoxic) Sections
Evaluation Remarks		
Serial No.	Observation	Response of applicant
1	3.2.S.4.2 & 3.2.S.4.4: Test for palladium and water content are included in drug substance testing specifications, according to reference drug product literature. These tests are not included in API specifications and CoA provided with your application. Justify.	The drug substance manufacturer has performed heavy metal testing in accordance with applicable guidelines, and the results comply with the specified limit of less than 20 ppm. However, this test was inadvertently omitted from our laboratory's analytical method. We acknowledge this oversight and confirm that heavy metal testing will be incorporated into our routine analytical procedure to ensure alignment with regulatory expectations and comprehensive quality assessment. Both the drug substance and drug product manufacturers, including Kaizen, have employed the Loss on Drying (LOD) method instead of a specific water content test. Since palbociclib does not possess water of hydration in its molecular structure, a Karl Fischer titration is not appropriate. The LOD method is more appropriate in this case, as it effectively captures both adsorbed moisture and any residual organic solvents that may be present, providing a more relevant estimation of volatile content. Therefore, our current approach is scientifically justified and consistent with the drug substance manufacturer's practice.
2	3.2.P.2.2.1 & 3.2.P.5.1: Test for water content is included in finished product specifications of innovator. However, this test is not included in pharmaceutical equivalence report and finished product specifications. Justify. Submit prescribed fee in case of revision of specifications.	During the development of the finished product testing stage, it was observed that there was no significant source of water contribution from either the active pharmaceutical ingredient or the excipients. Additionally, the granules were adequately dried using a tray dryer to achieve a moisture content below the desired threshold to ensure smooth tablet compression. Based on these findings, the decision was made not to include water content as a test parameter at the finished product stage. However, in light of your recommendation and in alignment with the reference product literature, we confirm that the water content test will be incorporated into the finished product specification to ensure regulatory compliance and product quality assurance.

		Specifications have been revised along with submission of requisite fee (PKR9000/-)
3	3.2.P.8: Accelerated and real time stability studies data is submitted for three months only. Stability studies data of 6-month time point shall be submitted.	Submitted
Decision		
Approved		
531	Case Category	Routine (Maham Misbah)
	Name, address of Applicant.	Islam Pharmaceuticals 7km Pasrur Road Sialkot (000885)
	Application Form Dy. No / Tracking ID & date of submission	(U68-NY7-NABR, 2024-03-18)
	Detail of Fee Submitted	30000.0, 2023-11-24,
	The proposed proprietary name / brand name	Tizid 4mg
	Label Claim	Each uncoated tablet contains: Tizanidine as Hydrochloride 4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30 Celsius
	For generic drugs (me-too Status)	Movax 4mg, Reg. No. 042139, SAMI Pharmaceutical (ptv)Ltd
	Pharmacotherapeutic Group of (API)	Muscle relaxant
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Viswa Laboratories Pvt.LTD. Plot No. D-35, M.I.D.C., kurkumbh, Tal, Daund, Dist. Pune 413 802, Maharashtra (India).
	Detail of stability batches of drug product	3 batches 1000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP performed against Movax Tablet of M/s SAMI
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	As per Zone Iva
	The status in reference regulatory authorities	MHRA Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 08-02-2023 specifies the following sections Tablet (General), Capsule(General), sachet(General), Dry suspension(General), Liquid Ampule (SVP) (General)
	Evidence of approval of manufacturing facility	Section approval letter No.F.1-19/2014-Lic dt 29-08-2018 specifies the following sections: Tablet (General), Capsule(General), sachet(General), Dry suspension(General)

	Evaluation Remarks	
	Decision	
	Approved	
532	Case Category	Priority As Per 257-M of RB (Maham Misbah)
	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	(VRA-ZLY-R8S4, 2025-04-23)
	Detail of Fee Submitted	37000.0, 9000.0 2025-02-14, 2025-06-27
	The proposed proprietary name / brand name	Palbolib (Palbociclib) 75mg Capsule
	Label Claim	Each Hard Capsule Contains: Palbociclib 75mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,20's-As per SRO,21'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)	Ibrance Capsule 75mg, Imported by:Pfizer Pakistan Limited, Manufacturer: M/s Pfizer Manufacturing Deutschland GmbH
	Pharmacotherapeutic Group of (API)	ATC Code: L01EF01 Cyclin-dependent kinase (CDK) inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Kaifeng Pharmaceutical (Group) Company Limited. Address: No.1, Yunan Street, Kaifeng,Henan Province, China
	Detail of stability batches of drug product	3 batches, 1000 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 and invoice are submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence and CDP have been provided against Ibrance capsule by M/s Pfizer Ltd
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	As per Zone IVa
	The status in reference regulatory authorities	Ibrance USFDA Approved
	GMP status of the firm	GMP inspection report generated on the basis of inspection conducted on 20-11-24 concluded “satisfactory” GMP conformance.
	Evidence of approval of manufacturing facility	Letter for grant of additional sections dated 10-05-2024 specifies Tablet (Cytotoxic) and Capsule (Cytotoxic) Sections
	Evaluation Remarks	
	Serial No.	Response of applicant

1	3.2.S.4.2 & 3.2.S.4.4: Test for palladium and water content are included in drug substance testing specifications, according to reference drug product literature. These tests are not included in API specifications and CoA provided with your application. Justify.	The drug substance manufacturer has performed heavy metal testing in accordance with applicable guidelines, and the results comply with the specified limit of less than 20 ppm. However, this test was inadvertently omitted from our laboratory's analytical method. We acknowledge this oversight and confirm that heavy metal testing will be incorporated into our routine analytical procedure to ensure alignment with regulatory expectations and comprehensive quality assessment. Both the drug substance and drug product manufacturers, including Kaizen, have employed the Loss on Drying (LOD) method instead of a specific water content test. Since palbociclib does not possess water of hydration in its molecular structure, a Karl Fischer titration is not appropriate. The LOD method is more appropriate in this case, as it effectively captures both adsorbed moisture and any residual organic solvents that may be present, providing a more relevant estimation of volatile content. Therefore, our current approach is scientifically justified and consistent with the drug substance manufacturer's practice.
2	3.2.P.2.2.1 & 3.2.P.5.1: Test for water content is included in finished product specifications of innovator. However, this test is not included in pharmaceutical equivalence report and finished product specifications. Justify. Submit prescribed fee in case of revision of specifications.	During the development of the finished product testing stage, it was observed that there was no significant source of water contribution from either the active pharmaceutical ingredient or the excipients. Additionally, the granules were adequately dried using a tray dryer to achieve a moisture content below the desired threshold to ensure smooth tablet compression. Based on these findings, the decision was made not to include water content as a test parameter at the finished product stage. However, in light of your recommendation and in alignment with the reference product literature, we confirm that the water content test will be incorporated into the finished product specification to ensure regulatory compliance and product quality assurance. Specifications have been revised along with submission of requisite fee (PKR9000/-)
3	3.2.P.8: Accelerated and real time stability studies data is submitted for three months only. Stability studies data of 6-month time point shall be submitted.	Submitted

Decision

Approved

533	Case Category	Priority As Per 257-M of RB (Maham Misbah)
	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		(WT4-24J-G1YX, 2025-04-23)
Detail of Fee Submitted		37000.0, 9000.0 2025-02-14, 2025-06-27
The proposed proprietary name / brand name		palbolib 100mg capsule
Label Claim		Each Hard Capsule Contains: Palbociclib 100mg
Reference to Finished product specifications		As per Innovators Specification
Proposed Pack Size		10's-As per SRO,20's-As per SRO,21's-As per SRO
Shelf Life (Unit)		2 Year(s)store below 30°C in a cool and dry place
For generic drugs (me-too Status)		Ibrance capsule 100mg, Manufactured by pfizer pakistan limited
Pharmacotherapeutic Group of (API)		ATC Code: L01EF01 Cyclin-dependent kinase (CDK) inhibitor
Name, address of Manufacturing site:		Self Manufacturing
Name & address of API manufacturer		Kaifeng Pharmaceutical (Group) Company Limited . ADDRESS:No.1, Yunan Street, Kaifeng,Henan Province, China
Detail of stability batches of drug product		03 batches; batch size 1000units
Documents for the procurement of API with approval from DRAP (in case of Import)		Form 6 and invoice are submitted
Pharmaceutical Equivalence and Comparative Dissolution Profile		Pharmaceutical equivalence and CDP have been provided against Ibrance capsule by M/s Pfizer Ltd
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		As per Zona IVa
The status in reference regulatory authorities		Ibrance 100mg hard gel capsule Approved in Medicines and Healthcare Regulatory Agency (MHRA)Medicines and Healthcare Regulatory Agency (MHRA)
GMP status of the firm		GMP inspection report generated on the basis of inspection conducted on 20-11-24 concluded “satisfactory” GMP conformance.
Evidence of approval of manufacturing facility		Letter for grant of additional sections dated 10-05- 2024 specifies Tablet (Cytotoxic) and Capsule (Cytotoxic) Sections
Evaluation Remarks		
Serial No.	Observation	Response of applicant
1	3.2.S.4.2 & 3.2.S.4.4: Test for palladium and water content are included in drug substance testing specifications, according to reference drug product literature. These tests are not included in API specifications and CoA provided with your application. Justify.	The drug substance manufacturer has performed heavy metal testing in accordance with applicable guidelines, and the results comply with the specified limit of less than 20 ppm. However, this test was inadvertently omitted from our laboratory’s analytical method. We acknowledge this oversight and confirm that heavy metal testing will be incorporated into our routine analytical procedure to ensure alignment with regulatory expectations and comprehensive quality assessment. Both the drug substance and drug product manufacturers, including Kaizen, have employed the

		Loss on Drying (LOD) method instead of a specific water content test. Since palbociclib does not possess water of hydration in its molecular structure, a Karl Fischer titration is not appropriate. The LOD method is more appropriate in this case, as it effectively captures both adsorbed moisture and any residual organic solvents that may be present, providing a more relevant estimation of volatile content. Therefore, our current approach is scientifically justified and consistent with the drug substance manufacturer's practice.
2	3.2.P.2.2.1 & 3.2.P.5.1: Test for water content is included in finished product specifications of innovator. However, this test is not included in pharmaceutical equivalence report and finished product specifications. Justify. Submit prescribed fee in case of revision of specifications.	During the development of the finished product testing stage, it was observed that there was no significant source of water contribution from either the active pharmaceutical ingredient or the excipients. Additionally, the granules were adequately dried using a tray dryer to achieve a moisture content below the desired threshold to ensure smooth tablet compression. Based on these findings, the decision was made not to include water content as a test parameter at the finished product stage. However, in light of your recommendation and in alignment with the reference product literature, we confirm that the water content test will be incorporated into the finished product specification to ensure regulatory compliance and product quality assurance. Specifications have been revised along with submission of requisite fee (PKR9000/-)
3	3.2.P.8: Accelerated and real time stability studies data is submitted for three months only. Stability studies data of 6-month time point shall be submitted.	Submitted
Decision		
Approved		
534	Case Category	Routine (Maham Misbah)
	Name, address of Applicant.	Martin Dow Marker Limited 7, Jail Road Quetta. (000028)
	Application Form Dy. No / Tracking ID & date of submission	(X52-LBU-JJ4Z, 2024-03-14)
	Detail of Fee Submitted	30000.0, 2024-02-29,
	The proposed proprietary name / brand name	Seroblock Oral Solution 4mg/5ml
	Label Claim	Each 5ml contains: Ondansetron 4mg. (as Ondansetron Hydrochloride Dihydrate)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	60ml-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30 C

For generic drugs (me-too Status)	Name of Product: Onseron 4mg/5ml Oral Solution Company: Indus Pharma (Pvt.) Ltd. Reg. No.: 058677
Pharmacotherapeutic Group of (API)	Serotonin (5HT3) antagonists
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	CTX Lifesciences Pvt. Ltd
Detail of stability batches of drug product	3 batches, batch size: 100 bottles of 50ml
Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is Submitted
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE performed against Onseron 4mg/5ml Oral Solution Company: Indus Pharma (Pvt.) Ltd. Reg. No.: 058677
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	As per Zone Iva
The status in reference regulatory authorities	RRA: US FDA Product Name: ZOFRAN Oral Solution Company: GlaxoSmithKline Research Triangle Park
GMP status of the firm	GMP report issued on the basis of inspection conducted on 10-07-24 is submitted
Evidence of approval of manufacturing facility	GMP report issued on the basis of inspection conducted on 10-07-24 is submitted specifying Liquid Syrup (general) section

Evaluation Remarks

Serial no.	Observations	Response of applicant
1	3.2.P: Sorbitol is included in the applied formulation as sweetener. Clarify the batch details and source of sorbitol used in the formulation and submit tests results of EG and DEG impurity testing of the relevant batch.	Batch detail of used sorbitol Manufacturer Batch Name: 0823 Mfg. Date: 15.09.2023 Expiry Date: 14.09.2026 Source of Sorbitol: Habib Rice Products Ltd. Karachi Testing of EG and DEG: The results were taken from the Manufacturer COA. Limit of EG and DEG (NMT 0.1%: Complies) Note: Copy of Manufacturer COA is attached. Justification and Undertaking: Sorbitol was not tested for EG and DEG earlier at the time of product development as it was a new material at site. However, now we have full testing facility for EG and DEG. We undertake that we shall perform EG and DEG parameters along with all other parameters as specified in the official monograph, now an onward all incoming supply of sorbitol that will be procured for manufacturing of commercial batches of finished products.

Decision

Approved

Approved. With reference to DRAP's Letter No. F.3-41/2023-QC dated 01-12-2023, applicant shall perform proper testing to verify that DEG and EG impurities are within limits in the batch of Sorbitol used for the manufacturing of stability batches and submit the in-house CoA of the relevant batch to Registration section, prior to issuance of registration letter.

535	Case Category	Routine (Maham Misbah)
	Name, address of Applicant.	BF Biosciences Limited 5-KM Sundar Raiwind Road, Raiwind, Lahore (000655)
	Application Form Dy. No / Tracking ID & date of submission	(XNA-WYS-N3NV, 2024-03-12)
	Detail of Fee Submitted	30000.0, 2023-08-01,
	The proposed proprietary name / brand name	Vancin 1g Injection
	Label Claim	Each 30mL vial contains Vancomycin Hydrochloride equivalent to Vancomycin 1000mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's -As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 15°C to 30°C
	For generic drugs (me-too Status)	Vancomycin 1g Injection(Abbot Laboratories)
	Pharmaceutical Group of (API)	J01XA01 Anti infectives for systemic use
	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	1 batch of 200 vials, 2 batches of 500 vials each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE submitted against Vancomycin Injection by M/s Abbot
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	As per Zone IV
	The status in reference regulatory authorities	Vancocin HCl Injectiion (Abbot Laboratories) FDA Approved
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Decision	
	Approved	
536	Case Category	Routine (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Graton Pharma Suite # 501 & 502, 5th Floor, Plot # 42C/2, Lane 8,, Bukhari Commercial, DHA Phase VI, (208)
	Application Form Dy. No / Tracking ID & date of submission	(36D-GJ1-6ZTB, 2024-12-20)
	Detail of Fee Submitted	75000.0, 225000.0 2024-11-27, 2024-12-16
	The proposed proprietary name / brand name	Cixadin-LP
	Label Claim	Each vial contains: Doxorubicin hydrochloride eq. to Doxorubicin 2mg/ml
	Reference to Finished product specifications	Manufacturer Specification

	Proposed Pack Size	2mg/ml :10ML-As per SRO
	Shelf Life (Unit)	24 Year(s)store below 2-8 degrees
	For generic drugs (me-too Status)	Adriblastina
	Pharmacotherapeutic Group of (API)	L01DB Anthracyclines and related substances
	Name, address of Manufacturing site:	Jodas Expoim-Plot No.55, Biotech Park, Phase III, Karkapatla (V), Markook (M), Siddipet (D), Telangana State Pin – 502 279, India-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The pharmaceutical equivalent of Doxorubicin Pegylated Liposomal refers to generic or alternative formulations that have the same active ingredient, dosage form, strength, and route of administration as the innovator (brand-name) drug while meeting bioequivalence requirements is not submitted.
	Name, address of Marketing Authorization Holder:	Graton Pharma, 501& 502. 5th floor Plot 42c/2 Phase 6 lane 8 bukhari commercial DHA Karachi, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	confirmed
	Details of Authorization Letter :	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	submitted
	The status in reference regulatory authorities	CCaelyx-20mg/10mL,50mg/25mL, JJanssen Pharmaceutica NV,and axter Oncology GmbH.
	Evaluation Remarks	
	Decision	
	Approved	
537	Case Category	Routine (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	AMB HK ENTERPRISES (PVT) LTD, LAHORE 2nd floor plaza 60, Commercial Block K, Phase-1 DHA, Lahore. (05-352-0058)
	Application Form Dy. No / Tracking ID & date of submission	(748-9GW-7MA2, 2024-10-10)
	Detail of Fee Submitted	300000.0, 2024-09-11,
	The proposed proprietary name / brand name	ZYBROX TABLET
	Label Claim	Each Uncoated tablet contains:Abiraterone Acetate USP 250 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-Controlled
	Shelf Life (Unit)	3 Year(s)Store below 30°C, protect from light and Moisture
	For generic drugs (me-too Status)	Generic
	Pharmacotherapeutic Group of (API)	L02BX Other hormone antagonists and related agents
	Name, address of Manufacturing site:	GLOBELA PHARMA PVT LTD-Plot number:357 & 358,Road No.3,GIDC,Sachin,Surat-394230,Gujarat,India-India

	Pharmaceutical Equivalence and Comparative Dissolution Profile	submitted
	Name, address of Marketing Authorization Holder:	M/s AMB HK ENTERPRISES (PVT) LTD, 2nd Floor, Plaza 60, Commercial Block-K, Phase-1,DHA, Lahore, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	confirmed
	Details of Authorization Letter :	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	submitted
	The status in reference regulatory authorities	FDA
	Evaluation Remarks	
	Decision	
	Approved	
538	Case Category	Routine (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Graton Pharma Suite # 501 & 502, 5th Floor, Plot # 42C/2, Lane 8,, Bukhari Commercial, DHA Phase VI, (208)
	Application Form Dy. No / Tracking ID & date of submission	(SU9-P69-56XJ, 2024-12-20)
	Detail of Fee Submitted	75000.0, 225000.0 2024-11-27, 2025-01-23
	The proposed proprietary name / brand name	Cixadin-LP
	Label Claim	store in a cool place
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	2mg/ml :25ML-As per SRO
	Shelf Life (Unit)	24 Month(s)store below 2-8 degrees
	For generic drugs (me-too Status)	Adriblastina
	Pharmacotherapeutic Group of (API)	L01DB Anthracyclines and related substances
	Name, address of Manufacturing site:	Jodas Expoim-Plot No.55, Biotech Park, Phase III, Karkapatla (V), Markook (M), Siddipet (D), Telangana State Pin – 502 279, India-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The pharmaceutical equivalent of Doxorubicin Pegylated Liposomal refers to generic or alternative formulations that have the same active ingredient, dosage form, strength, and route of administration as the innovator (brand-name) drug while meeting bioequivalence requirements is not submitted.
	Name, address of Marketing Authorization Holder:	Graton Pharma, 42c/2 5th floor Phase 6 lane 8 bukhari commercial DHA clifton, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	confirmed
	Details of Authorization Letter :	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	submitted
	The status in reference regulatory authorities	CCaelyx-20mg/10mL,50mg/25mL, JJanssen Pharmaceutica NV,and axter Oncology GmbH.
	Evaluation Remarks	

	Decision	
	Approved	
539	Case Category	Routine (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Aamster Laboratories Plot # 18, Street # SS-2 RCCI Industrial Estate, Rawat - Islamabad (000908)
	Application Form Dy. No / Tracking ID & date of submission	(Z91-981-E72V, 2024-02-26)
	Detail of Fee Submitted	30000.0, 2024-02-26,
	The proposed proprietary name / brand name	CLAYMOX-B ORAL POWDER
	Label Claim	EACH GM CONTAINS:- AMOXICILLIN as TRIHYDRATE...200MG SPECTINOMYCIN DIHYDROCHLORIDE PENTAHYDRATE EQ TO SPECTINOMYCIN.....88MG LINCOMYCIN AS HCL.....88MG VITAMIN E.....30MG
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g-De-Controlled,250g-De-Controlled,500g-De- Controlled,Kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Keep in Cool and dry place. Keep out of the reach of children.
	For generic drugs (me-too Status)	CLAVMOX FORTE W/S POWDER (081697) SANNA LABORATORIES FAISLABAD
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was found operating at good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Firm revised formulation with pre-registration fee Rs.9000/-	
	Decision	
	Approved	
540	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	INTERVAC (PVT) LTD 18KM SHEIKHUPURA ROAD (000623)
	Application Form Dy. No / Tracking ID & date of submission	(12G-WM7-GWVH, 2024-11-08)
	Detail of Fee Submitted	37000.0, 2024-11-06,
	The proposed proprietary name / brand name	Meloxifas-10 Injection
	Label Claim	Each ml Contains: Meloxicam = 10 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Meloxi-10 Injection (Registration no. 049643) Selmore Pharmaceuticals

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The firm M/s Intervac (Pvt.) Ltd. 18 Km, Lahore Sheikhpura Road, Sheikhpura was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, Quality Control / Quality Assurance, production operations and facilities, Keeping in view th
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
541	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	ACME PHARMACEUTICALS Plot No. 29, Street SS-2, RCCI Industrial Estate Rawat (000967)
	Application Form Dy. No / Tracking ID & date of submission	(1S7-Q2M-BBQQ, 2024-11-21)
	Detail of Fee Submitted	37000.0, 2024-11-13,
	The proposed proprietary name / brand name	Avenfield-Drench
	Label Claim	Each 100ml contains: Albendazole USP.... 10gm, Ivermectin BP..... 0.2gm, Triclabendazole MS.... 12gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml, 100ml, 200ml, -De-Controlled
	Shelf Life (Unit)	2 Year(s)storage at room temperature
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Good Level
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
542	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	INTERVAC (PVT) LTD 18KM SHEIKHUPURA ROAD (000623)
	Application Form Dy. No / Tracking ID & date of submission	(2UX-YLL-Z71T, 2024-11-08)

	Detail of Fee Submitted	37000.0, 2024-11-06,
	The proposed proprietary name / brand name	Lid-Ox 5% Injection
	Label Claim	Each ml Contains: Oxytetracycline HCl = 50 mg Lignocain HCl = 10 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Oxyjet-50 Inj (Registration no. 111561) Grand Pharma Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The firm M/s Intervac (Pvt.) Ltd. 18 Km, Lahore Sheikhpura Road, Sheikhpura was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, Quality Control / Quality Assurance, production operations and facilities, Keeping in view th
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
543	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Aamster Laboratories Plot # 18, Street # SS-2 RCCI Industrial Estate, Rawat - Islamabad (000908)
	Application Form Dy. No / Tracking ID & date of submission	(2XY-NXA-JQEP, 2024-08-09)
	Detail of Fee Submitted	30000.0, 2024-08-07,
	The proposed proprietary name / brand name	PROFEN INJECTION
	Label Claim	Each ml contains (BP Spec.) Ketoprofen BP 100mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	KETOGESIC INJECTION (062160) ATTABAK PHARMA ISLAMABAD
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was found operating at good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	Decision	
	Approved	
544	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Biorific Pharma Plot 143, Industrial Triangle, Kahuta Road. (000848)
	Application Form Dy. No / Tracking ID & date of submission	(34N-6AJ-BGUD, 2024-08-30)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-30, 2025-05-27
	The proposed proprietary name / brand name	COLIFIC-550 Oral Powder (VET)
	Label Claim	Each 100g Powder Contains : Colistin Sulfate .550 MIU (Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000gm-De-Controlled,200gm-De-Controlled,500gm-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	071023 COLTIN Powder by M/s Eros Pharmaceutical Karachi.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Recommended the Renewal of Drug Manufacturing license
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
545	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	ONE HEALTH PHARMA Plot# 28/2-A, SITE Kotri, sindh. (000993)
	Application Form Dy. No / Tracking ID & date of submission	(38B-UX4-4UEN, 2024-07-21)
	Detail of Fee Submitted	30000.0, 2024-07-10,
	The proposed proprietary name / brand name	Toldi One Liquid injection
	Label Claim	Each mL contains Todimfos Sodium 100 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 mL-De-Controlled
	Shelf Life (Unit)	2 YearStore at Cool and Dry Place, Protect From Heat and Sunlight
	For generic drugs (me-too Status)	Metofos Injection (027498) Star
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
546	Approved	
	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	ONE HEALTH PHARMA Plot# 28/2-A, SITE Kotri, sindh. (000993)
	Application Form Dy. No / Tracking ID & date of submission	(3RG-UW8-BN8Q, 2024-07-21)
	Detail of Fee Submitted	30000.0, 2024-07-10,
	The proposed proprietary name / brand name	Cyno One Forte Liquid injection
	Label Claim	Each mL contains Cyanocobalamin (Vitamin B 12) USP 1000 mcg.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100 mL-De-Controlled
	Shelf Life (Unit)	2 YearStore at Cool and Dry Place, Protect From Heat and Sunlight
	For generic drugs (me-too Status)	Cyanocob 1000 (074021) Prix
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
547	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Selmore Pharmaceuticals (Pvt.) Ltd. Plant: 36- KM Multan Road, Lahore: Head Office: SPL House No. 82, R-1 Johar Town (000507)
	Application Form Dy. No / Tracking ID & date of submission	(1UE-LT2-J5M7, 2024-11-28)
	Detail of Fee Submitted	37000.0, 2024-11-27,
	The proposed proprietary name / brand name	Sulprim Oral Suspension
	Label Claim	Each ml contains: Enrofloxacin = 75mg Sulphamethoxypyridazine = 75mg

		Sulphamethazine = 50mg Trimethoprim = 25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Litre-De-Controlled, 2.5 Litre-De-Controlled, 5 Litre-De-Controlled
	Shelf Life (Unit)	2 Year Below 25 degree
	For generic drugs (me-too Status)	Cenatin Oral Liquid (Reg. No. 078379)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	M/s Selmore Pharmaceuticals (Pvt) Ltd. 36-Km, Multan Road, Lahore was operating at a satisfactory level of CMP compliance.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	4 antibiotics containing formulations are under review of sub-committee on veterinary drugs.	
	Decision	
	Deferred	
	for submission of valid international references in support of their product, if available.	
548	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	INTERVAC (PVT) LTD 18KM SHEIKHUPURA ROAD (000623)
	Application Form Dy. No / Tracking ID & date of submission	(3TL-Y3T-QJ2D, 2024-11-08)
	Detail of Fee Submitted	37000.0, 2024-11-06,
	The proposed proprietary name / brand name	Intermectin 2% Injection
	Label Claim	Each ml Contains: Ivermectin = 20 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s) Room Temperature
	For generic drugs (me-too Status)	Selmec Injection (Registration no. 071087) Selmore Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The firm M/s Intervac (Pvt.) Ltd. 18 Km, Lahore Sheikhpura Road, Sheikhpura was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, Quality Control / Quality Assurance, production operations and facilities, Keeping in view th
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	

549	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	ONE HEALTH PHARMA Plot# 28/2-A, SITE Kotri, sindh. (000993)
	Application Form Dy. No / Tracking ID & date of submission	(4UZ-PVT-XY51, 2024-07-21)
	Detail of Fee Submitted	30000.0, 2024-07-10,
	The proposed proprietary name / brand name	Cyno One Liquid injection
	Label Claim	Each mL contains Cyanocobalamin (Vit B 12) USP 250 mcg.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50 mL-De-Controlled
	Shelf Life (Unit)	2 YearStore at Cool and Dry Place, Protect From Heat and Sunlight
	For generic drugs (me-too Status)	Elkomin (021476) Elko
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
550	Decision	
	Approved	
	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Mylab pvt ltd Khanqah Sharif, Bahawalpur (000747)
	Application Form Dy. No / Tracking ID & date of submission	(237-SNL-7HLW, 2024-11-11)
	Detail of Fee Submitted	37000.0, 2024-10-22,
	The proposed proprietary name / brand name	TRISULPHA INJECTION
	Label Claim	Each mL contains: Sulphamerazine = 100 mg Sulphadiazine = 60 mg Sulphathiazole = 40 mg Trimethoprim = 40 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100mL-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30C
	For generic drugs (me-too Status)	TRISULPHA INJECTION by Selmore Pharmaceuticals (Reg. No. 057003)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	in view of the above inspection proceedings, and facilities verified such as company profile, building, production, in-process controls, quality control testing, machinery/equipment, material

		management, air handling, water treatment system, personnel an
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	formulation already referred to Expert working Group on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
	Decision	
	Deferred	
	for submission of valid international references in support of their product, if available.	
551	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	ONE HEALTH PHARMA Plot# 28/2-A, SITE Kotri, sindh. (000993)
	Application Form Dy. No / Tracking ID & date of submission	(51L-7AH-H36Z, 2024-07-21)
	Detail of Fee Submitted	30000.0, 2024-07-10,
	The proposed proprietary name / brand name	Cyno One Forte Liquid injection
	Label Claim	Each mL contains Cyanocobalamin (Vitamin B 12) USP 1000 mcg.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10 mL-De-Controlled
	Shelf Life (Unit)	2 YearStore at Cool and Dry Place, Protect From Heat and Sunlight
	For generic drugs (me-too Status)	Cyanocob 1000 (074021) Prix
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
552	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	ONE HEALTH PHARMA Plot# 28/2-A, SITE Kotri, sindh. (000993)
	Application Form Dy. No / Tracking ID & date of submission	(51U-4MA-5XDJ, 2024-07-20)
	Detail of Fee Submitted	30000.0, 2024-07-10,
	The proposed proprietary name / brand name	One Melox 20 Liquid injection
	Label Claim	Each mL contains Meloxicam BP 20 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	50 mL-De-Controlled

	Shelf Life (Unit)	2 YearStore at Cool and Dry Place, Protect From Heat and Sunlight
	For generic drugs (me-too Status)	Melocam-20 (057007) Selmore
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
553	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Aamster Laboratories Plot # 18, Street # SS-2 RCCI Industrial Estate, Rawat - Islamabad (000908)
	Application Form Dy. No / Tracking ID & date of submission	(55A-3L5-BXTU, 2024-11-05)
	Detail of Fee Submitted	37000.0, 2024-11-05,
	The proposed proprietary name / brand name	AMULIN POWDER
	Label Claim	Each 100g contains -Tiamulin hydrogen fumarate eq to Tiamulin Base 45g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g-De-Controlled,25Kg-De-Controlled,500g-De-Controlled,5Kg-De-Controlled,Kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	TIAMUBAK 45% POWDER (048170) ATTABAK PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was found operating at good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
554	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	ONE HEALTH PHARMA Plot# 28/2-A, SITE Kotri, sindh. (000993)
	Application Form Dy. No / Tracking ID & date of submission	(5MH-RVE-9AAJ, 2024-07-21)

	Detail of Fee Submitted	30000.0, 2024-07-10,
	The proposed proprietary name / brand name	Toldi One Liquid injection
	Label Claim	Each mL contains Todimfos Sodium 100 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 mL-De-Controlled
	Shelf Life (Unit)	2 YearStore at Cool and Dry Place, Protect From Heat and Sunlight
	For generic drugs (me-too Status)	Metofos Injection (027498) Star
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
555	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	ONE HEALTH PHARMA Plot# 28/2-A, SITE Kotri, sindh. (000993)
	Application Form Dy. No / Tracking ID & date of submission	(5MY-AZP-WG5A, 2024-07-21)
	Detail of Fee Submitted	30000.0, 2024-07-10,
	The proposed proprietary name / brand name	Cyno One Forte Liquid injection
	Label Claim	Each mL contains Cyanocobalamin (Vitamin B 12) USP 1000 mcg.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50 mL-De-Controlled
	Shelf Life (Unit)	2 YearStore at Cool and Dry Place, Protect From Heat and Sunlight
	For generic drugs (me-too Status)	Cyanocob 1000 (074021) Prix
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
556	Case Category	Routine (Najia Saleem)

	Name, address of Applicant.	Evergreen Pharmaceutical 69/70-B, Glaxo Town Industrial Estate.(Opposite Annam Weaving Mills) 20-Km Ferozpur Road, Lahore. (000736)
	Application Form Dy. No / Tracking ID & date of submission	(5PT-7ZT-1JD6, 2024-04-30)
	Detail of Fee Submitted	30000.0, 2024-04-22,
	The proposed proprietary name / brand name	KETOX INJECTION
	Label Claim	Each ml contain: Oxytetracycline 200 mg Ketoprofen 30 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ML-De-Controlled
	Shelf Life (Unit)	2 YearStore below 25 degree in a cool & dry place.
	For generic drugs (me-too Status)	OXYFEN-LA Injection by Selmore Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm is operating at satisfactory level of GMP Compliance at the time of inspection.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
557	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	VETEC LABORATORIES Plot No. 20, Street S-5, National Industrial Zone (RCCI), Rawat, Rawalpindi (000893)
	Application Form Dy. No / Tracking ID & date of submission	(5ZD-U8H-RDLH, 2024-06-24)
	Detail of Fee Submitted	30000.0, 2024-06-21,
	The proposed proprietary name / brand name	BENZOLE Drench
	Label Claim	Each 100ml liquid suspension(Drench) containsAlbendazole..... 10%
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1 Liter-De-Controlled,100mL-De-Controlled,250mL-De-Controlled,500mL-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room temperature
	For generic drugs (me-too Status)	043143 ALBENSEL-10
	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	
558	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Aptly Pharmaceuticals 5-Km, Sargodha Road Bypass, Faisalabad. (000887)
	Application Form Dy. No / Tracking ID & date of submission	(61V-SGN-Y3JH, 2024-11-08)
	Detail of Fee Submitted	37000.0, 2024-10-21,
	The proposed proprietary name / brand name	CALMYTAR-M Oral Powder
	Label Claim	Each 100 gm Contains Calcium Fosfomycin 20 gm Tylosin as Tartrate 5 gm Fructose 1,6 Diphosphate 18 gm Sodium Phosphate 15 gm Magnesium Phosphate 10 gm As per innovators specifications
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 kg-De-Controlled,100 gm-De-Controlled,250 gm-De-Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 YearAt room temperature
	For generic drugs (me-too Status)	FOSFOROX-20 Oral Powder reg. # 112343
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
559	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Aamster Laboratories Plot # 18, Street # SS-2 RCCI Industrial Estate, Rawat - Islamabad (000908)
	Application Form Dy. No / Tracking ID & date of submission	(2RZ-MRL-BPXB, 2024-11-05)
	Detail of Fee Submitted	37000.0, 2024-11-05,
	The proposed proprietary name / brand name	LEVOSTER LIQUID
	Label Claim	Each ml contains (As Per Innovator Spec.) L-Carnitine 50mg Betaine 20mg Inositol 7mg Choline Chloride 100mg Sorbitol 200mg Magnesium Sulphate 10mg
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	100ml-De-Controlled,250ml-De-Controlled,500ml-De-Controlled,5Litr-De-Controlled,Litr-De-Controlled
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	HEPACARE SOLUTION (049630) SELMORE PHARMA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was found operating at good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
560	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Hirra Pharmaceutical Laboratories (Pvt) Ltd 3A, 2nd floor, Queen's Center, Queen's Road, (000449)
	Application Form Dy. No / Tracking ID & date of submission	(2T6-EHG-4MDS, 2024-04-22)
	Detail of Fee Submitted	30000.0, 2024-04-22,
	The proposed proprietary name / brand name	HIRRA MECTIN DRENCH
	Label Claim	Each ml Contains:IVERMECTIN----- 10MG
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,250ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 25 Degree Centigrade
	For generic drugs (me-too Status)	ECTON DRENCH, M/S ICI PAKISTAN LIMITED 45KM ,OFF MULTAN ROAD LAHORE-55270
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Keeping in view the manufacturing facilities like installing and availabilities of HVAC system, sanitation, production machinery, equipment in quality control/ testing facilities technical personnel and documentation, the panel of inspection is of the op
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved	
561	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	VETEC LABORATORIES Plot No. 20, Street S-5, National Industrial Zone (RCCI), Rawat, Rawalpindi (000893)
	Application Form Dy. No / Tracking ID & date of submission	(64B-9RV-GWXU, 2024-07-11)
	Detail of Fee Submitted	30000.0, 2024-07-11,
	The proposed proprietary name / brand name	COLISIN Water soluble powder
	Label Claim	Each gram contains Colistin sulphate.....6,000,000 IU
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1000gram-De-Controlled, 100gram-De-Controlled, 10kg-De-Controlled, 2500gram-De-Controlled, 500gram-De-Controlled, 5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s) Room temperature
	For generic drugs (me-too Status)	Neflorex 60 wsp 113529
	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	
562	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Aamster Laboratories Plot # 18, Street # SS-2 RCCI Industrial Estate, Rawat - Islamabad (000908)
	Application Form Dy. No / Tracking ID & date of submission	(6S8-LL4-VW4M, 2024-08-17)
	Detail of Fee Submitted	30000.0, 2024-08-15,
	The proposed proprietary name / brand name	POLYCOL-40 INJECTION
	Label Claim	Each 100ml contains (As Per Innovator Spec.) Colistin Sulphate eq. to Colistin 40MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year Store Below 30°C
	For generic drugs (me-too Status)	WALCOL INJECTION (073971) NAWAL PHARMACEUTICALS TAXILLA

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was found operating at good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
563	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Aamster Laboratories Plot # 18, Street # SS-2 RCCI Industrial Estate, Rawat - Islamabad (000908)
	Application Form Dy. No / Tracking ID & date of submission	(73J-NGD-961W, 2024-08-09)
	Detail of Fee Submitted	30000.0, 2024-08-07,
	The proposed proprietary name / brand name	TRASIN 20% INJECTION
	Label Claim	Each ml contains (BP Spec.) Tylosin (As Tylosin Tartrate) 200mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	LAWRSIN INJECTION (062041) LAW RANCE PHARMA LAHORE
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was found operating at good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
564	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Aamster Laboratories Plot # 18, Street # SS-2 RCCI Industrial Estate, Rawat - Islamabad (000908)
	Application Form Dy. No / Tracking ID & date of submission	(8ZH-N27-1YEZ, 2024-08-09)
	Detail of Fee Submitted	30000.0, 2024-08-07,
	The proposed proprietary name / brand name	CLOVER 10 INJECTION

	Label Claim	Each 100ml contains (USP Spec.) Ivermectin USP..... 1g Clorsulon USP..... 10g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	ACTIMEC PLUS INJECTION (033251) SELMORE PHARMA LAHORE
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was found operating at good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
565	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Aamster Laboratories Plot # 18, Street # SS-2 RCCI Industrial Estate, Rawat - Islamabad (000908)
	Application Form Dy. No / Tracking ID & date of submission	(9BG-73W-723U, 2024-08-09)
	Detail of Fee Submitted	30000.0, 2024-08-07,
	The proposed proprietary name / brand name	ADE MIN INJECTION
	Label Claim	Each ml contains (As Per Innovators Spec.) VITAMIN-A 80,000-I.U VITAMIN-D3 40,000-I.U VITAMIN-E 20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	3-VITZ INJECTION (069614) EPOCH PHARMACEUTICALS KARACHI
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was found operating at good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	

566	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Aamster Laboratories Plot # 18, Street # SS-2 RCCI Industrial Estate, Rawat - Islamabad (000908)
	Application Form Dy. No / Tracking ID & date of submission	(9W7-UJT-Z379, 2024-08-09)
	Detail of Fee Submitted	30000.0, 2024-08-07,
	The proposed proprietary name / brand name	BENFLOX 20% INJECTION
	Label Claim	Each 100ml contains (As Per Innovators Spec.) Enrofloxacin BP 20g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	EFLOCIN 20% INJECTION EROS PHARMA KARACHI (063766)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was found operating at good level of GMP Compliance
	Evidence of approval of manufacturing facility	
567	Evaluation Remarks	
	Decision	
	Approved	
	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	ONE HEALTH PHARMA Plot# 28/2-A, SITE Kotri, sindh. (000993)
	Application Form Dy. No / Tracking ID & date of submission	(9YG-A4L-G7JZ, 2024-05-27)
	Detail of Fee Submitted	30000.0, 2024-05-22,
	The proposed proprietary name / brand name	Hepa One Liquid Injection
	Label Claim	Each mL ContainsPhenoxy-2-Methyl-2-Propionic Acid MS 100 mg
	Reference to Finished product specifications	
	Proposed Pack Size	100 mL-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at Cool and Dry Place, Protect From Heat and Sunlight
	For generic drugs (me-too Status)	Hepaguard (063624) Star. 2. Hepasel (046518) Selmore
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"

	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
568	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Aamster Laboratories Plot # 18, Street # SS-2 RCCI Industrial Estate, Rawat - Islamabad (000908)
	Application Form Dy. No / Tracking ID & date of submission	(A65-22H-EWP5, 2024-08-09)
	Detail of Fee Submitted	30000.0, 2024-08-07,
	The proposed proprietary name / brand name	ADE MIN INJECTION
	Label Claim	Each ml contains (As Per Innovators Spec.) VITAMIN-A 80,000-I.U VITAMIN- D3 40,000-I.U VITAMIN-E 20mg
	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)	3-VITZ INJECTION (069614) EPOCH PHARMACEUTICALS KARACHI
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was found operating at good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
569	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Aamster Laboratories Plot # 18, Street # SS-2 RCCI Industrial Estate, Rawat - Islamabad (000908)
	Application Form Dy. No / Tracking ID & date of submission	(ASX-74U-X1GY, 2024-08-09)
	Detail of Fee Submitted	30000.0, 2024-08-07,
	The proposed proprietary name / brand name	TRASIN 20% INJECTION
	Label Claim	Each ml contains (BP Spec.) Tylosin (As Tylosin Tartrate) 200mg

	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	LAWRSIN INJECTION (062041) LAWRENCE PHARMA LAHORE
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was found operating at good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
570	Decision	
	Approved	
	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Aamster Laboratories Plot # 18, Street # SS-2 RCCI Industrial Estate, Rawat - Islamabad (000908)
	Application Form Dy. No / Tracking ID & date of submission	(B4P-BJN-UWB6, 2024-08-09)
	Detail of Fee Submitted	30000.0, 2024-08-07,
	The proposed proprietary name / brand name	PROFEN INJECTION
	Label Claim	Each ml contains (BP Spec.) Ketoprofen BP 100mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	KETOGESIC INJECTION (062160) ATTABAK PHARMA ISLAMABAD
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was found operating at good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
571	Approved	
	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	ONE HEALTH PHARMA Plot# 28/2-A, SITE Kotri, sindh. (000993)

	Application Form Dy. No / Tracking ID & date of submission	(BB7-8VG-SV5B, 2024-07-21)
	Detail of Fee Submitted	30000.0, 2024-07-10,
	The proposed proprietary name / brand name	Toldi One Liquid injection
	Label Claim	Each mL contains Todimfos Sodium 100 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 mL-De-Controlled
	Shelf Life (Unit)	2 YearStore at Cool and Dry Place, Protect From Heat and Sunlight
	For generic drugs (me-too Status)	Metofos Injection (027498) Star
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
572	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	VETEC LABORATORIES Plot No. 20, Street S-5, National Industrial Zone (RCCI), Rawat, Rawalpindi (000893)
	Application Form Dy. No / Tracking ID & date of submission	(BWM-BTM-QVV1, 2024-06-26)
	Detail of Fee Submitted	30000.0, 2024-06-26,
	The proposed proprietary name / brand name	NEOCIN 72% Oral powder
	Label Claim	Each 100 gram contains:Neomycin Sulphate 72gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000gram-De-Controlled,100gram-De-Controlled,2.5kg-De-Controlled,25kg-De-Controlled,500gram-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room temperature
	For generic drugs (me-too Status)	081309 MYCIN 72 O/P
	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	
573	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Aamster Laboratories Plot # 18, Street # SS-2 RCCI Industrial Estate, Rawat - Islamabad (000908)
	Application Form Dy. No / Tracking ID & date of submission	(D4T-YSZ-MAL5, 2024-08-17)
	Detail of Fee Submitted	30000.0, 2024-08-15,
	The proposed proprietary name / brand name	POLYCOL-50 INJECTION
	Label Claim	Each 100ml contains; Colistin Sulphate eq. to Colistin 50MIU
	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)	WAL INJECTION (073970) NAWAL PHARMACEUTICALS TAXILLA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was found operating at good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
574	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	(4UP-APJ-Z7M8, 2024-07-14)
	Detail of Fee Submitted	30000.0, 2024-07-12,
	The proposed proprietary name / brand name	ENRO AMANTA ORAL SOLUTION
	Label Claim	Each 100ml Contains: - Enrofloxacin.....10% Colistin Sulphate.....3.5% Amantadine.....4%
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 liter-De-Controlled,100ml-De-Controlled,500ml- De-Controlled
	Shelf Life (Unit)	2 YearStore below 25 °C. Protect from light

	For generic drugs (me-too Status)	BIOGEN PHARMA RAWAT (ENCODIN SOLUTION REG. No. 059874)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision of M-335 meeting: The Registration Board deliberated on the matter in detail and based on the recommendation of the Sub-committee on Veterinary Drugs decided that in the absence of any recognized scientific data regarding the use of amantadine by any Reference Regulatory Authority (RRA). Registration Board decided to issue show cause notices to the firms holding registrations of "Amantadine in combination with other antibiotics/ antibacterial for veterinary use only" for cancellation of registration under Section 42 of the Drugs Act, 1976. The Board further decided to allow only single amantadine containing formulations.	
	Decision	
	Deferred	
	for review of formulation to Sub-committee on veterinary drugs.	
575	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Selmore Pharmaceuticals (Pvt.) Ltd. Plant: 36-KM Multan Road, Lahore: Head Office: SPL House No. 82, R-1 Johar Town (000507)
	Application Form Dy. No / Tracking ID & date of submission	(DY7-DRH-GQ1W, 2024-07-06)
	Detail of Fee Submitted	30000.0, 2024-06-12,
	The proposed proprietary name / brand name	Tetrosel 250 Water Soluble Powder
	Label Claim	Each gm contains: Chlortetracycline HCl = 250mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1kg-De-Controlled, 2.5kg-De-Controlled, 500gm-De-Controlled
	Shelf Life (Unit)	2 Year(s) Below 25 degree
	For generic drugs (me-too Status)	Meralin 250 WSP Reg. No. 101462 Mylab Pvt. Ltd. BWP
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	M/s Selmore Pharmaceuticals (Pvt) Ltd. 36-Km, Multan Road, Lahore was operating at a satisfactory level of CMP compliance.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
576	Case Category	Routine (Najia Saleem)

	Name, address of Applicant.	Majestic Pharma plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad (000873)
	Application Form Dy. No / Tracking ID & date of submission	(E4E-AG4-M9A5, 2024-08-21)
	Detail of Fee Submitted	30000.0, 2024-08-09,
	The proposed proprietary name / brand name	REHA NEO 600 powder
	Label Claim	Each 1000gm contains:Neomycin Sulphate ----- ----- 600gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000g-De-Controlled,100g-De-Controlled,250g-De-Controlled,500g-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature and avoid from heat and sunlight.
	For generic drugs (me-too Status)	Neofas-600 Reg.No.058750 M/s Intervac (Pvt) Ltd Sheikhupura.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
577	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	ONE HEALTH PHARMA Plot# 28/2-A, SITE Kotri, sindh. (000993)
	Application Form Dy. No / Tracking ID & date of submission	(G4R-UMH-1LZL, 2024-07-21)
	Detail of Fee Submitted	30000.0, 2024-07-10,
	The proposed proprietary name / brand name	Bupra One Liquid injection
	Label Claim	Each mL contains Bupravaquone 50 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 mL-De-Controlled
	Shelf Life (Unit)	2 YearStore at Cool and Dry Place, Protect From Heat and Sunlight
	For generic drugs (me-too Status)	Buprex Injection (033264) Star
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	Decision	
	Approved	
578	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	ONE HEALTH PHARMA Plot# 28/2-A, SITE Kotri, sindh. (000993)
	Application Form Dy. No / Tracking ID & date of submission	(GYW-LLM-QG2W, 2024-07-21)
	Detail of Fee Submitted	30000.0, 2024-07-10,
	The proposed proprietary name / brand name	Bupra One Liquid injection
	Label Claim	Each mL contains Bupravaquone 50 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	20 mL-De-Controlled
	Shelf Life (Unit)	2 YearStore at Cool and Dry Place, Protect From Heat and Sunlight
	For generic drugs (me-too Status)	Buprex Injection (033264) Star
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
579	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Evergreen Pharmaceutical 69/70-B, Glaxo Town Industrial Estate.(Opposite Annam Weaving Mills) 20-Km Ferozpur Road, Lahore. (000736)
	Application Form Dy. No / Tracking ID & date of submission	(HW7-HQT-U6S8, 2024-05-13)
	Detail of Fee Submitted	30000.0, 2024-05-13,
	The proposed proprietary name / brand name	Evermec Plus Injection
	Label Claim	Each ml contain: IVERMECTIN 20 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	50 ML-De-Controlled
	Shelf Life (Unit)	2 YearStore below 25 degree in a cool & dry place.
	For generic drugs (me-too Status)	Selmec Injection by Selmore Pharmaceuticals.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm is operating at satisfactory level of GMP Compliance at the time of inspection.

	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
580	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	ONE HEALTH PHARMA Plot# 28/2-A, SITE Kotri, sindh. (000993)
	Application Form Dy. No / Tracking ID & date of submission	(JAG-98P-EX2T, 2024-07-20)
	Detail of Fee Submitted	30000.0, 2024-07-10,
	The proposed proprietary name / brand name	One Melox Liquid injection
	Label Claim	Each mL Contains Meloxicam BP 7.5 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	50 mL-De-Controlled
	Shelf Life (Unit)	2 YearStore at Cool and Dry Place, Protect From Heat and Sunlight
	For generic drugs (me-too Status)	Camilox (071089) Selmore
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
581	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Aptly Pharmaceuticals 5-Km, Sargodha Road Bypass, Faisalabad. (000887)
	Application Form Dy. No / Tracking ID & date of submission	(JPE-N8D-9X9J, 2024-08-06)
	Detail of Fee Submitted	30000.0, 2024-08-02,
	The proposed proprietary name / brand name	CLOBENSOLE Oral Liquid (suspension)
	Label Claim	Each 100 ml contains; Triclabendazole 5 gm Levamisole 3.75 gm (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ml-De-Controlled,1000 ml-De-Controlled,250 ml-De-Controlled,50 ml-De-Controlled,500 ml-De-Controlled

	Shelf Life (Unit)	2 Year(s)at room temperature
	For generic drugs (me-too Status)	VAMISOL-T Suspension (reg no 079132) M/s Univet Pharmaceuticals Rawalpindi.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
582	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	ONE HEALTH PHARMA Plot# 28/2-A, SITE Kotri, sindh. (000993)
	Application Form Dy. No / Tracking ID & date of submission	(LER-UTW-W2WX, 2024-07-21)
	Detail of Fee Submitted	30000.0, 2024-07-10,
	The proposed proprietary name / brand name	Cyno One Liquid injection
	Label Claim	Each mL contains Cyanocobalamin (Vit B 12) USP 250 mcg.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100 mL-De-Controlled
	Shelf Life (Unit)	2 YearStore at Cool and Dry Place, Protect From Heat and Sunlight
	For generic drugs (me-too Status)	Elkomin (021476) Elko
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
583	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	VETEC LABORATORIES Plot No. 20, Street S-5, National Industrial Zone (RCCI), Rawat, Rawalpindi (000893)
	Application Form Dy. No / Tracking ID & date of submission	(5PD-NHB-E797, 2024-06-26)
	Detail of Fee Submitted	30000.0, 9000.0 2024-06-26, 2025-06-13

	The proposed proprietary name / brand name	OXATEC oral liquid
	Label Claim	Each ml contains Oxolinic acid.....100mg
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	1000ml-De-Controlled, 100mL-De-Controlled, 200ml-De-Controlled, 2500ml-De-Controlled, 5000ml-De-Controlled, 500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s) Room temperature
	For generic drugs (me-too Status)	046668 vety oxol liquid
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Firm has submitted fee Rs. 9,000/- for pre-approval correction/revision of FPP specifications as prescribed vide S.R.O. 1324(I)/2024 dated 30-08-2024 since the official monograph of Oxolinic acid oral liquid does not exist in Eur. pharmacopoeia.	
	Decision	
	Approved	
584	with as per innovator's specifications.	
	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	ONE HEALTH PHARMA Plot# 28/2-A, SITE Kotri, sindh. (000993)
	Application Form Dy. No / Tracking ID & date of submission	(MQ1-YJA-1EPX, 2024-07-21)
	Detail of Fee Submitted	30000.0, 2024-07-10,
	The proposed proprietary name / brand name	Buta One C Liquid injection
	Label Claim	Each mL contains Butaphosphon 100 mg. Cyanocobalamin (Vitamin B 12) BP 0.05 mg.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50 mL-De-Controlled
	Shelf Life (Unit)	2 Year Store at Cool and Dry Place, Protect From Heat and Sunlight
	For generic drugs (me-too Status)	Butafos (109795) Mallard
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	

585	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	ONE HEALTH PHARMA Plot# 28/2-A, SITE Kotri, sindh. (000993)
	Application Form Dy. No / Tracking ID & date of submission	(NNG-2DJ-DYSX, 2024-07-20)
	Detail of Fee Submitted	30000.0, 2024-07-10,
	The proposed proprietary name / brand name	One Melox 20 Liquid injection
	Label Claim	Each mL contains Meloxicam BP 20 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100 mL-De-Controlled
	Shelf Life (Unit)	2 YearStore at Cool and Dry Place, Protect From Heat and Sunlight
	For generic drugs (me-too Status)	Melocam-20 (057007) Selmore
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Evidence of approval of manufacturing facility	
586	Evaluation Remarks	
	Decision	
	Approved	
586	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Evergreen Pharmaceutical 69/70-B, Glaxo Town Industrial Estate.(Opposite Annam Weaving Mills) 20-Km Ferozpur Road, Lahore. (000736)
	Application Form Dy. No / Tracking ID & date of submission	(NP3-RNE-E2BW, 2024-05-13)
	Detail of Fee Submitted	30000.0, 2024-05-13,
	The proposed proprietary name / brand name	Evermec Plus Injection
	Label Claim	Each ml contain: IVERMECTIN 20 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10 ML-De-Controlled
	Shelf Life (Unit)	2 YearStore in cool & dry place. Protect from direct sunlight.
	For generic drugs (me-too Status)	Selmec Injection by Selmore Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm is operating at satisfactory level of GMP Compliance at the time of inspection.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	Decision	
	Approved	
587	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Aamster Laboratories Plot # 18, Street # SS-2 RCCI Industrial Estate, Rawat - Islamabad (000908)
	Application Form Dy. No / Tracking ID & date of submission	(NPD-WB2-VRJ7, 2024-08-17)
	Detail of Fee Submitted	30000.0, 2024-08-15,
	The proposed proprietary name / brand name	POLYCOL-20 INJECTION
	Label Claim	Each 100ml contains (As Per Innovator Spec.) Colistin Sulphate eq. to Colistin 20MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	WALTAK INJECTION (073969) NAWAL PHARMACEUTICALS TAXILLA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was found operating at good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
588	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Aamster Laboratories Plot # 18, Street # SS-2 RCCI Industrial Estate, Rawat - Islamabad (000908)
	Application Form Dy. No / Tracking ID & date of submission	(PHN-EAJ-DP6Q, 2024-11-05)
	Detail of Fee Submitted	37000.0, 2024-11-05,
	The proposed proprietary name / brand name	CO GENTYL INJECTION
	Label Claim	Each ml contains (As per Innovators Spec.) Gentamicin Sulphate BP 50mg Tylosin as tartrate BP 100mg Colistin sulphate BP 0.6MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 YearStore Below 30°C

	For generic drugs (me-too Status)	GENTA T.COLI INJECTION (053993) ALINA COMBINE KARACHI
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was found operating at good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
589	Approved	
	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Aamster Laboratories Plot # 18, Street # SS-2 RCCI Industrial Estate, Rawat - Islamabad (000908)
	Application Form Dy. No / Tracking ID & date of submission	(QPW-W62-6R6D, 2024-08-09)
	Detail of Fee Submitted	30000.0, 2024-08-07,
	The proposed proprietary name / brand name	FLOPEN 30% INJECTION
	Label Claim	Each 100ml contains (As Per Innovator Spec.) Florfenicol USP 30g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	NEFLOX INJECTION (049648) SELMORE PHARMA LAHORE
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was found operating at good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
590	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	VETEC LABORATORIES Plot No. 20, Street S-5, National Industrial Zone (RCCI), Rawat, Rawalpindi (000893)
	Application Form Dy. No / Tracking ID & date of submission	(QYT-68P-HPPB, 2024-07-02)

	Detail of Fee Submitted	30000.0, 2024-07-02,
	The proposed proprietary name / brand name	Oxynide Drench
	Label Claim	Each ml contains OXYCLOZANIDE....62.5mg OXFENDAZOLE sulphate.....1.67mg Sodium selenite.....0.50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 Liter-De-Controlled, 1000ml-De- Controlled, 100ml-De-Controlled, 20 Liter-De- Controlled, 200ml-De-Controlled, 2500ml-De- Controlled, 5 Liter-De-Controlled, 500ml-De- Controlled
	Shelf Life (Unit)	2 Year(s) Room temperature
	For generic drugs (me-too Status)	046669 cloxa Gold drench
	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	
591	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	ONE HEALTH PHARMA Plot# 28/2-A, SITE Kotri, sindh. (000993)
	Application Form Dy. No / Tracking ID & date of submission	(RDA-4MZ-YWV2, 2024-07-21)
	Detail of Fee Submitted	30000.0, 2024-07-10,
	The proposed proprietary name / brand name	Buta One C Liquid injection
	Label Claim	Each mL contains Butaphosphon 100 mg. Cyanocobalamin (Vitamin B 12) BP 0.05 mg.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100 mL-De-Controlled
	Shelf Life (Unit)	2 Year Store at Cool and Dry Place, Protect From Heat and Sunlight
	For generic drugs (me-too Status)	Butafos (109795) Mallard
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved	
592	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	ONE HEALTH PHARMA Plot# 28/2-A, SITE Kotri, sindh. (000993)
	Application Form Dy. No / Tracking ID & date of submission	(REP-M4Q-VRQW, 2024-07-20)
	Detail of Fee Submitted	30000.0, 2024-07-10,
	The proposed proprietary name / brand name	One Melox 10 Liquid injection
	Label Claim	Each mL contains Meloxicam BP 10 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	50 mL-De-Controlled
	Shelf Life (Unit)	2 YearStore at Cool and Dry Place, Protect From Heat and Sunlight
	For generic drugs (me-too Status)	Meloxi-10 (049643) Selmore
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
593	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Selmore Pharmaceuticals (Pvt.) Ltd. Plant: 36-KM Multan Road, Lahore: Head Office: SPL House No. 82, R-1 Johar Town (000507)
	Application Form Dy. No / Tracking ID & date of submission	(6RB-Y9Z-BJDD, 2024-07-06)
	Detail of Fee Submitted	30000.0, 2024-06-12,
	The proposed proprietary name / brand name	Rifaxel Intramammary Suspension (for Dry Cows)
	Label Claim	Each syringe of 5gm oily suspension contains: Rifaximin = 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5gm x 20's-De-Controlled
	Shelf Life (Unit)	2 YearBelow 25 degree
	For generic drugs (me-too Status)	Sealer Dry Pre-filled Syringe for intramammary infusion Reg. no. 093831 by U.M. Interprises
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--

	GMP status of the firm	M/s Selmore Pharmaceuticals (Pvt) Ltd. 36-Km, Multan Road, Lahore was operating at a satisfactory level of CMP compliance.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Registration letter shall be issued after confirmation of semi-automatic syringe filling machine in liquid injectable (General) veterinary section	
594	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Selmore Pharmaceuticals (Pvt.) Ltd. Plant: 36-KM Multan Road, Lahore: Head Office: SPL House No. 82, R-1 Johar Town (000507)
	Application Form Dy. No / Tracking ID & date of submission	(6Y9-574-WH2X, 2024-07-06)
	Detail of Fee Submitted	30000.0, 2024-06-12,
	The proposed proprietary name / brand name	Oxysel 95 Oral Powder
	Label Claim	Each kg contains:Oxytetracycline Hydrochloride = 0.95kg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100gm-De-Controlled,15kg-De-Controlled,1kg-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 25 degree
	For generic drugs (me-too Status)	Oxy-Tec Powder Reg. No. 090651 by Evergreen Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	M/s Selmore Pharmaceuticals (Pvt) Ltd. 36-Km, Multan Road, Lahore was operating at a satisfactory level of CMP compliance.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
595	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	ONE HEALTH PHARMA Plot# 28/2-A, SITE Kotri, sindh. (000993)
	Application Form Dy. No / Tracking ID & date of submission	(S19-S9S-BYYJ, 2024-05-21)
	Detail of Fee Submitted	30000.0, 2024-05-10,
	The proposed proprietary name / brand name	Hepa One Liquid Injection

	Label Claim	Each mL contains Phenoxy-2-Methyl-2-Propionic Acid MS 100 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 mL-De-Controlled
	Shelf Life (Unit)	2 YearStore at Cool and Dry Place, Protect From Heat and Sunlight
	For generic drugs (me-too Status)	Hepaguard (063624) Star. 2. Hepasel (046518) Selmore
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
596	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Evergreen Pharmaceutical 69/70-B, Glaxo Town Industrial Estate.(Opposite Annam Weaving Mills) 20-Km Ferozpur Road, Lahore. (000736)
	Application Form Dy. No / Tracking ID & date of submission	(SEZ-82N-XH31, 2024-05-13)
	Detail of Fee Submitted	30000.0, 2024-05-13,
	The proposed proprietary name / brand name	VetyMeg Injection
	Label Claim	Each ml contain: FLUNIXIN as MEGLUMINE 50 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100 ml-De-Controlled
	Shelf Life (Unit)	2 YearStore below 25 degree & protect from direct sunlight.
	For generic drugs (me-too Status)	MAXIN INJECTION BY Alina Combine Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm is operating at satisfactory level of GMP Compliance at the time of inspection.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	

597	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Aptly Pharmaceuticals 5-Km, Sargodha Road Bypass, Faisalabad. (000887)
	Application Form Dy. No / Tracking ID & date of submission	(SG5-Q63-PB1Q, 2024-11-08)
	Detail of Fee Submitted	37000.0, 2024-10-21,
	The proposed proprietary name / brand name	LINC-1.1 Oral Powder
	Label Claim	Each 100 gm Powder Contain Lincomycin as HCl 1.1 gm USP specifications
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 kg-De-Controlled,100 gm-De-Controlled,250 gm-De-Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 YearAt room temperature
	For generic drugs (me-too Status)	LINCOROX 1.1 Powder Reg. # 111505
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
598	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Majestic Pharma plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad (000873)
	Application Form Dy. No / Tracking ID & date of submission	(751-QHR-5VT9, 2024-08-21)
	Detail of Fee Submitted	30000.0, 2024-08-09,
	The proposed proprietary name / brand name	EMICOCID Oral Powder
	Label Claim	Each 100 gm contains:Amprolium HCl ----- 90gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000g-De-Controlled,100g-De-Controlled,250g-De-Controlled,500g-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature and avoid from heat and sunlight.
	For generic drugs (me-too Status)	AMPROAK Reg.No. 080139 M/s A&K Pharmaceuticals Faisalabad.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	The firm has submitted the fee Rs. 9000/- of product Emicocid oral powder for pre-approval correction in FPP Specifications from as per innovator's to USP specifications. Paid Receipt of voucher # 322263177 dated 27/06/2025 is also attached	
	Decision	
	Approved	
	with USP specifications.	
599	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Selmore Pharmaceuticals (Pvt.) Ltd. Plant: 36-KM Multan Road, Lahore: Head Office: SPL House No. 82, R-1 Johar Town (000507)
	Application Form Dy. No / Tracking ID & date of submission	(SMH-E3X-M7B3, 2024-11-28)
	Detail of Fee Submitted	37000.0, 2024-11-27,
	The proposed proprietary name / brand name	Selmix Powder
	Label Claim	Each 100gm contains: Erythromycin Thiocyanate = 10gm Oxytetracycline HCl = 10gm Neomycin Sulphate = 10gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1kg-De-Controlled,2.5kg-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 YearBelow 25 degree
	For generic drugs (me-too Status)	Neo-Oxy-E Powder (Reg. No. 048255)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	M/s Selmore Pharmaceuticals (Pvt) Ltd. 36-Km, Multan Road, Lahore was operating at a satisfactory level of CMP compliance.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
600	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	ONE HEALTH PHARMA Plot# 28/2-A, SITE Kotri, sindh. (000993)
	Application Form Dy. No / Tracking ID & date of submission	(SN4-BAE-U7HB, 2024-07-20)
	Detail of Fee Submitted	30000.0, 2024-07-10,
	The proposed proprietary name / brand name	One Melox 10 Liquid injection
	Label Claim	Each mL contains Meloxicam BP 10 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10 mL-De-Controlled

	Shelf Life (Unit)	2 YearStore at Cool and Dry Place, Protect From Heat and Sunlight
	For generic drugs (me-too Status)	Meloxi-10 (049643) Selmore
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
601	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Aamster Laboratories Plot # 18, Street # SS-2 RCCI Industrial Estate, Rawat - Islamabad (000908)
	Application Form Dy. No / Tracking ID & date of submission	(SNY-TUD-URY6, 2024-08-17)
	Detail of Fee Submitted	30000.0, 2024-08-15,
	The proposed proprietary name / brand name	POLYCOL-60 INJECTION
	Label Claim	Each 100ml contains (As Per Innovator Spec.) Colistin Sulphate eq. to Colistin 60MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	WALBAK INJECTION (073972) NAWAL PHARMACEUTICALS TAXILLA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was found operating at good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
602	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Aamster Laboratories Plot # 18, Street # SS-2 RCCI Industrial Estate, Rawat - Islamabad (000908)
	Application Form Dy. No / Tracking ID & date of submission	(TAX-UJB-4WS7, 2024-08-09)

	Detail of Fee Submitted	30000.0, 2024-08-07,
	The proposed proprietary name / brand name	BENFLOX 20% INJECTION
	Label Claim	Each 100ml contains (As Per Innovators Spec.) Enrofloxacin BP 20g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	EFLOCIN 20% INJECTION EROS PHARMA KARACHI (063766)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was found operating at good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
603	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	VETEC LABORATORIES Plot No. 20, Street S- 5, National Industrial Zone (RCCI), Rawat, Rawalpindi (000893)
	Application Form Dy. No / Tracking ID & date of submission	(TXW-YV3-ZAYW, 2024-07-04)
	Detail of Fee Submitted	30000.0, 2024-07-03,
	The proposed proprietary name / brand name	TRICOS oral suspension
	Label Claim	Each ml containsoxfendazole.....22.65mgcobalt sulphate....3.82mgsodium selenite.....0.35mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100mL-De- Controlled,200ml-De-Controlled,2500ml-De- Controlled,5000ml-De-Controlled,500ml-De- Controlled
	Shelf Life (Unit)	2 Year(s)Room temperature
	For generic drugs (me-too Status)	057194 OXFENDACON PLUS
	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	

604	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Selmore Pharmaceuticals (Pvt.) Ltd. Plant: 36-KM Multan Road, Lahore: Head Office: SPL House No. 82, R-1 Johar Town (000507)
	Application Form Dy. No / Tracking ID & date of submission	(U8G-NL9-BZNA, 2024-07-06)
	Detail of Fee Submitted	30000.0, 2024-06-12,
	The proposed proprietary name / brand name	Tylosel Oral Powder
	Label Claim	Each gm contains: Tylosin Tartrate = 1000mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm-De-Controlled, 1kg-De-Controlled, 500gm-De-Controlled
	Shelf Life (Unit)	2 Year Below 25 degree
	For generic drugs (me-too Status)	Tyloveto-S Soluble Powder Reg. No. 018408 by Orient Traders International Karachi
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	M/s Selmore Pharmaceuticals (Pvt) Ltd. 36-Km, Multan Road, Lahore was operating at a satisfactory level of CMP compliance.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
605	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Aamster Laboratories Plot # 18, Street # SS-2 RCCI Industrial Estate, Rawat - Islamabad (000908)
	Application Form Dy. No / Tracking ID & date of submission	(V3S-WPS-HTU2, 2024-11-05)
	Detail of Fee Submitted	37000.0, 2024-11-05,
	The proposed proprietary name / brand name	CO GENTYL INJECTION
	Label Claim	Each ml contains (As per Innovators Spec.) Gentamicin Sulphate BP 50mg Tylosin as tartrate BP 100mg Colistin sulphate BP 0.6MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year Store Below 30°C
	For generic drugs (me-too Status)	GENTA T.COLI INJECTION (053993) ALINA COMBINE KARACHI
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was found operating at good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
606	Approved	
	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Biorific Pharma Plot 143, Industrial Triangle, Kahuta Road. (000848)
	Application Form Dy. No / Tracking ID & date of submission	(X69-U4E-5S7B, 2024-08-30)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-30, 2025-05-27
	The proposed proprietary name / brand name	COLIFIC-400 Oral Powder (VET)
	Label Claim	Each 100g Powder Contains:- Colistin Sulphate 400,000,000 IU (Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000gm-De-Controlled, 200gm-De-Controlled, 5 Kg-De-Controlled, 500gm-De-Controlled
	Shelf Life (Unit)	2 Year(s) Room Temperature
	For generic drugs (me-too Status)	058927 Colis AR oral Powder M/s Mallard Pharmaceutical Multan.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Recommended the Renewal of Drug Manufacturing license
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
607	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	VETEC LABORATORIES Plot No. 20, Street S-5, National Industrial Zone (RCCI), Rawat, Rawalpindi (000893)
	Application Form Dy. No / Tracking ID & date of submission	(XE1-Z8W-A2JG, 2024-06-14)
	Detail of Fee Submitted	30000.0, 2024-06-13,
	The proposed proprietary name / brand name	Renatec oral powder

	Label Claim	Each 100 gram containsHexamethylene tetramine 95.50gRiboflavin 1000mgcalcium pentothenate 500mgnicotinamide 2500mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100g, 500g,5kg,20kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room temperature
	For generic drugs (me-too Status)	046552 symorenal
	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	
608	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Aptly Pharmaceuticals 5-Km, Sargodha Road Bypass, Faisalabad. (000887)
	Application Form Dy. No / Tracking ID & date of submission	(XW9-1DZ-TPS6, 2024-08-07)
	Detail of Fee Submitted	30000.0, 2024-08-02,
	The proposed proprietary name / brand name	MENTHOVIL-50 Oral Liquid
	Label Claim	Each ml contains; Bromhexine HCl 50 mg Menthol 40 mg (As per innovator's specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ml-De-Controlled,1000 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,50 ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)at room temperature
	For generic drugs (me-too Status)	HEXTHOL Liquid (reg. # 097984) M/s Nawal Pharmaceuticals Rawalpindi.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
609	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Aamster Laboratories Plot # 18, Street # SS-2 RCCI Industrial Estate, Rawat - Islamabad

		(000908)
	Application Form Dy. No / Tracking ID & date of submission	(YA9-ZAY-EX9W, 2024-08-26)
	Detail of Fee Submitted	30000.0, 2024-08-26,
	The proposed proprietary name / brand name	AMI CON 11% PREMIX
	Label Claim	Each 1000g contains (USP Spec.)Lincomycine (As HCl) 110g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100g-De-Controlled,25Kg-De-Controlled,500g-De-Controlled,5Kg-De-Controlled,Kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	LINCO-MIX 11 PREMIX (059159) BREEZE PHARMA ISLAMABAD.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was found operating at good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
610	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Mylab pvt ltd Khanqah Sharif, Bahawalpur (000747)
	Application Form Dy. No / Tracking ID & date of submission	(Z9W-AH1-UZTP, 2024-11-08)
	Detail of Fee Submitted	37000.0, 2024-10-22,
	The proposed proprietary name / brand name	Oxyfen LA Injection
	Label Claim	Each mL Contains: Oxytetracycline = 200 mg Ketoprofen = 30 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50mL-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30C
	For generic drugs (me-too Status)	Oxyfen LA Injection by Selmore Pharmaceuticals (Reg. No. 071091)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	in view of the above inspection proceedings, and facilities verified such as company profile, building, production, in-process controls, quality control testing, machinery/equipment, material management, air handling, water treatment system, personnel an

	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
611	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Aamster Laboratories Plot # 18, Street # SS-2 RCCI Industrial Estate, Rawat - Islamabad (000908)
	Application Form Dy. No / Tracking ID & date of submission	(ZH1-U19-XH75, 2024-08-09)
	Detail of Fee Submitted	30000.0, 2024-08-07,
	The proposed proprietary name / brand name	CLOVER 10 INJECTION
	Label Claim	Each 100ml contains (USP Spec.) Ivermectin USP..... 1g Clorsulon USP..... 10g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	ACTIMEC PLUS INJECTION (033251) SELMORE Pharmaceuticals LAHORE.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was found operating at good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
612	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Aptly Pharmaceuticals 5-Km, Sargodha Road Bypass, Faisalabad. (000887)
	Application Form Dy. No / Tracking ID & date of submission	(ZRU-68T-1WD2, 2024-08-07)
	Detail of Fee Submitted	30000.0, 2024-08-02,
	The proposed proprietary name / brand name	APADEK Oral Liquid
	Label Claim	Each ml containsVitamin A 10000 IUVitamin D3 2000 IU Vitamin E 4 mgVitamin K3 2mgAs per Innovators Specifications
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	100 ml-De-Controlled,1000 ml-De-Controlled,250 ml-De-Controlled,50 ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)at room temperature
	For generic drugs (me-too Status)	ADEK EXCEL Oral Solution (reg. # 058985)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
613	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Aamster Laboratories Plot # 18, Street # SS-2 RCCI Industrial Estate, Rawat - Islamabad (000908)
	Application Form Dy. No / Tracking ID & date of submission	(ZTN-4HY-HRHS, 2024-08-09)
	Detail of Fee Submitted	30000.0, 2024-08-07,
	The proposed proprietary name / brand name	CLOVER 20 INJECTION
	Label Claim	Each ml contains (USP Spec.) Ivermectin USP..... 20mg Clorsulon USP..... 10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	IVOCOLOR INJECTION (078244) NAWAL Pharmaceuticals Taxila.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was found operating at good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
614	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Aamster Laboratories Plot # 18, Street # SS-2 RCCI Industrial Estate, Rawat - Islamabad (000908)

	Application Form Dy. No / Tracking ID & date of submission	(8YB-8G8-6R19, 2024-08-09)
	Detail of Fee Submitted	30000.0, 2024-08-07,
	The proposed proprietary name / brand name	CLOSOLE ORAL SUSPENSION
	Label Claim	Each 100ml contains (As Per Innovator Spec.) Oxyclozanide 3% Levamisole HCl BP 1.5% Cobalt Sulphate 0.382%
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Lit-De-Controlled,100ml-De-Controlled,150ml- De-Controlled,250ml-De-Controlled,500ml-De- Controlled
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	RANGER PLUS ORAL SUSPENSION (057044) MEDICURE LABS KARACHI
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was found operating at good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
615	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Evergreen Pharmaceutical 69/70-B, Glaxo Town Industrial Estate.(Opposite Annam Weaving Mills) 20-Km Ferozpur Road, Lahore. (000736)
	Application Form Dy. No / Tracking ID & date of submission	(97P-VLS-LH6N, 2024-04-26)
	Detail of Fee Submitted	30000.0, 2024-04-22,
	The proposed proprietary name / brand name	GUMBOZAL SP POWDER
	Label Claim	Each 1000 Gm Contains AMMONIUM CHLORIDE 650 gm METHIONINE 100 gm SORBITOL 50 gm VITAMIN A 250000 IU VITAMIN C 100 gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 GM-De-Controlled,1000 GM-De- Controlled,250 GM-De-Controlled,500 GM-De- Controlled
	Shelf Life (Unit)	2 YearSTANDARD
	For generic drugs (me-too Status)	RINOL-FLUSH POWDER by LEADS PHARMA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--

	GMP status of the firm	Firm is operating at satisfactory level of GMP Compliance at the time of inspection.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
616	Decision	
	Approved	
	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Aamster Laboratories Plot # 18, Street # SS-2 RCCI Industrial Estate, Rawat - Islamabad (000908)
	Application Form Dy. No / Tracking ID & date of submission	(AGW-YGM-ZDN7, 2024-11-05)
	Detail of Fee Submitted	37000.0, 2024-11-05,
	The proposed proprietary name / brand name	BROMOX POWDER
	Label Claim	Each 1000g powder contains (As Per Innovator Spec.) Amoxicillin as Trihydrate B.P 100g Lincomycin as HCl 50g Colistin Sulphate B.P..... 500MIU Bromhexine HCl 5g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g-De-Controlled,1Kg-De-Controlled,250g-De-Controlled,25Kg-De-Controlled,500g-De-Controlled,5Kg-De-Controlled
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	BROLIN POWDER (122652) ARCHARD PHARMACEUTICALS BHIMBER
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was found operating at good level of GMP Compliance
	Evidence of approval of manufacturing facility	
617	Evaluation Remarks	
	Decision	
	Approved	
	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Mylab pvt ltd Khanqah Sharif, Bahawalpur (000747)
	Application Form Dy. No / Tracking ID & date of submission	(B45-9HX-9RNL, 2024-11-11)
	Detail of Fee Submitted	37000.0, 2024-10-22,

	The proposed proprietary name / brand name	TRISULPHA INJECTION
	Label Claim	Each mL contains: Sulphamerazine = 100 mg Sulphadiazine = 60 mg Sulphathiazole = 40 mg Trimethoprim = 40 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50mL-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30C
	For generic drugs (me-too Status)	TRISULPHA INJECTION by Selmore Pharmaceuticals (Reg. No. 057003)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	in view of the above inspection proceedings, and facilities verified such as company profile, building, production, in-process controls, quality control testing, machinery/equipment, material management, air handling, water treatment system, personnel and
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	formulation already referred to Expert working Group on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
	Decision	
	Deferred	
	for submission of valid international references in support of their product, if available.	
618	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Biogen PHarma 8-KM, Chak Beli Road, Rawat, (000639)
	Application Form Dy. No / Tracking ID & date of submission	(BEG-JZ5-XV2V, 2024-08-27)
	Detail of Fee Submitted	75000.0, 2024-08-21,
	The proposed proprietary name / brand name	B.G Oxytocin Injection
	Label Claim	Each ml contains: -Oxytocin.....10 I.U(B.P Specification)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Condition
	For generic drugs (me-too Status)	Oxytocin Injection (10 I.U) by Star Laboratories
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Intervac (pvt.) Ltd-18-Km, Lahore Sheikhpura road Sheikhpura Pakistan-
	GMP status of the firm	Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Observation	Firm's reply
	You are already having registration of B.G oxytocin Injection 10IU/ml Reg. No. 072697 in the	We would like to clarify that due to internal financial strategies and operational optimization,

name of M/s Biogen Pharma Rawat. Now you are applying for contract manufacturing of the same product. Clarification required pls.	M/s Biogen Pharma has decided to outsource the manufacturing of the aforementioned product under a contract manufacturing arrangement. This step is being taken to ensure sustainable business continuity, cost-effectiveness, and efficient resource allocation without compromising on product quality or regulatory compliance. We request your kind consideration for processing our application accordingly.

Decision

Approved

Registration Board deliberated that instead of filing a fresh registration application, the applicant should have applied for a post registration variation approval in manufacturing facility of above-mentioned product. The Board decided to issue a post registration variation approval for change in manufacturing facility of already registered product.

619	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	ACME PHARMACEUTICALS Plot No. 29, Street SS-2, RCCI Industrial Estate Rawat (000967)
	Application Form Dy. No / Tracking ID & date of submission	(BZD-XPZ-23TD, 2024-11-21)
	Detail of Fee Submitted	37000.0, 2024-11-13,
	The proposed proprietary name / brand name	Flush Art WSP
	Label Claim	Each Kg contains: Sodium Chloride BP....35gm, Magnesium Sulphate BP 35gm, Manganese Sulphate BP... 1gm, Potassium Chloride BP....400mg, Furosemide BP 20gm, Calcium Carbonate BP 45gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50gm, 100gm, 250gm, -De-Controlled
	Shelf Life (Unit)	2 Year(s)storage at room temperature
	For generic drugs (me-too Status)	071072 NEYPHRALYTE POWDER "EACH KG CONTAINS:- SODIUM CHLORIDE.....35GM MAGNESIUM SULPHATE...35GM MANGANESE SULPHATE.....1GM POTASSIUM CHLORIDE.....400MG FRUSEMIDE.....20GM CALCIUM CARBONATE.....45GM " LOCALLY MA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Good Level
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	

620	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Pharmonix Pharmaceuticals Plot 28, Street SS-2, National Industrial Zone, Rawat (000990)
	Application Form Dy. No / Tracking ID & date of submission	(E47-HBQ-JEBB, 2024-06-12)
	Detail of Fee Submitted	30000.0, 2024-06-05,
	The proposed proprietary name / brand name	FOSO NIX Oral Powder
	Label Claim	Each 100 gm contains: Tylosin as Tartrate 5gm Calcium Fosfomycin 20gm Fructose 1,6 di phosphate 18gm Sodium Phosphate 15gm Magnesium Phosphate 10gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	01Kg-De-Controlled,05kg-De-Controlled,100gm- De-Controlled,10Kg-De-Controlled,15Kg-De- Controlled,250gm-De-Controlled,25Kg-De- Controlled,500gm-De-Controlled,50gm-De- Controlled
	Shelf Life (Unit)	2 Year25°C
	For generic drugs (me-too Status)	Acme fos Water Soluble Powder (Reg. # 116953)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel based on the available equipment / machinery required in production and quality control such as availability of FTIR, HPLC, UV- Visible Spectrophotometer, stability chambers etc., technical staff, SOPs, documents and commitment of the management
	Evidence of approval of manufacturing facility	
621	Evaluation Remarks	
	Decision	
	Approved	
621	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	BIORISE PHARMACEUTICALS 19KM, LAHORE ROAD, MULTAN (000934)
	Application Form Dy. No / Tracking ID & date of submission	(G1N-8V4-PU6G, 2024-11-26)
	Detail of Fee Submitted	37000.0, 2024-11-20,
	The proposed proprietary name / brand name	Novanic Forte Injection
	Label Claim	EACH ML CONTAINS: - NOVAMINSULFON...40MG ETILEFRIN...0.2MG CALCIUM GLUCONATE.....100MG MAGNESIUM GLUCONATE....10MG SODIUM

		SALICYLATE...7MG NICOTINAMIDE...0.3MG CAFFEINE...10MG BORIC ACID....10MG
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	250ml-De-Controlled
	Shelf Life (Unit)	2 YearStore in a cool and Dry place, away from moisture and direct sunlight.
	For generic drugs (me-too Status)	Nicofrin Injection 250ml by M/S Leads Pharma Islamabad Reg. No. 058863
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel of inspectors found the premises satisfactory and recommend the grant of DML.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has mentioned Vial filling and sealing machine (10ml-500ml) in list of production machinery and equipment.	
	Decision	
	Approved	
622	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Aamster Laboratories Plot # 18, Street # SS-2 RCCI Industrial Estate, Rawat - Islamabad (000908)
	Application Form Dy. No / Tracking ID & date of submission	(H75-9YL-BT9P, 2024-11-05)
	Detail of Fee Submitted	37000.0, 2024-11-05,
	The proposed proprietary name / brand name	PARA CAL-C POWDER
	Label Claim	Each 100 g contains (As per Innovator Specs.) Vitamin-C 20.0 g Paracetamol. 2.0 g Potassium chloride.....4.0 g Calcium carbonate.....4.5 g Magnesium Sulphate.....3.5 g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g-De-Controlled,1Kg-De-Controlled,250g-De-Controlled,25Kg-De-Controlled,500g-De-Controlled,5Kg-De-Controlled
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	SPIN-C POWDER (078239) LEADS PHARMA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was found operating at good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved	
623	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	ONE HEALTH PHARMA Plot# 28/2-A, SITE Kotri, sindh. (000993)
	Application Form Dy. No / Tracking ID & date of submission	(H8B-PG5-3AU3, 2024-05-20)
	Detail of Fee Submitted	30000.0, 2024-05-13,
	The proposed proprietary name / brand name	Bromone Oral Liquid
	Label Claim	Each mL contains Bromhexine HCL BP 50 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1.0 L-De-Controlled,10 .0 L-De-Controlled,100 mL-De-Controlled,15 .0 L-De-Controlled,2.5 L-De-Controlled,25 .0 L-De-Controlled,250 mL-De-Controlled,5.0 L-De-Controlled,50 mL-De-Controlled,500 mL-De-Controlled
	Shelf Life (Unit)	2 YearStore at Cool and Dry Place, Protect From Heat and Sunlight
	For generic drugs (me-too Status)	Bromo 5% (069631) Cherish. 2, Bromofa (057108) Intervac.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
624	Case Category	Import (Najia Saleem)
	Name, address of Applicant.	Remedix Pvt Ltd Aazam Medicine Market 2nd Floor C#8 & C#9 Namak Mandi Peshawar (whole sale/)
	Application Form Dy. No / Tracking ID & date of submission	(H96-ZZQ-JD46, 2024-10-09)
	Detail of Fee Submitted	75000.0, 2024-10-08,
	The proposed proprietary name / brand name	C-Methol Powder
	Label Claim	Each gram contains: Ascorbic acid.....250mg Paracetamol.....250mg DL-Methionine.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	500gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)25C

For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	Anti-inflammatory & antipyretic
Name, address of Manufacturing site:	VAPCO(VETERINERY & AGRICULTURAL PRODUCTS MANUFACTU-King Hussien street No (120) Al Dhulail Area,Al Zarka Province-Jordan.-Jordan
Name, address of Marketing Authorization Holder:	VAPCO(VETERINERY & AGRICULTURAL PRODUCTS MANUFACTU, King Hussien street No (120) Al Dhulail Area,Al Zarka Province-Jordan. , Jordan
Details of Certificates (CoPP/FSC/cGMP):	Scanned copy of legalized CoPP dated 24-07-2024 confirms free sale status of the product in exporting country and GMP status of the manufacturer
Details of Authorization Letter :	Scanned copy of legalized LOA dated 24-07-2024 in the name of Ms Remedix Pvt. Ltd. Peshawar Pakistan from VAPCO Jordan; valid for 2 years
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	6 months accelerated and 24 months real time stability studies data submitted as per zone-IV-A conditions

Evaluation Remarks

The firm has submitted differential fee Rs. 225000/- vide challan number 885303609672. Moreover, the applied product is neither already registered in Pakistan nor the firm has submitted its approval status in RRAs declared by RB in its 275th meeting. Hence the case was referred to Sub-committee on Veterinary Drugs. The firm has submitted that the applied product manufactured by VAPCO is exported to Afghanistan, Iraq, Ivory coast, Kuwait, Libya, Mali, Qatar, Syria and Yemen After deliberation, the sub-committee on veterinary drugs recommended the above formulation for veterinary use.

Decision

Approved

subject to import policy order. Moreover, firm shall submit original legalized valid LOA and CoPP before issuance of registration letter, since the already submitted copies are scanned.

625	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Selmore Pharmaceuticals (Pvt.) Ltd. Plant: 36-KM Multan Road, Lahore: Head Office: SPL House No. 82, R-1 Johar Town (000507)
	Application Form Dy. No / Tracking ID & date of submission	(JGJ-385-LLGR, 2024-07-06)
	Detail of Fee Submitted	30000.0, 2024-06-12,
	The proposed proprietary name / brand name	Tylosel 50 Oral Powder
	Label Claim	Each gm contains: Tylosin Tartrate = 500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1kg-De-Controlled,500gm-De-Controlled
	Shelf Life (Unit)	2 YearBelow 25 degree
	For generic drugs (me-too Status)	Tylo-50 Oral Powder Reg. No. 063847 by Symans-Pharma Lahore
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--

	GMP status of the firm	M/s Selmore Pharmaceuticals (Pvt) Ltd. 36-Km, Multan Road, Lahore was operating at a satisfactory level of CMP compliance.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has submitted that we are revising the label claim and FPP Specification as under: Each gram contains Tylosin tartrate eq. to Tylosin...500mg (As per Innovator's Specification) In this regard, the firm has deposited requisite fee Rs. 9000/- Bank deposit slip number 213041170 dated 25.06.2025 for revision label claim and finished products specifications of our product Tylosel 50 Oral Powder.	
	Decision	
	Approved	
	with following label claim:	
	Each gram contains	
	Tylosin tartrate eq. to Tylosin...500mg	
	(As per Innovator's Specification)	
626	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Aamster Laboratories Plot # 18, Street # SS-2 RCCI Industrial Estate, Rawat - Islamabad (000908)
	Application Form Dy. No / Tracking ID & date of submission	(JNX-1R5-BAU3, 2024-11-05)
	Detail of Fee Submitted	37000.0, 2024-11-05,
	The proposed proprietary name / brand name	OXFAMIDE SUSPENSION
	Label Claim	Each 1000ml Contains (As Per Innovator Spec.) Niclosamide 250g Oxfendazole..... 10g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled, 250ml-De-Controlled, 500ml-De-Controlled, 5Litr-De-Controlled, Litr-De-Controlled
	Shelf Life (Unit)	2 Year Store Below 30°C
	For generic drugs (me-too Status)	NICZOLE DRENCH (063865) SYMANS PHARMA KARACHI
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was found operating at good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	

627	Case Category	Import (Najia Saleem)
	Name, address of Applicant.	Remedix Pvt Ltd Aazam Medicine Market 2nd Floor C#8 & C#9 Namak Mandi Peshawar (whole sale/)
	Application Form Dy. No / Tracking ID & date of submission	(MHJ-ZGW-ABP5, 2024-10-09)
	Detail of Fee Submitted	75000.0, 2024-10-08,
	The proposed proprietary name / brand name	Enroxin Plus oral solution
	Label Claim	Each ml contains: Enrofloxacin.....200mg Bromhexine HCl.....15mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1Ltr-De-Controlled
	Shelf Life (Unit)	3 Year(s)25C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Antibacterial, mucolytic expectorant
	Name, address of Manufacturing site:	VAPCO(VETERINERY & AGRICULTURAL PRODUCTS MANUFACTU-King Hussien street No (120) Al Dhulail Area,Al Zarka Province-Jordan.-Jordan
	Name, address of Marketing Authorization Holder:	VAPCO(VETERINERY & AGRICULTURAL PRODUCTS MANUFACTU, King Hussien street No (120) Al Dhulail Area,Al Zarka Province-Jordan. , Jordan
	Details of Certificates (CoPP/FSC/cGMP):	Scanned copy of legalized CoPP dated 24-07-2024 confirms free sale status of the applied product in exporting country as well as GMP status of the manufacturer.
	Details of Authorization Letter :	Scanned copy of LOA dated 24-07-2024 submitted; valid for 2 years.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	6 months accelerated and 36 months real time data as per zone-IV/A submitted
Evaluation Remarks		
The firm has submitted differential fee Rs. 225000/- vide challan number 6601680181. Moreover, the applied product is neither already registered in Pakistan nor the firm has submitted its approval status in RRAs declared by RB in its 275th meeting. Hence the case was referred to Sub-committee on Veterinary Drugs. The firm has submitted that the applied product manufactured by VAPCO is exported to Afghanistan, Azerbaijan, Iraq, Ivory coast, Libya, Syria, Uzbekistan and Vietnam After deliberation, the sub-committee on veterinary rugs recommended the above formulation for veterinary use.		
Decision		
Approved		
subject to import policy order. Moreover, firm shall submit original legalized valid LOA and CoPP before issuance of registration letter, since the already submitted copies are scanned.		
628	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	VETEC LABORATORIES Plot No. 20, Street S-5, National Industrial Zone (RCCI), Rawat, Rawalpindi (000893)

	Application Form Dy. No / Tracking ID & date of submission	(PBQ-S4T-351G, 2024-07-18)
	Detail of Fee Submitted	30000.0, 2024-07-18,
	The proposed proprietary name / brand name	LEVOXY-CS Drench
	Label Claim	Each ml suspension(Drench)containsOxyclozanide.....30mg Hcl.....15mgCobalt chloride....1.67mgSodium selenite.....0.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100mL-De- Controlled,10liter-De-Controlled,150ml-De- Controlled,2.5liter-De-Controlled,200ml-De- Controlled,20liter-De-Controlled,500ml-De- Controlled,50ml-De-Controlled,5liter-De- Controlled
	Shelf Life (Unit)	2 Year(s)Room temperature
	For generic drugs (me-too Status)	118671 ACMELEV-S ORAL SUSPENSION M/S. ACME PHARMACEUTICALS, RAWAT
	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	
629	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Majestic Pharma plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad (000873)
	Application Form Dy. No / Tracking ID & date of submission	(PX3-831-2UGE, 2024-08-21)
	Detail of Fee Submitted	30000.0, 2024-08-09,
	The proposed proprietary name / brand name	ACEPO MIN oral powder
	Label Claim	Each 1000 gm contains:Acetyl Salicylic Acid ----- ----- 67gm Vitamin C ----- 200gmPotassium Chloride ----- 3gmSodium Citrate ----- 7gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000g-De-Controlled,100g-De-Controlled,250g- De-Controlled,5000g-De-Controlled,500g-De- Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature and avoid from heat and sunlight.
	For generic drugs (me-too Status)	Asperlyte-C Reg.No. 074789 M/s Bio-Oxime Pharmaceuticals Faisalabad.

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
630	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Vetz Pharmaceutical Pvt Ltd Plot No. Q-1, Site Kotri, Sindh (000813)
	Application Form Dy. No / Tracking ID & date of submission	(Q99-RN3-H9A2, 2024-07-30)
	Detail of Fee Submitted	30000.0, 2024-07-09,
	The proposed proprietary name / brand name	Fenazid Drench
	Label Claim	Each ml Contains: Oxfendazole... 22.65 mg Oxyclozanide ... 62.5 mg (As per Innovator Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50, 100,150,250,500 -De-Controlled
	Shelf Life (Unit)	24 MonthStore below 30°C. Protect from light and heat.
	For generic drugs (me-too Status)	Oxycloz Drench (Wimits)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	In conclusion, it is found that the firm is committed towards continuous upgrading and compliance as per the Drug Act 1976 & DRAP Act 2012 & operating at good level of GMP compliance with enthusiasm of export contribution and automation.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
631	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Remedix Pvt Ltd Aazam Medicine Market 2nd Floor C#8 & C#9 Namak Mandi Peshawar (whole sale/)
	Application Form Dy. No / Tracking ID & date of submission	(RR6-LRM-3L96, 2024-10-09)

	Detail of Fee Submitted	75000.0, 2024-10-08,
	The proposed proprietary name / brand name	Levozan Suspension
	Label Claim	Each ml contains: Levamisole HCl.....30mg Oxyclozanide.....60mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1Ltr-De-Controlled
	Shelf Life (Unit)	3 Year(s)25C
	For generic drugs (me-too Status)	101445 NAWAZAN DS SUSPENSION M/S. NAWAN LABORATORIES (PVT.) LTD, KARACHI.
	Pharmacotherapeutic Group of (API)	Anthelmintics
	Name, address of Manufacturing site:	VAPCO(VETERINERY & AGRICULTURAL PRODUCTS MANUFACTU-King Hussien street No (120) Al Dhulail Area,Al Zarka Province- Jordan.-Jordan
	Name, address of Marketing Authorization Holder:	VAPCO(VETERINERY & AGRICULTURAL PRODUCTS MANUFACTU, King Hussien street No (120) Al Dhulail Area,Al Zarka Province- Jordan. , Jordan
	Details of Certificates (CoPP/FSC/cGMP):	Scanned copy of legalized CoPP confirms free sale status of the applied product in exporting country and GMP status of the manufacturer abroad
	Details of Authorization Letter :	Scanned copy of LOA dated 24-07-2024 for the applied product; valid for 2 years
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	6 months accelerated and 36 months real time data as per zone-IV/A conditions submitted for three batches
	Evaluation Remarks	
	The firm has submitted differential fee Rs. 225000/- vide challan number 927994174. Moreover, scanned copies of COPP and LOA are submitted the firm shall submit original legalized documents before issuance of registration letter.	
	Decision	
	Approved	
	subject to import policy order. Moreover, firm shall submit original legalized valid LOA and CoPP before issuance of registration letter, since the already submitted copies are scanned.	
632	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Remedix Pvt Ltd Aazam Medicine Market 2nd Floor C#8 & C#9 Namak Mandi Peshawar (whole sale/)
	Application Form Dy. No / Tracking ID & date of submission	(SQX-9MY-JTJ4, 2024-10-09)
	Detail of Fee Submitted	75000.0, 2024-10-08,
	The proposed proprietary name / brand name	Oxydone Fort 20% LA injectable solution
	Label Claim	Each ml contains: Oxytetracycline HCl.....200mg
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	3 Year(s)25C
	For generic drugs (me-too Status)	122784
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	VAPCO(VETERINERY & AGRICULTURAL PRODUCTS MANUFACTU-King Hussien street No (120) Al Dhulail Area,Al Zarka Province-Jordan.-Jordan
	Name, address of Marketing Authorization Holder:	VAPCO(VETERINERY & AGRICULTURAL PRODUCTS MANUFACTU, King Hussien street No (120) Al Dhulail Area,Al Zarka Province-Jordan. , Jordan
	Details of Certificates (CoPP/FSC/cGMP):	Scanned copy submitted confirms free sale status and GMP status
	Details of Authorization Letter :	Scanned copy dated 24-07-2024, valid for 2 years
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	6 months accelerated and 36 months real time stability data as per zone IV-A conditions.
	Evaluation Remarks	
	The firm has submitted differential fee Rs. 225000/- vide challan number 80409402749. Moreover, scanned copies of COPP and LOA are submitted the firm shall submit original legalized documents before issuance of registration letter.	
	Decision	
	Approved	
	subject to import policy order. Moreover, firm shall submit original legalized valid LOA and CoPP before issuance of registration letter, since the already submitted copies are scanned.	
633	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Aptly Pharmaceuticals 5-Km, Sargodha Road Bypass, Faisalabad. (000887)
	Application Form Dy. No / Tracking ID & date of submission	(TJ5-DSX-5AR5, 2024-11-08)
	Detail of Fee Submitted	37000.0, 2024-10-21,
	The proposed proprietary name / brand name	DULPHA-C Oral Powder
	Label Claim	Each gm contains Doxycycline HCl 200 mg Tylosin as Tartrate 100 mg Colistin Sulphate 0.5 MIU Bromhexine HCl 5 mg Streptomycin Sulphate 20 mg As per innovators specifications
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 kg-De-Controlled,100 gm-De-Controlled,250 gm-De-Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 YearAt room temperature
	For generic drugs (me-too Status)	Riz Wan-S Water Soluble Powder reg. # 078296
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	Applied formulation contains 04 antibiotics, already referred to Expert working Group on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
	Decision	
	Deferred	
	for submission of valid international references in support of their product, if available.	
634	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Vetz Pharmaceutical Pvt Ltd Plot No. Q-1, Site Kotri, Sindh (000813)
	Application Form Dy. No / Tracking ID & date of submission	(TQZ-JB9-Y2H3, 2024-07-22)
	Detail of Fee Submitted	30000.0, 2024-07-09,
	The proposed proprietary name / brand name	V-Cozol Suspension
	Label Claim	Each 100ml Contains: Albendazole :10 gm Closantel as Sodium Dihydrate :2gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50, 100,150,250,500 -De-Controlled
	Shelf Life (Unit)	24 Year(s)Store below 30°C. Protect from light and heat.
	For generic drugs (me-too Status)	Boxer 10 % Suspension (Leads Pharma)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	In conclusion, it is found that the firm is committed towards continuous upgrading and compliance as per the Drug Act 1976 & DRAP Act 2012 & operating at good level of GMP compliance with enthusiasm of export contribution and automation.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
635	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Aamster Laboratories Plot # 18, Street # SS-2 RCCI Industrial Estate, Rawat - Islamabad (000908)
	Application Form Dy. No / Tracking ID & date of submission	(TTP-MR9-D9JT, 2024-11-05)
	Detail of Fee Submitted	37000.0, 2024-11-05,
	The proposed proprietary name / brand name	CETA VIT POWDER
	Label Claim	Each 100 g contains (As Per Innovator Spec.) Vitamin-C BP.....5g Paracetamol BP. 20g Potassium carbonate BP.....12.5g Sodium Bicarbonate

		BP.....12.5g Vitamin E BP.....12.5g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g-De-Controlled,1Kg-De-Controlled,250g-De-Controlled,25Kg-De-Controlled,500g-De-Controlled,5Kg-De-Controlled
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	PARACET POWDER (079826) DECENT PHARMA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was found operating at good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
636	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Aamster Laboratories Plot # 18, Street # SS-2 RCCI Industrial Estate, Rawat - Islamabad (000908)
	Application Form Dy. No / Tracking ID & date of submission	(U32-EZJ-MA2W, 2024-11-05)
	Detail of Fee Submitted	37000.0, 2024-11-05,
	The proposed proprietary name / brand name	VERI LINE POWDER
	Label Claim	Each Kg Contains (As per Innovator's specification) Sulphaquinoxaline Sodium 200g Sulfadimidine sodium..... 82.5g, Diaveridine HCl 40g VIT A 2.8MIU VIT K3 2g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g-De-Controlled,1Kg-De-Controlled,250g-De-Controlled,25Kg-De-Controlled,500g-De-Controlled,5Kg-De-Controlled
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	COXYDA POWDER (Reg. No. 058970) BIOGEN PHARMA RAWAT
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was found operating at good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	Decision	
	Approved	
637	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Selmore Pharmaceuticals (Pvt.) Ltd. Plant: 36-KM Multan Road, Lahore: Head Office: SPL House No. 82, R-1 Johar Town (000507)
	Application Form Dy. No / Tracking ID & date of submission	(URU-GE6-PRVN, 2024-07-06)
	Detail of Fee Submitted	30000.0, 2024-06-12,
	The proposed proprietary name / brand name	Oxytel 50 Oral Powder
	Label Claim	Each gm contains: Oxytetracycline Hydrochloride = 500mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1000gm-De-Controlled, 100gm-De-Controlled, 10kg-De-Controlled, 25kg-De-Controlled, 500gm-De-Controlled
	Shelf Life (Unit)	2 Year Below 25 degree
	For generic drugs (me-too Status)	Oxyveto-50 Soluble Powder Reg. No. 049545 by Orient traders International Karachi
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	M/s Selmore Pharmaceuticals (Pvt) Ltd. 36-Km, Multan Road, Lahore was operating at a satisfactory level of CMP compliance.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
638	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	VETEC LABORATORIES Plot No. 20, Street S-5, National Industrial Zone (RCCI), Rawat, Rawalpindi (000893)
	Application Form Dy. No / Tracking ID & date of submission	(V8S-19W-45JJ, 2024-07-24)
	Detail of Fee Submitted	30000.0, 2024-07-23,
	The proposed proprietary name / brand name	LECOS Liquid drench
	Label Claim	Each ml Liquid Drench contains Levamisole Hcl.....15mg Cobalt Sulphate.....3.82mg Sodium Selenite.....0.50mg
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	10 Liter-De-Controlled,1000ml-De-Controlled,100ml-De-Controlled,20 Liter-De-Controlled,200ml-De-Controlled,2500ml-De-Controlled,5 Liter-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room temperature
	For generic drugs (me-too Status)	029604 Levasel Liquid drench
	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	
639	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Remedix Pvt Ltd Aazam Medicine Market 2nd Floor C#8 & C#9 Namak Mandi Peshawar (whole sale/)
	Application Form Dy. No / Tracking ID & date of submission	(V8T-XW7-ZX24, 2024-10-09)
	Detail of Fee Submitted	75000.0, 2024-10-08,
	The proposed proprietary name / brand name	Theilacide Injection
	Label Claim	Each ml contains: Buparvaquone.....50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50mL-De-Controlled
	Shelf Life (Unit)	3 Year(s)25C
	For generic drugs (me-too Status)	125854 Butarise Injection M/s. Biorise Pharmaceuticals, Multan.
	Pharmacotherapeutic Group of (API)	Antiprotozoal
	Name, address of Manufacturing site:	VAPCO(VETERINERY & AGRICULTURAL PRODUCTS MANUFACTU-King Hussien street No (120) Al Dhulail Area,Al Zarka Province-Jordan.-Jordan
	Name, address of Marketing Authorization Holder:	VAPCO(VETERINERY & AGRICULTURAL PRODUCTS MANUFACTU, King Hussien street No (120) Al Dhulail Area,Al Zarka Province-Jordan. , Jordan
	Details of Certificates (CoPP/FSC/cGMP):	scanned copy of COPP submitted confirms free sale status of the applied product in exporting country and GMP status of the manufacturer
	Details of Authorization Letter :	Scanned copy submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	6 months accelerated and 36 months real time stability data submitted as per zone IV-A conditions
	Evaluation Remarks	

	The firm has submitted differential fee Rs. 225000/- vide challan number 09247400973	
	Decision	
	Approved	
	subject to import policy order. Moreover, firm shall submit original legalized valid LOA and CoPP before issuance of registration letter, since the already submitted copies are scanned.	
640	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	ONE HEALTH PHARMA Plot# 28/2-A, SITE Kotri, sindh. (000993)
	Application Form Dy. No / Tracking ID & date of submission	(VVE-D2U-DPZV, 2024-05-26)
	Detail of Fee Submitted	30000.0, 2024-05-13,
	The proposed proprietary name / brand name	Tricla Oral Liquid
	Label Claim	Each ML Contains Triclabendazole BP 50 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1.0 L-De-Controlled,10.0 L-De-Controlled,100 mL-De-Controlled,15.0 L-De-Controlled,2.5 L-De-Controlled,25.0 L-De-Controlled,250 mL-De-Controlled,5.0 L-De-Controlled,50 mL-De-Controlled,500 mL-De-Controlled
	Shelf Life (Unit)	2 YearStore at Cool and Dry Place, Protect From Heat and Sunlight
	For generic drugs (me-too Status)	Fasisym (026490) Symans
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
641	Case Category	Import (Najia Saleem)
	Name, address of Applicant.	Mustafa Brothers 186-D, Peoples Colony No. 1, Faisalabad (06-331-0168)
	Application Form Dy. No / Tracking ID & date of submission	(WEQ-T13-EEP9, 2024-05-10)
	Detail of Fee Submitted	300000.0, 2024-05-09,
	The proposed proprietary name / brand name	Ivercen-10 mg/ml
	Label Claim	Each ml contains: Ivermectin.....10 mg
	Reference to Finished product specifications	European Pharmacopeia

	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temprature
	For generic drugs (me-too Status)	Actimec (Selemore Pharmaceuticals Pvt. Ltd).,
	Pharmacotherapeutic Group of (API)	Endectocides
	Name, address of Manufacturing site:	CENAVISA, S.L.-Camí Pedra Estela s/n 43205 Reus (Tarragona)-Spain
	Name, address of Marketing Authorization Holder:	Tariq Mustafa, 186-D, Peoples Colony No. 1,, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Scanned copy of apostille certified COPP issued by AEMPS submitted, confirming free sale status of the product in exporting country and GMP status of the manufacturer
	Details of Authorization Letter :	Scanned copy of notarized LOA submitted valid till 22-02-2028
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	submitted 6 months accelerated and 24 months' long term stability studies data as per zone IV-A
	Evaluation Remarks	
	Since scanned copy of LOA is submitted, the firm shall submit original valid LOA notarized from country of origin before issuance of registration letter.	
	Decision	
	Approved	
	subject to import policy order. Moreover, firm shall submit original valid LOA notarized from country of origin before issuance of registration letter, since the already submitted copy is scanned.	
642	Case Category	New Section (Najia Saleem)
	Name, address of Applicant.	MEDPHARM RESEARCH LAB 28 KM FEROZPUR ROAD LAHORE (000878)
	Application Form Dy. No / Tracking ID & date of submission	(WQ4-LG5-92G4, 2024-03-03)
	Detail of Fee Submitted	30000.0, 2024-02-28,
	The proposed proprietary name / brand name	AR TRIMED oral liquid
	Label Claim	Each ML Contains: Trimethoprim 80 mg Sulphadiazime 400 mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1 Liter-De-Controlled,100 ML-De-Controlled,5 Liter-De-Controlled,500 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)15 - 30C
	For generic drugs (me-too Status)	Tribactral Forte Oral Suspension
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP Certified
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision of 335th RB meeting:Deferred for clarification regarding intended use in specifically cows and mares only.The firm has initially submitted target species: Poultry, cattle, cows, maresThe firm has deposited fee vide slip 034955337 of Rs. 7500/- deposited on 23-05-2024 for correction/revision of FPP specs.The firm has now revised target species to cats, dogs, birds, reptiles, and small mammals	

	Decision	
	Approved	
	with as per innovator's specifications.	
643	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Vetz Pharmaceutical Pvt Ltd Plot No. Q-1, Site Kotri, Sindh (000813)
	Application Form Dy. No / Tracking ID & date of submission	(X1N-8M1-ZG84, 2024-07-18)
	Detail of Fee Submitted	30000.0, 2024-07-09,
	The proposed proprietary name / brand name	Vetzcid suspension
	Label Claim	Each liter Contains: Triclabendazole BP(Vet).....85 gOxfendazole BP(Vet).....22.65 g(As per Innovator Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50, 100,150,250,500 -De-Controlled
	Shelf Life (Unit)	24 Month(s)Store below 30°C. Protect from light and heat.
	For generic drugs (me-too Status)	Vorcid Suspension(ICI)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	In conclusion, it is found that the firm is committed towards continuous upgrading and compliance as per the Drug Act 1976 & DRAP Act 2012 & operating at good level of GMP compliance with enthusiasm of export contribution and automation.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
644	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	(XGT-XZ8-G7JV, 2024-07-15)
	Detail of Fee Submitted	30000.0, 2024-07-12,
	The proposed proprietary name / brand name	ETER BROMO WATER SOLUBLE POWDER
	Label Claim	Each 100 gm contains: Bromhexine HCL 1gm Tartaric acid..... 15gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	25Kg-De-Controlled,100gm-De-Controlled,10Kg -De-Controlled,1Kg-De-Controlled,250gm-De-

		Controlled,500gm-De-Controlled,5Kg-De-Controlled
	Shelf Life (Unit)	2 YearStore below 25 °C. Protect from light
	For generic drugs (me-too Status)	Lucky Core Industries Lahore (Bromotartic Water Soluble Powder Reg.# 089822)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The applied formulation is already registered in the name of applicant with same brand name vide Reg. No. 125606	
	Decision	
	Rejected	
	since same formulation has already been registered for the applicant with same brand name vide Reg. No.125606	
645	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	BIORISE PHARMACEUTICALS 19KM, LAHORE ROAD, MULTAN (000934)
	Application Form Dy. No / Tracking ID & date of submission	(XNM-LV1-JXJ9, 2024-11-26)
	Detail of Fee Submitted	37000.0, 2024-11-20,
	The proposed proprietary name / brand name	Novanic Forte Injection 500ml
	Label Claim	EACH ML CONTAINS: - NOVAMINSULFON...40MG ETILEFRIN...0.2MG CALCIUM GLUCONATE.....100MG MAGNESIUM GLUCONATE....10MG SODIUM SALICYLATE...7MG NICOTINAMIDE...0.3MG CAFFEINE...10MG BORIC ACID....10MG
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	500ml-De-Controlled
	Shelf Life (Unit)	2 YearStore in a cool and Dry place, away from moisture and direct sunlight.
	For generic drugs (me-too Status)	Nicofrin Injection 500ml by M/S Leads Pharma Islamabad Reg. No. 058863
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel of inspectors found the premises satisfactory and recommend the grant of DML.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has mentioned Vial filling and sealing machine (10ml-500ml) in list of production machinery and equipment.	
	Decision	
	Approved	

646	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	ONE HEALTH PHARMA Plot# 28/2-A, SITE Kotri, sindh. (000993)
	Application Form Dy. No / Tracking ID & date of submission	(ZJV-3XA-6W7G, 2024-05-20)
	Detail of Fee Submitted	30000.0, 2024-05-09,
	The proposed proprietary name / brand name	Toltra K Oral Liquid
	Label Claim	Each 1000 mL contains Toltrazuril 25 gm Vitamin K3 3 gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1.0 L-De-Controlled,10.0 L-De-Controlled,100 mL-De-Controlled,15.0 L-De-Controlled,2.5 L-De-Controlled,25.0 L-De-Controlled,250 mL-De-Controlled,5.0 L-De-Controlled,50 mL-De-Controlled,500 mL-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at Cool and Dry Place, Protect From Heat and Sunlight
	For generic drugs (me-too Status)	Toltra-2.5% (058752) Intervac. 2. Bio-toltra plus (078232) Bio Labs
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Evidence of approval of manufacturing facility	
647	Evaluation Remarks	
	Decision	
	Approved	
	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Aamster Laboratories Plot # 18, Street # SS-2 RCCI Industrial Estate, Rawat - Islamabad (000908)
	Application Form Dy. No / Tracking ID & date of submission	(ZUJ-Y84-UBMH, 2024-11-05)
	Detail of Fee Submitted	37000.0, 2024-11-05,
	The proposed proprietary name / brand name	AMIZOLE POWDER
	Label Claim	Each Kg contains (As Per Innovator Spec.) - Furazolidone 950g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g-De-Controlled,25Kg-De-Controlled,500g-De-Controlled,Kg-De-Controlled
	Shelf Life (Unit)	2 YearStore Below 30°C

	For generic drugs (me-too Status)	FURASYM POWDER (023435) SYMANS PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was found operating at good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The formulation is already under review of sub-committee on veterinary drugs	
	Decision	
	Deferred	
	for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
648	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Aptly Pharmaceuticals 5-Km, Sargodha Road Bypass, Faisalabad. (000887)
	Application Form Dy. No / Tracking ID & date of submission	(177-2JN-S73G, 2024-09-30)
	Detail of Fee Submitted	37000.0, 2024-09-24,
	The proposed proprietary name / brand name	APLINC-S Injection (50ml)
	Label Claim	Each ml contains Lincomycin as HCl 40 mg Spectinomycin as HCl 80 mg Alcohol Benzyl 9 mg Innovators specifications
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ml vial-De-Controlled
	Shelf Life (Unit)	2 Yearat room temperature
	For generic drugs (me-too Status)	LSA Injection Reg# 063724
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Pharmacotherapeutic group of API is ANTIBIOTIC	
	Decision	
	Approved	
649	Case Category	Routine (Sabahat Zehra)
	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	(2UE-5YM-Z853, 2024-03-07)
	Detail of Fee Submitted	30000.0, 2024-03-04,
	The proposed proprietary name / brand name	Imec Injection

	Label Claim	Each ml contains: Ivermectin.....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10mL-De-Controlled
	Shelf Life (Unit)	2 YearIVA
	For generic drugs (me-too Status)	Ivergen Injection
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the above states observations their current GMP compliance level is rated as good.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
650	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	MEDPHARM RESEARCH LAB 28 KM FEROZPUR ROAD LAHORE (000878)
	Application Form Dy. No / Tracking ID & date of submission	(33L-WGW-M4VN, 2024-03-04)
	Detail of Fee Submitted	30000.0, 2024-02-27,
	The proposed proprietary name / brand name	AR TT MED 98
	Label Claim	Each G Contains: TYLOSIN TARTARATE 0.98KG
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 KG-De-Controlled,5 KG-De-Controlled
	Shelf Life (Unit)	2 Year(s)15 - 30C
	For generic drugs (me-too Status)	TYLOTOR-98 Powder
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP Certified
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
651	Case Category	Routine (Sabahat Zehra)
	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	(1TB-JD9-TDT5, 2024-09-26)

	Detail of Fee Submitted	37000.0, 2024-09-12,
	The proposed proprietary name / brand name	Hilfen Liquid
	Label Claim	Each ml contains: Florfenicol.....250mg Colistin Sulphate, USP.....0.5MIU (As per Manufacturer's Specifications)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1 liter-De-Controlled,5 liter-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30°C. Protect from sunlight and moisture. Keep out of reach of children
	For generic drugs (me-too Status)	Poliflor Liquid by Hawk BioPharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the stated facts M/s Hilton Pharma was noted operating at good level of GMP compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Pharmacotherapeutic group of API is ANTIBACTERIAL.	
	Decision	
	Approved	
652	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Selmore Pharmaceuticals (Pvt.) Ltd. Plant: 36- KM Multan Road, Lahore: Head Office: SPL House No. 82, R-1 Johar Town (000507)
	Application Form Dy. No / Tracking ID & date of submission	(4M7-8M1-41R9, 2024-03-19)
	Detail of Fee Submitted	,
	The proposed proprietary name / brand name	Triclasole Forte Suspension
	Label Claim	Each ml contains: Triclabendazole = 120mg Levamisole Hydrochloride = 75mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De- Controlled,500ml-De-Controlled,50ml-De- Controlled
	Shelf Life (Unit)	2 YearBelow 25 degree
	For generic drugs (me-too Status)	Endosym 19.5% Suspension Reg. 025796 by No. M/s Symans Pharmaceuticals (Pvt) Limited
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	M/s Selmore Pharmaceuticals (Pvt) Ltd. 36-Km, Multan Road, Lahore was operating at a satisfactory level of CMP compliance.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved	
653	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	MEDPHARM RESEARCH LAB 28 KM FEROZPUR ROAD LAHORE (000878)
	Application Form Dy. No / Tracking ID & date of submission	(56T-6WM-H1N4, 2024-03-04)
	Detail of Fee Submitted	30000.0, 2024-02-28,
	The proposed proprietary name / brand name	AR-MED-C
	Label Claim	Each G Contains: Acetyl salicylic acid...67mg Vitamin C...200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 KG-De-Controlled,10 KG-De-Controlled,5 KG-De-Controlled
	Shelf Life (Unit)	2 Year(s)15 - 30C
	For generic drugs (me-too Status)	Hyper-C oral powder
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP Certified
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
654	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Aptly Pharmaceuticals 5-Km, Sargodha Road Bypass, Faisalabad. (000887)
	Application Form Dy. No / Tracking ID & date of submission	(692-6VP-3ZPM, 2024-09-30)
	Detail of Fee Submitted	37000.0, 2024-09-24,
	The proposed proprietary name / brand name	APAGEN-20 INJECTION (50ml)
	Label Claim	Each ml contains Gentamycin sulphate eq to gentamycin 200 mg USP specifications
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50 ml vial-De-Controlled
	Shelf Life (Unit)	2 Yearat room temperature
	For generic drugs (me-too Status)	GANTASIN-20% Injection (50ml) reg. # 112222
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	Decision	
	Approved	
655	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Selmore Pharmaceuticals (Pvt.) Ltd. Plant: 36-KM Multan Road, Lahore: Head Office: SPL House No. 82, R-1 Johar Town (000507)
	Application Form Dy. No / Tracking ID & date of submission	(7G5-79D-66Y8, 2024-12-03)
	Detail of Fee Submitted	37000.0, 2024-11-27,
	The proposed proprietary name / brand name	Coccivet Powder
	Label Claim	Each Kg contains: Amprolium HCL = 200gm Ethopabate = 10gm Sulphaquinoxaline = 120mg Pyrimethamine = 10gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1kg-De-Controlled,2.5kg-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 YearBelow 25 degree
	For generic drugs (me-too Status)	Noxin Powder by MyLab Reg. No. 105056
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	M/s Selmore Pharmaceuticals (Pvt) Ltd. 36-Km, Multan Road, Lahore was operating at a satisfactory level of CMP compliance.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
656	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	ACME PHARMACEUTICALS Plot No. 29, Street SS-2, RCCI Industrial Estate Rawat (000967)
	Application Form Dy. No / Tracking ID & date of submission	(7Y2-UTL-EUAL, 2024-12-23)
	Detail of Fee Submitted	37000.0, 2024-12-19,
	The proposed proprietary name / brand name	Metheo-950
	Label Claim	Each gram contains: Methenamine 950mg, Vitamin B1 8 mg Vitamin B2 9.2mg Vitamin K3.....2mg
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	Jar of 50gm,100gm,2-De-Controlled
	Shelf Life (Unit)	2 Year(s)storage at room temperature
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Good Level
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
657	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	MEDPHARM RESEARCH LAB 28 KM FEROZPUR ROAD LAHORE (000878)
	Application Form Dy. No / Tracking ID & date of submission	(92J-3Z5-X633, 2024-03-03)
	Detail of Fee Submitted	30000.0, 2024-02-27,
	The proposed proprietary name / brand name	AR DOXIMED -60
	Label Claim	Each 100GM Contains doxycycline HCL....40g Tylosin Tartarte.... 20g
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1 KG -De-Controlled,5 KG-De-Controlled,500 G- De-Controlled
	Shelf Life (Unit)	2 Year(s)15 - 30C
	For generic drugs (me-too Status)	Doxil oral powder
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP Certified
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
658	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Aptly Pharmaceuticals 5-Km, Sargodha Road Bypass, Faisalabad. (000887)
	Application Form Dy. No / Tracking ID & date of submission	(97H-1YT-TMEE, 2024-09-30)
	Detail of Fee Submitted	37000.0, 2024-09-24,
	The proposed proprietary name / brand name	APLAMARQUIN Injection (20ml)
	Label Claim	Each ml contains Marbofloxacin 100 mg BP VET specifications

	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	20 ml vial-De-Controlled
	Shelf Life (Unit)	2 Yearat room temperature
	For generic drugs (me-too Status)	MARBOFLOX Injection (20ml) reg# 088088
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
659	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	ACME PHARMACEUTICALS Plot No. 29, Street SS-2, RCCI Industrial Estate Rawat (000967)
	Application Form Dy. No / Tracking ID & date of submission	(9S1-XXV-56R6, 2024-12-23)
	Detail of Fee Submitted	37000.0, 2024-12-19,
	The proposed proprietary name / brand name	DOCK-TC WSP
	Label Claim	Each kg contains “Tylosin Tartrate (BP) 100gm, Doxycycline HCL (BP)..... 200gm, Colistin Sulphate (BP) 500MIU, Bromhexine HCL (BP)..... 5gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50gm, 100gm, 250gm, -De-Controlled
	Shelf Life (Unit)	2 Year(s)storage at room temperature
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Good Level
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
660	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Selmore Pharmaceuticals (Pvt.) Ltd. Plant: 36-KM Multan Road, Lahore: Head Office: SPL House No. 82, R-1 Johar Town (000507)
	Application Form Dy. No / Tracking ID & date of submission	(3VH-UX8-1QU6, 2024-03-19)

	Detail of Fee Submitted	30000.0, 2024-02-16,
	The proposed proprietary name / brand name	Enersel Injection 100ml
	Label Claim	Each ml contains:L-Arginine HCl 1.42mgL-Cysteine HCl 0.02mgMonosodium Glutamate..... 0.08mgL- Histidine HCl 0.02mgL-Isoleucine HCl 0.525mgL-Leucine 0.6m
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 25 degree
	For generic drugs (me-too Status)	Aminovital High Injection Reg. No. 020083 by Atzan Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	M/s Selmore Pharmaceuticals (Pvt) Ltd. 36-Km, Multan Road, Lahore was operating at a satisfactory level of CMP compliance.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
661	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Aptly Pharmaceuticals 5-Km, Sargodha Road Bypass, Faisalabad. (000887)
	Application Form Dy. No / Tracking ID & date of submission	(A3S-716-GDTG, 2024-09-28)
	Detail of Fee Submitted	37000.0, 2024-09-24,
	The proposed proprietary name / brand name	APAGEN-10 Injection (50 ml)
	Label Claim	Each ml contains Gentamycin as sulphate 100 mg USP Specifications
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50 ml vial-De-Controlled
	Shelf Life (Unit)	2 Yearat room temperature
	For generic drugs (me-too Status)	GANTASIN-10% Injection (50ml) reg # 112218
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	Name & address of API manufacturer	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (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	DRAP approved
	GMP status of the firm	cGMP Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
662	Decision	
	Approved	
	Case Category	Routine (Sabahat Zehra)
	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	(4JJ-729-AW1H, 2024-09-26)
	Detail of Fee Submitted	37000.0, 2024-09-12,
	The proposed proprietary name / brand name	Nemhil Powder
	Label Claim	Each 100gm contains: Neomycin sulphate, USP equivalent to neomycin.....71.5gm (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 kg-De-Controlled,5 kg-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30°C. Protect from sunlight and moisture. Keep out of reach of children
	For generic drugs (me-too Status)	Neoskill-72% Veterinary Powder by Bioskills Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the stated facts M/s Hilton Pharma was noted operating at good level of GMP compliance
	Evidence of approval of manufacturing facility	
663	Evaluation Remarks	
	Decision	
	Approved	
	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Selmore Pharmaceuticals (Pvt.) Ltd. Plant: 36-KM Multan Road, Lahore: Head Office: SPL House No. 82, R-1 Johar Town (000507)
	Application Form Dy. No / Tracking ID & date of submission	(4P8-VWT-HH62, 2024-12-12)
	Detail of Fee Submitted	37000.0, 2024-12-11,

	The proposed proprietary name / brand name	MUCOSIN POWDER
	Label Claim	Each gram contains:Roxithromycin = 10mgTylosin Tartrate = 10mgGuaifenesin = 17.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1kg-De-Controlled,2.5kg-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 25degree centigrade, protect from light and moisture
	For generic drugs (me-too Status)	Roxi-TG Oral Powder Registration No: 058931 by Mallard Pharmaceutical (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	M/s Selmore Pharmaceuticals (Pvt.) Ltd. 36-KM Multan Road, Lahore was operating at a satisfactory level of GMP compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
664	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Aptly Pharmaceuticals 5-Km, Sargodha Road Bypass, Faisalabad. (000887)
	Application Form Dy. No / Tracking ID & date of submission	(AMQ-2ZU-W7RJ, 2024-09-30)
	Detail of Fee Submitted	37000.0, 37000.0 2024-09-24, 2025-06-12
	The proposed proprietary name / brand name	APTYL-20 Injection (50ml)
	Label Claim	Each ml contains Tylosin as Tartrate eq to Tylosin base 200 mg BP specifications
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	50 ml vial-De-Controlled
	Shelf Life (Unit)	2 Yearat room temperature
	For generic drugs (me-too Status)	TYRATE-20% Injection (50ml) reg # 109933
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Applicant has submitted extra fee Rs.37000/- for standardization of label claimed in line with reference product which is not required.	
	Decision	
	Approved	

665	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Majestic Pharma plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad (000873)
	Application Form Dy. No / Tracking ID & date of submission	(ATG-Z63-U7H6, 2024-12-30)
	Detail of Fee Submitted	37000.0, 2024-12-28,
	The proposed proprietary name / brand name	MAJI-SON ORAL POWDER
	Label Claim	Each gm contains: Neomycin Sulphate 60 mg Oxytetracycline HCl 200 mg Streptomycin Sulphate 20 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000gm-De-Controlled,100gm-De-Controlled,250gm-De-Controlled,5000gm-De-Controlled,500gm-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temperature and avoid from heat and sunlight.
	For generic drugs (me-too Status)	SONDEX VET DRY POWDER (088138)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory level of GMP Compliance
	Evidence of approval of manufacturing facility	
666	Evaluation Remarks	
	Decision	
	Approved	
	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	MEDPHARM RESEARCH LAB 28 KM FEROZPUR ROAD LAHORE (000878)
	Application Form Dy. No / Tracking ID & date of submission	(HU4-753-T7BE, 2024-03-03)
	Detail of Fee Submitted	30000.0, 2024-02-27,
	The proposed proprietary name / brand name	AR CHLOR-MED 25
	Label Claim	Each GM Contains: chlortetracycline as HCL.....250mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 KG-De-Controlled,5 KG-De-Controlled,500 G-De-Controlled
	Shelf Life (Unit)	2 Year(s)15 - 30C
	For generic drugs (me-too Status)	Meralin-250 W.S.P
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP Certified
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	Decision	
	Approved	
667	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	ACME PHARMACEUTICALS Plot No. 29, Street SS-2, RCCI Industrial Estate Rawat (000967)
	Application Form Dy. No / Tracking ID & date of submission	(HZG-VX6-3PDZ, 2024-12-23)
	Detail of Fee Submitted	37000.0, 2024-12-19,
	The proposed proprietary name / brand name	BROACID WSP
	Label Claim	Each gram contains Bromhexine HCL (BP) ...10mg, Tartaric Acid (BP).....150 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Jar of 50gm,100gm,2-De-Controlled
	Shelf Life (Unit)	2 Year(s)storage at room temperature
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Good Level
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
668	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Majestic Pharma plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad (000873)
	Application Form Dy. No / Tracking ID & date of submission	(JWD-W2B-Z2AJ, 2024-12-30)
	Detail of Fee Submitted	37000.0, 2024-12-28,
	The proposed proprietary name / brand name	MAJIOX-95 ORAL POWDER
	Label Claim	Each 1000gm contains: Oxytetracycline HCl.....950 gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000gm-De-Controlled,100gm-De-Controlled,250gm-De-Controlled,5000gm-De-Controlled,500gm-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temperature and avoid from heat and sunlight.
	For generic drugs (me-too Status)	OXYFAG-950 ORAL POWDER (118568)

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
669	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Aptly Pharmaceuticals 5-Km, Sargodha Road Bypass, Faisalabad. (000887)
	Application Form Dy. No / Tracking ID & date of submission	(L2Q-DEX-9X7P, 2024-09-30)
	Detail of Fee Submitted	37000.0, 2024-09-24,
	The proposed proprietary name / brand name	APAGEN-20 Injection (100ml)
	Label Claim	Each ml contains gentamycin sulphate eq to gentamycin 200 mg USP specifications
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100 ml vial-De-Controlled
	Shelf Life (Unit)	2 Yearat room temperature
	For generic drugs (me-too Status)	GENTRAX Injection (100ml) Reg# 113552
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
670	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Aptly Pharmaceuticals 5-Km, Sargodha Road Bypass, Faisalabad. (000887)
	Application Form Dy. No / Tracking ID & date of submission	(L7N-4ZZ-Z6JE, 2024-09-30)
	Detail of Fee Submitted	37000.0, 37000.0 2024-09-24, 2025-06-12
	The proposed proprietary name / brand name	APAGEN-20 Injection (10ml)
	Label Claim	Each ml contains Gentamycin Sulphate eq to gentamycin 200 mg USP specifications
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10 ml vial-De-Controlled

	Shelf Life (Unit)	2 Yearat room temperature
	For generic drugs (me-too Status)	GENTAVET FORTE Injection Reg# 046541
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Applicant has submitted extra fee Rs.37000/- for standardization of label claim in line with reference product which is not required.	
	Decision	
	Approved	
671	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	ACME PHARMACEUTICALS Plot No. 29, Street SS-2, RCCI Industrial Estate Rawat (000967)
	Application Form Dy. No / Tracking ID & date of submission	(MEW-N9W-Q68D, 2024-12-23)
	Detail of Fee Submitted	37000.0, 2024-11-13,
	The proposed proprietary name / brand name	The Ethasod
	Label Claim	“The Ethasod WSP” Brand of “Sodium Benzoate 500 gm, Ethanol beta amino phosphoric acid 100 gm, Vitamin A 10 MIU, Vitamin K3 1.0 gm, Vitamin E 2.5 gm, Vitamin C 2.5 gm” (Each Kg contains)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Jar of 50gm,100gm,2-De-Controlled
	Shelf Life (Unit)	2 Year(s)storage at room temperature
	For generic drugs (me-too Status)	Betatox Powder reg#046660
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Good Level
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
672	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Selmore Pharmaceuticals (Pvt.) Ltd. Plant: 36-KM Multan Road, Lahore: Head Office: SPL House No. 82, R-1 Johar Town (000507)
	Application Form Dy. No / Tracking ID & date of submission	(5N8-1JM-Q35S, 2024-12-10)

	Detail of Fee Submitted	37000.0, 2024-11-27,
	The proposed proprietary name / brand name	Specnol Powder
	Label Claim	Each 100gm contains:Lincomycin as HCL = 5gmSpectinomycin HCL = 7.5gmSpiramycin Adipate = 2.5gmBromhexine HCL = 0.5gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1kg-De-Controlled,2.5kg-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 25 degree
	For generic drugs (me-too Status)	Lexob Oral Power Reg. No. 118391 by QAS International, Gujranwala
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	M/s Selmore Pharmaceuticals (Pvt) Ltd. 36-Km, Multan Road, Lahore was operating at a satisfactory level of CMP compliance.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
673	Case Category	Routine (Sabahat Zehra)
	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	(5S4-ZTL-Q9ZJ, 2024-09-26)
	Detail of Fee Submitted	37000.0, 2024-09-12,
	The proposed proprietary name / brand name	Parahil Powder
	Label Claim	Each gm contains: Paracetamol.....200mg Vitamin C, USP.....50mg Potassium Carbonate, USP.....125mg Sodium Bicarbonate, USP.....125mg Vitamin E, USP.....125mg (As per Manufacturer's Specifications)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1 kg-De-Controlled,2.5 kg-De-Controlled,5 kg-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30°C. Protect from sunlight and moisture. Keep out of reach of children
	For generic drugs (me-too Status)	Parascorbic powder by Baariq Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the stated facts M/s Hilton Pharma was noted operating at good level of GMP compliance

	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
674	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Aptly Pharmaceuticals 5-Km, Sargodha Road Bypass, Faisalabad. (000887)
	Application Form Dy. No / Tracking ID & date of submission	(PUE-H82-JW79, 2024-09-30)
	Detail of Fee Submitted	37000.0, 2024-09-24,
	The proposed proprietary name / brand name	APLINC-S Injection (100 ml)
	Label Claim	Each ml contains Lincomycin as HCl 40 mg Spectinomycin as HCl 80 mg Alcohol Benzyl 9 mg innovators specifications
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ml vial-De-Controlled
	Shelf Life (Unit)	2 Yearat room temperature
	For generic drugs (me-too Status)	LSA Injection Reg# 063724
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
675	Case Category	Contract Manufacturing (Sabahat Zehra)
	Name, address of Applicant.	Majestic Pharma plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad (000873)
	Application Form Dy. No / Tracking ID & date of submission	(6P2-PUE-DQST, 2024-12-12)
	Detail of Fee Submitted	93000.0, 2024-12-11,
	The proposed proprietary name / brand name	MAJI MOX-ESL WATER SOLUBLE POWDER
	Label Claim	Each gm powder contains (As Per Innovator Spec.) Amoxicillin Trihydrate eq. to Amoxicillin BP..... 200mg Lincomycin HCl eq. to Lincomycin BP..... 88mg Spectinomycin Sulphate eq. to Spectinomycin BP..... 88mg Vitamin E Acetate BP..... 30mg

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 kg-De-Controlled,100gm-De-Controlled,250gm-De-Controlled,500gm-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temperature and avoid from heat and sunlight.
	For generic drugs (me-too Status)	MOX SEL E POWDER
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Aamster Laboratories-Plot # 18 St#SS-2, RCCI National Industrial Zone Rawat, Islamabad-
	GMP status of the firm	Good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
676	Decision	
	Approved	
	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Aptly Pharmaceuticals 5-Km, Sargodha Road Bypass, Faisalabad. (000887)
	Application Form Dy. No / Tracking ID & date of submission	(RDB-S2M-ZEH2, 2024-09-30)
	Detail of Fee Submitted	37000.0, 2024-09-24,
	The proposed proprietary name / brand name	APLINC-S Injection 10ml
	Label Claim	Each ml contains Lincomycin as HCl 40 mg Spectinomycin as HCl 80 mg Alcohol Benzyl 9 mg Innovators specifications
	Reference to Finished product specifications	As per Innovators Specification
677	Proposed Pack Size	10 ml vial-De-Controlled
	Shelf Life (Unit)	2 Yearat room temperature
	For generic drugs (me-too Status)	LSA Injection Reg# 063724
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
677	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Aptly Pharmaceuticals 5-Km, Sargodha Road Bypass, Faisalabad. (000887)
	Application Form Dy. No / Tracking ID & date of submission	(RR6-7EW-NRHE, 2024-09-30)

	Detail of Fee Submitted	37000.0, 2024-09-24,
	The proposed proprietary name / brand name	TMP-S Injection (10ml)
	Label Claim	Each ml contains Sulfadiazine 400 mg Trimethoprim 80 mg As per Innovators Specification
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 ml vial-De-Controlled
	Shelf Life (Unit)	2 Year(s) at room temperature
	For generic drugs (me-too Status)	TRIFACE Injection (10ml) Reg # 057135
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
678	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	MEDPHARM RESEARCH LAB 28 KM FEROZPUR ROAD LAHORE (000878)
	Application Form Dy. No / Tracking ID & date of submission	(RRG-UZN-9L1G, 2024-03-03)
	Detail of Fee Submitted	30000.0, 2024-02-28,
	The proposed proprietary name / brand name	AR COXIMED
	Label Claim	Each 500GM Contains 2,4 Diamino-5 Veralrylpyrimidine 25g, vitamin K3 2.5g, Vitamin A1 250MIU, sulphabenzpyrazine 100g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 KG-De-Controlled, 5 KG-De-Controlled, 500 G-De-Controlled
	Shelf Life (Unit)	2 Year(s) 15 - 30C
	For generic drugs (me-too Status)	COCXITIN POWDER reg#063784
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP Certified
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
679	Case Category	Routine (Sabahat Zehra)

	Name, address of Applicant.	ACME PHARMACEUTICALS Plot No. 29, Street SS-2, RCCI Industrial Estate Rawat (000967)
	Application Form Dy. No / Tracking ID & date of submission	(U4H-VWL-TSYQ, 2024-12-23)
	Detail of Fee Submitted	37000.0, 2024-12-19,
	The proposed proprietary name / brand name	DOX-TD
	Label Claim	Each kg contains Tylosin Tartrate (BP) 200gm, Doxycycline HCL (BP)..... 400gm, Colistin Sulphate (BP) 500MIU, Bromhexine HCL (BP)..... 10gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50gm, 100gm, 250gm, -De-Controlled
	Shelf Life (Unit)	2 Year(s)storage at room temperature
	For generic drugs (me-too Status)	Reg#114923 Respisin DS Powder
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Good Level
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
680	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Aptly Pharmaceuticals 5-Km, Sargodha Road Bypass, Faisalabad. (000887)
	Application Form Dy. No / Tracking ID & date of submission	(U6D-N5P-DXPW, 2024-09-30)
	Detail of Fee Submitted	37000.0, 2024-09-24,
	The proposed proprietary name / brand name	APLAMARQUIN Injection (50ml)
	Label Claim	Each ml contains Marbofloxacin 100 mg BP vet specifications
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	50 ml vial-De-Controlled
	Shelf Life (Unit)	2 Yearat room temperature
	For generic drugs (me-too Status)	MARBO-VETZ 10% Injection (50ml) reg # 099431
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	Decision	
	Approved	
681	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Aptly Pharmaceuticals 5-Km, Sargodha Road Bypass, Faisalabad. (000887)
	Application Form Dy. No / Tracking ID & date of submission	(UN7-G8R-JZ2J, 2024-09-30)
	Detail of Fee Submitted	37000.0, 2024-09-24,
	The proposed proprietary name / brand name	APRO-EN-10 injection 50 ml
	Label Claim	Each ml contains Enrofloxacin 100 mg BP vet Specifications
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	50 ml vial-De-Controlled
	Shelf Life (Unit)	2 Yearat room temperature
	For generic drugs (me-too Status)	ENFLOX-10 % Injection (50ml) Reg. # 112212
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
682	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Aptly Pharmaceuticals 5-Km, Sargodha Road Bypass, Faisalabad. (000887)
	Application Form Dy. No / Tracking ID & date of submission	(UQR-TT5-LP5X, 2024-09-30)
	Detail of Fee Submitted	37000.0, 2024-09-24,
	The proposed proprietary name / brand name	TMP-S Injection (50ml)
	Label Claim	Each ml contains Sulfadiazine 400 mg Trimethoprim 80 mg innovator specifications
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ml vial-De-Controlled
	Shelf Life (Unit)	2 Yearat room temperature
	For generic drugs (me-too Status)	SULBECTRA Injection (50ml) Reg. # 088121
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP Approved
	Evidence of approval of manufacturing facility	

	Evaluation Remarks	
	Decision	
683	Approved	
	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Majestic Pharma plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad (000873)
	Application Form Dy. No / Tracking ID & date of submission	(UXA-UPY-2Y28, 2024-12-31)
	Detail of Fee Submitted	37000.0, 2024-12-31,
	The proposed proprietary name / brand name	MENTHOMAG-B ORAL LIQUID
	Label Claim	Each ml contains: Bromhexine HCl ----- 50mg Menthol ----- 40 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,10lit-De-Controlled,250ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temperature and avoid from heat and sunlight.
	For generic drugs (me-too Status)	Bronchoment-50 Oral Liquid (120588)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
684	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	MEDPHARM RESEARCH LAB 28 KM FEROZPUR ROAD LAHORE (000878)
	Application Form Dy. No / Tracking ID & date of submission	(VJU-HN5-5UNQ, 2024-03-04)
	Detail of Fee Submitted	30000.0, 2024-02-28,
	The proposed proprietary name / brand name	AR TP MED 10
	Label Claim	Each KG Contains tylosin as phosphate 100g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 KG-De-Controlled,10 KG-De-Controlled,5 KG-De-Controlled
	Shelf Life (Unit)	2 Year(s)15 - 30C
	For generic drugs (me-too Status)	Vety-Tylomix Powder

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
685	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Aptly Pharmaceuticals 5-Km, Sargodha Road Bypass, Faisalabad. (000887)
	Application Form Dy. No / Tracking ID & date of submission	(X2J-4EU-ZJ48, 2024-09-28)
	Detail of Fee Submitted	37000.0, 2024-09-24,
	The proposed proprietary name / brand name	APAGEN-10 Injection (10 ml)
	Label Claim	Each ml contains Gentamycin as sulphate 100 mg USP Specifications
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10 ml vial-De-Controlled
	Shelf Life (Unit)	2 Yearat room temperature
	For generic drugs (me-too Status)	GENTAVET PLUS Injection reg # 046542
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
686	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Aptly Pharmaceuticals 5-Km, Sargodha Road Bypass, Faisalabad. (000887)
	Application Form Dy. No / Tracking ID & date of submission	(XNG-81R-EL7M, 2024-09-28)
	Detail of Fee Submitted	37000.0, 2024-09-24,
	The proposed proprietary name / brand name	APAGEN-10 Injection (100ml)
	Label Claim	Each ml contains Gentamycin as sulphate 100 mg USP specifications
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100 ml vial-De-Controlled

	Shelf Life (Unit)	2 Yearat room temperature
	For generic drugs (me-too Status)	GANTASIN-10% Injection (100ml) reg# 112219
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
687	Case Category	Routine (Sabahat Zehra)
	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	(Y1N-SSA-Z7M6, 2024-03-07)
	Detail of Fee Submitted	30000.0, 9000.0 2024-03-04, 2025-06-23
	The proposed proprietary name / brand name	Triox-P Injection
	Label Claim	Each ml contains: Thiamphenicol.....200mg Tylosin.....57.500mg Prednisolone.....5mg
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	10ml-De-Controlled
	Shelf Life (Unit)	2 YearIVA
	For generic drugs (me-too Status)	Tylophen Injection
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the above states observations their current GMP compliance level is rated as good.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Firm has submitted fee Rs.9000/- for revision of label claim in line with reference product	
	Decision	
	Approved	
688	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Majestic Pharma plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad (000873)
	Application Form Dy. No / Tracking ID & date of submission	(ZUY-QXP-TB1L, 2024-12-30)
	Detail of Fee Submitted	37000.0, 2024-12-28,
	The proposed proprietary name / brand name	MAJISTREP-CN ORAL POWDER

	Label Claim	Each gm contains: Neomycin Sulphate..... 60 mg Chlortetracycline HCl..... 200mg Streptomycin Sulphate..... 20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000gm-De-Controlled,100gm-De-Controlled,250gm-De-Controlled,5000gm-De-Controlled,500gm-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temperature and avoid from heat and sunlight.
	For generic drugs (me-too Status)	Nechlosin Powder (117249)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
689	Case Category	Contract Manufacturing (Sabahat Zehra)
	Name, address of Applicant.	Majestic Pharma plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad (000873)
	Application Form Dy. No / Tracking ID & date of submission	(B2T-6HV-ETJR, 2024-12-12)
	Detail of Fee Submitted	93000.0, 2024-12-11,
	The proposed proprietary name / brand name	CAN MOX WATER SOLUBLE POWDER
	Label Claim	Each Kg powder contains Amoxicillin as Trihydrate BP..... 100g Colistin sulphate BP..... 50g Neomycin Sulphate BP..... 200g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 kg-De-Controlled,10 kg-De-Controlled,100gm-De-Controlled,25 kg-De-Controlled,250gm-De-Controlled,5 kg-De-Controlled,500gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature and avoid from heat and sunlight.
	For generic drugs (me-too Status)	NEO AC W/S POWDER
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Aamster Laboratories-Plot # 18 St#SS-2, RCCI National Industrial Zone Rawat, Islamabad-
	GMP status of the firm	Good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved	
690	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Pharmonix Pharmaceuticals Plot 28, Street SS-2, National Industrial Zone, Rawat (000990)
	Application Form Dy. No / Tracking ID & date of submission	(BWR-SRT-DSU9, 2024-03-20)
	Detail of Fee Submitted	30000.0, 2024-03-07,
	The proposed proprietary name / brand name	NIXTON Powder
	Label Claim	Each gm contains:-Propionic Acid Calcium 250 mg,Propionic Acid Sodium 400 mg, Acetanilide 150 mg, Magnesium Oxide 125 mg, Iron II Sulphate 0.40 mg,
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	01 Kg-De-Controlled,10 Kg-De-Controlled,100gm-De-Controlled,15 Kg-De-Controlled,25 Kg-De-Controlled,250gm-De-Controlled,5 Kg-De-Controlled,500gm-De-Controlled,50gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)25°C
	For generic drugs (me-too Status)	Gestone Oral Powder (Reg. # 044911)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel based on the available equipment / machinery required in production and quality control such as availability of FTIR, HPLC, UV-Visible Spectrophotometer, stability chambers etc., technical staff, SOPs, documents and commitment of the management
	Evidence of approval of manufacturing facility	
691	Evaluation Remarks	
	Decision	
	Approved	
691	Case Category	Contract Manufacturing (Sabahat Zehra)
	Name, address of Applicant.	Majestic Pharma plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad (000873)
	Application Form Dy. No / Tracking ID & date of submission	(D2E-E82-9MT3, 2024-12-12)
	Detail of Fee Submitted	93000.0, 2024-12-11,
	The proposed proprietary name / brand name	CLAVAMOX-M ORAL WATER SOLUBLE POWDER

	Label Claim	Each 100g powder contains (As Per Innovator Spec.) Amoxicillin as Amoxicillin Trihydrate BP 16g Clavulanic acid as Potassium clavulanate BP 4g Bromhexine HCl BP..... 0.5g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 kg-De-Controlled,100g-De-Controlled,250g-De-Controlled,500gm-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temperature and avoid from heat and sunlight.
	For generic drugs (me-too Status)	CLAVMOX FORTE W/S POWDER
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Aamster Laboratories-Plot # 18 St#SS-2, RCCI National Industrial Zone Rawat, Islamabad-
	GMP status of the firm	Good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
692	Case Category	Contract Manufacturing (Sabahat Zehra)
	Name, address of Applicant.	Majestic Pharma plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad (000873)
	Application Form Dy. No / Tracking ID & date of submission	(H99-4HE-J2AW, 2024-12-12)
	Detail of Fee Submitted	93000.0, 2024-12-11,
	The proposed proprietary name / brand name	LYZOMOX G ORAL WATER SOLUBLE POWDER
	Label Claim	Each Kg powder contains (As Per Innovator Spec.) Amoxicillin as Trihydrate BP..... 50g Lysozyme HCl 10g Guaifenesin..... 35g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 kg-De-Controlled,100gm-De-Controlled,250gm-De-Controlled,500gm-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temperature and avoid from heat and sunlight.
	For generic drugs (me-too Status)	LYZOMOX W/S POWDER
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Aamster Laboratories-Plot # 18 St#SS-2, RCCI National Industrial Zone Rawat, Islamabad-
	GMP status of the firm	Good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	Decision	
	Approved	
693	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Pharmonix Pharmaceuticals Plot 28, Street SS-2, National Industrial Zone, Rawat (000990)
	Application Form Dy. No / Tracking ID & date of submission	(HSV-J26-GBUU, 2024-03-14)
	Detail of Fee Submitted	30000.0, 2024-03-07,
	The proposed proprietary name / brand name	AMPRO-90 Oral Powder
	Label Claim	Each gram contains:Amprolium HCl 900 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	01 Kg-De-Controlled,10 Kg-De-Controlled,100gm-De-Controlled,15 Kg-De-Controlled,25 Kg-De-Controlled,250gm-De-Controlled,500gm-De-Controlled,50gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)25°C
	For generic drugs (me-too Status)	Acme Pro-90 Water Soluble Powder (Reg. # 117043)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel based on the available equipment / machinery required in production and quality control such as availability of FTIR, HPLC, UV-Visible Spectrophotometer, stability chambers etc., technical staff, SOPs, documents and commitment of the management
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
694	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Pharmonix Pharmaceuticals Plot 28, Street SS-2, National Industrial Zone, Rawat (000990)
	Application Form Dy. No / Tracking ID & date of submission	(LP1-7JE-97LD, 2024-03-12)
	Detail of Fee Submitted	30000.0, 2024-03-07,
	The proposed proprietary name / brand name	BRONIOL Oral Liquid
	Label Claim	Each ml Contains:Bromhexine HCL 10mgMenthol 20mg
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,120ml-De-Controlled,2.5 Litre-De-Controlled,25 Litre-De-Controlled,250ml-De-Controlled,30ml-De-Controlled,5 Litre-De-Controlled,500ml-De-Controlled,50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)25°C
	For generic drugs (me-too Status)	BROMITHOL- Oral Liquid (Reg. # 117031)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel based on the available equipment / machinery required in production and quality control such as availability of FTIR, HPLC, UV-Visible Spectrophotometer, stability chambers etc., technical staff, SOPs, documents and commitment of the management
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
695	Case Category	Routine (Sabahat Zehra)
	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	(N33-3QM-GGEP, 2024-09-26)
	Detail of Fee Submitted	37000.0, 2024-09-12,
	The proposed proprietary name / brand name	Fosthil Powder
	Label Claim	Each Kg contains: Fosfomycin calcium.....200gm Tylosin Tartrate, BP.....100gm (As per Manufacturer's Specifications)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1 kg-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30°C. Protect from sunlight and moisture. Keep out of reach of children
	For generic drugs (me-too Status)	Fosfomax oral Powder by Biogen Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the stated facts M/s Hilton Pharma was noted operating at good level of GMP compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved	
696	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Pharmonix Pharmaceuticals Plot 28, Street SS-2, National Industrial Zone, Rawat (000990)
	Application Form Dy. No / Tracking ID & date of submission	(NH3-A7J-N6QA, 2024-03-13)
	Detail of Fee Submitted	30000.0, 2024-03-07,
	The proposed proprietary name / brand name	AMPRO-20 Oral Powder
	Label Claim	Each gram contains:Amprolium HCl 200 mg
	Reference to Finished product specifications	
	Proposed Pack Size	01 Kg-De-Controlled,10 Kg-De-Controlled,100gm-De-Controlled,15 Kg-De-Controlled,25 Kg-De-Controlled,250gm-De-Controlled,5 Kg-De-Controlled,500gm-De-Controlled,50gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)25°C
	For generic drugs (me-too Status)	AMPROLIUM POWDER Water Soluble Powder (Reg. # 002481)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel based on the available equipment / machinery required in production and quality control such as availability of FTIR, HPLC, UV-Visible Spectrophotometer, stability chambers etc., technical staff, SOPs, documents and commitment of the management
	Evidence of approval of manufacturing facility	
697	Evaluation Remarks	
	Decision	
	Approved	
697	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Aptly Pharmaceuticals 5-Km, Sargodha Road Bypass, Faisalabad. (000887)
	Application Form Dy. No / Tracking ID & date of submission	(QHX-RWJ-6P4L, 2024-09-30)
	Detail of Fee Submitted	37000.0, 37000.0 2024-09-24, 2025-06-12
	The proposed proprietary name / brand name	APTYL-20 Injection (100ml)
	Label Claim	Each ml contains Tylosin as Tartrate eq to tylosin base 200 mg BP specifications
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100 ml vial-De-Controlled

	Shelf Life (Unit)	2 Yearat room temperature
	For generic drugs (me-too Status)	TYLOX-20 Injection (100ml) Reg# 113562
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Applicant has submitted extra fee Rs.37000/- for standardization of label claim in line with reference product.	
	Decision	
	Approved	
698	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Pharmonix Pharmaceuticals Plot 28, Street SS-2, National Industrial Zone, Rawat (000990)
	Application Form Dy. No / Tracking ID & date of submission	(RMA-7VJ-Q7Z7, 2024-03-20)
	Detail of Fee Submitted	30000.0, 2024-03-07,
	The proposed proprietary name / brand name	TRINIX-98 Powder
	Label Claim	Each 1000 gram contains:Trichlorfon 980gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	01 Kg-De-Controlled,10 Kg-De-Controlled,100gm-De-Controlled,15 Kg-De-Controlled,25 Kg-De-Controlled,250gm-De-Controlled,5 Kg-De-Controlled,500gm-De-Controlled,50gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)25°C
	For generic drugs (me-too Status)	Trigold Powder (Reg. # 049700)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel based on the available equipment / machinery required in production and quality control such as availability of FTIR, HPLC, UV-Visible Spectrophotometer, stability chambers etc., technical staff, SOPs, documents and commitment of the management
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
699	Case Category	Contract Manufacturing (Sabahat Zehra)
	Name, address of Applicant.	Majestic Pharma plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad (000873)

	Application Form Dy. No / Tracking ID & date of submission	(U35-4N5-BLBY, 2024-12-12)
	Detail of Fee Submitted	93000.0, 2024-12-11,
	The proposed proprietary name / brand name	MAJI MOX-50 ORAL WATER SOLUBLE POWDER
	Label Claim	Each 100gm powder contains (As Per Innovator Spec.) Amoxicillin as Trihydrate BP..... 50g Colistin sulphate BP..... 50MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 kg-De-Controlled,100gm-De-Controlled,250gm-De-Controlled,500gm-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temperature and avoid from heat and sunlight.
	For generic drugs (me-too Status)	AMOX-C MAARSON W/S POWDER
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Aamster Laboratories-Plot # 18 St#SS-2, RCCI National Industrial Zone Rawat, Islamabad-
	GMP status of the firm	Good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
700	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Majestic Pharma plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad (000873)
	Application Form Dy. No / Tracking ID & date of submission	(V12-VBE-PE6N, 2024-12-30)
	Detail of Fee Submitted	37000.0, 2024-12-28,
	The proposed proprietary name / brand name	TIAMUCLOR ORAL POWDER
	Label Claim	Each 100gm contains: Tiamulin Hydrogen Fumarate..... 10 gm Chlortetracycline HCl..... 30 gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000gm-De-Controlled,100gm-De-Controlled,25000gm-De-Controlled,250gm-De-Controlled,5000gm-De-Controlled,500gm-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temperature and avoid from heat and sunlight.
	For generic drugs (me-too Status)	Mycochlor water Soluble Powder (074028)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory level of GMP Compliance

	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
701	Case Category	Contract Manufacturing (Sabahat Zehra)
	Name, address of Applicant.	Majestic Pharma plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad (000873)
	Application Form Dy. No / Tracking ID & date of submission	(V17-39X-U645, 2024-12-11)
	Detail of Fee Submitted	93000.0, 2024-12-11,
	The proposed proprietary name / brand name	BC MOX WATER SOLUBLE POWDER
	Label Claim	Each 1000g powder contains (As Per Innovator Spec.) Amoxicillin as Trihydrate B.P 100g Lincomycin as HCl 50g Colistin Sulphate B.P..... 500MIU Bromhexine HCl 5g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000gm-De-Controlled,100gm-De-Controlled,25000-De-Controlled,250gm-De-Controlled,5000gm-De-Controlled,500gm-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temperature and avoid from heat and sunlight.
	For generic drugs (me-too Status)	BROLIN POWDER
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Aamster Laboratories-Plot # 18 St#SS-2, RCCI National Industrial Zone Rawat, Islamabad-
	GMP status of the firm	Good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
702	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Pharmonix Pharmaceuticals Plot 28, Street SS-2, National Industrial Zone, Rawat (000990)
	Application Form Dy. No / Tracking ID & date of submission	(W2J-Y9M-QDT1, 2024-03-12)
	Detail of Fee Submitted	30000.0, 2024-03-07,
	The proposed proprietary name / brand name	TDBC-COLI Oral Liquid

	Label Claim	Each 1000ml Contains:Tylosin Tartrate 100 gmDoxycycline HCl 200 gmBromhexine HCl 3gmColistin Sulphate 480 MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,120ml-De-Controlled,2.5 Litre-De-Controlled,25 Litre-De-Controlled,250ml-De-Controlled,30ml-De-Controlled,5 Litre-De-Controlled,500ml-De-Controlled,50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)25°C
	For generic drugs (me-too Status)	Dacotysin TDBC-30 Oral Liquid (Reg. # 099418)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel based on the available equipment / machinery required in production and quality control such as availability of FTIR, HPLC, UV-Visible Spectrophotometer, stability chambers etc., technical staff, SOPs, documents and commitment of the management
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
703	Case Category	Contract Manufacturing (Sabahat Zehra)
	Name, address of Applicant.	Majestic Pharma plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad (000873)
	Application Form Dy. No / Tracking ID & date of submission	(WY3-D1P-QUAM, 2024-12-12)
	Detail of Fee Submitted	93000.0, 2024-12-11,
	The proposed proprietary name / brand name	MAJIPRO-BCS POWDER
	Label Claim	Each Kg powder contains (As Per Innovator Spec.) Procaine Penicillin BP..... 12g Streptomycin Sulphate BP..... 36g Colistin sulphate BP..... 60MIU Zinc Bacitracin BP..... 52g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Kg-De-Controlled,100gm-De-Controlled,250gm-De-Controlled,500gm-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temperature and avoid from heat and sunlight.
	For generic drugs (me-too Status)	ZEPTOCOL W/S POWDER
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Aamster Laboratories-Plot # 18 St#SS-2, RCCI National Industrial Zone Rawat, Islamabad-

	GMP status of the firm	Good level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Deferred for submission of valid international references in support of their product	
	Decision	
	Deferred	
704	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Pharmonix Pharmaceuticals Plot 28, Street SS-2, National Industrial Zone, Rawat (000990)
	Application Form Dy. No / Tracking ID & date of submission	(X7S-L8H-76RA, 2024-03-12)
	Detail of Fee Submitted	30000.0, 2024-03-07,
	The proposed proprietary name / brand name	BRONIOL PLUS Oral Liquid
	Label Claim	Each ml Contains:Bromhexine HCL 20mgMenthol 40mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,120ml-De-Controlled,2.5 Litre-De-Controlled,25 Litre-De-Controlled,250ml-De-Controlled,30ml-De-Controlled,5 Litre-De-Controlled,500ml-De-Controlled,50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)25°C
	For generic drugs (me-too Status)	BROMITHOL-PLUS Oral Liquid (Reg. # 118387)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel based on the available equipment / machinery required in production and quality control such as availability of FTIR, HPLC, UV-Visible Spectrophotometer, stability chambers etc., technical staff, SOPs, documents and commitment of the management
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
705	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Pharmonix Pharmaceuticals Plot 28, Street SS-2, National Industrial Zone, Rawat (000990)
	Application Form Dy. No / Tracking ID & date of submission	(XHV-PRT-Y5M9, 2024-03-12)

	Detail of Fee Submitted	30000.0, 2024-03-07,
	The proposed proprietary name / brand name	TDBC GOLD Oral Liquid
	Label Claim	Each 1000ml Contains: Tylosin Tartrate 100 gm Doxycycline HCl 200 gm Bromhexine HCl 2.5 gm Colistin Sulphate 450 MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled, 100ml-De-Controlled, 120ml-De-Controlled, 2.5 Litre-De-Controlled, 25 Litre-De-Controlled, 250ml-De-Controlled, 30ml-De-Controlled, 5 Litre-De-Controlled, 500ml-De-Controlled, 50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s) 25°C
	For generic drugs (me-too Status)	Dacotysin TDOX-60- Oral Liquid (Reg. # 101492)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel based on the available equipment / machinery required in production and quality control such as availability of FTIR, HPLC, UV-Visible Spectrophotometer, stability chambers etc., technical staff, SOPs, documents and commitment of the management
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
706	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Pharmonix Pharmaceuticals Plot 28, Street SS-2, National Industrial Zone, Rawat (000990)
	Application Form Dy. No / Tracking ID & date of submission	(Z3X-Y8P-QWENZ, 2024-03-14)
	Detail of Fee Submitted	30000.0, 2024-03-07,
	The proposed proprietary name / brand name	AMPRO-50 Oral Powder
	Label Claim	Each gram contains: Amprolium HCl 500 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	01 Kg-De-Controlled, 10 Kg-De-Controlled, 100gm-De-Controlled, 15 Kg-De-Controlled, 25 Kg-De-Controlled, 250gm-De-Controlled, 500gm-De-Controlled, 50gm-De-Controlled
	Shelf Life (Unit)	2 Year(s) 25°C
	For generic drugs (me-too Status)	Acme Pro-50 Water Soluble Powder (Reg. # 117042)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--

	GMP status of the firm	The panel based on the available equipment / machinery required in production and quality control such as availability of FTIR, HPLC, UV-Visible Spectrophotometer, stability chambers etc., technical staff, SOPs, documents and commitment of the management
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
707	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	Martin Dow Marker Limited 7, Jail Road Quetta. (000028)
	Application Form Dy. No / Tracking ID & date of submission	(1BD-LUS-P6LZ, 2024-03-10)
	Detail of Fee Submitted	75000.0, 2024-01-15,
	The proposed proprietary name / brand name	Rebamipide Tablet 100mg
	Label Claim	Each film coated tablet contains: Rebamipide.....100mg
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	As per DPC-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Rebapide Tablet 100mg
	Pharmaceutical Group of (API)	Antacid /Anti reflux agent
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	FUAN Pharmaceutical Group Co., Ltd 1 Hun'nan 1 Road Changshou District Chongqing
	Detail of stability batches of drug product	Stability data of batches (PDS-42-23, PDS-43-23, PDS-44-23) 6000 tablet each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP performed against the product Mucosta tablet 100mg Rebamipide Batch no. 225102 M/s. Otsuka Pharmaceuticals Co. ltd.,Japan
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone iv condition is submitted.
	The status in reference regulatory authorities	Mucosta Tablet 100mg (PMDA - Japan)
	GMP status of the firm	GMP Certificate dated 10th September,2021 is submitted by the firm
	Evidence of approval of manufacturing facility	Regularization of section letter dated 31st may,2021 attached in which tablet (general) section is mentioned.
	Evaluation Remarks	

Sr.no.	Shortcoming	Response of the Firm
1.	justify why the drug product manufacturer has not adopted the HPLC method for the assay of the drug substance, considering that the API manufacturer has performed the assay using a validated HPLC technique.	Firm replied that Reason for not adopting the HPLC technique is because of API Rebamipide Specification complies with Japanese Pharmacopoeia where Assay is via Titration Technique.
2.	In the CDP report, dissolution testing at 45 minutes in pH 4.5 medium showed that 6 units from both the test and comparator products exhibited drug release greater than 100%, while the remaining 6 units demonstrated drug release below 25%. Please provide a scientific justification for this observed variability in drug release at 45 minutes in pH 4.5 medium.	Firm replied that “We would like to clarify that the reported values were the result of a typographical error in the CDP report table for the 45-minute time point in pH 4.5 medium. The dissolution release values mentioned in the report were mistakenly copied from the pH 6.8 medium results and not updated accordingly. However, the dissolution graph in the same report correctly reflects the actual data for the pH 4.5 medium. The revised and corrected CDP report, with accurate tabulated values, is attached herewith for your review.
3.	Submit updated stability data of drug product since you have submitted the data of only three months.	Firm submitted the stability data of 6th month of drug product.
4.	Submit valid GMP certificate of API Manufacturer.	Firm submit the GMP certificate of API Manufacturer which is valid till 05-07-2025

Decision

Deferred

Deferred for on site inspection of the firm for the authenticity/verification of submitted pharmaceutical development data and stability data.

708	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(6G4-5YN-XE82, 2024-03-18)
	Detail of Fee Submitted	30000.0, 45000.0 2023-12-15, 2024-02-15
	The proposed proprietary name / brand name	Nextol 180mg tablet
	Label Claim	Each Film Coated Tablet contains: Bempedoic acid -----180mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x10's, 2x7'-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature below 30
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	adenosine triphosphate citrate lyase (ACL) inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Stability data of batches TBY001,TBY002,TBY003 (1500 TABLETS

	EACH) is submitted	
Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is submitted	
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP is submitted against the Comparator drug Product (Nexletol 180mg Tablet)	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	stability data as per zone iv condition is submitted by the firm.	
The status in reference regulatory authorities	Nexletol 180mg Tablet by M/S Esperion Theuraeputics ,Inc.(USFDA Approved)	
GMP status of the firm	GMP certificate dated 14-11-2023 is submitted by the firm.	
Evidence of approval of manufacturing facility	GMP certificate dated 14-11-2023 mentioned that firm has tablet (general) section.	
Evaluation Remarks		
Sr.no.	Shortcomings	Response of the Firm
1.	According to the innovator’s literature, Bempedoic acid exhibits low solubility at pH levels below 6.0, consistent with the characteristics of a BCS Class II compound, and demonstrates high solubility above pH 6.0. In light of this, please justify the observed drug release behavior reported in the submitted comparative dissolution profile (CDP), wherein more than 80% of the drug was released within 15 minutes at both pH 1.2 and pH 4.5, despite the known low solubility of Bempedoic acid under these conditions.	Firm replied that Bempedoic acid is a BCS Class II drug with low solubility below pH 6.0. As there is no official FDA-recommended dissolution method for this API, we developed a discriminatory method using surfactants in pH 1.2 and 4.5 media to ensure adequate solubilization and maintain sink conditions.The use of surfactant (e.g., SLS) enhances the solubility in acidic media, which explains the rapid drug release (>80% in 15 minutes) despite its poor solubility in plain buffer.
2.	Justify the rationale for setting the dissolution acceptance limit as NLT 80% (Q) in 30 minutes, whereas the innovator recommends an acceptance limit of NLT (Q) in 20 minutes.	Firm replied that The dissolution acceptance limit of NLT 80% (Q) in 30 minutes was set based on general US FDA Dissolution Data base, which commonly recommends evaluating dissolution for immediate-release formulations at a 30-minute time point unless otherwise specified.
3.	Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Firm submitted the Form-6.
Decision		
Approved		

709	Case Category	Routine (Saima Hussain)							
	Name, address of Applicant.	Neutro Pharma (Pvt.) Ltd., 9.5-Km, Sheikhpura Road, Lahore (000576)							
	Application Form Dy. No / Tracking ID & date of submission	(32T-9NX-1M4M, 2024-03-19)							
	Detail of Fee Submitted	30000.0, 2024-03-04,							
	The proposed proprietary name / brand name	Ertuneu-Met 2.5/1000mg Tablet							
	Label Claim	Each film coated tablet contains: Ertugliflozin L-Pyrogutamic acid Eq. to Ertugliflozin.....2.5.mg Metformin HCl.....1000mg As per Innovator Specifications							
	Reference to Finished product specifications	As per Innovators Specification							
	Proposed Pack Size	14s, 28s, 30s-As per SRO							
	Shelf Life (Unit)	2 Year(s)Store at 25°C excursions permitted to 15-30°C							
	For generic drugs (me-too Status)	Ertuvia-M 2.5/1000mg Tablet by FEROZSONS							
	Pharmaceutical Group of (API)	Ertugliflozin (Sodium Glucose Cotransporter 2 (SGLT-2) Inhibitors) +Biguanides							
	Name, address of Manufacturing site:	Self Manufacturing							
	Name & address of API manufacturer								
	Detail of stability batches of drug product	stability data of batches 2.5mg/1000 mg EMBt SB1-22, 2.5mg/1000 mg EMBt SB2-22,2.5mg/1000 mg EMBt SB3-22 is submitted by the firm.							
	Documents for the procurement of API with approval from DRAP (in case of Import)	Submitted							
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP performed against the Ertuvia-M 2.5/1000mg Tablet by FEROZSONS							
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data conducted under zone-IV condition is submitted.							
	The status in reference regulatory authorities	Segluromet 2.5/1000mg Tablet by Merck Sharp & Dohme LLC USFDA Approved							
	GMP status of the firm	GMP Certificate dated 30-06-2022 submitted.							
	Evidence of approval of manufacturing facility	GMP Certificate dated 30-06-2022 ,mentioned that firm has tablet (general) section.							
Evaluation Remarks									
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	Decision	
	Approved	
710	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(47Q-2TS-Q4GD, 2024-04-29)
	Detail of Fee Submitted	30000.0, 2024-04-17,
	The proposed proprietary name / brand name	Ibuprofen-P 500mg+150mg Tablet
	Label Claim	Each Film Coated tablet contains: Paracetamol 500mg Ibuprofen.....150mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x7's, 1x10's, 2x10'-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at cool &dry place below 30
	For generic drugs (me-too Status)	Provas Duo Tablet 500mg/150mg M/s SAMI Pharmaceuticals Pvt. Ltd. Registration # 108837
	Pharmacotherapeutic Group of (API)	Paracetamol (Analgesic and Antipyretics) Ibuprofen (Non-steroidal Anti-inflammatory Drug)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CarryforPharmaceuticals(Pvt)Ltd M/s PlotNo.E-81,NorthwestIndustrial Zone, Port Qasim,Karachi,Citi Pharma Ltd. Address 3 Km Head Balloki Road, Phool Nagar, Kasur -55050 Punjab
	Detail of stability batches of drug product	Stability data of batches TIK001 TIK002 TIK003 (2500 tablet each) submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	NA since both API has been procured locally from Carryfor Pharmaceuticals (Pvt) Limited, Karachi & M/s. Citi Pharma Ltd. 588-Q, Johar Town,Lahore
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP performed against the Comparator drug Product Easolief Duo 500mg/150mg Filmcoated Tablets
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone-IV is submitted by the firm.
	The status in reference regulatory authorities	Easolief Duo 500mg/150mg Film-coated Tablets M/s Clonmel Healthcare Ltd Waterford Road Clonmel, Co.
	GMP status of the firm	GMP certificate dated 14-11-2023 is submitted by the firm
	Evidence of approval of manufacturing facility	GMP certificate dated 14-11-2023 mentioned that firm has tablet (General) section.
	Evaluation Remarks	

	Decision	
	Approved	
711	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	(HH2-BG8-TB8H, 2024-03-19)
	Detail of Fee Submitted	75000.0, 75000.0 2023-12-05, 2024-01-16
	The proposed proprietary name / brand name	Memorin 21mg ER Capsule
	Label Claim	Each capsule contains : 131.25mg of Memantine HCl 16% SR pellets equivalent to.....21mg of Memantine HCl
	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 oC
	For generic drugs (me-too Status)	None
	Pharmacotherapeutic Group of (API)	NMDA receptor antagonist.
	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	Stability batches (TF-01, TF-02,TF-03) 1000 Tablets each is submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	clearance certificate and form-6 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP is performed against the reference product Memantine HCl Extended Release Capsules 21mg of M/s. Amneal.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone -IV condition is submitted
	The status in reference regulatory authorities	Food and Drug Administration (FDA) USA
	GMP status of the firm	GMP certificate dated 26, june,2023 is submitted by the firm
	Evidence of approval of manufacturing facility	GMP certificate dated 26th june,2023 mentioned that firm has tablet (general) section
Evaluation Remarks		
	Sr.no.	Shortcomings
	1.	A prominent unidentified peak is consistently observed between 2.0–2.5 minutes in all sample chromatograms submitted in the verification report. Kindly clarify and appropriately label this peak, as it appears in all sample
		Response of the Firm
		Firm replied that the peak is identified as originating from placebo pellets. It is consistently present in all samples, does not interfere with the API peak, and has no impact on assay results.

	chromatograms and is not present in the chromatograms of the blank, diluent, or mobile phase, confirming that it does not originate from any of these sources.	
2.	As the innovator's manufacturing technique involves the use of sugar spheres as inert cores, which are subsequently coated with a drug layer followed by an extended-release coating, kindly submit a brief description of the manufacturing process for the sustained-release pellets of Memantine HCl to verify the pelletization technique employed in your product.	The Memantine HCl 16% extended-release pellets are procured as a finished intermediate from Pellets Pharma, India. As per the submitted DMF, the manufacturing technique involves layering the drug and extended-release coating over inert cores, similar to the innovator's approach. The process description from the DMF is provided as Annexure I for verification.
3.	The sample preparation procedure for assay begins with the instruction to "Weigh and transfer 180 mg into a 50 mL volumetric flask," without specifying the source of the material (e.g., tablets, capsule content, or pellets). Kindly clarify whether this weight corresponds to capsule content, or a specific amount of pellets. Additionally, confirm whether this amount is equivalent to the label claim of the active ingredient.	The 180 mg sample weight mentioned in the assay method refers specifically to the weight of extended-release pellets filled into the capsules. This amount corresponds to the labeled strength of the active ingredient. The updated and clarified assay method, specifying pellet weight and equivalency to label claim, is attached.
4.	Justify for not including the content uniformity test in the specification of finished product, when the innovator include the test in the specification of drug product.	Content uniformity testing has been performed at the finished product stage; however, it was unintentionally omitted from the initially submitted specifications. This oversight has been rectified, and the updated analytical specifications now include the content uniformity test in accordance with pharmacopoeial requirements. The revised specification document is attached
5.	As per the USFDA recommendation, the dissolution sampling time points for Memantine extended-release capsules are 1, 2, 3, 4, 6, 8, 10, and 12 hours. However, in your application, only 1, 4, 8, and 12-hour time points have been considered. Kindly justify the selection of these limited sampling points and provide supporting evidence or references from the innovator product literature to substantiate your approach.	The dissolution sampling points of 1, 4, 8, and 12 hours were selected based on the method provided by the pellet vendor (Annexure III) and aligned with the dissolution behavior of the product. Literature on the innovator's product and internal comparative data demonstrate a gradual and sustained drug release pattern, with minimal changes between adjacent time points. Therefore, the reduced sampling schedule is considered scientifically justified and sufficient for establishing a robust dissolution profile.
6.	As per the sample preparation procedure described in the assay method for the drug product, a sample weight of 180 mg has been specified. However, the raw data	The sample weights recorded in raw data sheets (174–175 mg) are within the acceptable $\pm 5\%$ tolerance range (171–189 mg) from the nominal 180 mg specified in the assay method. Due to the particulate and non-uniform nature of the

	sheets of stability study indicate that sample weights of 174 mg or 175 mg were actually used. Kindly provide clarification regarding this discrepancy.	extended-release pellets, slight variations in weighed quantities are practically unavoidable. Each weight was accurately recorded, and calculations were adjusted accordingly to maintain assay precision and result reliability.
7.	Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	he firm has submitted the commercial invoice, Form 6, and Air Waybill (AWB) as documentary evidence of API procurement (Annexure IV). The specific lot number of the API used in all manufactured batches, FRD2301001/MEM, is clearly mentioned in the Certificate of Analysis
Decision		
Approved		
712	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	(NRR-7XE-A5WD, 2024-03-21)
	Detail of Fee Submitted	75000.0, 2024-03-04,
	The proposed proprietary name / brand name	Metolaz 2.5mg Tablet
	Label Claim	Each tablet contains: Metolazone.....2.5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C in a cool and dry place
	For generic drugs (me-too Status)	Nil
	Pharmacotherapeutic Group of (API)	Thiazide diuretic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. Azico Biophore India. Address: Plot No.40/A, Sy Nos:13,15,16,51,52 & 182, Jawaharlal Nehru Pharma City, Thanam (V), Parawada Mandal Visakhapatnam District- 531 021, Andhra Pradesh, India.
	Detail of stability batches of drug product	Stability data of batches (TF-02,TF-03,TF-04)500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	DRAP attested commercial invoice attached.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP is performed against Zaroxolyn 2.5mg Tablet UCB, Inc.

Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		Stability data as per zone-IV is submitted by the firm.
The status in reference regulatory authorities		Food & Drug Administration-FDA
GMP status of the firm		GMP certificate dated 26th June,2023 is submitted by the firm.
Evidence of approval of manufacturing facility		GMP certificate dated 26th June,2023 mentioned that firm has tablet (general section).
Evaluation Remarks		
Sr.no.	Shortcomings	Response of the Firm
1.	The submitted stability data for the drug substance is not in accordance with Zone IV conditions. Therefore, the applicants advised to provide stability data conducted under Zone TV long-term storage conditions (30°C ± 2°C / 75% RH ± 5% RH).	Stability data for the drug substance in accordance with Zone IV conditions is attached
2.	In compliance with Notification No. 14-1/2022-PEC dated 16th January 2023 issued by DRAP, the applicant is requested to submit an image, picture, or snapshot of the innovator/reference/comparator product used for pharmaceutical equivalence and comparative dissolution profile studies. This is particularly important as the innovator brand mentioned in the relevant section has been discontinued in the USFDA database.	The referenced innovator product has indeed been discontinued from the USFDA database. However, it is important to clarify that this discontinuation was not due to safety or health-related concerns. Based on available information, the discontinuation appears to be for non-clinical reasons or marketing or commercial strategy. Furthermore, at the time we submitted our application, the product was still listed in the USFDA database and was available. The discontinuation occurred afterward. In support of our application, we are providing a reference to another approved Regulatory Authority where the innovator product is registered. Unfortunately, we are currently unable to provide the image of the specific strength pack used during the studies, as the empty pack was discarded by mistake during the testing phase. However, as supporting evidence, we are attaching a photograph of the 10 mg strength pack which serves to confirm that all three strengths of the innovator were procured simultaneously and used for the comparative studies.
3.	Provide a justification for not including the content uniformity test in the finished product specification, considering that USP General Chapter <905> 'Uniformity of Dosage Units' recommends performing the content uniformity test for formulations containing less than 25 mg of drug substance per dosage unit.	It was mistakenly missed in finished product specifications. But we have performed the content uniformity testing as per compendial requirements. Updated and corrected method attached for your reference and review.
4.	The USP monograph for Metolazone Tablets recommends using a 4.6 mm × 15 cm, 5-µm L7 column for dissolution testing. However, as evident from the raw data sheets, the firm used a C18 column	The column was used as per specification and compendial requirements verified by column usage log but there is transcription error while preparing the raw data sheet. Specs. Attached as Annexure IV

	(L1) while performing dissolution testing during the stability study. Clarification is required regarding the use of a column that does not align with the monograph specifications.	
5.	Valid GMP certificate/DML of drug substance manufacturer shall be submitted issued by relevant regulatory authority of country of origin	Valid GMP certificate/DML of drug substance manufacturer shall be submitted issued by relevant regulatory authority of country of origin.
Decision		
Deferred		
Deferred for on-site inspection of the firm for the authenticity/verification of submitted pharmaceutical development data and stability data.		
713	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	(SUN-AB1-N7WZ, 2024-03-14)
	Detail of Fee Submitted	30000.0, 2024-03-04,
	The proposed proprietary name / brand name	Metolaz 5mg Tablet
	Label Claim	Each tablet contains: Metolazone.....5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C in a cool and dry place
	For generic drugs (me-too Status)	Metxone Tablets 5mg, Reg. No. 090699, Manufactured by: Genome Pharmaceuticals (Pvt.) Ltd
	Pharmacotherapeutic Group of (API)	Thiazide diuretic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. Azico Biophore India. Address: Plot No.40/A, Sy Nos:13,15,16,51,52 & 182, Jawaharlal Nehru Pharma City, Thanam (V), Parawada Mandal Visakhapatnam District- 531 021, Andhra Pradesh, India.
	Detail of stability batches of drug product	Stability data of batches (TF-01,TF-02,TF-03) 500 TABLET EACH.
	Documents for the procurement of API with approval from DRAP (in case of Import)	DRAP attested invoice submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP is performed against Zaroxolyn 5mg Tablet UCB, Inc.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone-IV is submitted by the firm.
	The status in reference regulatory authorities	Food & Drug Administration-FDA
	GMP status of the firm	GMP certificate dated 26th June,2023 is submitted by the firm.

Evidence of approval of manufacturing facility		GMP certificate dated 26th June,2023 mentioned that firm has tablet (general section).
Evaluation Remarks		
Sr.no.	Shortcomings	Response of the Firm
1.	The submitted stability data for the drug substance is not in accordance with Zone IV conditions. Therefore, the applicants advised to provide stability data conducted under Zone TV long-term storage conditions (30°C ± 2°C / 75% RH ± 5% RH).	Stability data for the drug substance in accordance with Zone IV conditions is attached
2.	In compliance with Notification No. 14-1/2022-PEC dated 16th January 2023 issued by DRAP, the applicant is requested to submit an image, picture, or snapshot of the innovator/reference/comparator product used for pharmaceutical equivalence and comparative dissolution profile studies. This is particularly important as the innovator brand mentioned in the relevant section has been discontinued in the USFDA database.	The referenced innovator product has indeed been discontinued from the USFDA database. However, it is important to clarify that this discontinuation was not due to safety or health-related concerns. Based on available information, the discontinuation appears to be for non-clinical reasons or marketing or commercial strategy. Furthermore, at the time we submitted our application, the product was still listed in the USFDA database and was available. The discontinuation occurred afterward. In support of our application, we are providing a reference to another approved Regulatory Authority where the innovator product is registered. Unfortunately, we are currently unable to provide the image of the specific strength pack used during the studies, as the empty pack was discarded by mistake during the testing phase. However, as supporting evidence, we are attaching a photograph of the 10 mg strength pack which serves to confirm that all three strengths of the innovator were procured simultaneously and used for the comparative studies.
3.	Provide a justification for not including the content uniformity test in the finished product specification, considering that USP General Chapter <905> 'Uniformity of Dosage Units' recommends performing the content uniformity test for formulations containing less than 25 mg of drug substance per dosage unit.	It was mistakenly missed in finished product specifications. But we have performed the content uniformity testing as per compendial requirements. Updated and corrected method attached for your reference and review.
4.	The USP monograph for Metolazone Tablets recommends using a 4.6 mm × 15 cm, 5-µm L7 column for dissolution testing. However, as evident from the raw data sheets, the firm used a C18 column (L1) while performing dissolution testing during the stability study. Clarification is required regarding the use of a column that does not align with the monograph specifications.	The column was used as per specification and compendial requirements verified by column usage log but there is transcription error while preparing the raw data sheet. Specs. Attached as Annexure IV

	5.	Valid GMP certificate/DML of drug substance manufacturer shall be submitted issued by relevant regulatory authority of country of origin	Valid GMP certificate/DML of drug substance manufacturer shall be submitted issued by relevant regulatory authority of country of origin.
	Decision		
	Deferred		
	Deferred for on-site inspection of the firm for the authenticity/verification of submitted pharmaceutical development data and stability data.		
714	Case Category		Routine (Saima Hussain)
	Name, address of Applicant.		Neutro Pharma (Pvt.) Ltd., 9.5-Km, Sheikhpura Road, Lahore (000576)
	Application Form Dy. No / Tracking ID & date of submission		(7M6-Z4W-72W1, 2024-04-23)
	Detail of Fee Submitted		30000.0, 2024-03-04,
	The proposed proprietary name / brand name		Ertuneu-Met 7.5/1000mg Tablet
	Label Claim		Each film coated tablet contains: Ertugliflozin L-Pyroglutamic acid Eq. to Ertugliflozin.....7.5 mg Metformin HCl.....1000mg
	Reference to Finished product specifications		As per Innovators Specification
	Proposed Pack Size		14s, 28s, 30s-As per SRO
	Shelf Life (Unit)		2 Year(s)Store at 25°C (77°F); excursions permitted to 15-30°C
	For generic drugs (me-too Status)		Ertuvia-M 7.5/1000mg Tablet by FEROSONS
	Pharmacotherapeutic Group of (API)		Ertugliflozin (Sodium Glucose Cotransporter 2 (SGLT-2) Inhibitors) +Biguanides
	Name, address of Manufacturing site:		Self Manufacturing
	Name & address of API manufacturer		
	Detail of stability batches of drug product		Stability data of batches EMDt SB1-22,EMDt SB2-22,EMDt SB3-22 (1500 TABLETS Each)
	Documents for the procurement of API with approval from DRAP (in case of Import)		Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile		PE and CDP performed against the Ertuvia-M 7.5/1000mg Tablet by FEROSONS
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		Stability data conducted under zone-IV condition is submitted.
	The status in reference regulatory authorities		Segluromet 7.5/1000mg Tablet by Merck Sharp & Dohme LLC USFDA Approved
	GMP status of the firm		GMP Certificate dated 30-06-2022 submitted.
	Evidence of approval of manufacturing facility		GMP Certificate dated 30-06-2022 ,mentioned that firm has tablet (general) section.
	Evaluation Remarks		
	Sr.no.	Shortcoming	Response of the Firm
	1.	Provide a justification for selecting pH 4.5 acetate buffer as the dissolution medium, whereas the innovator recommends	Selection of dissolution medium buffer is as per USFDA quality assessment report and the chromatographic conditions are

		phosphate buffer pH 6.8 for dissolution testing. Additionally, the innovator specifies distinct dissolution conditions for each active ingredient and performs HPLC determination of drug release at different wavelengths than those used in your method. Justify the rationale for not adopting the same dissolution and chromatographic conditions as those established in the review literature of the innovator product.	developed inhouse as per guidelines and validated.
2.		Clarify the following: the chromatograms attached with the stability data are neither properly labeled nor accompanied by a table indicating which API elutes between 3–4 minutes and which one elutes around 5–7 minutes. Furthermore, in some chromatograms, the peaks are inconsistently labeled — in certain cases, the first eluting peak is identified as metformin and the later one as ertugliflozin, while in others the labeling is reversed. Therefore, clarification is required regarding the consistent retention time of each API in both the dissolution test and assay methods	Firm replied that, sometimes Software settings not capable of matching peaks to known compounds and automatically labeling them. Sensitivity of the detection method is low or if the concentration of the analyte is below the detection threshold, it might be difficult to confidently label a peak as a specific compound. However, RT of the Peaks are within the window. Eluting First large Peak representing Metformin and Second small one is Ertugliflozin. Change of Retention time in Assay and Dissolution Chromatograms due to change in chromatographic conditions in analytical method like: Flow rate, diluent. Moreover, Product test method is attached.
Decision			
Deferred			
Deferred for on-site inspection of the firm for the authenticity/verification of submitted pharmaceutical development data and stability data.			
715	Case Category	Routine (Saima Hussain)	
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)	
	Application Form Dy. No / Tracking ID & date of submission	(WTQ-MX1-BB52, 2024-03-19)	
	Detail of Fee Submitted	30000.0, 45000.0 2024-01-26, 2024-02-27	
	The proposed proprietary name / brand name	Noxamit 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 at room temperature below 30	
For generic drugs (me-too Status)	NA	
Pharmacotherapeutic Group of (API)	Posaconazole belongs to a class of drugs Azole antifungals that inhibits the enzyme lanosterol 14α-demethylase (CYP51), which catalyses an essential step in ergosterol biosynthesis.	
Name, address of Manufacturing site:	Self Manufacturing	
Name & address of API manufacturer		
Detail of stability batches of drug product	Stability data of batches TCN001 TCN002 TCN003 4.5 liters each is submitted by the firm.	
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted by the firm.	
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP performed against the comparator product posaconazole 200mg/5ml oral suspension	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone iv condition is submitted	
The status in reference regulatory authorities	Posaconazole 40mg/ml oral suspension by Thornton & Ross Ltd. (trading as STADA)Linthwaite,Huddersfie	
GMP status of the firm	GMP Certificate dated 20-04-2023 is submitted by the firm.	
Evidence of approval of manufacturing facility	Issuance of DML letter dated 7th February,2014 mentioned that firm has tablet (general) section.	
Evaluation Remarks		
Noxafil is indicated for the prophylaxis of invasive Aspergillus and Candida infections in patients who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graftversus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy.Noxafil oral suspension is indicated for the treatment of oropharyngeal candidiasis (OPC), including OPC refractory (rOPC) to itraconazole and/or fluconazole in adult and pediatric patients aged 13 years and older.		
Sr.no.	Shortcomings	Response of the Firm
1.	Since the innovator recommends the use of chiral HPLC for the assay of the drug substance due to the presence of four chiral centers in Posaconazole and its synthesis as a single (R,R,S,S) enantiomer, please justify why a chiral HPLC method was not adopted for the assay of the drug substance by both the drug substance and drug product manufacturers.	Firm replied that The Chiral HPLC in Assay test is recommended due to the polymorphism of the drug substance with presence of 4 chiral centers. It is submitted that the polymorphic form -I has been extensively characterized by the drug substance manufacturer by applying advanced analytical techniques i.e., Elemental analysis, Infrared, Ultraviolet spectroscopy, Nuclear magnetic resonance, High resolution mass spectrometry, Differential scanning Calorimeter, thermogravimetric analysis, X-Ray powder diffraction, specific rotation & single X-ray diffraction. By applying the aforementioned techniques, the elucidation of structure of drug substance was satisfactorily established as Polymorphic form I and the details of which have been provided in section

		3.2.S.3.1. Due to this extensive characterization studies the routine Assay analysis has been performed in conventional manner, also test of specific optical rotation in drug substance specifications applies a check on the structural characterization of drug substance.
2.	Considering that the drug substance is classified as a BCS Class II compound and, as per the innovator's data, exhibits extremely low solubility in aqueous media at pH values above 4, please provide a scientific justification for the results presented in the Comparative Dissolution Profile (CDP) report, which demonstrate more than 80% drug release within 15 minutes across all three physiological medias. This rapid dissolution appears inconsistent with the known solubility characteristics of the API.	Firm in their reply clarify that Although Posaconazole is a BCS Class II compound with low aqueous solubility above pH 4, there is no specific regulatory guidance available for its Comparative Dissolution Profile (CDP). The only available reference is the US FDA Dissolution Database, which recommends 0.3% SLS in 900 mL as the dissolution medium. To ensure proper drug solubilization and discriminatory testing across physiological pH conditions, we used media containing surfactants (e.g., SLS) in all three pH conditions during the CDP study. This enhanced solubility of the API, resulting in >80% drug release within 15 minutes. The observed rapid dissolution is therefore attributed to the use of surfactant-containing media and does not contradict the known solubility characteristics of Posaconazole.
3.	The assay procedure described in the relevant section indicates that the final concentration of each solution used in the assay is 1 mg/mL, except for the system suitability standard, which is prepared at 0.001 mg/mL of each standard. However, during the assay validation study of drug substance performed by drug product manufacturer, the target or 100% test concentration was set at 10 mg/mL. Please justify the rationale for selecting 10 mg/mL as the target concentration for assay method validation. Additionally, the validation data include system suitability results only for the Posaconazole reference standard, whereas the procedure outlined also involves the use of PO-D3 and PO-D7 reference standards. Please clarify why these additional standards were not included in the validation study.	Firm replied that The correct target concentration used in the assay method and its validation is 1 mg/mL, as mentioned in the main assay procedure. The reference to 10 mg/mL in the assay validation study was a typographical or overwrite error, and does not reflect the actual test conditions. All validation parameters, including accuracy, precision, and linearity, were performed using the correct concentration of 1 mg/mL. The revised and corrected documentation has been provided for clarity.
4.	The reference standards used (Posaconazole Form-I, PO-D3, and PO-D7) are mentioned in section 3.2.S.5, please provide the Certificate of Analysis (CoA) for each reference standard supplied by the drug substance	The reference standards Posaconazole Form-I, PO-D3, and PO-D7 mentioned in section 3.2.S.5 are qualified and used specifically for related substances testing, not for assay purposes. For assay of the drug substance, a separately qualified primary reference standard

	manufacturer to support their qualification for use in the assay of the drug substance.	is used, and its Certificate of Analysis (CoA), including full qualification details, is already provided in section 3.2.S.5. Therefore, the use of PO-D3 and PO-D7 does not require additional qualification for assay, as they are not intended for that purpose.
5.	According to literature of innovator product, the dissolution rate of Posaconazole is enhanced by micronization at the end of the synthesis process, with further particle size reduction occurring during the manufacture of the finished product. However, the particle size of the drug substance is not analyzed during quality analysis, either by the drug substance manufacturer or the drug product manufacturer. Additionally, the manufacturing process for the suspension dosage form does not include any particle size reduction steps, nor is particle size included in the finished product specifications. This is in contrast to the innovator, who includes particle size testing in the specifications for both the drug substance and the drug product. Can you clarify why particle size control and testing are not considered necessary in this case, despite its known impact on dissolution.	Firm clarify that Although particle size is known to influence the dissolution of Posaconazole, routine particle size testing is not included in our specifications because the API used is pre-micronized and consistently meets internal particle size criteria verified during process validation. In our product, we incorporate a granulation process at the initial stage of manufacturing based on referenced practices aligned with the innovator's approach which ensures uniform dispersion of the micronized API. This process, along with high-shear mixing and homogenization, contributes to maintaining consistent particle distribution without requiring further particle size reduction. Most importantly, dissolution testing validated and included in the finished product specification serves as a critical quality attribute and an effective surrogate to detect any variation in particle size that might affect product performance. Therefore, particle size testing is not deemed necessary as a release specification for either the drug substance or the drug product.
6.	Justify for not including the test of sodium benzoate content (HPLC) and viscosity in the finished product specification of drug product since this test is included in the specification of innovator product.	Firm replied that although sodium benzoate content (by HPLC) and viscosity are not included in our drug product specification because their control is ensured through alternative validated approaches. Sodium benzoate is added at a fixed concentration during compounding and its effectiveness as a preservative is confirmed through microbial limit tests, including TAMC and TYMC, which are routinely performed and comply with pharmacopeial limits. This ensures the preservative system is adequate throughout the product's shelf life. Similarly, viscosity is controlled through the manufacturing process parameters and excipient grades (such as suspending agents), and batch-to-batch consistency is demonstrated through uniform appearance, dispersibility, and pourability of the suspension. As these attributes are consistently within acceptable ranges and critical quality attributes such as dissolution and assay are met, routine testing for sodium benzoate content and viscosity in the finished

		product specification is not considered necessary.
7.	Considering that the dissolution results consistently show more than 90% drug release at the 45-minute time point throughout the submitted stability studies, and in light of the USFDA's recommended dissolution criteria in the dissolution database, please justify the rationale for adopting a broader acceptance limit of 'Not Less Than 75% (Q) in 45 minutes' for the finished product.	Firm in their reply stated that, "The dissolution limit of 'NLT 75% in 45 minutes' is based on the general dissolution criteria in the Pharmacopoeia, with the 45-minute time point taken from the USFDA Dissolution Database for Posaconazole. Although our product consistently releases over 90% drug at 45 minutes, the broader limit ensures regulatory compliance, accommodates normal batch variability, and maintains product quality and performance.
8.	In-use stability studies of opened bottles are required to be submitted along with proposed in-use storage statement and in-use shelf-life.	As the product is a ready-to-use suspension (not a powder for reconstitution), in-use stability is less critical in that and microbial control is ensured through TAMC and TYMC testing in the finished product specifications. The proposed in-use shelf-life and storage conditions will follow general guidance for oral suspensions (e.g., 28 days at below 25°C).
9.	Provide copy of Batch Manufacturing Record (BMR) of all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.	Submitted
10.	Approval of API/DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted

Decision

Deferred

The Registration Board decided to defer the case to provide justification for not adopting the chiral HPLC technique for the assay of the drug substance, as the innovator product recommends the use of chiral HPLC for assay due to the presence of four chiral centers in Posaconazole.

716	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	(7P6-YEZ-RNHA, 2024-04-23)
	Detail of Fee Submitted	75000.0, 2024-02-12,
	The proposed proprietary name / brand name	Bempido Plus
	Label Claim	Each film coated tablet contains: Bempedoic acid.....180mg Ezetimibe.....10mg
	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 oC
	For generic drugs (me-too Status)	None

Pharmacotherapeutic Group of (API)	combination of bempedoic acid, an adenosine triphosphate citrate lyase (ACL) inhibitor, and ezetimibe, a dietary cholesterol absorption inhibitor	
Name, address of Manufacturing site:	Self Manufacturing	
Name & address of API manufacturer	Glenmark Life Sciences Limited Address: Plot No. 141-143/160-165/170-172, Chandramouli Sahakari Audhogik Vasahat Maryadit, Pune-Hyderabad Highway, Mohol, Dist. Solapur, 413213, Maharashtra, India, Metrochem API Private Limited Address: 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	Stability data of batches (TF01,TF02,TF03)500 Tablets of each	
Documents for the procurement of API with approval from DRAP (in case of Import)	Form-6 is submitted.	
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP performed against the innovator product Nexlizet 180/10mg tablet Manufacturer Esperion Therapeutics, Inc.	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone-IV conditions is submitted	
The status in reference regulatory authorities	Food and Drug Administration (FDA) USA	
GMP status of the firm	GMP certificate dated 26-06-2023 is submitted by the firm.	
Evidence of approval of manufacturing facility	GMP certificate dated 26-06-2023 mentioned that firm has tablet (general) section	
Evaluation Remarks		
Sr.no.	Shortcomings	Response of the Firm
1.	Submit specification and analytical procedure used for analysis of both drug substances by drug product manufacturer.	Firm submit the specification and detailed analytical procedure of drug substance by drug product manufacturer.
2.	Submit analytical method verification report of both drug substance performed by the drug product manufacturer.	Firm submit the analytical method verification report of both drug substance performed by the drug product manufacturer.
3.	Justify for not including the content uniformity test in the specification of finished product when the innovator product include the test in the finished product specification.	Firm submit the revised finished product specification including the content uniformity test.
4.	According to the innovator's review literature, Ezetimibe is reported to be soluble at low pH (e.g., pH 1.2) and insoluble at pH above 4.0, and practically insoluble in water. In light of this, kindly clarify the observed 0%	Ezetimibe is a BCS Class II drug, characterized by poor aqueous solubility and high permeability, with limited dissolution under practical test conditions despite some solubility at low pH (e.g., pH 1.2). Its lipophilic nature and

	drug release of Ezetimibe at low pH (pH 1.2) up to 45 minutes, despite its claimed solubility under the acidic condition.	hydrophobic surface result in slow wettability and negligible drug release in acidic media without solubilizing agents. This explains the 0% release observed at 45 minutes in pH 1.2 medium. To address this, the FDA dissolution database recommends using buffered media with surfactants, such as pH 4.5 acetate buffer with 0.45% SLS, which enhances solubilization and mimics sink conditions. This medium has been adopted in the current method to ensure discriminatory and biorelevant dissolution testing.
5.	Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Firm submitted the Form-6 only.

Decision

Approved

717	Case Category	New Section (Saima Hussain)
	Name, address of Applicant.	Horizon Healthcare (pvt.) ltd. 35-A Small Industrial Estate - Taxila (000856)
	Application Form Dy. No / Tracking ID & date of submission	(9JM-1X3-D7DD, 2024-08-23)
	Detail of Fee Submitted	75000.0, 2024-07-26,
	The proposed proprietary name / brand name	Salbutin 2.5mg/2.5ml
	Label Claim	Each single 2.5 mL unit-dose ampoule contains: 2.5 mg Salbutamol as sulphate (As per BP's Specs.)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C in Cool & Dry Place.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Salbutamol is a beta-2 adrenergic receptor agonist
	Name, address of Manufacturing site:	Self Manufacturing

Name & address of API manufacturer	VAMSI LABS LTD. An ISO-9001-2015 and WHO-GMP Company A-14/15, MIDC Area, Chincholi, Solapur-413255, Maharashtra (India),	
Detail of stability batches of drug product	Stability data of batches (SNL001, SNL002) 5000 container each	
Documents for the procurement of API with approval from DRAP (in case of Import)	Submitted	
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE is performed against the reference product salbutamol nebuliser solution Accord UK	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone iv condition is submitted	
The status in reference regulatory authorities	Registered drug by TGA as VENTOLIN NEBULES salbutamol 2.5mg/2.5mL (as sulfate) inhalation solution, for oral inhalation use.	
GMP status of the firm	GMP certificate dated 17th August,2022 is submitted by the firm.	
Evidence of approval of manufacturing facility	Grant of additional section letter dated 25th October,2023 mentioned that firm has grant solution for inhalation section.	
Evaluation Remarks		
Sr.no.	Shortcomings	Response of the Firm
1.	Justify for not including the Boron test while performing the quality analysis of drug substance by the drug product manufacturer since the test is recommended in BP monograph of Salbutamol sulphate.	We have performed the Boron test during the quality analysis of drug substance. But it was not added in SAP. The updated standard analytical procedure and specifications of salbutamol sulfate is attached.
2.	As the applied formulation claims compliance with the BP, justify the use of a UV spectrophotometric method for assay of drug product instead of the HPLC method specified in the BP monograph for salbutamol sulfate nebulizer solution.	We have conducted the assay test for the salbutamol drug product in accordance with the British Pharmacopoeia monograph, utilizing a UV spectrophotometer for the analysis. The B.P. monograph is attached here.
3.	Provide a detailed justification explaining how sterility of the final product is assured without including standard sterilization methods such as sterile filtration, aseptic processing, or terminal sterilization in the manufacturing process of the applied product.	The sterility of the salbutamol inhalation solution is ensured through a validated sterilizing filtration process using sequential 0.45-micron and 0.22-micron filters, which effectively remove microbial contaminants. This process is conducted in a controlled environment with closed systems to prevent post-filtration contamination. Final product testing confirms microbiological quality, ensuring compliance with pharmacopeial standards despite the absence of terminal sterilization.
4.	Provide a scientific justification for not including the bacterial endotoxin test in the finished product specification of sterile inhalation solution.	We have performed the product quality tests in accordance with the general chapter <5> of the United States Pharmacopeia (USP), titled 'Inhalation and Nasal Drug Products—General

		Information and Product Quality Tests'. As per this chapter, the bacterial endotoxin test is not recommended for these types of products.
Decision		
Approved		
Registration Board noted the fact that current title of the section i.e., "Solution for Inhalation" has been granted for the manufacturing facilities intended for the production of anaesthetic solutions while the instant formulation is not intended for anaesthesia purpose, hence Board decided that registration letter will be issued after revision of title of the section of "Solution for Inhalation" from Licensing Division. Furthermore, the firm is required to submit documentary evidence confirming the availability of a sterile manufacturing facility appropriate for the production of inhalation solutions.		
718	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	Bosch Pharmaceuticals (Pvt) Ltd. Plot No. 221-223, Sector-23, Korangi Industrial Area (000350)
	Application Form Dy. No / Tracking ID & date of submission	(9SZ-D5U-61J1, 2024-01-15)
	Detail of Fee Submitted	75000.0, 2023-02-28,
	The proposed proprietary name / brand name	Fortazim Injection 2g
	Label Claim	Each vial contains: Ceftazidime USP 2.0g (as Ceftazidime Pentahydrate)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 20°C - 25°C. Protect from light.
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	Third Generation Cephalosporin Antibiotic. ATC code: J01DD02
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	QILU Antibiotics Pharamceutical CO., LTD. Address: No 849 Dongjia Town, Licheng District, Jinan City, 250105 Shandong China
	Detail of stability batches of drug product	three batches (TR-FZIM-02 , TR-FZIM-03 , TR-FZIM-04) 400 vials
	Documents for the procurement of API with approval from DRAP (in case of Import)	submitted clearance certificate
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE against the reference product Tazicef Injection 2g M/s. Sandoz GmbH for Hospira (USA)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	submitted as per zone-iv condition
	The status in reference regulatory authorities	Food and Drug Administration (FDA)
	GMP status of the firm	GMP certificate dated 13th June,2022 and valid for 2 years.

Evidence of approval of manufacturing facility		verified from GMP certificate dated 13th June, 2022, mentioning that the firm has dry powder Cephalosporin Injectable section.
Evaluation Remarks		
Sr.no.	Shortcoming	Response of the Firm
1.	Submit the specification and detailed analytical procedure of drug substance by drug product manufacturer.	Firm submitted the specification and detailed analytical procedure of drug substance that has actually been used by the drug product manufacturer for the analysis of drug substance.
2.	Provide analytical method validation report performed by drug product manufacturer.	Firm submitted the assay verification report of drug substance performed by drug product manufacturer.
Decision		
Approved		
719	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(AMU-8XB-RX7Y, 2024-04-30)
	Detail of Fee Submitted	30000.0, 2024-04-17,
	The proposed proprietary name / brand name	Ibuprofen-P 500mg+200mg Tablet
	Label Claim	Each Film Coated tablet contains: Paracetamol 500mg Ibuprofen.....200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x7's, 1x10's, 2x10'-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at cool &dry place below 30
	For generic drugs (me-too Status)	Provas Duo Tablet 500mg/200mg M/s SAMI Pharmaceuticals Pvt. Ltd. Registration # 108579
	Pharmacotherapeutic Group of (API)	Paracetamol (Analgesic and Antipyretics) Ibuprofen (Non-steroidal Anti-inflammatory Drug)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CarryforPharmaceuticals(Pvt)Ltd M/s PlotNo.E-81,NorthwestIndustrial Zone, Port Qasim,Karachi,Citi Pharma Ltd. Address 3 Km Head Balloki Road, Phool Nagar, Kasur -55050 Punjab
	Detail of stability batches of drug product	Stability data of batches TIJ001 TIJ002 TIJ003 (2500 tablet each) submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	NA since both API has been procured locally from Carryfor Pharmaceuticals (Pvt) Limited, Karachi & M/s. Citi Pharma Ltd. 588-Q, Johar Town,Lahore

	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP performed against the Comparator drug Product Nuromol Dual Action Pain Relief 200mg/500mg Tablet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone-IV is submitted by the firm.
	The status in reference regulatory authorities	Nuromol Dual Action Pain Relief 200mg/500mg tablets M/S Reckitt Benckiser Healthcare International
	GMP status of the firm	GMP certificate dated 14-11-2023 is submitted by the firm
	Evidence of approval of manufacturing facility	GMP certificate dated 14-11-2023 mentioned that firm has tablet (General) section.
	Evaluation Remarks	
	Decision	
	Approved	
720	Case Category	New Section (Saima Hussain)
	Name, address of Applicant.	Horizon Healthcare (pvt.) ltd. 35-A Small Industrial Estate - Taxila (000856)
	Application Form Dy. No / Tracking ID & date of submission	(DST-9DJ-1RWV, 2024-08-21)
	Detail of Fee Submitted	75000.0, 2024-07-26,
	The proposed proprietary name / brand name	Salbutin 5mg/2.5ml
	Label Claim	Each single 2.5 mL unit-dose ampoule contains: 5 mg Salbutamol as sulphate (As per BP's Specs.)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C in Cool & Dry Place.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Salbutamol is a beta-2 adrenergic receptor agonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	VAMSI LABS LTD. An ISO-9001-2015 and WHO-GMP Company A-14/15, MIDC Area, Chincholi, Solapur-413255, Maharashtra (India),
	Detail of stability batches of drug product	Stability data of batches (SNH001, SNH002) 5000 container each
	Documents for the procurement of API with approval from DRAP (in case of Import)	submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP is performed against the reference product salbutamol nebuliser solution Accord UK
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone iv condition is submitted
	The status in reference regulatory authorities	Registered drug by TGA as VENTOLIN NEBULES salbutamol 5mg/2.5mL (as sulfate) inhalation solution, for oral inhalation use.

GMP status of the firm	GMP certificate dated 17th August,2022 is submitted by the firm.
Evidence of approval of manufacturing facility	Grant of additional section letter dated 25th October,2023 mentioned that firm has grant solution for inhalation section.

Evaluation Remarks

Sr.no.	Shortcomings	Response of the Firm
1.	Justify for not including the Boron test while performing the quality analysis of drug substance by the drug product manufacturer since the test is recommended in BP monograph of Salbutamol sulphate.	We have performed the Boron test during the quality analysis of drug substance. But it was not added in SAP. The updated standard analytical procedure and specifications of salbutamol sulfate is attached.
2.	As the applied formulation claims compliance with the BP, justify the use of a UV spectrophotometric method for assay of drug product instead of the HPLC method specified in the BP monograph for salbutamol sulfate nebulizer solution.	We have conducted the assay test for the salbutamol drug product in accordance with the British Pharmacopoeia monograph, utilizing a UV spectrophotometer for the analysis. The B.P. monograph is attached here.
3.	Provide a detailed justification explaining how sterility of the final product is assured without including standard sterilization methods such as sterile filtration, aseptic processing, or terminal sterilization in the manufacturing process of the applied product.	The sterility of the salbutamol inhalation solution is ensured through a validated sterilizing filtration process using sequential 0.45-micron and 0.22-micron filters, which effectively remove microbial contaminants. This process is conducted in a controlled environment with closed systems to prevent post-filtration contamination. Final product testing confirms microbiological quality, ensuring compliance with pharmacopeial standards despite the absence of terminal sterilization.
4.	Provide a scientific justification for not including the bacterial endotoxin test in the finished product specification of sterile inhalation solution.	We have performed the product quality tests in accordance with the general chapter <5> of the United States Pharmacopeia (USP), titled 'Inhalation and Nasal Drug Products—General Information and Product Quality Tests'. As per this chapter, the bacterial endotoxin test is not recommended for these types of products.

Decision

Approved

Registration Board noted the fact that current title of the section i.e., "Solution for Inhalation" has been granted for the manufacturing facilities intended for the production of anaesthetic solutions while the instant formulation is not intended for

anaesthesia purpose, hence Board decided that registration letter will be issued after revision of title of the section of "Solution for Inhalation" from Licensing Division. Furthermore, the firm is required to submit documentary evidence confirming the availability of a sterile manufacturing facility appropriate for the production of inhalation solutions.

721	Case Category		Routine (Saima Hussain)
	Name, address of Applicant.		Nabiqasim Industries (Pvt) Ltd., 17/24, Korangi Industrial Area, Karachi. (000105)
	Application Form Dy. No / Tracking ID & date of submission		(H26-X1L-V8A3, 2024-03-15)
	Detail of Fee Submitted		30000.0, 2024-03-05,
	The proposed proprietary name / brand name		Rinitis 20mg Tablet
	Label Claim		Each tablet contains: Bilastine.....20mg (Innovator’s Specs.)
	Reference to Finished product specifications		As per Innovators Specification
	Proposed Pack Size		10’s, 20’s, 30’s, 40-As per SRO
	Shelf Life (Unit)		2 Year(s)Store below 30°C
	For generic drugs (me-too Status)		Yes
	Pharmacotherapeutic Group of (API)		Antihistamine
	Name, address of Manufacturing site:		Self Manufacturing
	Name & address of API manufacturer		Bilastine manufactured by Metrochem API Private Limited
	Detail of stability batches of drug product		Stability data of batches (760DS01,760DS02) 5000 TABLETS EACH
	Documents for the procurement of API with approval from DRAP (in case of Import)		Form-6 and clearance certificate is attached.
	Pharmaceutical Equivalence and Comparative Dissolution Profile		PE and CDP is submitted against the Innovator Ilaxten 20 mg tablets.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		Stability data as per zone-iv condition is submitted
	The status in reference regulatory authorities		EMA Approved (Drymol 20 mg tablet by Menarini International Operations Luxembourg S.A.)
	GMP status of the firm		GMP certificate dated 26-07-2023 is submitted by the firm.
	Evidence of approval of manufacturing facility		GMP certificate dated 26-07-2023 mentioned that firm has tablet (general) section.
Evaluation Remarks			
Sr.no.		Shortcomings	Response of the firm
1.		Based on the pH-dependent solubility data provided in the drug substance section, the API is classified as slightly soluble in 0.1N HCl (pH 1.2), with a solubility of 70 mg/10.0 mL. Despite this limited solubility, 0.1N HCl has been selected as the dissolution medium for the drug product. Additionally, the comparative dissolution profile (CDP) indicates that both the test and reference products demonstrate more than 90% drug release within 15 minutes across	The specification and test method for the dissolution of Bilastine tablets were developed based on USP <1092> and FDA guidance on dissolution testing for immediate-release solid oral dosage forms. Solubility data across physiological pH buffers demonstrate that Bilastine meets the FDA criteria for a highly soluble drug substance, as the dose/solubility ratio (20 mg/250 mL = 0.08 mg/mL) is less than the lowest observed solubility (0.1 mg/mL at pH 6.8). Among

	all three media (0.1N HCl, pH 4.5 acetate buffer, and pH 6.8 phosphate buffer). In this context, please provide a scientific justification for the selection of 0.1N HCl as the dissolution medium, including the criteria used for its choice . Further, elaborate on the role of formulation excipients in enhancing the solubility and dissolution of the API in this medium, and how these formulation strategies contribute to the observed high release profile.	the tested media, 0.1 N HCl provided the highest solubility, significantly greater than in pH 4.5 and pH 6.8 buffers, justifying its selection as the dissolution medium.
2.	Submit valid GMP certificate of API Manufacturer	Submit the valid GMP certificate of API Manufacturer.
3.	Submit updated stability data of drug product since you have submitted the dat of only three months.	Firm submit the stability data of 6th month in their reply.

Decision

Approved

722	Case Category	Routine (Saima Hussain)
	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	(LS9-WSB-1LTN, 2024-03-12)
	Detail of Fee Submitted	30000.0, 2023-12-07,
	The proposed proprietary name / brand name	ErtagMet
	Label Claim	Each film coated tablet contains: Ertugliflozin L-Pyroglutamic acid eq. to Ertugliflozin..... 2.5mg Metformin HCl 500mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	10's-As per SRO,14's-As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO,7's-As per SRO
	Shelf Life (Unit)	2 Year(s)Storage below 30°C.
	For generic drugs (me-too Status)	Ertuvi-M 2.5/500mg Tablet (Ferozesons Laboratories Ltd)
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Aarti Drugs Ltd,Chifeng Arker Pharmaceutical Technology Co., Ltd.

Detail of stability batches of drug product		Stability data of batches 2EMPD01/22, 2EMPD02/22,2EMPD03/22 (2409 tablet of each batch) is submitted
Documents for the procurement of API with approval from DRAP (in case of Import)		Clearance certificate(Metformin) and DRAP attested commercial invoice is attached.
Pharmaceutical Equivalence and Comparative Dissolution Profile		PE and CDP is performed against the comparator product Ertuvia-M 2.5/500mg Tablet.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		Stability data as per zone-iv condition is submitted.
The status in reference regulatory authorities		SEGLUROMET 2.5mg/500mg (USFDA Approved)
GMP status of the firm		GMP certificate dated 18th may,2023 is attached.
Evidence of approval of manufacturing facility		GMP certificate dated 18th May,2023 mentioned that firm has tablet (general) section.
Evaluation Remarks		
Sr.no.	Shortcoming	Response of the Firm
1.	The assay verification report, which includes chromatograms of both the blank (diluent: 70% methanol) and the sample, shows a peak at approximately 2.8 minutes in the blank chromatogram. This retention time coincides with that of the principal peak for Ertugliflozin observed in the sample chromatogram. This overlap necessitates clarification regarding the specificity of the method, as it raises concern about the ability to distinguish the Ertugliflozin peak from potential interference originating from the diluent.	Firm replied that "Please note that in the blank chromatogram, behavior of diluent is at 2.5 minutes (scale 0 to 125), whereas the principle peak in the sample chromatogram is at 2.8 minutes (scale 0 to 1200). The sample chromatogram shows that the diluent behavior and the principle peak are not merged, i.e., no interference, therefore the analytical method can safely be declared as specific. This is also supported by the validation data which confirms no interference from the diluent on the assay results of Ertugliflozin. Had there been interference from the diluent, the outcome of accuracy, linearity and repeatability tests would not have been meeting the acceptance criteria".
2.	As per the batch manufacturing record, the specified weight limit for one tablet is 830 mg ± 5% (i.e., 788.5 mg to 871.5 mg). However, the sample preparation procedure described in section 3.2.P.5.2 of the assay method requires crushing 20 tablets, determining the average tablet weight, and weighing a quantity of powder equivalent to one tablet. During method validation and stability testing, the raw data	Firm replied that Please note that 830 mg ± 5% (i.e., 788.5 mg to 871.5 mg) is the weight limit for uncoated tablet, as mentioned in the BMR, while for assay in stability testing, method validation etc. Film coated tablets are used. The weight limit for film coated tablet, as per BMR, is 830mg (uncoated) + 33 mg (film coating) = 863 mg ± 5% (i.e., 819.85 mg to 906.15 mg), hence

	sheets indicate that sample weights taken were ~890 mg, which exceeds the defined upper tablet weight limit. Given this discrepancy, please clarify how the assay method ensures compliance with the specification for using the weight equivalent to a single tablet, and how accuracy is maintained when sample weights exceed the acceptable tablet weight range	the weight of sample taken (~890 mg) by us was within the limits.
3.	Import invoice of both drug substance for confirmation of API lot no. which is actually used in the preparation of stability batches	Clearance certificate of Metformin hydrochloride and DRAP attested commercial invoice of Ertugliflozin is submitted by the firm.
4.	Approval of API DML/GMP certificate of both API manufacturer issued by concerned regulatory authority of country of origin.	Valid GMP certificates of both API Manufacturer are submitted by the firm.

Decision

Approved

The firm shall submit all relevant blank chromatograms, specifically the placebo chromatogram containing only excipients and diluents, to demonstrate the elution behavior of non-active components. This is required to confirm that no interfering peaks are present at the retention times of Ertugliflozin and Metformin, prior the issuance of the registration letter.

723	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(NU3-Z35-WV6H, 2024-03-19)
	Detail of Fee Submitted	30000.0, 45000.0 2024-01-26, 2024-02-27
	The proposed proprietary name / brand name	Noxamit 100mg DR Tablet
	Label Claim	Each Delayed-Release Tablet contains: Posaconazole.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x10's, 2x7's, -As per SRO
	Shelf Life (Unit)	2 Year(s) Store at room temperature below 30
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Posaconazole belongs to a class of drugs Azole antifungals that inhibits the enzyme lanosterol 14 α -demethylase (CYP51), which catalyses an essential step in ergosterol biosynthesis.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Stability data of batches TCG001 TCG002 TCG003 (2500 tablet each) is submitted

Documents for the procurement of API with approval from DRAP (in case of Import)	Form-6 is submitted by the Firm.	
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP is performed against the comparator product posaconazole 100mg DR Tablet	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone iv condition is submitted	
The status in reference regulatory authorities	Posaconazole 100mg DR Tablet by M/S Merck Sharp & Dohme LLC (118446553),(USFDA Approved)	
GMP status of the firm	GMP Certificate dated 20-04-2023 is submitted by the firm.	
Evidence of approval of manufacturing facility	GMP certificate dated 20-04-2023 mentioned that firm has tablet (general) section.	
Evaluation Remarks		
Noxafil is an azole antifungal indicated as follows: • Noxafil injection and Noxafil delayed-release tablets are indicated for the treatment of invasive aspergillosis in adults and pediatric patients 13 years of age and older.		
Sr.no.	Shortcomings	Response of the Firm
1.	Since the innovator recommends the use of chiral HPLC for the assay of the drug substance due to the presence of four chiral centers in Posaconazole and its synthesis as a single (R,R,S,S) enantiomer, please justify why a chiral HPLC method was not adopted for the assay of the drug substance by both the drug substance and drug product manufacturers.	Firm replied that The Chiral HPLC in Assay test is recommended due to the polymorphism of the drug substance with presence of 4 chiral centers. It is submitted that the polymorphic form -I has been extensively characterized by the drug substance manufacturer by applying advanced analytical techniques i.e., Elemental analysis, Infrared, Ultraviolet spectroscopy, Nuclear magnetic resonance, High resolution mass spectrometry, Differential scanning Calorimeter, thermogravimetric analysis, X-Ray powder diffraction, specific rotation & single X-ray diffraction. By applying the aforementioned techniques the elucidation of structure of drug substance was satisfactorily established as Polymorphic form I and the details of which have been provided in section 3.2.S.3.1. Due to this extensive characterization studies the routine Assay analysis has been performed in conventional manner , also test of specific optical rotation in drug substance specifications applies a check on

		the structural characterization of drug substance.
2.	As evident from the submitted CDP report of the drug product, justify the release behavior of the delayed-release formulation in 0.1N HCl, which shows more than 10% drug release within 45 minutes, considering that delayed-release tablets are generally expected to withstand the acidic stage for up to 120 minutes without significant release i.e. NMT 10%.	Firm replied that "The observed drug release of more than 10% within 45 minutes in 0.1N HCl as reported in the CDP is part of the sequential dissolution procedure, which was initiated after the formulation had already undergone a 120-minute exposure in acidic media (pH 1.2). During this initial stage, the formulation complied with delayed-release requirements by releasing not more than 10% of the active ingredient, thereby demonstrating acceptable acid resistance and enteric coating integrity. Therefore, the overall performance remains consistent with pharmacopeial expectations for delayed-release formulations".
3.	Submit the detailed analytical procedure of drug product that has actually been used for the analysis of drug product.	Firm submitted the detailed analytical procedure of drug product that has actually been used for the analysis of finished product.
4.	Provide a justification for not adopting the same acceptance criteria for dissolution testing as recommended for the innovator product approved by the USFDA.	Firm replied that As the drug product is not listed in any recognized pharmacopoeia, we have applied the general acceptance criteria for delayed-release formulations, which require not more than 10% drug release in acid stage (0.1N HCl for 2 hours) and not less than 80% release in buffer stage. Both the dissolution media and time points were adopted from the USFDA Dissolution Methods Database.
5.	Provide copy of Batch Manufacturing Record (BMR) of all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.	Firm submitted the BMR of three trial batches.
6.	Approval of API/DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm submitted the GMP certificate of API manufacturer which is valid till 20-09-2026
Decision		

724	Deferred				
	The Registration Board decided to defer the case to provide justification for not adopting the chiral HPLC technique for the assay of the drug substance, as the innovator product recommends the use of chiral HPLC for assay due to the presence of four chiral centers in Posaconazole.				
	Case Category	Routine (Saima Hussain)			
	Name, address of Applicant.	Neutro Pharma (Pvt.) Ltd., 9.5-Km, Sheikhpura Road, Lahore (000576)			
	Application Form Dy. No / Tracking ID & date of submission	(PB4-753-BZGM, 2024-03-14)			
	Detail of Fee Submitted	30000.0, 2024-02-13,			
	The proposed proprietary name / brand name	Ertuneu-S 15/100mg Tablet			
	Label Claim	Each Film Coated Tablet contains: Ertugliflozin L-Pyroglutamic Acid.....15mg Sitagliptin Phosphate Monohydrate.....100mg (As per Innovators Specifications)			
	Reference to Finished product specifications	As per Innovators Specification			
	Proposed Pack Size	14s, 28s, 30s-De-Controlled			
	Shelf Life (Unit)	2 Year(s)Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F)			
	For generic drugs (me-too Status)	Ertuvia-S Tablet 15/100mg by Ferozsons Laboratories Ltd.,			
	Pharmacotherapeutic Group of (API)	Ertugliflozin (Sodium Glucose Cotransporter 2 (SGLT-2) Inhibitors) Sitagliptin (Dipeptidyl Peptidase IV (DPP-IV) Inhibitors) Type II Diabetes			
	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 +86 0418-8229677 +86 0418-8229766 office@lrpharmaceutical.com			
	Detail of stability batches of drug product	Stability data of batches ESBt SB1-22 , ESBt SB2-22, ESBt SB3-22 are submitted			
	Documents for the procurement of API with approval from DRAP (in case of Import)	DRAP Attested commercial invoices are submitted.			
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP performed against the Trevia R2 Tablet 15/100mg tablet of M/s. Getz Pharma is attached.			
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data conducted under zone-IV condition is submitted.			
	The status in reference regulatory authorities	Steglujan Tablet 15/100mg by Merck Sharp & Dohme LLC			
	GMP status of the firm	GMP Certificate dated 30-06-2022 submitted.			
	Evidence of approval of manufacturing facility	GMP Certificate dated 30-06-2022 ,mentioned that firm has tablet (general) section.			
Evaluation Remarks					
<table> <tr> <td>Sr.no.</td><td>Shortcomings</td><td>Response of the Firm</td></tr> </table>			Sr.no.	Shortcomings	Response of the Firm
Sr.no.	Shortcomings	Response of the Firm			

1.	Provide the stability data for the drug substance Ertugliflozin L-Pyroglutamic Acid, conducted under Zone IV-a conditions, up to the claimed re-test period.	The firm has submitted 2 data of the drug substance under Zone IVa conditions."
2.	Provide documented evidence for the availability of an L10 column used for the assay of Sitagliptin Phosphate in accordance with the USP monograph. Additionally, confirm and submit supporting documentation for the availability of an L51 column, required for the enantiomeric purity test as per USP specifications.	The firm has submitted the data for both columns as evidence of availability.
3.	Submit the Certificate of Analysis (COA) for the USP Sitagliptin System Suitability Mixture reference or working standard, which is required for performing the S-enantiomeric purity test in accordance with the USP monograph, as the batch analysis report of Sitagliptin Phosphate API indicates that the test has been conducted by the drug product manufacturer.	The firm has submitted a Certificate of Analysis (COA) for the USP Sitagliptin System Suitability reference standard, which is required for performing the S-enantiomeric purity test per the USP monograph. The batch analysis report made in support of the batch of Sitagliptin Phosphate API indicates that the test was conducted by the drug product manufacturer..
4.	A peak eluting at approximately 2.1 minutes is observed in the dissolution chromatograms, in close proximity to the main peak of the active pharmaceutical ingredient (API), sitagliptin, which elutes at approximately 2.9 minutes. This peak is neither labeled nor explained in the submitted chromatograms. Additionally, it is not observed in the chromatograms obtained during the assay, nor is it present in the chromatograms of the standard preparations. Please clarify the nature of this peak, including whether it has been investigated, and justify its presence in the dissolution profile.	Firm replied that "A peak eluting at approximately 2.1 minutes is observed in the dissolution chromatograms, in close proximity to the main peak of the active pharmaceutical ingredient (API), sitagliptin, which elutes at approximately 2.9 minutes. This peak is neither labeled nor explained in the submitted chromatograms. Additionally, it is not observed in the chromatograms obtained during the assay, nor is it present in the chromatograms of the standard preparations. Please clarify the nature of this peak, including whether it has been investigated, and justify its presence in the dissolution profile."
5.	Approval of API/DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm submitted the valid certificate of API Manufacturer.

Decision

Approved

725	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	Neutro Pharma (Pvt.) Ltd., 9.5-Km, Sheikhpura Road, Lahore (000576)
	Application Form Dy. No / Tracking ID & date of submission	(PSM-JUZ-2EZ3, 2024-03-14)
	Detail of Fee Submitted	30000.0, 2024-02-13,
	The proposed proprietary name / brand name	Ertuneu 5mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid.....5mg (As per Innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification

Proposed Pack Size	14s, 28s, 30s-De-Controlled
Shelf Life (Unit)	2 Year(s)Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F)
For generic drugs (me-too Status)	Ertuget Tablet 5mg by Getz Pharma (Pvt) Ltd.,
Pharmacotherapeutic Group of (API)	Sodium Glucose Cotransporter 2 (SGLT-2) Inhibitors
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 +86 0418-8229677 +86 0418-8229766 office@lrpharmaceutical.com
Detail of stability batches of drug product	Stability data of batches 5mg ETAt SB1-22,5mg ETAt SB2-22,5mg, ETAt SB3-22 (2000 tablet each) is submitted
Documents for the procurement of API with approval from DRAP (in case of Import)	DRAP attested commercial invoice is submitted by the firm.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP performed against the comparator product Ertuget tablet 5mg of M/s. Getz Pharma.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone-IV conditions is submitted by the firm.
The status in reference regulatory authorities	Steglatro Tablet 5mg by Merck Sharp & Dohme LLC
GMP status of the firm	GMP certificate dated 30-06-2022 is submitted by the firm.
Evidence of approval of manufacturing facility	GMP certificate dated 30-06-2022 mentioned that firm has tablet (general) section
Evaluation Remarks	
Decision	
Approved	
Case Category	Routine (Saima Hussain)
Name, address of Applicant.	Neutro Pharma (Pvt.) Ltd., 9.5-Km, Sheikhupura Road, Lahore (000576)
Application Form Dy. No / Tracking ID & date of submission	(SZV-MW3-4E88, 2024-03-18)
Detail of Fee Submitted	30000.0, 2024-03-04,
The proposed proprietary name / brand name	Ertuneu-Met 2.5/500mg Tablet
Label Claim	Each film coated tablet contains: Ertugliflozin L- Pyroglutamic acid Eq. to Ertugliflozin.....2.5mg Metformin HCl.....500mg (As per Innovators Specifications)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	14s, 28s, 30s-Controlled

Shelf Life (Unit)	2 Year(s)Store at 25°C excursions permitted to 15-30°C
For generic drugs (me-too Status)	ERTUCO-M Tablet by ATCO Laboratories
Pharmacotherapeutic Group of (API)	Ertugliflozin (Sodium Glucose Cotransporter 2 (SGLT-2) Inhibitors) +Biguanides
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	
Detail of stability batches of drug product	Stability data of batches (2.5mg/500 mg EMAAt SB1-22 1500 Tablets ,2.5mg/500 mg EMAAt SB2-22 1500 Tablets, EMAAt SB3-22)
Documents for the procurement of API with approval from DRAP (in case of Import)	Submitted
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP performed against the Ertuco-M Tablet of M/s. Atco Pharma
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data conducted under zone-IV condition is submitted.
The status in reference regulatory authorities	Segluromet 2.5/500mg Tablet by Merck Sharp & Dohme LLC USFDA Approved
GMP status of the firm	GMP Certificate dated 30-06-2022 submitted.
Evidence of approval of manufacturing facility	GMP Certificate dated 30-06-2022 ,mentioned that firm has tablet (general) section.

Evaluation Remarks

Sr.no.	Shortcoming	Response of the Firm
1.	Provide a justification for selecting pH 4.5 acetate buffer as the dissolution medium, whereas the innovator recommends phosphate buffer pH 6.8 for dissolution testing. Additionally, the innovator specifies distinct dissolution conditions for each active ingredient and performs HPLC determination of drug release at different wavelengths than those used in your method. Justify the rationale for not adopting the same dissolution and chromatographic conditions as those established in the review literature of the innovator product.	Firm replied that selection of dissolution medium buffer is as per USFDA quality assessment report and the chromatographic conditions are developed inhouse as per guidelines and validated.

Decision

Approved

727	Case Category	Routine (Saima Hussain)
	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	(T8H-E32-VP94, 2024-04-19)
	Detail of Fee Submitted	75000.0, 2024-03-19,
	The proposed proprietary name / brand name	Bemcid 180mg Tablet
	Label Claim	Each film coated tablet contains Bempedoic acid 180mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per PRC-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30C, protect from light, heat & moisture. Keep out of reach of children.
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	Adenosine triphosphate-citrate lyase (ACL) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	AMI LifeSciences Pvt. Ltd.
	Detail of stability batches of drug product	Stability batches of TF-190623 1500 tablets ,TF-200623 1500 tablets, TF-210623 1500 tablets is submitted by the firm.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form-6 is submitted by the firm,
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP is performed against the reference product Nexletol 180mg Tablets (Piramal Healthcare UK Limited) is submitted by the firm.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone-iv condition is submitted.
	The status in reference regulatory authorities	Nexletol 180mg Tablet by Piramal Healthcare Ltd. US-FDA
	GMP status of the firm	GMP certificate dated 19th December, 2023 is submitted by the firm.
	Evidence of approval of manufacturing facility	GMP certificate dated 19th December, 2023 mentioned that firm has tablet (genera) section.
	Evaluation Remarks	
	Decision	
	Approved	
728	Case Category	Routine (Saima Hussain)
	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	(UE2-UGS-SWN2, 2024-03-12)
	Detail of Fee Submitted	30000.0, 2023-12-07,
	The proposed proprietary name / brand name	ErtagMet
	Label Claim	Each film coated tablet contains: Ertugliflozin LPGA equivalent to Ertugliflozin.....7.5mg

	Metformin HCl.....500mg
Reference to Finished product specifications	Manufacturer Specification
Proposed Pack Size	10's-As per SRO,14's-As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO,7's-As per SRO
Shelf Life (Unit)	2 Year(s)Store below 30°C
For generic drugs (me-too Status)	Ertuvia-M 7.5/500mg (Ferozsons Laboratories Ltd)
Pharmacotherapeutic Group of (API)	Antidiabetic
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Aarti drugs ltd.,Chifeng Arker Pharmaceutical technology co.ltd
Detail of stability batches of drug product	Stability data of batches 7EMPD01/22, 7EMPD02/22,7EMPD03/22 (2409 tablet of each batch) is submitted
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate(Metformin) and DRAP attested commercial invoice is attached.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP is performed against the comparator product Ertuvia-M 7.5/500mg Tablet.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone-iv condition is submitted.
The status in reference regulatory authorities	Segluromet 7.5/500mg Tablet (USFDA Approved)
GMP status of the firm	GMP certificate dated 18th may,2023 is attached.
Evidence of approval of manufacturing facility	GMP certificate dated 18th May,2023 mentioned that firm has tablet (general) section.

Evaluation Remarks

Sr.no.	Shortcomings	Response of the Firm
1.	The assay verification report, which includes chromatograms of both the blank (diluent: 70% methanol) and the sample, shows a peak at approximately 2.8 minutes in the blank chromatogram. This retention time coincides with that of the principal peak for Ertugliflozin observed in the sample chromatogram. This overlap necessitates clarification regarding the specificity of the method, as it raises concern about the ability to distinguish the Ertugliflozin peak from potential interference originating from the diluent.	Firm replied that "e that in the blank chromatogram, behavior of diluent is at 2.5 minutes (scale 0 to 125), whereas the principle peak in the sample chromatogram is at 2.8 minutes (scale 0 to 1200). The sample chromatogram shows that the diluent behavior and the principle peak are not merged, i.e., no interference, therefore the analytical method can safely be declared as specific. This is also supported by the validation data which confirms no interference from the diluent on the assay results of Ertugliflozin. Had there been interference from the diluent, the outcome of accuracy, linearity and repeatability tests would not have been meeting the acceptance criteria".
2.	As per the batch manufacturing record, the specified weight limit	Firm replied that Please note that 830 mg $\pm$ 5% (i.e., 788.5 mg to

	for one tablet is 830 mg $\pm$ 5% (i.e., 788.5 mg to 871.5 mg). However, the sample preparation procedure described in section 3.2.P.5.2 of the assay method requires crushing 20 tablets, determining the average tablet weight, and weighing a quantity of powder equivalent to one tablet. During method validation and stability testing, the raw data sheets indicate that sample weights taken were ~890 mg, which exceeds the defined upper tablet weight limit. Given this discrepancy, please clarify how the assay method ensures compliance with the specification for using the weight equivalent to a single tablet, and how accuracy is maintained when sample weights exceed the acceptable tablet weight range	871.5 mg) is the weight limit for uncoated tablet, as mentioned in the BMR, while for assay in stability testing, method validation etc. Film coated tablets are used. The weight limit for film coated tablet, as per BMR, is 830mg (uncoated) + 33 mg (film coating) = 863 mg $\pm$ 5% (i.e., 819.85 mg to 906.15 mg), hence the weight of sample taken (~890 mg) by us was within the limits.
3.	Import invoice of both drug substance for confirmation of API lot no. which is actually used in the preparation of stability batches	Clearance certificate of Metformin hydrochloride and DRAP attested commercial invoice of Ertugliflozin is submitted by the firm.
4.	Approval of API! DML/GMP certificate of both API manufacturer issued by concerned regulatory authority of country of origin.	Valid GMP certificates of both API Manufacturer are submitted by the firm.

Decision

Approved

The firm shall submit all relevant blank chromatograms, specifically the placebo chromatogram containing only excipients and diluents, to demonstrate the elution behavior of non-active components. This is required to confirm that no interfering peaks are present at the retention times of Ertugliflozin and Metformin, prior the issuance of the registration letter.

729	Case Category	Routine (Saima Hussain)
	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	(VHU-7A8-8HHA, 2024-04-19)
	Detail of Fee Submitted	30000.0, 2024-01-09,
	The proposed proprietary name / brand name	Bilfast 20mg Tablet
	Label Claim	Each tablet contains Bilastine 20mg
	Reference to Finished product specifications	As per Innovators Specification

Proposed Pack Size	As per PRC-As per SRO
Shelf Life (Unit)	2 Year(s)Keep away from direct sunlight, heat and water. Store in air tight container.
For generic drugs (me-too Status)	Bilfaxin 20mg Tablet by Searle Pakistan
Pharmacotherapeutic Group of (API)	Anti histamine(H1 Receptor antagonist)
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Virupaksha Organics Limited
Detail of stability batches of drug product	Stability data of batches (TF-020922A ,TF-020922B, TF-020922C) 1000 each is submitted.
Documents for the procurement of API with approval from DRAP (in case of Import)	DRAP attested commercial invoice is attached.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP is performed against the reference product Reference Product: Bilaxten 20mg Tablet (Jazeera pharmaceuticals industries, Riyadh Saudi Arabia) (Under license of: FAES Farma, S.A Spain) is attached.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone-iv conditions is submitted by the firm.
The status in reference regulatory authorities	Bilaxten 20mg Tablet by Faes Pharma Spain
GMP status of the firm	GMP certificate dated 19th December,2023 is submitted by the firm
Evidence of approval of manufacturing facility	GMP certificate dated 19th December,2023 mentioned that firm has tablet (general) section

Evaluation Remarks

Sr.no.	Shortcomings	Response of the Firm
1.	Please specify the Reference used for the selection of the dissolution medium and the acceptance criteria for the dissolution test	Firm submitted the reply that "Proposed Dissolution conditions: Dissolution Test parameter: i. Apparatus: Paddle ii. Dissolution medium: 0.1N HCl iii. Medium volume: 900ml iv. RPM: 50 v. Time: 30 minutes vi. Temperature: 37°C vii. Acceptance Criteria: NLT 80% (Q) With reference to above dissolution conditions, we have developed them by using following guidance document: 1. USP chapter 1092 2. FDA guidance document for Dissolution Testing of Immediate Release Solid Oral Dosage Forms 3. DRB Minutes of 293rd Meeting of Registration Board (6 – 8th January, 2020) 4. Pharmaceutical equivalence study with reference product. 5. CDP study with reference product".
2.	Submit documents for the procurement of API including	Firm submitted the DRAP attested commercial invoice of

		readable copy of commercial invoice attested by AD (I&E) DRAP.	API Bilastine.
Decision			
Approved			
730	Case Category	Routine (Saima Hussain)	
	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	(W6Y-GNH-YJ8S, 2024-04-17)	
	Detail of Fee Submitted	75000.0, 2024-01-02,	
	The proposed proprietary name / brand name	Bilfast Oral Solution	
	Label Claim	Each ml contains Bilastine 2.5mg	
	Reference to Finished product specifications	Manufacturer Specification	
	Proposed Pack Size	As per PRC-As per SRO	
	Shelf Life (Unit)	2 Year(s)Store below 30C, protect from light, heat & moisture. Keep out of reach of children.	
	For generic drugs (me-too Status)	Not Applicable	
	Pharmacotherapeutic Group of (API)	Anti-histamine (H1 Receptor Antagonist)	
	Name, address of Manufacturing site:	Self Manufacturing	
	Name & address of API manufacturer	Virupaksha Organics Limited	
	Detail of stability batches of drug product	Stability batches (TF-221122 , TF-231122 ,TF-211122)3.5 liters each	
	Documents for the procurement of API with approval from DRAP (in case of Import)	DRAP attested commercial invoice is attached.	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE is performed against the reference product BILAXTEN 2,5mg/ml Solution oral of M/s. (FAES FARMA S.A) is attached.	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone-iv conditions is submitted by the firm.	
	The status in reference regulatory authorities	Bilaxten 2,5mg/ml Oral Solution (The Spanish Agency of Medicines & Medical Devices-AEMPS)	
	GMP status of the firm	GMP Certificate dated 19th December,2023 is submitted by the firm.	
	Evidence of approval of manufacturing facility	GMP certificate dated 19th December,2023 mentioned that firm has Liquid Syrup (general section)	
Evaluation Remarks			
Sr.no.	Shortcomings	Response of the Firm	
1.	Justify for not including the deliverable volume test in the finished product specification, although the test is recommended	Firm replied that In our process, deliverable volume is verified in-process during bottle filling, not at the finished product stage. This	

	in official pharmacopeias for oral liquid dosage forms packaged in multiple-dose containers, in accordance with the requirements described in USP General Chapter <698> Deliverable Volume.	control is documented in the commercial batch manufacturing record (BMR) and verified by Quality Assurance Department. Since, PD trial batches were not intended for sale, the test was not included. For commercial batches, deliverable volume is part of routine in-process controls for all oral liquid products.
2.	In-use stability studies of the opened bottles are required to be submitted along with the proposed in-use storage conditions and in-use shelf-life, as the innovator product approved by MHRA specifies a defined shelf-life for the oral solution after first opening.	The firm has submitted 28-day in-use stability data, as the shelf life after opening the bottle is 28 days, in accordance with the innovator product information available on the MHRA website.
3.	Submit documents for the procurement of API including readable copy of commercial invoice attested by AD (I&E) DRAP.	Firm submitted the DRAP attested commercial invoice of API Bilastine.

Decision

Approved

731	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	Neutro Pharma (Pvt.) Ltd., 9.5-Km, Sheikhpura Road, Lahore (000576)
	Application Form Dy. No / Tracking ID & date of submission	(X6A-EBQ-BZ7T, 2024-03-14)
	Detail of Fee Submitted	30000.0, 2024-02-13,
	The proposed proprietary name / brand name	Ertuneu-S 5/100mg Tablet
	Label Claim	Each Film Coated Tablet contains: Ertugliflozin L-Pyroglutamic Acid.....5mg Sitagliptin Phosphate Monohydrate.....100mg (As per Innovators Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14s, 28s, 30s-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F)
	For generic drugs (me-too Status)	Ertuvia-S Tablet 5/100mg by Ferozsans Laboratories Ltd.,
	Pharmacotherapeutic Group of (API)	Ertugliflozin (Sodium Glucose Cotransporter 2 (SGLT-2) Inhibitors) Sitagliptin (Dipeptidyl Peptidase IV (DPP-IV) Inhibitors) Type II Diabetes
	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 +86 0418-8229677 +86 0418-8229766 office@lrpharmaceutical.com
Detail of stability batches of drug product		Stability data of batches ESAAt SB1-22 , ESAAt SB2-22, ESAAt SB3-22 are submitted
Documents for the procurement of API with approval from DRAP (in case of Import)		DRAP Attested commercial invoices are submitted
Pharmaceutical Equivalence and Comparative Dissolution Profile		PE and CDP performed against the Trevia R2 Tablet 5/100mg tablet
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		Stability data conducted under zone-IV condition is submitted.
The status in reference regulatory authorities		Steglujan Tablet 5/100mg by Merck Sharp & Dohme LLC
GMP status of the firm		GMP Certificate dated 30-06-2022 submitted.
Evidence of approval of manufacturing facility		GMP Certificate dated 30-06-2022 ,mentioned that firm has tablet (general) section.
Evaluation Remarks		
Sr.no.	Shortcomings	Response of the Firm
1.	Provide the stability data for the drug substance Ertugliflozin L- Pyroglutamic Acid, conducted under Zone IV-a conditions, up to the claimed re-test period.	The firm has submitted 24-month stability data of the drug substance, conducted under Zone IVa conditions."
2.	Provide documented evidence for the availability of an L10 column used for the assay of Sitagliptin Phosphate in accordance with the USP monograph. Additionally, confirm and submit supporting documentation for the availability of an L51 column, required for the enantiomeric purity test as per USP specifications.	The firm has submitted the purchase invoices for both columns as evidence of their availability.
3.	Submit the Certificate of Analysis (COA) for the USP Sitagliptin System Suitability Mixture reference or working standard, which is required for performing the S-enantiomeric purity test in accordance with the USP monograph, as the batch analysis report of Sitagliptin Phosphate API indicates that the test has been conducted by the drug product manufacturer.	The firm has submitted a copy of the Certificate of Analysis (CoA) of USP-grade Sitagliptin System Suitability Mixture reference standard, which is required for performing the S-enantiomeric purity test as per the USP monograph. This submission is made in support of the batch analysis report of Sitagliptin Phosphate API, which indicates that the test was conducted by the drug product manufacturer..
4.	A peak eluting at approximately 2.1 minutes is observed in the dissolution chromatograms, in	Firm replied that "A peak eluting at approximately 2.1 minutes is observed in the dissolution

	close proximity to the main peak of the active pharmaceutical ingredient (API), sitagliptin, which elutes at approximately 2.9 minutes. This peak is neither labeled nor explained in the submitted chromatograms. Additionally, it is not observed in the chromatograms obtained during the assay, nor is it present in the chromatograms of the standard preparations. Please clarify the nature of this peak, including whether it has been investigated, and justify its presence in the dissolution profile.	chromatograms, in close proximity to the main peak of the active pharmaceutical ingredient (API), sitagliptin, which elutes at approximately 2.9 minutes. This peak is neither labeled nor explained in the submitted chromatograms. Additionally, it is not observed in the chromatograms obtained during the assay, nor is it present in the chromatograms of the standard preparations.
5.	Approval of API/DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm submitted the valid GMP certificates of both API Manufacturer.

Decision

Approved

732	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(XPQ-DXN-1G2B, 2024-03-14)
	Detail of Fee Submitted	30000.0, 2023-12-15,
	The proposed proprietary name / brand name	Nextol -EZ 180mg/10mg Tablet
	Label Claim	Each Film Coated tablet contains: Bempedoic Acid.....180mg Ezetimibe.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x7's, 1x10's, 2x10'-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at cool &dry place below 30
	For generic drugs (me-too Status)	BEMPID EZE Tablet 180mg/10mg M/sNabiqasim Industries (PVT) LTD. 17 / 24, Korangi Industrial Area,Karachi approved in 331 Minutes of meeting
	Pharmacotherapeutic Group of (API)	Bempedoic Acid (adenosine triphosphate-citrate lyase (ACL) inhibitors) Ezetimibe (selective cholesterol-absorption inhibitors)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Metrochem API Private Limited Address: Unit-IV, Plot No. 34B, 40B & 60B, J.N. Pharma City, Thanam Village, Parawada Mandal, Visakhapatnam District, Andhra Pradesh, 531021, India

	(IND).,Saptagir Laboratories Pvt Ltd Address: Sy.No. Parts of 27, 46 & 50 to 56, Ananthasagar (Vill), Chegunta (Mandal), Medak (Dist.), Telangana, India-502 247	
Detail of stability batches of drug product	Stability data submitted (TZE001,TZE002,TZE003)	
Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 submitted.	
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP submitted against the comparator product Nustendi 180 mg/10 mg film-coated tablets	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of three batches conducted as per zone-IV condition is submitted	
The status in reference regulatory authorities	Nustendi 180 mg/10 mg film-coated tablets M/s Daiichi Sankyo UK Limited(United Kingdom (Great Britain	
GMP status of the firm	Wimit: GMP certificate dated 14-11-2023 is submitted mentioning that firm has tablet section.	
Evidence of approval of manufacturing facility	Wimit: GMP certificate dated 14-11-2023 is submitted mentioning that firm has tablet section.	
Evaluation Remarks		
Sr.no.	Shortcomings	Response of the Firm
1.	Considering the solubility characteristics of both Bempedoic Acid and Ezetimibe, as reported in the innovator product literature, both are classified as BCS Class II compounds. Bempedoic Acid exhibits pH-dependent solubility, with higher solubility at increased pH levels, while Ezetimibe demonstrates low solubility across the physiological pH range—being soluble at low pH (1.2), but insoluble above pH 4.01 and practically insoluble in water. In light of these solubility profiles, please justify the observed dissolution behavior reported in Section 3.2.P.2.2.1 of your application, where comparative dissolution data show greater than 80% release of both APIs in all three media, despite their pH-dependent solubility.	Firm replied that to overcome these solubility limitations and ensure meaningful comparative dissolution profiling, surfactants were included in all three media (pH 1.2, 4.5, and 6.8). The addition of surfactant (e.g., Sodium Lauryl Sulfate) helps maintain sink conditions and enhances the solubility of both APIs across the pH range. The observed drug release of >80% in all media reflects the effect of surfactant and does not contradict the intrinsic solubility profiles of the APIs in plain buffer.
2.	Please provide a justification for adopting a wider dissolution acceptance criterion of NLT 75% (Q) in 45 minutes for both APIs, whereas the innovator product	The dissolution acceptance criterion of NLT 75% (Q) in 45 minutes for both Bempedoic Acid and Ezetimibe was established in accordance with US FDA Dissolution Database, which

		specifies the dissolution limit of (Q) in 30 minutes.	allows for a 45-minute dissolution time point.
Decision			
Approved			
733	Case Category	Routine (Saima Hussain)	
	Name, address of Applicant.	Neutro Pharma (Pvt.) Ltd., 9.5-Km, Sheikhpura Road, Lahore (000576)	
	Application Form Dy. No / Tracking ID & date of submission	(Z28-7LG-DQPS, 2024-03-26)	
	Detail of Fee Submitted	30000.0, 2024-03-04,	
	The proposed proprietary name / brand name	Ertuneu-Met 7.5/500mg Tablet	
	Label Claim	Each film coated Tablet contains: Ertugliflozin L-pyrogutamic Acid Eq. to Ertugliflozin.....7.5mg Metformin HCl.....500mg (As per Innovators Specifications)	
	Reference to Finished product specifications	As per Innovators Specification	
	Proposed Pack Size	14s, 28s, 30s-As per SRO	
	Shelf Life (Unit)	2 Year(s)Store at 25°C; excursions permitted to 15-30°C	
	For generic drugs (me-too Status)	Ertuvia-M 7.5/500mg Tablet by ATCO Laboratories	
	Pharmacotherapeutic Group of (API)	Ertugliflozin (Sodium Glucose Cotransporter 2 (SGLT-2) Inhibitors) +Biguanides	
	Name, address of Manufacturing site:	Self Manufacturing	
	Name & address of API manufacturer		
	Detail of stability batches of drug product	Stability data of batches (EMCt SB1-22 ,EMCt SB2-22, EMCt SB3-22) 1500 TABLETS EACH	
	Documents for the procurement of API with approval from DRAP (in case of Import)	Submitted	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP performed against the Ertuvia 7.5mg/500mg Tablet of M/s. Ferozsos	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data conducted under zone-IV condition is submitted.	
	The status in reference regulatory authorities	Segluromet 7.5/500mg Tablet by Merck Sharp & Dohme LLC USFDA Approved	
	GMP status of the firm	GMP Certificate dated 30-06-2022 submitted.	
	Evidence of approval of manufacturing facility	GMP Certificate dated 30-06-2022 ,mentioned that firm has tablet (general) section.	
Evaluation Remarks			
Sr.no.	Shortcoming	Response of the Firm	
1.	Provide a justification for selecting pH 4.5 acetate buffer as the dissolution medium, whereas the innovator recommends phosphate buffer pH 6.8 for	Selection of dissolution medium buffer is as per USFDA quality assessment report and the chromatographic conditions are	

		dissolution testing. Additionally, the innovator specifies distinct dissolution conditions for each active ingredient and performs HPLC determination of drug release at different wavelengths than those used in your method. Justify the rationale for not adopting the same dissolution and chromatographic conditions as those established in the review literature of the innovator product.	developed inhouse as per guidelines and validated.
	Decision		
	Approved		
734	Case Category	Routine (Saima Hussain)	
	Name, address of Applicant.	Neutro Pharma (Pvt.) Ltd., 9.5-Km, Sheikhpura Road, Lahore (000576)	
	Application Form Dy. No / Tracking ID & date of submission	(ZHS-G4Z-V954, 2024-03-20)	
	Detail of Fee Submitted	30000.0, 2024-03-04,	
	The proposed proprietary name / brand name	Ertuneu 15mg Tablet	
	Label Claim	Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid.....15mg (As per Innovator Specifications)	
	Reference to Finished product specifications	As per Innovators Specification	
	Proposed Pack Size	14s, 28s, 30s-De-Controlled	
	Shelf Life (Unit)	2 Year(s)Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F)	
	For generic drugs (me-too Status)	Ertuget Tablet 15mg by Getz Pharma (Pvt) Ltd.,	
	Pharmacotherapeutic Group of (API)	Sodium Glucose Cotransporter 2 (SGLT-2) Inhibitors	
	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 +86 0418-8229677 +86 0418-8229766 office@lrpharmaceutical.com	
	Detail of stability batches of drug product	Stability data of batches 5mg ETB SB1-22,5mg ETB SB2-22,5mg, ETB SB3-22 (2000 tablet each) is submitted	
	Documents for the procurement of API with approval from DRAP (in case of Import)	DRAP attested commercial invoice is submitted by the firm.	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP performed against the comparator product Ertuget tablet 15mg of M/s. Getz Pharma.	

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone-IV conditions is submitted by the firm.
	The status in reference regulatory authorities	Steglatro Tablet 15mg by Merck Sharp & Dohme LLC
	GMP status of the firm	GMP certificate dated 30-06-2022 is submitted by the firm.
	Evidence of approval of manufacturing facility	GMP certificate dated 30-06-2022 mentioned that firm has tablet (general) section
	Evaluation Remarks	
	Decision	
	Approved	
735	Case Category	New Molecule/Formulation (Shahid Nawaz)
	Name, address of Applicant.	Nabiqasim Industries (Pvt) Ltd., 17/24, Korangi Industrial Area, Karachi. (000105)
	Application Form Dy. No / Tracking ID & date of submission	(7DN-D1Z-EDWP, 2025-02-13)
	Detail of Fee Submitted	75000.0, 2025-02-10,
	The proposed proprietary name / brand name	Tadalafil
	Label Claim	Each film-coated tablet contains: Tadalafil 20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	7's, 10's, 14's, 20'-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 degree celsius
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Urologicals, Drugs used in erectile dysfunction. ATC code: G04BE08
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals
	Detail of stability batches of drug product	03 batches having batch size of 2000 Tablets each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of Form-6 No. DIL-C-B69633 dated 05-11-2024 mentioning 0.3kg of Tadalafil USP from M/s Century Pharmaceuticals, India. Firm has also submitted copy of clearance certificate No. RO-197A60 dated 07-11-2022 mentioning 0.3kg of Tadalafil USP, B. No. 13366013-TDF, Mfg. date 01-02-2024 from M/s Century Pharmaceuticals, India.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and PE studies are performed against innovator product i.e. Cialis 5mg Tablet, B No. D771047, Exp. date 09-2026 manufactured by M/s Eli Lilly, Spain and both reference and applied formulation have shown similar release pattern in all the three mediums wherein the value of F2 is within acceptable range.

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of 3 batches of drug substance as per Zone IV-B is submitted. Accelerated 06 months and real time for 60 months.
	The status in reference regulatory authorities	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. 51/2023-DRAP (K) dated 26-07-2023 issued on the basis of inspection conducted on 22-05-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-20/85-Lic (Vol-V) dated 27-04-2020 mentioning Tablet (General) section.
	Evaluation Remarks	
	Firm has submitted 06th month time point data along with Raw data sheets and chromatograms.	
	Decision	
	Approved	
	Registration letter will be issued after verification of authenticity of submitted data by the panel constituted by the Chairman Registration Board.	
736	Case Category	New Molecule/Formulation (Shahid Nawaz)
	Name, address of Applicant.	Nabiqasim Industries (Pvt) Ltd., 17/24, Korangi Industrial Area, Karachi. (000105)
	Application Form Dy. No / Tracking ID & date of submission	(AWM-7R2-E9NV, 2025-02-13)
	Detail of Fee Submitted	75000.0, 2025-02-10,
	The proposed proprietary name / brand name	Tadalafil Tablet 2.5mg
	Label Claim	Each film-coated tablet contains: Tadalafil USP.....2.5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2, 4, 8, 10, 12, 14,-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Not available
	Pharmacotherapeutic Group of (API)	Urologicals, Drugs used in erectile dysfunction. ATC code: G04BE08
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceutical Limited
	Detail of stability batches of drug product	03 batches having batch size of 2000 Tablets each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of Form-6 No. DIL-C-B69633 dated 05-11-2024 mentioning 0.3kg of Tadalafil USP from M/s Century Pharmaceuticals, India. Firm has also submitted copy of clearance certificate No. RO-197A60 dated 07-11-2022 mentioning 0.3kg of Tadalafil USP, B. No. 13366013-TDF, Mfg. date 01-02-2024 from M/s Century Pharmaceuticals, India.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and PE studies are performed against innovator product i.e. Cialis 2.5mg Tablet, B No. D763687, Exp. date 10-SE-2026 manufactured by M/s Eli Lilly, Canada and both reference and

		applied formulation have shown similar release pattern in all the three mediums wherein the value of F2 is within acceptable range.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of 3 batches of drug substance as per Zone IV-B is submitted. Accelerated 06 months and real time for 60 months.
	The status in reference regulatory authorities	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. 51/2023-DRAP (K) dated 26-07-2023 issued on the basis of inspection conducted on 22-05-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-20/85-Lic (Vol-V) dated 27-04-2020 mentioning Tablet (General) section.
	Evaluation Remarks	
	Firm has submitted 06th month time point data along with Raw data sheets and chromatograms.	
	Decision	
	Approved	
	Registration letter will be issued after verification of authenticity of submitted data by the panel constituted by the Chairman Registration Board.	
737	Case Category	New Molecule/Formulation (Shahid Nawaz)
	Name, address of Applicant.	Nabiqasim Industries (Pvt) Ltd., 17/24, Korangi Industrial Area, Karachi. (000105)
	Application Form Dy. No / Tracking ID & date of submission	(U9G-VSH-U6RA, 2025-02-13)
	Detail of Fee Submitted	75000.0, 2025-02-10,
	The proposed proprietary name / brand name	Tadalafil
	Label Claim	Each film-coated tablet contains: Tadalafil 10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	7's, 10's, 14's, 20'-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 degree celsius
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Urologicals, Drugs used in erectile dysfunction. ATC code: G04BE08
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals
	Detail of stability batches of drug product	03 batches having batch size of 2000 Tablets each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of Form-6 No. DIL-C-B69633 dated 05-11-2024 mentioning 0.3kg of Tadalafil USP from M/s Century Pharmaceuticals, India. Firm has also submitted copy of clearance certificate No. RO-197A60 dated 07-11-2022 mentioning 0.3kg of Tadalafil USP, B. No. 13366013-TDF, Mfg. date 01-02-2024 from M/s Century Pharmaceuticals, India.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and PE studies are performed against innovator product i.e. Cialis 5mg Tablet, B No. D772419, Exp. date 06-NO-2026 manufactured by M/s Eli Lilly, Canada and both reference and applied formulation have shown similar release pattern in all the three mediums wherein the value of F2 is within acceptable range.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of 3 batches of drug substance as per Zone IV-B is submitted. Accelerated 06 months and real time for 60 months.
	The status in reference regulatory authorities	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. 51/2023-DRAP (K) dated 26-07-2023 issued on the basis of inspection conducted on 22-05-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-20/85-Lic (Vol-V) dated 27-04-2020 mentioning Tablet (General) section.
	Evaluation Remarks	
	Firm has submitted 06th month time point data along with Raw data sheets and chromatograms.	
	Decision	
	Approved	
	Registration letter will be issued after verification of authenticity of submitted data by the panel constituted by the Chairman Registration Board.	
738	Case Category	New Molecule/Formulation (Shahid Nawaz)
	Name, address of Applicant.	Nabiqasim Industries (Pvt) Ltd., 17/24, Korangi Industrial Area, Karachi. (000105)
	Application Form Dy. No / Tracking ID & date of submission	(WAT-B9P-A9GZ, 2025-02-13)
	Detail of Fee Submitted	75000.0, 2025-02-10,
	The proposed proprietary name / brand name	Tadalis Tablet 5mg
	Label Claim	Each film-coated tablet contains: Tadalafil 5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2, 4, 8, 10, 12, 14,-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Not available
	Pharmacotherapeutic Group of (API)	Urologicals, Drugs used in erectile dysfunction. ATC code: G04BE08
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceutical Limited
	Detail of stability batches of drug product	03 batches having batch size of 2000 Tablets each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of Form-6 No. DIL-C-B69633 dated 05-11-2024 mentioning 0.3kg of Tadalafil USP from M/s Century Pharmaceuticals, India. Firm has also submitted copy of clearance certificate No. RO-197A60 dated 07-11-2022

		mentioning 0.3kg of Tadalafil USP, B. No. 13366013-TDF, Mfg. date 01-02-2024 from M/s Century Pharmaceuticals, India.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and PE studies are performed against innovator product i.e. Cialis 5mg Tablet, B No. D777364, Exp. date 05-2027 manufactured by M/s Eli Lilly, Canada and both reference and applied formulation have shown similar release pattern in all the three mediums wherein the value of F2 is within acceptable range.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of 3 batches of drug substance as per Zone IV-B is submitted. Accelerated 06 months and real time for 60 months.
	The status in reference regulatory authorities	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. 51/2023-DRAP (K) dated 26-07-2023 issued on the basis of inspection conducted on 22-05-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-20/85-Lic (Vol-V) dated 27-04-2020 mentioning Tablet (General) section.
	Evaluation Remarks	
	Firm has submitted 06th month time point data along with Raw data sheets and chromatograms.	
	Decision	
	Approved	
	Registration letter will be issued after verification of authenticity of submitted data by the panel constituted by the Chairman Registration Board.	
739	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	Scotmann Pharmaceuticals Plot #5D , Industrial Area, I-10/3 Islamabad (000498)
	Application Form Dy. No / Tracking ID & date of submission	(12V-XU1-MTAE, 2024-04-18)
	Detail of Fee Submitted	30000.0, 2024-01-16,
	The proposed proprietary name / brand name	Prucalax Tablet 1mg
	Label Claim	Each film coated tablet contains: Prucalopride succinate eq. to Prucalopride 1mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,14's-As per SRO,20's-As per SRO,28's-As per SRO,30's-Free of Cost
	Shelf Life (Unit)	2 Year(s)Between 15°C-30°C
	For generic drugs (me-too Status)	Pru-cic Tablet 1mg, Manufactured by: The Searle Company Limited
	Pharmacotherapeutic Group of (API)	A06A DRUGS FOR CONSTIPATION
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Source of Drug Substance: SYMED LABS LIMITED Address: Unit –VI, Survey No. 744, 745,

		750, 751, 752 & 753, Mandollagudem (Village), Choutuppal (Mandal), Yadadri Bhuvangiri (Dist) – 508 204, Telangana, I
	Detail of stability batches of drug product	1500 tablets 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	E-6284104804187 DRAP 23.8.23
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Prucalopride tablet 1 mg B. No T23001 Searle Pharmaceuticals
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Motegrity Tablet, Registered in Food and Drug Administration (FDA)
	GMP status of the firm	Inspection report attached for Renewal of DML 22.2.24
	Evidence of approval of manufacturing facility	No F.3-14/2018-Addl.Dir.(QA-LT-1) dated 17-12-2020 mentioning Tablet section
	Evaluation Remarks	
	Decision	
	Approved	
740	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	Next Pharmaceutical Products (Pvt.) Ltd Plot # 44 A & B, Sunder Industrial Estate Raiwind Road Lahore (000847)
	Application Form Dy. No / Tracking ID & date of submission	(MPX-2A5-ZPQP, 2024-01-02)
	Detail of Fee Submitted	75000.0, 2023-07-27,
	The proposed proprietary name / brand name	Ipragliflozin 25mg Tablet
	Label Claim	Each Film Coated Tablet Contains: 32.125mg Ipragliflozin L-proline eq. to 25mg of Ipragliflozin.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100's-As per SRO, 14's-As per SRO, 28's-As per SRO, 30's-As per SRO, 7's-As per SRO
	Shelf Life (Unit)	2 Year(s) Store in a cool & dry place.
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Fuxin Long Rui Pharmaceutical CO., Ltd : Fluoride industrial Park. Fumeng country (Yi Ma Tu), Fuxin city Liaoning Province-123000
	Detail of stability batches of drug product	3 batches of 2000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Commercial invoice attested by I&E Office DRAP Lahore dated 01-09-2021 has been submitted

Pharmaceutical Equivalence and Comparative Dissolution Profile	PE & CDP studies performed against reference product Suglat tablet
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
The status in reference regulatory authorities	Suglat 25mg Tablet approved by PMDA of Japan
GMP status of the firm	GMP certificate issued on basis of inspection conducted on 18-02-2022
Evidence of approval of manufacturing facility	GMP certificate issued on basis of inspection conducted on 18-02-2022 confirms availability of tablet general section

Evaluation Remarks

1	Valid DML/GMP certificate of drug substance
2.	Justification shall be submitted for not including test of "L-Proline content" and "Specific optical rotation" in drug substance specifications
3.	Justification shall be submitted for the proposed quantity of drug substance per unit tablet, considering the equivalency factor of the salt form reported by innovator drug product literature
4.	Drug substance specifications and analytical procedure shall be submitted from M/s Next Pharma
5.	Justification shall be submitted for not adopting dissolution parameters as per the innovator drug product literature, since innovator has adopted 0.1N HCl dissolution medium whereas firm has used pH 6.8 phosphate buffer as medium
6.	Drug product stability data of 6th month time point shall be submitted

Decision

Deferred

Decision: Deferred for change of specification of dissolution medium as per innovator specification with submission of fee for Pre-registration variation as per S. R.O S"R.O. 1324(I)12024.

741	Case Category	Routine (Shahrukh Ali)
	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	(DVJ-45U-UZR9, 2024-04-23)
	Detail of Fee Submitted	75000.0, 75000.0 2023-12-05, 2024-01-16
	The proposed proprietary name / brand name	Memorin 14mg ER Capsule
	Label Claim	Each capsule contains: 87.5mg of Memantine HCl 16% Sustained Release pellets equivalent to.....14mg of Memantine HCl
	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 oC
	For generic drugs (me-too Status)	None
	Pharmacotherapeutic Group of (API)	N06D ANTI-DEMENTIA DRUGS
	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	3 batches 1000 capsule each
	Documents for the procurement of API with approval from DRAP (in case of Import)	K- 1615146086793 28-Feb-2023
	Pharmaceutical Equivalence and Comparative Dissolution Profile	memantine hydrochloride by M/s Amneal pharmaceutical
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Food and Drug Administration (FDA) USA
	GMP status of the firm	48/2023-DRAP(K) dated 26june 23 mentioning capsule general section
	Evidence of approval of manufacturing facility	48/2023-DRAP(K) dated 26june 23 mentioning capsule general section
	Evaluation Remarks	
	Decision	
	Approved	
742	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	BF Biosciences Limited 5-KM Sundar Raiwind Road, Raiwind, Lahore (000655)
	Application Form Dy. No / Tracking ID & date of submission	(HQL-PQG-9PLQ, 2024-04-17)
	Detail of Fee Submitted	30000.0, 2024-03-25,
	The proposed proprietary name / brand name	Clarion
	Label Claim	Each vial contains Clarithromycin 500mg Product Specs: BP
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's -As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Klaricid (Abbot Laboratories)
	Pharmacotherapeutic Group of (API)	ANTIINFECTIVES FOR SYSTEMIC USE
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Nexchem Pharmaceutical Co., Ltd. 1318 Jinsha street Linjiang industrial zone, Wucheng district, Jinhua city, Zhejiang, 321025 P.R.China
	Detail of stability batches of drug product	1160 Vial 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form-6 K-1058022249234 DRAP 30.sep.22
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Klaricid I.V Injection 500 mg

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Klaricid (Abbot Laboratories) MHRA APPROVED
	GMP status of the firm	No. 153/2023-DRAP(AD-056391517-1346) issue date 27.9.23
	Evidence of approval of manufacturing facility	No. 153/2023-DRAP(AD-056391517-1346) issue date 27.9.23 mentioning parenteral section
	Evaluation Remarks	
	Decision	
	Approved	
743	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	CCL Pharmaceuticals (Pvt.) Ltd. 62-Quaid-e-Azam Industrial Estate, Kot Lakhpat (000052)
	Application Form Dy. No / Tracking ID & date of submission	(LBW-QB6-4Y3V, 2024-03-26)
	Detail of Fee Submitted	75000.0, 2024-01-25,
	The proposed proprietary name / brand name	Finero
	Label Claim	Each film coated tablet contains Finerenone 20 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,14's-As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30
	For generic drugs (me-too Status)	Not available
	Pharmacotherapeutic Group of (API)	Aldosterone antagonists. ATC Code: C03DA05
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	1000 tablets 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	E-3965544887651 DRAP 30.12.22
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Kerendia 20 tablet B. No BXJTVTI Bayer Pharmaceuticals
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Kernedia Tablets - USFDA Approved.
	GMP status of the firm	36/2023-DRAP(AD-957949223) valid till 21.03.25
	Evidence of approval of manufacturing facility	No F.1-8/84-LIC dated 08-6-2021 mentioning Tablet section
	Evaluation Remarks	
	Decision	
	Approved	

744	Case Category		Routine (Shahrukh Ali)								
	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		(UJH-V6X-95GH, 2024-04-02)								
	Detail of Fee Submitted		75000.0, 2024-02-13,								
	The proposed proprietary name / brand name		Misovag								
	Label Claim		Each Tablet contains: Misoprostol 200mcg								
	Reference to Finished product specifications		As per Innovators Specification								
	Proposed Pack Size		10's-As per SRO								
	Shelf Life (Unit)		2 Year(s)Store below 30° C								
	For generic drugs (me-too Status)		None								
	Pharmacotherapeutic Group of (API)		Synthetic prostaglandin E1 analogue G02AD06								
	Name, address of Manufacturing site:		Self Manufacturing								
	Name & address of API manufacturer		Lucent Drug private Ltd Address:Sy. No. 10, Gaddapotharam Village Jinnaram Mandal Sangareddy District -502319, Telangana India								
	Detail of stability batches of drug product		1000 tablets 3 batches								
	Documents for the procurement of API with approval from DRAP (in case of Import)		2205/20 24.07.20								
	Pharmaceutical Equivalence and Comparative Dissolution Profile		Misofar tablet (Laboratorios BIAL, S.A.								
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		IV-A								
	The status in reference regulatory authorities		Member of EC and EMA								
	GMP status of the firm		GMP certificate of the drug product manufacturer Certificate No. 29/2025-DRAP K dated 20.2.25								
	Evidence of approval of manufacturing facility		No F.2-5/2009-Lic(Vol-II) dated 23-march-2023 mentioning tablet section								
Evaluation Remarks											
<table><tr><td>Sr.No</td><td>Observation</td><td>Response</td></tr><tr><td></td><td>1.6.5: Valid copy of GMP certificate of the drug product & Substance manufacturer issued by concerned/relevant regulatory authority shall be submitted</td><td>Firm has submitted GMP certificate of the drug product manufacturer Certificate No. 29/2025-DRAP K dated 20.2.25 GMP certificate of the drug Substance manufacturer valid till 29.1.28</td></tr><tr><td></td><td>3.2.S.4.2 Analytical procedure of drug product manufacturer: Firm has adopted USP specification's however not in line to USP monograph. Flow rate: 1.0 mL/min, (USP 1.5 mL/min) Injection size: 80 µL, , (USP 100</td><td>Firm responded that flow rate was a typographic mistake and now rectified as 1.5ml Injection size: Firm stated that 100 µL injection volume resulted in broader peaks, impacting resolution and quantitation accuracy. A reduction to 80 µL resulted in sharper peaks</td></tr></table>			Sr.No	Observation	Response		1.6.5: Valid copy of GMP certificate of the drug product & Substance manufacturer issued by concerned/relevant regulatory authority shall be submitted	Firm has submitted GMP certificate of the drug product manufacturer Certificate No. 29/2025-DRAP K dated 20.2.25 GMP certificate of the drug Substance manufacturer valid till 29.1.28		3.2.S.4.2 Analytical procedure of drug product manufacturer: Firm has adopted USP specification's however not in line to USP monograph. Flow rate: 1.0 mL/min, (USP 1.5 mL/min) Injection size: 80 µL, , (USP 100	Firm responded that flow rate was a typographic mistake and now rectified as 1.5ml Injection size: Firm stated that 100 µL injection volume resulted in broader peaks, impacting resolution and quantitation accuracy. A reduction to 80 µL resulted in sharper peaks
Sr.No	Observation	Response									
	1.6.5: Valid copy of GMP certificate of the drug product & Substance manufacturer issued by concerned/relevant regulatory authority shall be submitted	Firm has submitted GMP certificate of the drug product manufacturer Certificate No. 29/2025-DRAP K dated 20.2.25 GMP certificate of the drug Substance manufacturer valid till 29.1.28									
	3.2.S.4.2 Analytical procedure of drug product manufacturer: Firm has adopted USP specification's however not in line to USP monograph. Flow rate: 1.0 mL/min, (USP 1.5 mL/min) Injection size: 80 µL, , (USP 100	Firm responded that flow rate was a typographic mistake and now rectified as 1.5ml Injection size: Firm stated that 100 µL injection volume resulted in broader peaks, impacting resolution and quantitation accuracy. A reduction to 80 µL resulted in sharper peaks									

		μL) Detector: UV 200 nm (USP 205nm and improved chromatographic performance. The method was subsequently validated and conforming confirming the method's suitability. Detection wavelength: Photodiode array (PDA) scan of the API, showed enhanced absorbance and improved SNR at 200 nm compared to 205 nm. This adjustment yielded better peak shape without compromising specificity. Analytical Method Validation was performed at 200 nm, and all validation parameters, including specificity, linearity, precision, and accuracy, were found to comply with established criteria.
	Pharmaceutical equivalence study provided has no pictorial evidence or batch number of comparator product	Batch number details updated
Decision		
Approved		
745	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	CCL Pharmaceuticals (Pvt.) Ltd. 62-Quaid-e-Azam Industrial Estate, Kot Lakhpat (000052)
	Application Form Dy. No / Tracking ID & date of submission	(Z17-N4G-44D6, 2024-03-26)
	Detail of Fee Submitted	75000.0, 2024-01-19,
	The proposed proprietary name / brand name	Finero
	Label Claim	Each film coated tablet contains: Finerenone 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30
	For generic drugs (me-too Status)	Not available
	Pharmacotherapeutic Group of (API)	Aldosterone antagonists. ATC Code: C03DA05
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	1000 tablets 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	E-3965544887651 DRAP 30.12.22
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Kerendia 10mg tablet B. No BXJTVTI Bayer Pharmaceuticals

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Kernedia Tablets - USFDA Approved.
	GMP status of the firm	36/2023-DRAP(AD-957949223) valid till 21.03.25
	Evidence of approval of manufacturing facility	No F.1-8/84-LIC dated 08-6-2021 mentioning Tablet section
	Evaluation Remarks	
	Decision	
	Approved	
746	Case Category	Priority As Per 257-M of RB (Tahir Waqas)
	Name, address of Applicant.	Martin Dow Marker Limited Nice Trade Orbit Building, 44-A, Block-6, P.E.C.H.S, Razi Road, Shahrah-e-Faisal, Karachi (0188)
	Application Form Dy. No / Tracking ID & date of submission	(5JN-BGS-6ZLQ, 2025-03-27)
	Detail of Fee Submitted	300000.0, 2024-12-17,
	The proposed proprietary name / brand name	Pexate Injection 100mg
	Label Claim	Each vial of lyophilized powder contains: Pemetrexed Disodium Equivalent to Pemetrexed ... 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Alimta 100mg Injection of M/s Eli Lilly Pakistan (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	L01BA04, Antifolate antineoplastic agent.
	Name, address of Manufacturing site:	M/s Shilpa Medicare Limited -Plot No. S-20 to s26, Pharma, SEZ, TSIIC, Green Industrial Park, Pollepally Village, Jadcherla Mandal, Mahaboobnagar District, Telangana State, India-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	M/s Shilpa Medicare Limited , Plot No. S-20 to s26, Pharma, SEZ, TSIIC, Green Industrial Park, Pollepally Village, Jadcherla Mandal, Mahaboobnagar District, Telangana State, 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	ALIMTA 100mg for Injection, USFDA approved.
	Evaluation Remarks	

	Pemetrexed in combination with cisplatin is indicated for the treatment of patients with malignant pleural mesothelioma whose disease is either unresectable or who are otherwise not candidates for curative surgery. Decision Approved	
747	Case Category	Priority As Per 257-M of RB (Tahir Waqas)
	Name, address of Applicant.	Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan (01-374-0006)
	Application Form Dy. No / Tracking ID & date of submission	(97U-9PD-M2EY, 2024-12-26)
	Detail of Fee Submitted	300000.0, 2024-12-20,
	The proposed proprietary name / brand name	Gadomine
	Label Claim	Each ml contains: Gadopentetate Dimeglumine ... 469mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's (20ml Vial)-As per SRO
	Shelf Life (Unit)	36 Month(s)Store at controlled room temperature at 20-25°C, excursion permitted to 15-30°C. Do not freeze. Protect from light and secondary X ray.
	For generic drugs (me-too Status)	Magnevist Injection (011539) of M/s Bayer Pakistan (Pvt) Limited.
	Pharmacotherapeutic Group of (API)	Contrast agent for intravenous use in diagnostic MRI.
	Name, address of Manufacturing site:	Unijules Life Sciences Limited-D-82, Cross road no 4 A, MIDC Area, Hingna, Nagpur – 440028 (M.S), India-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence conducted against Gadopentetate Dimeglumine Injection 469mg of M/s Unique Pharmaceutical Laboratories.
	Name, address of Marketing Authorization Holder:	Unijules Life Sciences Limited, D-82, Cross road no 4 A, MIDC Area, Hingna, Nagpur – 440028 (M.S), India, India
	Details of Certificates (CoPP/FSC/cGMP):	Scanned copy of GMP Certificate No. 6118257 valid till 28-02-2025, issued by FDA (Nagpur Division) Maharashtra State, India has been enclosed.
	Details of Authorization Letter :	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Studies conducted on Zone II by Drug Substance Manufacturer.
	The status in reference regulatory authorities	MAGNEVIST® (gadopentetate dimeglumine) 469.01MG/ML IV Injection of Bayer HealthCare, UDFDA (Discontinued)
	Evaluation Remarks	
	Case was deferred in 345th Registration Board Meeting for submission of response to the following deficiencies: 1) 1.3.3. Certificate of Pharmaceutical Product (CoPP) has not been submitted.2) Enclosed Distribution Certificate / Letter of Authorization is not notarized.The firm had submitted following response 1) Copy of Certificate of Pharmaceutical Product (CoPP).2) Firm had stated that, "Both the	

	Certificate of Pharmaceutical Product (COPP) and the Letter of Authorization (LOA) are currently undergoing the legalization process, and we are awaiting their shipment. We anticipate being able to submit the original documents within two weeks".Case was deferred in 347th Registration Board Meeting for further deliberation.	
	Decision	
	Approved	
748	Case Category	New Section (Tahir Waqas)
	Name, address of Applicant.	Bio-Labs(Pvt) Ltd Plot 145, Industrial Triangle, Kahuta Road (000296)
	Application Form Dy. No / Tracking ID & date of submission	(SH4-3W7-XGSP, 2024-10-22)
	Detail of Fee Submitted	30000.0, 7000.0 2024-03-01, 2024-10-16
	The proposed proprietary name / brand name	Miniox Topical Solution 2% (w/v)
	Label Claim	Each ml contain: Minoxidil ... 20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	60ml-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Minoxy Lotion 2% of M/s Danas Pharmaceuticals (Pvt) Ltd.
	Pharmacotherapeutic Group of (API)	D11AX01, Other dermatologicals
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Kumar Organic Products Limited, India.
	Detail of stability batches of drug product	03 Batches, 150 Bottles each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Copy of I&E Clearance Certificate for Import of 100Kgs API by MaxiTech Pharma, Karachi has been enclosed. No information on Loan of API has been submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence has been conducted against Minoxin Lotion of M/s Brookes Pharma.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Studies conducted on Zone IV by Drug Substance Manufacturer
	The status in reference regulatory authorities	ROGAINE (FOR MEN / WOMEN) Topical Solution 2%, USFDA approved (Over the counter)
	GMP status of the firm	Not provided
	Evidence of approval of manufacturing facility	Copy of Section approval letter from Licensing Division for Lotion (General) Section has been submitted.
Evaluation Remarks		
Case was initially deferred in 345th Meeting for submission of rule position under which sale / purchase of API has been conducted.In response to above, the firm had submitted clarification that, "Although invoice was issued for the purpose of documentation, it is important to clarify that no payment was made against this invoice. The invoice served solely as a formal record of the API loan and not as a commercial transaction."The firm had previously submitted Invoice (No. MTP230801 dated 01-08-2023 from M/s MaxiTech Pharma (Pvt) Ltd. E-178, SITE Super Highway, Phase-II Karachi) for Purchase of API, along with intimation of obtaining material (R&I date 02 Aug 2023) wherein Terms were mentioned as 'Paid'.Furthermore, Registration Board in its 347th Meeting deferred the case and decided to call both parties for a Personal Hearing along with all supporting evidence / data pertaining to the claim.Submitted for consideration of the Board.		

Decision**Deferred**

On July 2, 2025, in the Committee Room at DRAP Islamabad, Mr. Hafiz Tariq Khalil - Head of R&D and Ms. Darakhshan - Head of Regulatory from M/s Bio-Labs (Pvt.) Ltd., accompanied by Ms. Nazia Tauseef – Regulatory Affairs from M/s Maxitech Pharma (Pvt.) Ltd., appeared before the Registration Board.

Ms. Darakhshan from M/s Bio-Labs (Pvt.) Ltd., explained that the intimation of loan / invoice submitted to DRAP on 02-08-2023 was an administrative oversight and offered a formal apology and reaffirmed commitment to strict compliance with DRAP regulations going forward.

Meanwhile, Ms. Nazia Tauseef from M/s Maxitech Pharma (Pvt.) Ltd., confirmed that there was no transaction involved and the API was provided to M/s Bio-Labs (Pvt.) Ltd., on Loan basis and submitted the corresponding loan agreement.

The Board accepted M/s Bio-Labs (Pvt.) Ltd.'s apology for the administrative oversight and decided to issue Warning to M/s Bio-Labs (Pvt.) Ltd., for strict adherence to DRAP procedures.

Case was deferred for further deliberation.

749	Case Category	Priority As Per 257-M of RB (Tahir Waqas)
	Name, address of Applicant.	Martin Dow Marker Limited Nice Trade Orbit Building, 44-A, Block-6, P.E.C.H.S, Razi Road, Shahrah-e-Faisal, Karachi (0188)
	Application Form Dy. No / Tracking ID & date of submission	(ZAG-GDY-YDJQ, 2025-03-23)
	Detail of Fee Submitted	300000.0, 2024-12-17,
	The proposed proprietary name / brand name	Pexate
	Label Claim	Each vial of lyophilized powder contains: Pemetrexed Disodium Equivalent to Pemetrexed ... 500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Alimta 500mg Injection of M/s Eli Lilly Pakistan (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	L01BA04, Antifolate antineoplastic agent.
	Name, address of Manufacturing site:	M/s Shilpa Medicare Limited-Plot No. S-20 to s26, Pharma, SEZ, TSIIC, Green Industrial Park, Pollepally Village, Jadcherla Mandal, Mahaboobnagar District, Telangana State, India-India

Pharmaceutical Equivalence and Comparative Dissolution Profile	
Name, address of Marketing Authorization Holder:	M/s Shilpa Medicare Limited, Plot No. S-20 to s26, Pharma, SEZ, TSIIC, Green Industrial Park, Pollepally Village, Jadcherla Mandal, Mahaboobnagar District, Telangana State, 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	ALIMTA 500mg for Injection, USFDA approved.
Evaluation Remarks	
Pemetrexed in combination with cisplatin is indicated for the treatment of patients with malignant pleural mesothelioma whose disease is either unresectable or who are otherwise not candidates for curative surgery.	
Decision	
Approved	



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



Item No. V: Additional/Supplementary Minutes:
Applications submitted on e-App (PE&R)

Sr. No	Title	Description
1	Case Category	Routine (Abdul Mughees)
	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	(2X7-4X8-UVEL, 2024-03-22)
	Detail of Fee Submitted	30000.0, 2023-12-07,
	The proposed proprietary name / brand name	RASAGIL Tablets 0.5mg
	Label Claim	Each tablet contains: Rasagiline mesylate equivalent to Rasagiline.....0.5mg
	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)	Alzilo Tablets 0.5mg by Searle Pakistan
	Pharmacotherapeutic Group of (API)	Monoamine oxidase B inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Glenmark Life Science Limited - India
	Detail of stability batches of drug product	Submitted for 6 months.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 05-01-2021 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Alzilo tablet 2 mg manufactured by Searle Company Limited, Karachi, Pakistan
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability was performed on 40°±2°C/75±5% RH and 30°±2°C/65±5% RH. Stability chromatograms have been submitted.
	The status in reference regulatory authorities	Azilect® (rasagiline mesylate) Tablet by Teva Pharmaceuticals USA approved by USFDA
	GMP status of the firm	Certificate No. 146 /2022-DRAP (K) dated 25 August 2022 was submitted.
	Evidence of approval of manufacturing facility	REGULARIZATION OF SECTIONS letter dated 28th December, 2020 was submitted.
	Evaluation Remarks	
	Decision	
	Approved	

2	Case Category	Contract Manufacturing (Abdul Mughees)
	Name, address of Applicant.	Horizon Healthcare (pvt.) ltd. 35-A Small Industrial Estate - Taxila (000856)
	Application Form Dy. No / Tracking ID & date of submission	(S23-NLY-8QHT, 2024-01-11)
	Detail of Fee Submitted	75000.0, 2023-12-15,
	The proposed proprietary name / brand name	Rabmide 100mg Tablet
	Label Claim	Each film coated tablet contains: Rebamipide.....100mg
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30°C in cool and dry place.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Horizon Healthcare Pvt. Ltd.-Plot No. 33- Sundar Industrial Estate, Lahore-
	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	Approved drug by PMDA by MUCOSTA 100mg tablet by Otsuka Pharmaceutical Co., Ltd.
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
Evaluation Remarks		
1. 1.3.5 The attached GMP certificate No. F. 3- 29/2019-Addl. Dir. (QA & LT-I)-59 has expired on 15-08-2024. Please submit an updated GMP certificate (issued after aforementioned date). 2. 1.4 Correction of type of application to “Generic Drug Product” is required. 3. 1.6.5 Submit valid GMP certificate of Drug Substance manufacturer. 4. 2.3.S.1.1 Invalid CAS registry number is given. Please clarify. 5. 2.3.S.1.3 (c) Please specify which polymorph (form) of Rebamipide was used? 6. 2.3.S.1.3 (d) Submit correct λmax of Rebamipide along with evidence of a weblink containing correct information/COA from DS manufacturer/Pharmacopoeia page (if available).7. 2.3.P.3.2Please clarify why Isopropyl Alcohol (IPA) is mentioned in Section 2.3.P.1 (b) in the manufacturing of a core tablet, but then not explicitly listed or "accounted for" in the final batch formula in 2.3. P.3.2. Isopropyl Alcohol (IPA) was erroneously mentioned in Section 2.3.P.1(b). 8. 3.2 P.5.2 a. Submit sample preparation method for dissolution test.b. Clarification regarding dilution factor used in sample preparation in dissolution test is required.9. 3.2.P.8.3Submit 06 months’ stability data. 06 months stability data is attached here 10. Please flag DRAP cleared invoice of the Drug Substance. Invoice is attached here.		
Decision		
Approved		
Manufacturer will adopt complete Japanese Pharmacopoeia Specifications.		

	Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application. Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.	
3	Case Category	Routine (Abdul Mughees)
	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	(GEL-GZP-TRX5, 2024-03-18)
	Detail of Fee Submitted	30000.0, 2023-12-07,
	The proposed proprietary name / brand name	RASAGIL Tablets 1mg
	Label Claim	Each tablet contains: Rasagiline mesylate equivalent to Rasagiline.....1mg
	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)	Alzilo Tablets 1mg by Searle Pakistan
	Pharmacotherapeutic Group of (API)	Monoamine oxidase B inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Glenmark Life Science Limited - India
	Detail of stability batches of drug product	Submitted for 6 months.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 05-01-2021 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Alzilo tablet 1 mg AFD001 manufactured by Searle Company Limited, Karachi, Pakistan
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability was performed on 40°±2°C/75±5% RH and 30°±2°C/65±5% RH. Stability chromatograms have been submitted.
	The status in reference regulatory authorities	Azilect® (rasagiline mesylate) Tablet by Teva Pharmaceuticals USA approved by USFDA
	GMP status of the firm	Certificate No. 146 /2022-DRAP (K) dated 25 August 2022 was submitted.
	Evidence of approval of manufacturing facility	REGULARIZATION OF SECTIONS letter dated 28th December, 2020 was submitted.
	Evaluation Remarks	
	.	
	Decision	
	Approved	
4	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(7LR-7JZ-WG99, 2024-03-11)

	Detail of Fee Submitted	30000.0, 2024-01-26,
	The proposed proprietary name / brand name	Obetic 10mg Tablet
	Label Claim	Each Film Coated Tablet contains: Obeticholic Acid.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at cool &dry place below 30
	For generic drugs (me-too Status)	Abeticolic 10mg Tablet M/s Dyson Research Laboratories (Pvt) LTD
	Pharmacotherapeutic Group of (API)	A05AA04 Bile acids and derivatives
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Lianyungang Jari PharmaceuticalCo.,Ltd
	Detail of stability batches of drug product	3 batches, 2000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 (drug import license is submitted)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Abeticolic 10mg Tablet Batch No. DZ003 Mfg: Dyson
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	OCALIVA (obeticholic acid) tablet 10mg M/s Intercept Pharmaceuticals Morristown, NJ 07960 (USFDA app
	GMP status of the firm	GMP certificate issued on basis of inspection 03.04.2023 is submitted
	Evidence of approval of manufacturing facility	Section approval letter dated 07.02.2014 is submitted
	Evaluation Remarks	
	Decision	
	Approved	
5	Case Category	Priority As Per 257-M of RB (Adil Saeed)
	Name, address of Applicant.	Kaizen Pharmaceuticals (Pvt) Ltd Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi (000755)
	Application Form Dy. No / Tracking ID & date of submission	(8S2-V8W-S44G, 2025-05-05)
	Detail of Fee Submitted	37000.0, 2025-03-14,
	The proposed proprietary name / brand name	Myribo (Ribociclib) 200mg Tablet
	Label Claim	Each Film coated Tablet Contains: Ribociclib.....200 mg (equivalent to 254.40 mg of the succinate salt of Ribociclib).
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-As per SRO,21's-As per SRO,63'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)	Kisqali 200mg Film Coated Tablet Market Authorization Holder: Novartis Pharma (Pakistan) Limited
	Pharmacotherapeutic Group of (API)	Antineoplastic agents, protein kinase inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	GANSU HAOTIAN PHARMACEUTICAL CO., LTD Address:NO. 11, CHONGQING ROAD, SMALL AND MEDIUM- SIZED ENTERPRISE BUSINESS BASE BAIYIN GANSU P. R. CHINA
	Detail of stability batches of drug product	3 batches, 500 tablets each.
	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	Therapeutic Goods Administration (TGA)
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	attached
	Evaluation Remarks	
	Decision	
	Approved	
6	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(9MU-6XW-86QY, 2024-03-12)
	Detail of Fee Submitted	30000.0, 2024-01-26,
	The proposed proprietary name / brand name	Lasmi 50mg Tablet
	Label Claim	Each Film Coated Tablet contains Lasmiditan Hemisuccinate equivalent to Lasmiditan.....50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x4's, 1x10's, 2x7's, -As per SRO
	Shelf Life (Unit)	2 Year(s) Store at cool & dry place below 30
	For generic drugs (me-too Status)	N.A
	Pharmacotherapeutic Group of (API)	ANTIMIGRAINE PREPARATIONS Selective serotonin (5HT1) agonists N02CC08
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Metrochem API Pvt Ltd.
	Detail of stability batches of drug product	3 batches, 950 tablets each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 (import license)

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Rayvow 50mg Tablet Batch No. D753212 Mfg: Lilly USA, LLC Indianapolis, IN46285, USA Product of ireland
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	REYVOW (lasmiditan) tablet 50mg M/s Eli lilly and Company(USFDA approved) NDC 0002-4312-08
	GMP status of the firm	GMP certificate issued on basis of inspection dated 03.04.2023 is submitted
	Evidence of approval of manufacturing facility	Section approval letter dated 07.02.2014 is submitted
	Evaluation Remarks	
	Decision	
	Approved	
7	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(G8G-5Y5-NRJL, 2024-03-12)
	Detail of Fee Submitted	30000.0, 2024-01-26,
	The proposed proprietary name / brand name	Lasmi 100mg Tablet
	Label Claim	Each Film Coated Tablet contains Lasmiditan Hemisuccinate equivalent to Lasmiditan.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x4's, 1x10's, 2x7's,-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at cool &dry place below 30
	For generic drugs (me-too Status)	N.A
	Pharmacotherapeutic Group of (API)	Selective serotonin (5HT1) agonists N02CC08
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Metrochem API Pvt Ltd.
	Detail of stability batches of drug product	3 batches, 950 tabs each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 (drug import license is submitted.)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Rayvow 100mg Batch No. D6188338 Mfg: Lilly USA, LLC Indianapolis, IN46285, USA Product of ireland
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	REYVOW (lasmiditan) tablet 100mg M/s Eli lilly and Company(USFDA approved) NDC 0002-4491-08
	GMP status of the firm	GMP certificate is submitted
	Evidence of approval of manufacturing facility	Section approval letter is submitted

	Evaluation Remarks	
	Decision	
8	Approved	
	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(WQN-4SP-A88J, 2024-03-12)
	Detail of Fee Submitted	30000.0, 2024-01-26,
	The proposed proprietary name / brand name	Obetic 5mg Tablet
	Label Claim	Each Film Coated Tablet contains Obeticholic Acid.....5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at cool &dry place below 30
	For generic drugs (me-too Status)	Abeticolic 5mg Tablet M/s Dyson Research Laboratories (Pvt) LTD Registration #103521
	Pharmacotherapeutic Group of (API)	A05AA04 Bile acids and derivatives
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Lianyungang Jari PharmaceuticalCo.,Ltd
	Detail of stability batches of drug product	3 batches, 2000 tabs each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6(Import License) is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Abeticolic 5mg Tablet Batch No. DY001 Mfg: Dyson
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	OCALIVA (obeticholic acid) tablet 5mg M/s Intercept Pharmaceuticals Morristown, NJ 07960 (USFDA appr
	GMP status of the firm	GMP certificate issued on basis of inspection dated 03.04.2023 is submitted.
	Evidence of approval of manufacturing facility	Section approval letter dated 07.02.2014 is submitted
	Evaluation Remarks	
	Decision	
	Approved	
9	Case Category	Priority As Per 257-M of RB (Dr. Farhad Ullah)
	Name, address of Applicant.	MSA PHARMA 1304, Green Acre, Pine Avenue (05-352-0066)
	Application Form Dy. No / Tracking ID & date of submission	(P91-7A2-QJN9, 2025-04-22)

Detail of Fee Submitted	300000.0, 2025-02-04,
The proposed proprietary name / brand name	Azarest 300mg Tablet
Label Claim	Each film-coated tablet contains....Azacitidine 300mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	14's-As per SRO
Shelf Life (Unit)	24 Month(s)Store below 30°C.
For generic drugs (me-too Status)	Not Applicable
Pharmacotherapeutic Group of (API)	Antineoplastic agents, Antimetabolites, Pyrimidine analogues WHO ATC code; L01BC07
Name, address of Manufacturing site:	Everest Pharmaceuticals Limited.-Plot No: B-45, 46 & 33, BSCIC I/A, Kanchpur, Narayanganj, - Bangladesh
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE & CDP studies performed against Onureg 300 mg film-coated tablets Manufactured by Celgene Corporation A Wholly Owned Subsidiary of Bristol-Myers Squibb 86 Mon is A venue Surmnit, NJ 0790 1, Marketed by Bristol-Myers Squibb Pharma, Ireland.
Name, address of Marketing Authorization Holder:	Everest Pharmaceuticals Limited., Factory: Plot No: B-45, 46 & 33, BSCIC I/A, Kanchpur, Narayanganj, Bangladesh. Head office Address: Rahman's Regnum Centre (11th Floor) 191/1, Tejgaon C/A, Dhaka-1208, Bangladesh, Bangladesh
Details of Certificates (CoPP/FSC/cGMP):	GMP certificate: Firm has submitted notarized copy of cGMP certificate of product manufacturer issued by Director General of Drug Administration Oushad Bhaban Dhaka Bangladesh valid upto 30-09-2026. Certificate of Pharmaceutical Product: Firm has submit
Details of Authorization Letter :	Firm has submitted legalized copy of letter of authorization from M/s Everest Pharmaceuticals Limited., Rahman's Regnum Centre (11th floor) 191/1 Bir Uttam Mir Shawkat Sarak, Tejgaon C/A, Dhaka-1208, Bangladesh for applied product dated; 12-11-2024.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of three batches is submitted Real time (24 months): 30°C ± 2 °C /75% ±5%RH Accelerated (6 months): 40°C±2 °C /75% ±5%RH
The status in reference regulatory authorities	Onureg 300mg Film-coated Tablet, Netherlands Approved, USFDA Approved
Evaluation Remarks	
Shortcomings	Firm's response
The submitted COA of API from drug product manufacturer indicates that manufacturing date of API is Jan,2023, the Testing Date: Jan,2027, Reporting Date: Jan,2017 and Retest Date: Jan,6,2017. Furthermore, COAs are submitted without signatures. Could you please clarify how	Firm has submitted revised COA from drug product manufacturer and submitted that it was a typographically error.

the testing (Jan 2027), reporting (Jan 2017), and retest (Jan , 2017) dates are assigned, given that the manufacturing date of the API is Jan 2023?	
Justification shall be submitted for selecting value of Q below 75% in dissolution test of finished product which is not recommended in any pharmacopoeia or guidance document of any reference regulatory authority	The decision to adopt a Q value below 75% for the dissolution specification of the finished product is justified based on: • Formulation science and design intent, • A validated in-house dissolution method, • In vitro–in vivo correlation and/or clinical data, • Batch reproducibility and stability support, • Alignment with the principles of ICH Q8/Q9/Q10. This specification ensures that the product remains safe, effective, and of high quality throughout its lifecycle, even though it does not follow a Q threshold explicitly mentioned in any pharmacopoeia or regulatory guidance

Decision

Approved

Approved, As per policy for the inspection of the manufacturer abroad.

Registration Board further decided that Registration letter will be issued after submission of;

Revised dissolution specifications of the drug product indicating value of Q not less than 75% as per decision of 293rd meeting of Registration Board.

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

10	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	NovaMed Pharmaceuticals(Pvt.)Ltd 28-KM Ferozepur Road Lahore (000590)
	Application Form Dy. No / Tracking ID & date of submission	(RMV-BT9-6VYW, 2024-03-12)
	Detail of Fee Submitted	75000.0, 9000.0 2024-01-03, 2025-06-30
	The proposed proprietary name / brand name	Feroxyma injection 750mg/15ml
	Label Claim	Each ml contains:Ferric carboxymaltose equivalent to elemental iron.....50 mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	15ml (1's)-As per SRO
	Shelf Life (Unit)	2 Year(s)store at controlled room temperature below 30C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Anti-anaemic preparation
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Nanjing Hencer Pharmaceutical Co,Ltd
	Detail of stability batches of drug product	3 batches having batch size of 200 vial each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of commercial invoice cleared dated 20-05-2021 specifying 2.4kg Ferric Carboxymaltose.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Injectafer 750mg/15ml by M/s American Regent, Inc. Shirley, NY.
	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	INJECTAFER 750mg/15ml (50mg/ml) USFDA Approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate based on inspection dated 07-11-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional/regularization of DML dated 14-09-2021 specifying Liquid Injectable Ampoule/Vial General-Revised section.
	Evaluation Remarks	
	Shortcomings	Firm's response
	Justification shall be submitted for not including the test for content of chloride and assay test for dextrin in drug substance specifications by drug product manufacturer as given by drug substance manufacturer	The firm submitted that we acknowledge that these tests were not initially included in our specification. However, to ensure full alignment with the drug substance manufacturer's specifications, we have updated our specifications. Revised Analytical method is submitted for reference. Firm has also submitted fee Rs. 9000/ vide receipt No. 927775566 for revision of specifications
	Decision	
	Approved	
11	Case Category	New License (Dr. Farhad Ullah)
	Name, address of Applicant.	Nahal Pharmaceuticals (Pvt) Ltd. Plot No. 2, Street No. SS-4, RCCI, Industrial Estate Rawat (000989)
	Application Form Dy. No / Tracking ID & date of submission	(TJZ-GME-4Y73, 2025-04-14)
	Detail of Fee Submitted	37000.0, 2025-03-20,
	The proposed proprietary name / brand name	Nagaten 312.50 mg Dry Suspension
	Label Claim	When dispensed as directed. Each 5 ml contains: 250 mg amoxycillin as the amoxycillin trihydrate U.S.P. and 62.50 mg Clavulanic acid as the potassium salt B.P.
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	90 ml, & 60 ml-As per SRO
	Shelf Life (Unit)	2 Year(s) As per USP
	For generic drugs (me-too Status)	Augmentin DS 312.5mg/5ml Suspension by M/s GSK
	Pharmacotherapeutic Group of (API)	Combinations of penicillins, incl. beta-lactamase inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zafa Chemie Pakistan & Zhuhai United Laboratories China

Detail of stability batches of drug product	3 batches having batch size of 2000 Bottles each
Documents for the procurement of API with approval from DRAP (in case of Import)	Loan letter from M/s Fedro Pharma Peshawar and sale tax invoice from M/s Zafa Pharmaceutical (Zafa Chemie Division) is submitted for Amoxicillin trihydrate Loan letter from M/s Don valley Lahore and clearance document is submitted for Potassium Clavulanate.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Augmentin 312.5mg/5ml
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	Augmentin for Oral Suspension (250mg/62.5mg) USFDA Approved
GMP status of the firm	New DML
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML 25-01-2024 specifying Dry Powder Suspension (Penicillin) Section.
Evaluation Remarks	
Shortcomings	Firm's response
Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	Copy of letter of receiving for renewal of DML (Zafa Chemie) dated 05-11-2020 in licensing division DRAP is submitted
Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3	Submitted
Copy of loan agreement for API between the firms and intimation of borrowing of API submitted in DRAP shall be submitted	Firm has submitted copy of loan agreement for API between the firms and intimation of borrowing of API submitted in DRAP dated 11-03-2024
Decision	
Approved	
Registration Board further decided that Registration letter will be issued after Verification of loan letter of API.	
12	Case Category
	Routine (Dr. Farhad Ullah)
	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
	(TVX-J42-L6ST, 2024-03-27)
	Detail of Fee Submitted
	30000.0, 2024-02-19,
	The proposed proprietary name / brand name
	Eziday-DUO 10/50mg Tablets
	Label Claim
	Each Film Coated Tablet Contains:- Amlodipine as Besylate.....10mg Losartan Potassium.....50mg
	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)20oC -25oC
For generic drugs (me-too Status)	Pixiz 10/50mg Tablets By Tabros Pharma, Karachi
Pharmacotherapeutic Group of (API)	Losartan Potassium: Angiotensin II receptor blockers (ARBs) Amlodipine besylate: Calcium channel blockers
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	PRUDENCE PHARMA CHEM., India,Zhejiang Tianyu Pharmaceutical Co., Ltd., China
Detail of stability batches of drug product	3 batches having batch size of 1500 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate issued dated 23-06-2022 specifying 500kg Losartan potassium. Firm has submitted copy of commercial invoice cleared dated 20-08-2020 specifying 500kg Amlodipine besylate.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against LosAmlo 10mg/50mg Tablets.,
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	Losamlo 10/50mg Tablets TAD Pharma GmbH Germany Approved https://portal.dimdi.de/amguifree/am/docoutput/jpad
GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 12-08-2022.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 29-11-2022 specifying Tablet (General) section.
Evaluation Remarks	
Shortcomings	Firm's response
Justification shall be submitted for using six unit for dissolution test in CDP studies instead of 12 units as recommended by WHO guideline for conducting comparative dissolution profiles CDP studies using 12 units as recommended by WHO guideline for conducting comparative dissolution profiles shall be submitted.	The 6-unit study for dissolution test in CDP (Comparative Dissolution Profile) for our Product EzidayDUO 10/50mg Tablets was designed as a preliminary assessment to establish dissolution similarity between the test and reference products. The study adhered to the following WHO recommendations, including: • Identical test conditions for both products; • Inclusion of critical time points (including 15 minutes) to assess rapid dissolution and f2 applicability; • Testing in three physiological media: pH 1.2, 4.5, and 6.8. Study outcomes confirmed: • Comparable dissolution profiles with no significant differences; • f2 values >50, indicating profile similarity; • Low inter-unit variability, as evidenced by: • Coefficient of variation (CV) or Relative Standard Deviation (RSD) values consistently below 10% at each time point. • These values are well within the generally accepted variability limits for dissolution testing (e.g., ≤20% at early time points, ≤10% thereafter as per international regulatory standards). We would like to inform you that, in due course, the comparative product will be arranged by our firm

from an international source, as the local comparative product is currently unavailable in the market. 12Units CDP will be conducted at our earliest. We formally commit to conduct a complete 12-unit CDP study post approval, in full compliance with WHO requirements. Results will be submitted as part of post-marketing documentation or within the timeframe specified by DRAP. We respectfully request the grant of conditional registration of our product.

Decision

Deferred

Deferred for submission of CDP studies of applied product against innovator/reference/comparator using 12 units as recommended by WHO guideline for conducting comparative dissolution profiles

13	Case Category	Priority As Per 257-M of RB (Dr. Farhad Ullah)
	Name, address of Applicant.	Martin Dow Marker Limited Nice Trade Orbit Building, 44-A, Block-6, P.E.C.H.S, Razi Road, Shahrah-e-Faisal, Karachi (0188)
	Application Form Dy. No / Tracking ID & date of submission	(W4Z-Q93-4GP6, 2025-03-23)
	Detail of Fee Submitted	300000.0, 2024-12-17,
	The proposed proprietary name / brand name	Bortenat 3.5mg Injection
	Label Claim	Each vial of lyophilized powder contains: Bortezomib.....3.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Cytomib 3.5mg Injection (Helix Pharma (Pvt.) Ltd. Reg No:105660)
	Pharmacotherapeutic Group of (API)	Proteasome inhibitors WHO ATC code; L01XG
	Name, address of Manufacturing site:	M/s Shilpa Medicare Limited-Plot No. S-20 to s26, Pharma, SEZ, TSIIC, Green Industrial Park, Pollepally Village, Jadcherla Mandal, Mahaboobnagar District, Telangana State, India-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Velcade-Bortezomib for injection 3.5mg/vial by Takeda Pharmaceuticals America, Inc. [Formerly Marketed by Millennium Pharmaceuticals, Inc.]
	Name, address of Marketing Authorization Holder:	M/s Shilpa Medicare Limited, Plot No. S-20 to s26, Pharma, SEZ, TSIIC, Green Industrial Park, Pollepally Village, Jadcherla Mandal, Mahaboobnagar District, Telangana State, India, India
	Details of Certificates (CoPP/FSC/cGMP):	CoPP: Firm has submitted legalized copy of CoPP 4311910/TS/2024 issued by Drugs Control Administration, Telangana State India valid upto 14.03.2026 The certificate confirm the free sale

		status of the product in country of Origin along with GMP of the ma
	Details of Authorization Letter :	Firm has submitted legalized copy of letter of authorization from M/s Shilpa Medicare Limited., Plot No. S-20 to S-26, Pharma, SEZ, TSIIC, Green Industrial Park, Pollepally Village, Jadcherla Mandal, Mahaboobnagar District, Telangana State, India for applied product dated; 22-10-2024
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of three batches is submitted Real time (24 months): 30°C ± 2 °C /75% ±5%RH Accelerated (6 months): 40°C±2 °C /75% ±5%RH
	The status in reference regulatory authorities	VELCADE for injection (3.5mg), USFDA approved
	Evaluation Remarks	
	Decision	
	Approved	
	As per policy for the inspection of the manufacturer abroad.	
14	Case Category	New License (Dr. Farhad Ullah)
	Name, address of Applicant.	Nahal Pharmaceuticals (Pvt) Ltd. Plot No. 2, Street No. SS-4, RCCI, Industrial Estate Rawat (000989)
	Application Form Dy. No / Tracking ID & date of submission	(XMR-XXP-WW1A, 2025-04-14)
	Detail of Fee Submitted	37000.0, 2025-03-20,
	The proposed proprietary name / brand name	Nagaten 156.25 mg Dry Suspension
	Label Claim	when dispensed as directed.Each 5 ml contains: 125 mg amoxycillin as the amoxycillin trihydrate U.S.P. and 31.25 mg clavulanic acid as the potassium salt B.P.
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	90 ml-As per SRO
	Shelf Life (Unit)	2 Year(s)As per USP
	For generic drugs (me-too Status)	Augmentin 156.25mg/5ml Suspension by M/s GSK
	Pharmacotherapeutic Group of (API)	Combinations of penicillins, incl. beta-lactamase inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zafa Chemie Pakistan & Zhuhai United Laboratories China
	Detail of stability batches of drug product	3 batches having batch size of 2000 Bottles each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan letter from M/s Fedro Pharma Peshawar and sale tax invoice from M/s Zafa Pharmaceutical (Zafa Chemie Division) is submitted for Amoxicillin trihydrate Loan letter from M/s Don valley Lahore and clearance document is submitted for Poatssium Clavulanate.

Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Augmentin 156.25mg/5ml
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	Augmentin for Oral Suspension (125mg/31.25mg) USFDA Approved
GMP status of the firm	New DML
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML 25-01-2024 specifying Dry Powder Suspension (Penicillin) Section.

Evaluation Remarks

Shortcomings	Firm's response
Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	Copy of letter of receiving for renewal of DML (Zafa Chemie) dated 05-11-2020 in licensing division DRAP is submitted
Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3	Submitted
Copy of loan agreement for API between the firms and intimation of borrowing of API submitted in DRAP shall be submitted	Firm has submitted copy of loan agreement for API between the firms and intimation of borrowing of API submitted in DRAP dated 11-03-2024

Decision

Approved

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

15	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	(8NT-GLX-TY2P, 2024-08-20)
	Detail of Fee Submitted	30000.0, 2023-10-10,
	The proposed proprietary name / brand name	Dcad3 10000IU soft gelatin capsule
	Label Claim	each soft gel capsule contains: Vitamin D3(Cholecalciferol).....10000IU
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	3x10'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)	sunny-D 10000IU
	Pharmacotherapeutic Group of (API)	vitamin
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Sichuan Province Yuxin Pharmaceuticals Co.Ltd
	Detail of stability batches of drug product	3 months data is submitted.
	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)	36 Real time stability at 5°C □ 3°C and accelerated stability at 30°C □ 2°C /65% □ 5% RH is performed for 3 bathces
	The status in reference regulatory authorities	EURO-D 10000IU Health Canada)
	GMP status of the firm	GMP certificate issued in the basis of inspection conducted on 04.11.2021
	Evidence of approval of manufacturing facility	Soft gelatin capsule general REVISED section was approved on 27th Feb, 2023
	Evaluation Remarks	
	Reason	Reply
	Submission of P.E. studies by performing all the quality tests and detail of the product against which P.E. studies have been performed including batch number, name of manufacturer etc.	P.E studies have been performed against the reference product i.e. Euro D 10000IU softgel Cap by M.s Euro Pharma International Canada Inc. Batch: DFK2201
	Documents confirming (including invoice, clearance certificate etc) import of API.	Clearance certificate dated 06-03-2023 is submitted 1.2kg material.
16	Decision	
	Approved	
	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan (01-374-0006)
	Application Form Dy. No / Tracking ID & date of submission	(96L-3EZ-ZWNJ, 2024-03-15)
	Detail of Fee Submitted	300000.0, 2024-02-26,
	The proposed proprietary name / brand name	Emit capsule oral 125mg+80mg
	Label Claim	Each pack contains 02 capsules of 80 mg and 01 capsule of 125mg: Each capsule (80mg) contains: 200 mg Aprepitant 40% pellets eq. to Aprepitant.....80mg Each capsule (125mg) contains: 312.5mg Aprepitant 40% pellets eq. to Aprepitant.....125mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	3's 1's +2'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)	Apreon combo pack capsule 125mg, 80mg . Manufacturer: Ferozesons laboratories limited
	Pharmacotherapeutic Group of (API)	Anti-emetic/anti-vertigo
	Name, address of Manufacturing site:	Actoverco Pharmaceutical Company-No. 79, 4th Golestan Blv., Baharestan Industrial Zone, Karaj-Iran

	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies for 80mg and 125mg capsules have been performed against the reference product i.e. Emend Caps 80mg and 125mg by MSD USA respectively.
	Name, address of Marketing Authorization Holder:	Actoverco Pharmaceutical Company, No. 79, 4th Golestan Blv., Baharestan Industrial Zone, Karaj, Iran
	Details of Certificates (CoPP/FSC/cGMP):	GMP certificate valid till March, 2025 is submitted. GMP compliant as per submitted CoPP.
	Details of Authorization Letter :	CoPP: Copy of legalized CoPP No. 665/72115 dated 25-11-2023 is submitted. The applied product is available in free sale of the exporting country and the operations & facilities conform to WHO-GMP as per submitted CoPP. Distribution Certificate: M/s LDS has been authorized to sell, distribute and participate in different activities in Pakistan on behalf of the MAH for the applied product. DSL: Valid till 04-08-2024.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Mehta API Pvt. Ltd., India: 24 months real time and 06 months accelerated stability for 03 batches according to the conditions of zone IV-A. Zim Laboratries India: 06 months accelerated and 24 months real time stability data at 25oC/60%RH for 03 batches is submitted.
	The status in reference regulatory authorities	Emend®125mg,Emend® 80mg Capsule MAH: MSD (Merck Sharp & Dohme) USFDA Approved
	Evaluation Remarks	
	.	
	Decision	
	Approved as per import policy for inspection of manufacturer abroad.	
17	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Axis Pharmaceuticals (Pvt) Ltd 3-B, vale Addition City, 1.5Km Khurrianwala- Sahianwala Road Faisalabad (000667)
	Application Form Dy. No / Tracking ID & date of submission	(EX3-LX6-H16R, 2024-03-12)
	Detail of Fee Submitted	30000.0, 2024-01-29,
	The proposed proprietary name / brand name	Naprium Plus Tablet 375/20mg
	Label Claim	Each delayed released film coated tablet contains: Naproxen...375mg (Enteric coated core) Esomeprazole (as Magnesium Trihydrate) ... 20mg (Immediate Release coating)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	28's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 degree C
	For generic drugs (me-too Status)	Glomov tablet (373/20) Reg No. 109339 by M/s Global Pharmaceuticals
	Pharmacotherapeutic Group of (API)	NSAID / Anti-ulcer

	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Divi's Laboratories Limited (Unit-2),Metrochem API Pvt. Ltd.
	Detail of stability batches of drug product	Batches: T001, T002, T003 (Batch Size: 1500 tablets) 06 months real time and 06 months accelerated stability data according to zone IV-A is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	ADC attested invoice for 17.5kg Naproxen (Dy.No.1152/2022-DRAP dated 21-01-2022) is submitted. Clearance certificate dated 06-07-2022 for 2kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Glomov 375/20 tablet by M/s Global Pharmaceuticals.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Naproxen: 06 months accelerated and 60 months real time stability studies conducted under the conditions of zone IV-A submitted for 03 batches. Esomeprazole: 06 months accelerated and 60 months real time stability studies conducted under the conditions of zone IV-B submitted for 03 batches.
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection dated 13-06-2022.
	Evidence of approval of manufacturing facility	Tablet Section (General) is approved.
	Evaluation Remarks	
	.	
	Decision	
	Approved	
18	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	(GV5-JNY-EM73, 2024-08-27)
	Detail of Fee Submitted	30000.0, 2024-08-21,
	The proposed proprietary name / brand name	Carbosol 150mg/15ml Injection
	Label Claim	Each vial contains: Carboplatin 150mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store above 25°C
	For generic drugs (me-too Status)	Carboplatino 150mg Injection (043036) - GHAZALI BROTHERS
	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	Batches: E049, E050, E051 (Batch size: 66vials) 6 months real time and 6 months accelerated data is

	submitted.
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 10-07-2023 is submitted. (quantity: 2000 grams)
Pharmaceutical Equivalence and Comparative Dissolution Profile	P.E studies have been submitted against Kemobcarb 150mg
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	24 months realtime stability and 6 months accelerated data is submitted according to zone IV-A for 03 batches.
The status in reference regulatory authorities	Carboplatin 10 mg/ml concentrate for solution for infusion, 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 (anti-cancer) (human) section is approved

Evaluation Remarks

Reason	Reply
Clarification since the detail of batches used in in-use stability have not been included in the reply against the query of clarification regarding batch size. Moreover, a term of "skip testing have been used in the submitted reply, the clarification of the same is required.	Batch Size: 66 vials The utilization plan as per stability protocol is as under: No. of samples for skip testing: 3 No. of samples for complete testing: 6 Time points with skip testing for accelerated: 2 Time points with skip testing for real time: 4 So, 1. For initial batch testing: 6 samples Accelerated Stability Study: Skip testing: 2x3=6 samples Complete testing: 6x1= 6 samples For Real Time Stability Study: Skip testing: 3x4 = 12 samples Complete testing: 6x3 = 18 samples In-use stability study: Initial In-use stability study: 4 samples After 24M In-use stability study: 4 samples Total No of samples required: 56 samples Skip testing clarification: Sterility Testing and Bacterial Endotoxin will be performed only at Initial, 6M, 12 M and 24 M timepoints

Decision

Approved

19	Case Category	New Section (Farooq Aslam)
	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	(U4H-SPG-89A5, 2025-01-30)
	Detail of Fee Submitted	37000.0, 2025-01-27,
	The proposed proprietary name / brand name	SALBIMOL-B
	Label Claim	One pressurized container contains 24 mg of salbutamol sulfate (equivalent to 20 mg of salbutamol) and 50mg of beclomethasone dipropionate One metered dose (spray) contains 120 micrograms of salbutamol sulfate (equivalent to 100 micrograms of salbutamol) and 250 micrograms of beclomethasone dipropionate.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	200 Actuations-As per SRO

	Shelf Life (Unit)	2 Year(s)Store at a temperature upto 30°C
	For generic drugs (me-too Status)	Clenil Compositum by Chiesi Pharmaceutical (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Drugs for obstructive airway diseases: Adrenergic, Inhalants
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Avik Pharmaceutical Ltd.,MELODY HEALTHCARE PVT. LTD,
	Detail of stability batches of drug product	Data of 3 batches of 200 canisters each submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Salbutamol Sulphate: 23.04.2024, Drug import License Submitted Beclomethasone Dipropionate: Drug import license dated 12-02-2024 for 0.3kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Sabacomb, 100mcg/250mcg Pressurized Inhalation, Suspension; Pharmaceutical equivalence performed including tests of Uniformity of Delivered Dose and Aerodynamics Particle Size Distribution by Cascade Impactor.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of 3 batches as per Zone-IV A
	The status in reference regulatory authorities	Sabacomb pressurizedinhalation suspension by Chiesi Farmaceutici S.p.A.
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	New Section MDI vide No. F. 2-12/93-Lic (Vol-VI) dated 27.12.2023 granted.
	Evaluation Remarks	
	.	
20	Decision	
	Approved	
	Case Category	New Section (Farooq Aslam)
	Name, address of Applicant.	Carer Pharmaceuticals industries Plot no.27, Main Road Rawat Industrial Estate, Rawat (000925)
	Application Form Dy. No / Tracking ID & date of submission	(X97-ULB-ZBE2, 2025-02-12)
	Detail of Fee Submitted	37000.0, 2024-12-11,
	The proposed proprietary name / brand name	Fibricar 500mg Capsules
	Label Claim	Each capsule contain Tranexamic acid 500mg (JP Specifications)
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	20's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store between 15C-30C
	For generic drugs (me-too Status)	Transamin 500mg Capsules
	Pharmacotherapeutic Group of (API)	Anti-fibrinolytic agent
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Changzhou Yinsheng Pharmaceutical Co., Ltd. Manufacturing site address: Weitang Chemical

		Zone, Xinbei District, Changzhou, Jiangsu Province, 213033, China Tel: 86-519-85777178, 85771157, Fax: 86-519-85771157, E-mail: czysyy@126.com Website: www.czyspharm.
	Detail of stability batches of drug product	Batches: trial001, trial002, trial003 6 months stability data is submitted including real time and accelerated stability.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 07-06-2022 for 2.5kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against Transamin 500mg/Capsule by M/s Hilton Pharma.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Batches: 100301, 100302, 100303 Accelerated and real time stability data (till 48th months) is submitted according to zone IV-A for 3 batches..
	The status in reference regulatory authorities	AIFA
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 26-08-2024 is submitted,.
	Evidence of approval of manufacturing facility	Capsule General Section is approved vide letter No. F.1-32/2016-Lic dated 7th June, 2021.
	Evaluation Remarks	
	.	
	Decision	
	Approved	
21	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	PERFECT PHARMA (PVT) LTD 5Km, Manga Road, Raiwind, Lahore (000469)
	Application Form Dy. No / Tracking ID & date of submission	(14N-P9U-WNTX, 2025-06-17)
	Detail of Fee Submitted	93000.0, 2025-05-12,
	The proposed proprietary name / brand name	Perfizole 40mg Dry Powder Vial
	Label Claim	Each vial contains: Omeprazole as sodium.....40mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's -As per SRO
	Shelf Life (Unit)	2 Year25
	For generic drugs (me-too Status)	Risek 40mg for injection,
	Pharmacotherapeutic Group of (API)	PPI
	Name, address of Manufacturing site:	May & Baker (Pvt) Ltd-45 Km Dina Nath Multan Road Lahore-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	Omebak 40mg Dry Powder Vial, Minutes of 322nd meeting of Registration Board
	Evaluation Remarks	
	The applicant submitted this application for data approved of Omebak 40mg Dry Powder Vial of May & Baker in the Minutes of 322nd meeting of Registration Board. However, the Board approved Ozole 40mg dry powder vial IV of May & Baker in the aforementioned meeting. In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June,	

	2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
22	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	CUREXA HEALTH (PVT.) LIMITED 517 SUNDER INDUSTRIAL ESTSTE (000864)
	Application Form Dy. No / Tracking ID & date of submission	(2TM-PQ6-G19D, 2025-06-16)
	Detail of Fee Submitted	93000.0, 2025-02-11,
	The proposed proprietary name / brand name	Colixa Injection 68mg IV (2MIU)
	Label Claim	Each vial Contains: Colistimethate sodium (2MIU) eq. to 68mg Colistin Base Activity
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 30°C. Keep in a dry place. Protect from light.
	For generic drugs (me-too Status)	Colistimethate Sodium Injection, Marketed by: Mukhtar enterprises Lahore Pakistan, Manufactured by: Xellia pharmaceuticals Denmark (Reg No. 094757)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Labs (Pvt.) Ltd.-Plot # 145, Industrial Triangle, Kahuta Road, Islamabad-
	The status in reference regulatory authorities	Colistimethate sodium injection by Xellia Pharmaceuticals (Denmark)
	Detail of previous approval	Colicraft Injection I.V 2MIU, 324th DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
23	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medisynth Pharmaceuticals Khasra No. 1028/1029, Mouza Jellyari Gujri, Tehsil Gujar Khan, District Rawalpindi (000718)
	Application Form Dy. No / Tracking ID & date of submission	(4Y9-LB2-XQAW, 2025-06-05)

	Detail of Fee Submitted	93000.0, 2025-05-26,
	The proposed proprietary name / brand name	Synzone Injection 500mg IV
	Label Claim	Each vial contain: Ceftriaxone as sodium... 500 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	2 Year15C-30C
	For generic drugs (me-too Status)	Oxidil500 mg Injection I.V
	Pharmacotherapeutic Group of (API)	cephalosporins antibiotics
	Name, address of Manufacturing site:	Pharmaqio-10km Basali Chowk Chakbeli road Rawalpindi-
	The status in reference regulatory authorities	USFDA approved
	Detail of previous approval	Qiocephen 500mg Injection IV. 343th meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.The applicant will submit Details of Re constitution diluent.	
	Decision	
	Approved	
24	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	masfa indutries (pvt).ltd 17km sheikhupura road ,lahore (000713)
	Application Form Dy. No / Tracking ID & date of submission	(JSY-9P5-43Y6, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2025-01-21,
	The proposed proprietary name / brand name	exci suspension
	Label Claim	Each ml of reconstituted suspension contains: Sildenafil (as Citrate).....10mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	112ml-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30c
	For generic drugs (me-too Status)	Sildenafil Citrate Amneal Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	gray's pharmaceuticals -plot no.2 street no.N-3, national industrial zone,rawat-
	The status in reference regulatory authorities	usa
	Detail of previous approval	
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation,	

	specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
25	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	MEDPHARM RESEARCH LAB 28 KM FEROZPUR ROAD LAHORE (000878)
	Application Form Dy. No / Tracking ID & date of submission	(NYM-B8Q-HPZJ, 2025-06-18)
	Detail of Fee Submitted	75000.0, 18000.0 2024-04-25, 2024-11-26
	The proposed proprietary name / brand name	KETIN INJECTION 30MG/ML
	Label Claim	Each ml Contains: Ketorolac Tromethamine= 30mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	as per DPC-As per SRO
	Shelf Life (Unit)	2 Yearbelow 24 degree
	For generic drugs (me-too Status)	Toradol Injection
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	May & Baker Pvt Ltd-HOUSE NO 23, STREET NO 5 SECTOR B, GHORI BLOCK BAHRIA TOWN, Pakistan-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	Ket-May 30mg/ml Injection 323 injection
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
26	Case Category	Routine (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	(S73-HAA-7L1D, 2024-03-13)
	Detail of Fee Submitted	30000.0, 2024-02-14,
	The proposed proprietary name / brand name	Pagotras 50mg Tablet
	Label Claim	Each film coated Tablet Contains: Eltrombopag Olamine equivalent to 50mg Eltrombopag as Eltrombopag free acid.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3 x 10's-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store over 30 C

	For generic drugs (me-too Status)	Revolade 50mg tablet by Novartis (Pakistan) Ltd.
	Pharmacotherapeutic Group of (API)	B02BX05 Other systemic hemostatics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Sichuan D-innovation Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	3 batches. 2000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Revolade 25mg Tablets Batch No. B8812R Mfg.Novartis
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted.
	The status in reference regulatory authorities	PROMACTA 50mg Tablet by NOVARTIS PHARMACEUTICALS CORP.
	GMP status of the firm	GMP certificate issued on basis of inspection dated 12.06.2023 is submitted
	Evidence of approval of manufacturing facility	Renewal letter dated 30.06.2020 is submitted
	Evaluation Remarks	
	.	
	Decision	
	Approved	
27	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medisynth Pharmaceuticals Khasra No. 1028/1029, Mouza Jellyari Gujri, Tehsil Gujar Khan, District Rawalpindi (000718)
	Application Form Dy. No / Tracking ID & date of submission	(SZU-APV-HEMY, 2025-06-05)
	Detail of Fee Submitted	93000.0, 2025-05-29,
	The proposed proprietary name / brand name	Synfix Dry Powder Suspension 200mg/5ml
	Label Claim	Each 5ml Reconstituted Suspension contain: Cefixime as Tri hydrate.....200 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x1s-As per SRO
	Shelf Life (Unit)	2 Year 15C-30C
	For generic drugs (me-too Status)	Cefspan Dry Suspension
	Pharmacotherapeutic Group of (API)	cephalosporins antibiotics
	Name, address of Manufacturing site:	Pharmaqio-10-km Basali chowk Chakbeli road Rawalpindi-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Qioxime 200mg/5ml Dry suspension 343th meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned	

	notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
28	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medisynth Pharmaceuticals Khasra No. 1028/1029, Mouza Jellyari Gujri, Tehsil Gujar Khan, District Rawalpindi (000718)
	Application Form Dy. No / Tracking ID & date of submission	(TUX-8VG-RLUP, 2025-06-05)
	Detail of Fee Submitted	93000.0, 2025-05-31,
	The proposed proprietary name / brand name	Synzone Injection 1g IV
	Label Claim	Each vial contain: Ceftriaxone as sodium..... 1 g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	2 Year15C-30C
	For generic drugs (me-too Status)	Oxidil 1g Injection I.V
	Pharmacotherapeutic Group of (API)	cephalosporins antibiotics
	Name, address of Manufacturing site:	Pharmaio-10-km Basali chowk Chakbeli road Rawalpindi-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Qiocephen 1g Injection IV. 343th meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
29	Case Category	Routine (Maham Misbah)
	Name, address of Applicant.	Islam Pharmaceuticals 7km Pasrur Road Sialkot (000885)
	Application Form Dy. No / Tracking ID & date of submission	(RRH-RMP-SW1T, 2024-03-18)
	Detail of Fee Submitted	30000.0, 2023-11-24,
	The proposed proprietary name / brand name	Vominil
	Label Claim	Each film coated tablet contains Domperidone as maleate 10mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	50's-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30 Celsius

For generic drugs (me-too Status)	Motilium V Tablet, Aspin Pharma, Reg No. 021789
Pharmacotherapeutic Group of (API)	ATC code: A03FA03: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	VASUDHA PHARMA CHEM LTD Plot No.79, J.N Pharma city, parawada, Visakhapatnam-531021, Andhra Pradesh, INDIA
Detail of stability batches of drug product	3 batches 2000 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Submitted
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE & CDP is submitted against Motilium V Tablet, Aspin Pharma, Reg No. 021789
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	As per Zone Iv
The status in reference regulatory authorities	MHRA Approved
GMP status of the firm	GMP certificate is issued on the basis of inspection conducted on 08-02-2023 specifying tablet (general) section.
Evidence of approval of manufacturing facility	GMP certificate is issued on the basis of inspection conducted on 08-02-2023 specifying tablet (general) section.

Evaluation Remarks

Serial No.	Observations	Response of applicant
1	1.3.5: Submit copy of DML renewal of applicant due in 2023.	Copy of DML renewal certificate issued wef 29-08-2023 is submitted.
2	3.2.S.4.4: Submit the batch number of API used in manufacturing of stability batches and submit CoA of the relevant batch from drug product and drug substance manufacturer.	CoA of batch No. DOM-MAL/69/12/20 is submitted from drug product and drug substance manufacturer.
3	3.2.P.2.2.1: In comparative dissolution profiling, the dissolution results of each unit shall be recorded instead of providing mean only.	Submitted
4	3.2.R: Submit legible copies of BMRs of all three stability batches.	Submitted
5	Procurement documents of API shall be submitted, including DML/ GMP of API manufacturer issued by the country of origin and clearance certificate issued by DRAP.	Submitted

Decision

Approved

30	Case Category	Priority As Per 257-M of RB (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	REVIVE HEALTH CARE 503, 5TH FLOOR EDEN HEIGHTS 6 MAIN GULBERG JAIL ROAD (05-352-0065)
	Application Form Dy. No / Tracking ID & date of submission	(DEY-Z3U-VZY7, 2025-06-30)
	Detail of Fee Submitted	300000.0, 2025-06-27,
	The proposed proprietary name / brand name	PEMIXA Injection 500 mg
	Label Claim	Each Vial Contains: Pemetrexed (as disodium) 500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's Vial-As per SRO
	Shelf Life (Unit)	2 Yearstore below 30 degree centigrade
	For generic drugs (me-too Status)	Registration No. 082061 by Revive Healthcare
	Pharmacotherapeutic Group of (API)	ATC CODE: L01BA04 , Anticancer, folate analog metabolic inhibitor
	Name, address of Manufacturing site:	Qilu Pharmaceutical (Hainan) Co., Ltd.-No.273-A, Nanhai Avenue, National High-Tech Zone, Haikou, Hainan, 570314-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pemetrexed Injection 500 mg by Qilu Pharma VS Alimta Injection 500 mg by LILLIY is submitted in 3.2.P.2.2.1 (b)
	Name, address of Marketing Authorization Holder:	Qilu Pharmaceutical (Hainan) Co., Ltd., No.273-A, Nanhai Avenue, National High-Tech Zone, Haikou, Hainan, 570314, China
	Details of Certificates (CoPP/FSC/cGMP):	VALID EUDRA GMP CERTIFICATE NO. ES/106/HV/24
	Details of Authorization Letter :	Imported Product - Not Applicable
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Based on the currently available long-term (5o C ± 3o C, 24 months) and accelerated (25o C ± 2o C / 60% ±5% RH, 6 months) stability data submitted in 3.2.S.7.3
	The status in reference regulatory authorities	MHRA APPROVED: ALIMTA 500 mg powder for concentrate for solution for infusion by Eli Lilly
	Evaluation Remarks	
	Firm has submitted online verified USFDA CoPP.	
	Decision	
	Approved	
31	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	(7H5-85A-TS2M, 2024-08-27)

	Detail of Fee Submitted	30000.0, 2024-08-21,
	The proposed proprietary name / brand name	MEPRA INJECTION(10ML)
	Label Claim	Each ml contains:- Mepyramine maleate 50mg(BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	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)	ALLERGINIL INJECTION Reg. No. 069623 (SANNA LABORTORIES FAISALABAD)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
32	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Hirra Pharmaceutical Laboratories (Pvt) Ltd 3A, 2nd floor, Queen's Center, Queen's Road, (000449)
	Application Form Dy. No / Tracking ID & date of submission	(31T-X78-RAZY, 2024-04-22)
	Detail of Fee Submitted	30000.0, 2024-04-22,
	The proposed proprietary name / brand name	HIRRA TRI-LEVA DRENCH
	Label Claim	Each 100ml Contains:TRICLABENDAZOLE----- ----- 5gm LEVAMISOLE-AS-HCL----- -3.75gm COBALT -----0.04GM SELENIUM -- -----0.05GM COPPER -----0.21GM ZINC -----0.055GM
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 25 Degree Centigrade
	For generic drugs (me-too Status)	063685 PRIX PHARMACEUTICA (PRIVATE) LIMITED "Trimax 8.75% Mineralized TRICLABENDAZOLE.....5GLEVAMISOLE(
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--

	GMP status of the firm	Keeping in view the manufacturing facilities like installing and availabilities of HVAC system, sanitation, production machinery, equipment in quality control/ testing facilities technical personnel and documentation, the panel of inspection is of the op
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Firm has revised label claim in line with me-too product along with submission of fee of Rs37000/- vide challan No. 43917790967.	
	Decision	
	Approved	
33	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Hirra Pharmaceutical Laboratories (Pvt) Ltd 3A, 2nd floor, Queen's Center, Queen's Road, (000449)
	Application Form Dy. No / Tracking ID & date of submission	(3G8-RMP-GJUI, 2024-08-02)
	Detail of Fee Submitted	30000.0, 2024-08-02,
	The proposed proprietary name / brand name	HIRRA DICLAZURIL POWDER
	Label Claim	Each 1000gm powder containDICLAZURIL ----- -----05g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 g-De-Controlled,1000 g-De-Controlled,250 g-De-Controlled,500 g-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30 Degree Centigrade
	For generic drugs (me-too Status)	122198 "EMEZURIL POWDER " "EACH 1000GM CONTAINS:- DICLAZURIL.....5GM (AS PER INNOVATOR'S SPECIFICATIONS)*" LOCALLY MANUFACTURED "M/S. A & K PHARMACEUTICAL, 94-A PUNJAB SMALL INDUSTRIAL ESTATE,
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Keeping in view the manufacturing facilities like installing and availabilities of HVAC system, sanitation, production machinery, equipment in quality control/ testing facilities technical personnel and documentation, the panel of inspection is of the op
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	

34	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	(3HA-RXH-UT2P, 2024-08-27)
	Detail of Fee Submitted	30000.0, 2024-08-22,
	The proposed proprietary name / brand name	ADEK FORTE WATER SOLUBLE POWDER
	Label Claim	Each Kg contains:- vitamin A 20MIU Vitamin D..... 2MIU Vitamin E..... 6000mg Vitamin K3..... 5000mg(As per Innovator's Specs.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Kg -De-Controlled,100gm-De-Controlled,200gm-De-Controlled,250gm-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)	EDAK WATER SOLUBLE POWDER. Reg. # 027412 (ALINA COMBINE PAKISTAN (PVT.)LTD.KARACHI)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
35	Evaluation Remarks	
	Decision	
	Approved	
	with change of brand name since vitamin A, D, E and K are lipid soluble vitamins.	
35	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	(3MG-G6L-JZD4, 2024-08-26)
	Detail of Fee Submitted	30000.0, 2024-08-20,
	The proposed proprietary name / brand name	OPROCOL WSP
	Label Claim	Each gm contains:-Amprolium HCL 200mgColistin Sulphate 500,000IUVitamin K 50mgVitamin A 5,000 IU
	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)	AMPROCOL WATER SOLUBLE POWDER. REG. No. 034529 (ATTABAK PHARMACEUTICALS (PVT.)LTD. ISLAMABAD)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
36	Approved	
	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Hirra Pharmaceutical Laboratories (Pvt) Ltd 3A, 2nd floor, Queen's Center, Queen's Road, (000449)
	Application Form Dy. No / Tracking ID & date of submission	(47Z-GD3-3Y2T, 2024-08-02)
	Detail of Fee Submitted	30000.0, 2024-08-02,
	The proposed proprietary name / brand name	HIRRA NEO-100 POWDER
	Label Claim	Each KG containsNEOMYCIN SULPHATE----- -100%
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 g-De-Controlled,1000 g-De-Controlled,250 g-De-Controlled,500 g-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30 Degree Centigrade
	For generic drugs (me-too Status)	122864 "PAN-NEO 100 WATER SOLUBLE POWDER " "EACH GRAM CONTAINS:- NEOMYCIN SULPHATE.....1000MG (AS PER INNOVATOR'S SPECIFICATIONS)* " LOCALLY MANUFACTURED "M/S. PRIX PHARMACEUTICA, PLOT NO.5, PHARM
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Keeping in view the manufacturing facilities like installing and availabilities of HVAC system, sanitation, production machinery, equipment in quality control/ testing facilities technical personnel and documentation, the panel of inspection is of the op
	Evidence of approval of manufacturing facility	

	Evaluation Remarks	
	Decision	
	Approved	
37	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	(EB5-PE2-WVUU, 2024-07-16)
	Detail of Fee Submitted	30000.0, 2024-07-15,
	The proposed proprietary name / brand name	DE-TROX INJECTION (100ML)
	Label Claim	Each 100ml contains :- Nitroxynil 34.000gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 YearStore below 25 °C. Protect from light
	For generic drugs (me-too Status)	SELMORE PHARMACEUTICAL (PVT) LTD., LAHORE. (TROXY 34% INJECTION Reg. No. 034597)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
38	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	(PYJ-7QY-3G3A, 2024-08-27)
	Detail of Fee Submitted	30000.0, 2024-08-21,
	The proposed proprietary name / brand name	ADE INJECTION (20ml)
	Label Claim	Each ml contains:Vitamin A 100000 IUVitamin D3 40000 IUVitamin E 40 mg(As per innovator"s specs.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	20ml-De-Controlled

	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	ADEKA INJECTION Reg. No. 075792 (A & K PHARMA FAISALABAD)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
39	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	(T62-3H7-1G1P, 2024-08-27)
	Detail of Fee Submitted	30000.0, 2024-08-21,
	The proposed proprietary name / brand name	TICID INJECTION (10ml)
	Label Claim	Each ml contains: Gentamycin as Sulphate.....50mg Tylosin as Tartrate.....100mg(As per Innovator's Specs.)
	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)	GTRISE INJECTION Reg. No. 112178 (BIORISE PHARMA MULTAN)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
40	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	(TDT-TZ8-5L8L, 2024-06-18)

	Detail of Fee Submitted	30000.0, 2024-06-14,
	The proposed proprietary name / brand name	ELINE 40% WSP
	Label Claim	Each gm contains:- Lincomycin (as Lincomycin hydrochloride).....400mg (USP specs.)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	,10Kg-De-Controlled,100gm-De-Controlled,1Kg-De-Controlled,250gm-De-Controlled,25Kg-De-Controlled,500gm-De-Controlled,5Kg-De-Controlled
	Shelf Life (Unit)	2 YearStore below 25 °C. Protect from light
	For generic drugs (me-too Status)	Unicare Enterprises, (Lincosol 40% Oral Powder Reg. No. 081301)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
41	Case Category	Import (Najia Saleem)
	Name, address of Applicant.	Huzaifa International commercial area, aziz bhatti town, Sargodha (08-384-0120)
	Application Form Dy. No / Tracking ID & date of submission	(95V-G3Z-RQMZ, 2024-05-06)
	Detail of Fee Submitted	75000.0, 75000.0 2023-11-17, 2025-06-27
	The proposed proprietary name / brand name	Parvject Injection
	Label Claim	Each mL contains: Buparvaquone.....50 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	20 ml-De-Controlled
	Shelf Life (Unit)	36 Month(s)30 °C
	For generic drugs (me-too Status)	Parvon inj. (Reg. No. 034580) , Butalex Inj. (Reg. No. 017968)
	Pharmacotherapeutic Group of (API)	Anti-protozoal
	Name, address of Manufacturing site:	Komipharm International Co. Ltd.-17, GYEONGJE-RO, SIHEUNG-SI, GYEONGGI-DO, SOUTH KOREA-South
	Name, address of Marketing Authorization Holder:	Huzaifa International, commercial area aziz bhatti town Sargodha, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Scanned copy of apostilled certified FSC No. M2310626 confirming the applied product is registered and permitted to be freely sold in South Korea and overseas market.

	Details of Authorization Letter :	Un-notarized LOA dated 20-11-2023 submitted for the applied product
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted both accelerated and real time data for three batches as per zone IV-A conditions.
	Evaluation Remarks	
	The firm shall submit original legalized valid FSC, GMP certificate and LOA since the already submitted scanned copies were submitted and already submitted scanned copy of GMP was valid upon submission but is expired now. The revised GMP certificate submitted by the firm later on, was neither legalized nor bearing validity date.	
	Decision	
	Approved	
	subject to import policy order. Moreover, firm shall submit following before issuance of registration letter:	
	original valid LOA notarized from exporting country, since the already submitted copy is un-notarized.	
	original legalized valid FSC and GMP certificate since the already submitted copies are scanned.	
42	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	(ABH-P1J-WNWW, 2024-08-28)
	Detail of Fee Submitted	30000.0, 2024-08-22,
	The proposed proprietary name / brand name	CYCLOMIX FORTE WSP
	Label Claim	Each 1000gm contains:- Chlorotetracycline HCL 250gm Vitamin A 30,000,00IU Vitamin D3 20,000,00IU Thiamin HCL 200mg Riboflavin 400mg (As per Innovator's Specs.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm-De-Controlled, 1Kg-De-Controlled, 250gm-De-Controlled, 500gm-De-Controlled, 5Kg-De-Controlled
	Shelf Life (Unit)	2 YearStore below 25 °C. Protect from light
	For generic drugs (me-too Status)	CHLOROCIN 25% POWDER. Reg. No. 035080 (DELUX CHEMICAL INDUSTRIES KARACHI)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved	
	with change of brand name since vitamin A and D are lipid soluble vitamins.	
43	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Hirra Pharmaceutical Laboratories (Pvt) Ltd 3A, 2nd floor, Queen's Center, Queen's Road, (000449)
	Application Form Dy. No / Tracking ID & date of submission	(ABV-Z1E-D4RP, 2024-08-02)
	Detail of Fee Submitted	30000.0, 2024-08-02,
	The proposed proprietary name / brand name	HIRRA MADURA POWDER
	Label Claim	Contains per kgMaduramicin Ammonium ----- 4%Carrier ad-----Q.S
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 g-De-Controlled,1000 g-De-Controlled,25 kg- De-Controlled,250 g-De-Controlled,500 g-De- Controlled
	Shelf Life (Unit)	2 Year(s)Below 30 Degree Centigrade
	For generic drugs (me-too Status)	Maduramix-Premix, M/S Mettle Bio Sciences
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Keeping in view the manufacturing facilities like installing and availabilities of HVAC system, sanitation, production machinery, equipment in quality control/ testing facilities technical personnel and documentation, the panel of inspection is of the op
	Evidence of approval of manufacturing facility	
Evaluation Remarks		
Initially applied formulation is 4% powder and in revised form-5 both 1% and 2% strengths are mentioned, however, in master formula 4% is still mentioned. The evidence of approval of me-too product in 4% and 2% strengths could not be confirmed from available database. The firm has submitted fee Rs. 37000/- vide challan no. 5281730211		
Decision		
Approved		
with following label claim:		
Each Kg contains:		
Maduramicin Ammonium.....1%		
Firm shall submit revised form-5 with correct label claim and master formula in line with reference product.		
44	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	(DGP-819-VZNL, 2024-08-26)
	Detail of Fee Submitted	30000.0, 2024-08-20,
	The proposed proprietary name / brand name	CLOBENDOL CS SUSPENSION
	Label Claim	Each 100ml contains:-Albendazole 10gmClosental 2gm(As per Innovator"s specs.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled,150ml-De-Controlled,1liter-De-Controlled,200ml-De-Controlled,450ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	ALBACOL SUPER SUSPENSION. REG. No. 057110 (INTERVAC PVT.) LTD. SHEIKU PURA)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
45	Case Category	Import (Najia Saleem)
	Name, address of Applicant.	Orion Group 97 Commercaill Area, Usman Block, Muslim Town No.1, (06-331-0167)
	Application Form Dy. No / Tracking ID & date of submission	(G4Y-6VS-GW1X, 2024-09-24)
	Detail of Fee Submitted	300000.0, 2024-09-21,
	The proposed proprietary name / brand name	FLUNITONG 5
	Label Claim	Composition: Each ml contains: Flunixin (as Flunixin Meglumine) ----- 50mg Pharmacological Group: Antipyretic, anti-inflammatory and analgesic drug Proposed route of administration: Intravenous administration Indications: Flunixin Meglumine is a relatively potent non-narcotic, non steroidal analgesic with anti-endotoxic and antipyretic properties. In the horse Flunixin Injection is indicated for the alleviation of inflammation and pain associated with musculoskeletal disorders and for the alleviation of visceral pain associated with colic. In

		cattle Flunixin Injection is indicated for the control of acute inflammation associated with respiratory disease By intravenous administration to cattle and horses HORSES: For use in equine colic, the recommended doseratiois1.1mg/kg(1ml per 45kg body weight) by intravenous injection or intramuscular injection. Treatment may be repeated once or twice if colic recurs. Foruseinmusculo-skeletaldisor
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100 ml -De-Controlled
	Shelf Life (Unit)	3 Year(s)Below +30 Degree Celsius
	For generic drugs (me-too Status)	FLUMEGLU, Registration Number: 085471
	Pharmacotherapeutic Group of (API)	NSAID
	Name, address of Manufacturing site:	Chongqing Fangtong Animal Pharmaceutical Co., Ltd-No.80, East Part of Changzhou Road, Rongchang, Chongqing, China-China
	Name, address of Marketing Authorization Holder:	Chongqing Fangtong Animal Pharmaceutical Co., Ltd, No.80, East Part of Changzhou Road, Rongchang, Chongqing, China, China
	Details of Certificates (CoPP/FSC/cGMP):	Scanned copies of FSC and GMP certificate submitted
	Details of Authorization Letter :	scanned copy of valid power of attorney submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 36-month real time stability studies data submitted as per zone IV-A conditions
	Evaluation Remarks	
	Since scanned copies of FSC, GMP certificate and power of attorney are attached, the firm shall submit original legalized valid FSC, GMP and POA before issuance of registration letter.	
	Decision	
	Approved	
	subject to import policy order. Moreover, firm shall submit original legalized valid POA, FSC and GMP before issuance of registration letter, since the already submitted copies are scanned.	
46	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	(G6N-N2Z-64XQ, 2024-08-27)
	Detail of Fee Submitted	30000.0, 2024-08-22,
	The proposed proprietary name / brand name	ETER PIPRAZIN WSP
	Label Claim	Each gm Contains:- Piperazine Citrate..... 1000mg(As per Innovator's Specs.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1Kg-De-Controlled,100gm-De-Controlled,200gm-De-Controlled,250gm-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)	PIPERAPURE-1000 WATER SOLUBLE POWDER. REG. # 034530 (ATTABAK PHARMACEUTICALS ISLAMABAD)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
47	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Hirra Pharmaceutical Laboratories (Pvt) Ltd 3A, 2nd floor, Queen's Center, Queen's Road, (000449)
	Application Form Dy. No / Tracking ID & date of submission	(GER-SH7-31VW, 2024-08-02)
	Detail of Fee Submitted	30000.0, 2024-08-02,
	The proposed proprietary name / brand name	HIRRA TOLTRA-Z 2.5% SOLUTION
	Label Claim	Each 100ML Contains:TOLTRAZURIL 2.5GM
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML-De-Controlled,1000ML-De-Controlled,2500ML-De-Controlled,250ML-De-Controlled,5000 ML-De-Controlled,500ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30 Degree Centigrade
	For generic drugs (me-too Status)	029689 BAYCOX 2.5% ORAL SOLUTION. "EACH ML CONTAINS:- TOLTRAZURIL 25.0MG. " BAYER AG., GERMANY. GERMANY BAYER PAKISTAN (PRIVATE) LTD., KARACHI
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Keeping in view the manufacturing facilities like installing and availabilities of HVAC system, sanitation, production machinery, equipment in quality control/ testing facilities technical personnel and documentation, the panel of inspection is of the op
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	

48	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	(GHY-A2H-J178, 2024-08-27)
	Detail of Fee Submitted	30000.0, 2024-08-21,
	The proposed proprietary name / brand name	TYMIX-25 PREMIX
	Label Claim	Each Kg Contains:-Tylosin Phosphate 250gm(As per Innovator's Specs.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm-De-Controlled,10KG-De-Controlled,1Kg-De-Controlled,200gm-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)	TUFLAN PREMIX WATER SOLUBLE POWDER REG. No. 026481 (ALINA COMBINE KARACHI)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
49	Case Category	Import (Najia Saleem)
	Name, address of Applicant.	Orion Group 97 Commercaile Area, Usman Block, Muslim Town No.1, (06-331-0167)
	Application Form Dy. No / Tracking ID & date of submission	(JBX-U94-SMVD, 2024-09-25)
	Detail of Fee Submitted	300000.0, 2024-09-25,
	The proposed proprietary name / brand name	LIVERTONG NO. 1 SUSPENSION
	Label Claim	Brand Name: LIVERTONG NO.1 SUSPENSION Composition: Each ml contains: Levamisole hydrochloride 15mg Oxytoclozanide 30mg Pharmacological Group: Anthelmintic Route of administration: Oral administration Indications: LIVERTONG NO.1 SUSPENSION is indicated for the treatment and control of both gastrointestinal and pulmonary nematode infections, and adult liver

		fluke infections. Removes most mature Fasciola spp (flukes) present in the bile ducts of the liver Dosage: Thoroughly shake the container well before use to ensure that the two active substances are homogeneously resuspended and therefore the animals receive the correct dose. Dosing must be carried out using a suitable gun system, at a rate of 7.5 mg/kg bodyweight levamisole hydrochloride and 15 mg/kg bodyweight oxclozanide achieved by administering 5 ml per 10 kg bodyweight in cattle and 1 ml per 2 kg bodyweight in sheep and goats. To ensure administration of a correct dose, bodyweight should be determined
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Liter-De-Controlled
	Shelf Life (Unit)	3 Year(s)Below +30 Degree Celsius
	For generic drugs (me-too Status)	Nilzan, Registration Number: 002105
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Chongqing Fangtong Animal Pharmaceutical Co., Ltd-No. 80 East Part of Changzhou Road, Rongchang, Chongqing, China-China
	Name, address of Marketing Authorization Holder:	Chongqing Fangtong Animal Pharmaceutical Co., Ltd, No. 80 East Part of Changzhou Road, Rongchang, Chongqing, China, China
	Details of Certificates (CoPP/FSC/cGMP):	scanned copies of FSC and GMP certificate submitted
	Details of Authorization Letter :	scanned copy of POA submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 36 months real time stability studies data of three batches as per zone IV-A conditions submitted
	Evaluation Remarks	
	Since scanned copies of FSC, GMP certificate and power of attorney are attached, the firm shall submit original legalized valid FSC, GMP and POA before issuance of registration letter.	
	Decision	
	Approved	
	subject to import policy order. Moreover, firm shall submit original legalized valid POA, FSC and GMP before issuance of registration letter, since the already submitted copies are scanned.	
50	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	(M1W-9L2-ZMJU, 2024-08-27)
	Detail of Fee Submitted	30000.0, 2024-08-21,
	The proposed proprietary name / brand name	ETER FURAZIN 25% ORAL POWDER
	Label Claim	Each Kg Contains:-Furazolidone..... 250gm(As per Innovator's Specs.)
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	1000gm-De-Controlled,100gm-De-Controlled,200gm-De-Controlled,250gm-De-Controlled,500gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	SANFURA -25 ORAL POWDER REG. No. 035019 (SANNA LABORATORIES FAISALABAD)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Deferred	
	for review of formulation to Sub-committee on veterinary drugs.	
51	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	(MTD-PZ5-P5TH, 2024-08-26)
	Detail of Fee Submitted	30000.0, 2024-08-21,
	The proposed proprietary name / brand name	SUPER LYTE C WATER SOLUBLE POWDER
	Label Claim	Each gm contains:- Aspirin 200mg Vitamin C 600mg Sodium Chloride 35mg Sodium Citrate 7mg(As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm-De-Controlled,1kg-De-Controlled,200gm-De-Controlled,250gm-De-Controlled,500gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	ELECTRO RAS PLUS WATER SOLUBLE POWDER. Reg. No. 062188 (M/S.ATTABAK PHARMACEUTICAL ISLAMABAD)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	

52	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	(NN8-8LD-VWLM, 2024-10-26)
	Detail of Fee Submitted	37000.0, 2024-10-22,
	The proposed proprietary name / brand name	ETER BUTAZONE INJECTION
	Label Claim	Each ml contains: Phenylbutazone 200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ML-De-Controlled
	Shelf Life (Unit)	2 YearStore below 25 °C. Protect from light
	For generic drugs (me-too Status)	VUTAZON SS INJECTABLE SOLUTION INJECTION REG. # 048280 (ALINA COMBINE PHARMACEUTICALS(PVT.)LTD. KARACHI)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
53	Decision	
	Approved	
	in the light of recommendations of Sub-committee on Veterinary Drugs regarding use of Phenylbutazone primarily in non-food-producing animals in Reference Regulatory Authorities (RRA) and its use should be restricted to these animals only. Furthermore, a prominent warning on the label of drug products containing Phenylbutazone, restricting its use in equine animals, should also be shown clearly.	
	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	(PT1-RPX-D6Y1, 2024-10-28)
	Detail of Fee Submitted	37000.0, 2024-10-22,
	The proposed proprietary name / brand name	ETER BUTAZONE INJECTION (100ML)
	Label Claim	Each ml contains: Phenylbutazone 200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ML-De-Controlled
	Shelf Life (Unit)	2 YearStore below 25 °C. Protect from light
	For generic drugs (me-too Status)	VUTAZON SS INJECTABLE SOLUTION INJECTION REG. # 048280 (ALINA COMBINE PHARMACEUTICALS(PVT.)LTD. KARACHI)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--

	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
54	Decision	
	Approved	
	in the light of recommendations of Sub-committee on Veterinary Drugs regarding use of Phenylbutazone primarily in non-food-producing animals in Reference Regulatory Authorities (RRA) and its use should be restricted to these animals only. Furthermore, a prominent warning on the label of drug products containing Phenylbutazone, restricting its use in equine animals, should also be shown clearly.	
	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	(Q1Q-JZR-2EQS, 2024-08-26)
	Detail of Fee Submitted	30000.0, 2024-08-20,
	The proposed proprietary name / brand name	SUPER T-DOX ORAL POWDER
	Label Claim	Each kg contains:- Doxycycline HCL.....200gm Tylosin tartrate.....100gm Amantadine HCL.....40gm Colistin sulphate.....500MIU Bromhexine HCL.....5gm (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm-De-Controlled,1kg-De-Controlled,200gm- De-Controlled,250gm-De-Controlled,500gm-De- Controlled
	Shelf Life (Unit)	2 YearStore below 25 °C. Protect from light
	For generic drugs (me-too Status)	VIROX TD POWDER Reg. No. 075777 (LEADS PHARMA (PVT.)LTD ISLAMABAD)
	Pharmacotherapeutic Group of (API)	
55	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Deferred	
	for review of formulation to Sub-committee on veterinary drugs.	
	Case Category	Import (Najia Saleem)
	Name, address of Applicant.	Aves Care P-74, Rehman Town, Satiana Road, Faisalabad. (06-33101660)

	Application Form Dy. No / Tracking ID & date of submission	(R7J-QX9-7QBQ, 2024-10-15)
	Detail of Fee Submitted	300000.0, 9000.0 2024-09-19, 2025-06-30
	The proposed proprietary name / brand name	NEOCIN 700 WS
	Label Claim	Each G Contains: Neomycin sulphate.....700mg excipients ad..... 1 gm
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1kg-De-Controlled, 2 kg-De-Controlled, 5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s) Room Temperature
	For generic drugs (me-too Status)	Agrocin
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	VB PHARMA CORPORATION-Lot 7, Road 3, VSIP Bac Ninh, tu Son City, Bac Ninh Province,- Vietnam
	Name, address of Marketing Authorization Holder:	VB PHARMA CORPORATION, Lot 7, Road 3, VSIP Bac Ninh, tu Son City, Bac Ninh Province,, Vietnam
	Details of Certificates (CoPP/FSC/cGMP):	Scanned copy of COPP submitted which confirms free sale status of the applied product in exporting country as well as GMP status of the manufacturer.
	Details of Authorization Letter :	Scanned copy of agreement submitted for the applied product
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 24 months real time data submitted as per zone IV-A conditions
	Evaluation Remarks	
	Since scanned copies of FSC, GMP certificate and power of attorney are attached, the firm shall submit original legalized valid FSC, GMP and POA before issuance of registration letter.	
	Decision	
	Approved	
	with as per innovator's specifications subject to import policy order. Moreover, firm shall submit original legalized valid POA, FSC and GMP before issuance of registration letter, since the already submitted copies are scanned.	
56	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	(TMG-BM8-8XVA, 2024-08-27)
	Detail of Fee Submitted	30000.0, 2024-08-22,
	The proposed proprietary name / brand name	ETER FURAZOLA 95 POWDER
	Label Claim	Each Kg Contains: - Furazolidone.....950gm (As per Innovator's Specs.)
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	100gm-De-Controlled,1Kg-De-Controlled,200gm-De-Controlled,250gm-De-Controlled,500gm-De-Controlled,5Kg-De-Controlled
	Shelf Life (Unit)	2 YearStore below 25 °C. Protect from light
	For generic drugs (me-too Status)	FURASYM POWDER REG. No. 023435 (SYMANS PHARMACEUTICALS LAHORE)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Deferred	
	for review of formulation to Sub-committee on veterinary drugs.	
57	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Hirra Pharmaceutical Laboratories (Pvt) Ltd 3A, 2nd floor, Queen's Center, Queen's Road, (000449)
	Application Form Dy. No / Tracking ID & date of submission	(UEG-YM1-RZRE, 2024-08-02)
	Detail of Fee Submitted	30000.0, 2024-08-02,
	The proposed proprietary name / brand name	HIRRA-BROMO 10 LIQUID
	Label Claim	Each 1000ml contains: BROMHEXINE HCL----- -----50gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML-De-Controlled,1000ML-De-Controlled,250ML-De-Controlled,450ML-De-Controlled,500ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30 Degree Centigrade
	For generic drugs (me-too Status)	063650 AVICENNA LABORATORIES (PVT) LTD
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Keeping in view the manufacturing facilities like installing and availabilities of HVAC system, sanitation, production machinery, equipment in quality control/ testing facilities technical personnel and documentation, the panel of inspection is of the op
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has also submitted fee Rs. 37000/- for revision of formulation in line with reference product.	
	Decision	
	Approved	

58	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Hirra Pharmaceutical Laboratories (Pvt) Ltd 3A, 2nd floor, Queen's Center, Queen's Road, (000449)
	Application Form Dy. No / Tracking ID & date of submission	(WSX-ZRX-RX1P, 2024-08-02)
	Detail of Fee Submitted	30000.0, 2024-08-02,
	The proposed proprietary name / brand name	HIRRA-TYLO 50 POWDER
	Label Claim	Each 100gm powder containsTYLOSIN TARTRATE 50GM
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 g-De-Controlled,1000 g-De-Controlled,250 g- De-Controlled,500 g-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30 Degree Centigrade
	For generic drugs (me-too Status)	080925 PRIX PHARMACEUTICA (PRIVATE) LIMITED "Pri-Macrocid Water Soluble Powder Each 1000gm Contains Tylosin Tartrate_ 500 gm- "
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Keeping in view the manufacturing facilities like installing and availabilities of HVAC system, sanitation, production machinery, equipment in quality control/ testing facilities technical personnel and documentation, the panel of inspection is of the op
	Evidence of approval of manufacturing facility	
59	Evaluation Remarks	
	The firm has submitted fee Rs. 9000/- vide challan number 5553580157 for pre-approval revision of label claim in line with reference product.	
	Decision	
	Approved	
59	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	(Y6J-NTH-YWTX, 2024-08-27)
	Detail of Fee Submitted	30000.0, 2024-08-21,
	The proposed proprietary name / brand name	ETER ELECTROVIT WATER SOLUBLE POWDER
	Label Claim	GENERIC:Each kg contains:-Potassium chloride 87 gmSodium sulphate 212gmSodium chloride 50gmMagnesium sulphate

		59.50gmCopper sulphate..... 30gmZinc sulphate 30gmManganess sulphate 30gmCitric acid 5gm(As per Innovator's Specs.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000gm-De-Controlled,100gm-De-Controlled,200gm-De-Controlled,250gm-De-Controlled,500gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	ELECTROKAIL WATER SOLUBLE POWDER. Reg. No. 028505 (KAILGON AGRO INDUSTRIES (PVT.)LTD. BALOCHISTAN.)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
60	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	Global Pharmaceuticals Pvt Ltd Plot Number 204-205 Industrial Triangle Kahuta Road (000417)
	Application Form Dy. No / Tracking ID & date of submission	(71X-E5P-XNP5, 2024-03-14)
	Detail of Fee Submitted	30000.0, 2024-03-05,
	The proposed proprietary name / brand name	BILASTIN 20MG TABLETS
	Label Claim	Each Tablet contains: Bilastine.....20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5x10's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a cool dry place, below 30oC.
	For generic drugs (me-too Status)	BILFAXIN 20MG TABLET
	Pharmacotherapeutic Group of (API)	H1-Antihistamine
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Name: Metrochem API Private Limited Address: Unit-IV, Plot No. 34B, 40B & 60B, J.N. Pharma City, Thanam Village, Parawada Mandal, Visakhapatnam District, Andhra Pradesh, 531021, India (I
	Detail of stability batches of drug product	Stability data of batches ST-01, ST-02 5000 Tablets each is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Submitted

Pharmaceutical Equivalence and Comparative Dissolution Profile		PE and CDP is performed against the reference product Bilaxten 20mg TabletbyA. Menarini Manufacturing Logistics and Seervices S.r.I
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		stability data as per zone-iv condition is submitted.
The status in reference regulatory authorities		MHRA
GMP status of the firm		GMP certificate dated 4th January,2022 is submitted by the firm.
Evidence of approval of manufacturing facility		GMP certificate dated 4th January,2022 mentioned that firm has tablet (general) section.
Evaluation Remarks		
Sr.no.	Shortcomings	Response of the Firm
1.	The CoA specifies that the drug substance should be stored at 2°C to 8°C, indicating refrigerated storage. However, stability studies were conducted under room temperature conditions (30 ± 2°C / 65% RH and 40 ± 2°C / 75% RH), rather than ICH-recommended conditions for refrigerated products (5°C ± 3°C long-term, 25°C ± 2°C / 60% RH accelerated). Please justify the rationale for selecting these conditions and explain how they support the proposed storage and shelf life of the drug substance.	The Bilastine sample is stored at controlled room temperature (i.e.20–25°C, with excursions allowed between 15–30°C) because stability studies (from the manufacturing in-house) have demonstrated that the sample is stable under those conditions are Accelerated (40±2°C & 75±5% RH), Long term (30±2°C & 65±5% RH). The working standard, however, is stored at 2–8°C to ensure maximum stability over a longer period and to avoid degradation, especially since it may be used repeatedly multiple analyses, over months or years
2.	As per the pH-dependent solubility data submitted in the drug substance section, the API is very slightly soluble in acetate buffer (pH 4.5) (40 mg/100 mL). Given this limited solubility, please justify the selection of acetate buffer pH 4.5 as the dissolution medium for the drug product. Additionally, provide a justification for how the formulation has been designed to enhance the solubility or dissolution of the API in this medium, including the role of any excipients used. Explain how the selected medium and formulation approach together ensure appropriate dissolution characteristics and discriminatory power. Later in response of their reply, firm was again asked that considering the solubility data provided in the dossier, hydrochloric acid (HCl) appears to be the most suitable medium, as it exhibits higher solubility for the drug substance. Therefore, a justification is required for not selecting HCl as the dissolution medium. Additionally, if a relevant European patent document addressing this matter is available on an official platform, kindly provide the link to that document.	In pH-Dependent solubility data of drug substance, the API is very slightly soluble in acetate buffer (pH 4.5) (40mg/100ml, Conc 0.4mg/ml) at 25°C whereas in product, dissolution temperature is 37°C and concentration is 0.02mg/ml for 20mg/900ml. As per European patent, Dissolution profile of Bilastine Tablets have been performed in acetate Buffer pH 4.5 with satisfactory results, attached as annexure 01, Sodium Starch Glycolate has been used as disintegrant in such ration to facilitate release of active ingredient in the dissolution medium and formulation has been obtained from innovator’s available data attached. Firm again refer the patent document of European document and stated that Based on European Patent, 0.1N HCl and pH 4.5 acetate buffer, both mediums are suitable for bilastine tablets giving release within 15min. Then based on CDP, more specific results were found in pH 4.5 acetate buffer for innovator and our

		product therefore it was selected as dissolution medium.
3.	As per the CDP report, more than 90% of the drug is released within 20 minutes in acetate buffer (pH 4.5). Given this rapid and consistent release, please justify the rationale for setting a broader dissolution specification of NLT 75% (Q) in 20 minutes. Explain how the proposed limit ensures batch-to-batch consistency and maintains discriminatory power, while also reflecting the in vivo performance of the product.	We have developed Dissolution profile as per guidance stated in 293rd meeting minutes of DRAP “Cases of Dissolution specification of immediate release drug products” which states that; Identify the first time point in profile where mean drug release is $\geq 85\%$. Set this time point as dissolution time “T” provided the RSD value at this time point is $\leq 10\%$. In case if the RSD value is more than 10% consider the next time point as “T”. Like here in this case 86% drug release was achieved in 15 minutes and the RSD value at this time point is less than 10%, therefore T=15 minutes. Subtract 10% from the mean value at time point “T” selected in the above point and round the results to closer of 75% or 80% and select this value as “Q”. For example, in this case the mean drug release at 15 minutes time point “T” is 86%, by subtracting 10% it becomes 76%, and then rounding the results to closer to 75% to set the value of “Q” as 75. Keeping in view above statement, more than 85% release of Bilastine Tablets 20mg have been achieved in 15min as mentioned in CDP Acetate Buffer pH 4.5, So Subtracting 10% from the release value 75% (Q) has been selected. And to maintain batch to batch consistency, next time point 20min was Set as “T” to achieve maximum release.
4.	The raw data sheet submitted in section 3.2.P.8.3 indicates a sample weight of 310.8 mg used for assay analysis, while the analytical procedure in section 3.2.P.5.2 specifies that 20 tablets should be crushed and a sample equivalent to 50 mg of the API should be taken. However, the average weight of 20 tablets is 124.3 mg as per the submitted raw data sheets, making it unclear how a 310.8 mg sample could have been obtained from that amount of powder. Please clarify this discrepancy, specifically, confirm whether the sample weight corresponds correctly to 50 mg of API, and explain how the sample quantity aligns with the average tablet weight.	Firm replied that 20 Tablets were weighed and crushed into powder, 124.3mg is the average weight contains 20mg of API. For weight equivalent to 50mg, the calculation becomes; $124.3 \times 50/20 = 310.8\text{mg}$ that is taken for analysis.
Decision		
Approved		

61	Case Category	Routine (Sana Kanwal)
	Name, address of Applicant.	Pinnacle Biotech (Pvt.) Ltd. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi. (000939)
	Application Form Dy. No / Tracking ID & date of submission	(77Y-AMT-5BTW, 2024-02-21)
	Detail of Fee Submitted	30000.0, 2023-12-13,
	The proposed proprietary name / brand name	Empaxo-M XR Tablets 5mg-1000mg
	Label Claim	Each film coated tablets contains: Empagliflozin...5mg (as outer coat) Metformin Hydrochloride...1000mg (as extended release core)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14s Tablets-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 25°C
	For generic drugs (me-too Status)	Xenglu-Met XR 5mg-1000mg tablet by Hilton Pharma private Ltd.
	Pharmacotherapeutic Group of (API)	Blood glucose lowering agents Anti diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Exemed Pharmaceutical,Fuxin Long Rui Pharmaceutical Co. Ltd
	Detail of stability batches of drug product	Batch No: T-119, T-143, T-144 Batch size: 1500 tablets Conditions: as per zone IV-A Frequency: 0,3,6 months
	Documents for the procurement of API with approval from DRAP (in case of Import)	Import of 1.3kg Empagliflozin cleared by I&E, Karachi dated 10-12-2021 Import of 150kg Metformin HCl cleared by I&E, Karachi dated 10-12-2021
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Xenglu-Met 5mg/1000mg XR Tablet Batch No:139838 Manufacturer: M/s Hilton Pharma, Karachi (Reference product) Empaxo-M 5mg/1000mg XR Tablet Batch No: T-119 (Test product)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Metformin HCl: Submitted as per Zone IV-B 0, 3, 6 (accelerated study) 0,3,6,9,12,18 ,24,36 and 48 months (long term study) Batches: MFH211071AFP, MFH211072AFP, MFH211073AFP Empagliflozin: Submitted as per Zone IV-A L-E-20200409-D01-E06-02 L-E-20200409-D01-E06-03 L-E-20200409-D01-E06-04
	The status in reference regulatory authorities	Synjardy XR 5mg-1000mg by Boehringer Ingelheim Pharmaceuticals Inc. Food and Drug Regulatory Authori
	GMP status of the firm	GMP certificate (Finished product manufacturer) on the basis of inspection report dated 21-10-2022 is provided Metformin HCl: EXEMED PHARMACEUTICALS PLOT NO. 628 (A & B), ECP CANAL ROAD, VILLAGE - LUNA, TAL -

		PADRA 391 440, DIST.- VADODARA GUJARAT ST	
Evidence of approval of manufacturing facility		Tablet (General) section is approved vide letter dated 13-09-2021	
Evaluation Remarks			
S.No.	Observations	Reply	Remarks
1.	Declaration of solubility of Empagliflozin in water as “practically insoluble” shall be justified with reference to the innovator drug product literature.	Empagliflozin is a non-compendial material, it's a manufacturer spec's grade material. While manufacturer solubility claims, "Practically Insoluble in water" Manufacturer drug substance specification & testing method of empagliflozin is provided.	Empagliflozin is very slightly soluble in water (pH 1-7.4), as per Public assessment report of EMA approved formulation (Jardiance tablet) https://www.ema.europa.eu/en/documents/assessment-report/jardiance-epar-public-assessment-report_en.pdf
2.	Details of the reference material, against which structural characterization studies of Empagliflozin have been performed, shall be submitted.	Details of the reference material (working standard), against which structural characterization studies of empagliflozin have been performed is submitted.	CoA of working standard is providedBatch No. E6DZ202101
3	Details of the analytical methods applied for the control of "Enantiomeric purity" of Empagliflozin shall be submitted.	Empagliflozin is a non-compendial material, it's a manufacturer spec's grade material. We have tested enantiomeric purity (Isomer Test) test as per manufacturer provided testing method. Manufacturer drug substance testing method of empagliflozin & analytical raw data sheet of empagliflozin is provided	Analytical testing method HPLC (chiral) for enantiomeric purity is provided
4	Long term stability data of Empagliflozin shall be submitted till the claimed shelf life.	Long term stability studies data of Empagliflozin (Batch No.: L-E-20200409-D01-E06-02) provided for the period of 12 months.	
5	Results of individual units shall be submitted for the performance of CDP studies.	Results of individual units for the performance of CDP studies is provided	complied

6	Results of the dissolution profile of Empagliflozin reported in the Comparative dissolution profile studies shall be justified with reference to the BCS classification of Empagliflozin.	Empagliflozin belongs to a BCS class III drug (High solubility and Low permeability). Our CDP testing results complies with the statement of BCS Class III statement which is High solubility and Low permeability. CDP Studies report is attached	Results justified w.r.t to BCS classification as well as literature of innovator's product.
7	Justification shall be submitted for including the test for Assay for Empagliflozin at the blend stage in process validation protocol, since Empagliflozin has to be incorporated in via coating.	There was a typographical error in the test for Assay of Empagliflozin at the blend stage in the process validation protocol.	Challan has been attached for typographical error having No. 93039418576
8	Justification shall be submitted for including the test for Assay & Dissolution for Empagliflozin at the core stage in process validation protocol, since Empagliflozin has to be incorporated in via coating.	There was a typographical error in the Assay & Dissolution test for Empagliflozin at the core stage in the process validation protocol. Challan has been attached for typographical error having No. 763486638041.	Challan has been attached for typographical error having No. 763486638041.
9	Details shall be submitted for the in-process test applied to establish the fact that required content of Empagliflozin has been layered onto the core tablet, before proceeding for the final film coat.	To ensure the accurate application of Empagliflozin onto the core tablet, weight gain analysis is employed as an in-process test during the drug coating stage. This method provides a reliable measure of the coating's adherence to the required content specifications and confirms that the final product meets the declared levels of Empagliflozin.	Empagliflozin taken 15% in excess quantity to prevent loss during active coating process
10	Specificity of UV spectrophotometric method of Dissolution test for Metformin HCl shall be established with respect to the absorbance	In UV-Vis spectrophotometer we have performed specificity spectrum of metformin HCl in the range of 200nm - 400nm.	Verified from raw data and chromatograms provided under analytical validation studies.

	of Empagliflozin in the sample solution.	And found no interference of placebo. The Amax of Metformin HCl is 233nm.	
11	Reconciliation record for the imported quantity of 1.3Kg of Empagliflozin shall be submitted.	Reconciliation record of Empagliflozin has been provided.	Utilization of 1.3kg empagliflozin has been justified (trial batches, QC release and 29% excess quantity of total quantity of API required)
12	Justification shall be submitted for the declared quantity of Empagliflozin in the master formulation considering the method of manufacturing by way of coating for the drug substance.	To mitigate potential process losses during the coating process, an excess quantity of drug coating solution is utilized relative to the theoretical quantity to ensures that the final product contains the specified quantity of Empagliflozin. This process has been verified to confirm its compliance with all required specifications, including weight gain percentage, thereby ensuring that the declared or claimed values of Empagliflozin are accurately achieved in the final drug product.	

Decision

Approved

Approved

62	Case Category	New License (Shahid Nawaz)
	Name, address of Applicant.	QADIR PHARMACEUTICALS FATEH GHAR SAHUWALA ROAD SIALKOT (000944)
	Application Form Dy. No / Tracking ID & date of submission	(8GW-PH6-6BGA, 2024-10-09)
	Detail of Fee Submitted	37000.0, 2024-09-24,
	The proposed proprietary name / brand name	Loraqad 5mg/5mL Syrup
	Label Claim	Each 5mL Oral Solution Contains: Loratadine 5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's x 60mL-As per SRO
	Shelf Life (Unit)	2 Year(s)Protect from Light and Store below 30°C
	For generic drugs (me-too Status)	Antial Oral Solution, SAMI Pharmaceuticals, Reg. No. 019878.

Pharmacotherapeutic Group of (API)	Antihistamine. ATC code: R06AX13.
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Morepen Laboratories Limited
Detail of stability batches of drug product	03 batches having batch size of 100 packs.
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of Form 6 No. K-1626507554865 dated 15-03-2023 mentioning 100gm of Loratadine from M/s Morepen Laboratories Limited issued by DRAP, Lahore. Firm has also submitted copy of clearance certificate No. E-6578007555987 dated 08-09-2023 mentioning 100gm of Loratadine, B. No. LRD - 4123 from M/s Morepen Laboratories Limited cleared by DRAP, Lahore.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies are performed against comparator product i.e. Antial 5mg/5mL oral solution, B. No. B# AFM007 manufactured by M/s Sami Pharmaceuticals Limited.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of 3 batches of drug substance as per Zone IV-A is submitted. Accelerated 06 months and real time for 48 months.
The status in reference regulatory authorities	Loratadine 5mg/5ml Oral Solution, MHRA approved.
GMP status of the firm	New DML issued dated 13-09-2021.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of DML dated 17-09-2021 specifying Oral Liquid (General) section.
Evaluation Remarks	
Case was approved in 347th meeting. While in decision of the Board, deferred for further deliberation was also mentioned inadvertently.	
Decision	
Approved	
63	Case Category
	New License (Shahid Nawaz)
	Name, address of Applicant.
	QADIR PHARMACEUTICALS FATEH GHAR SAHUWALA ROAD SIALKOT (000944)
	Application Form Dy. No / Tracking ID & date of submission
	(9YA-7GX-WM8H, 2024-08-23)
	Detail of Fee Submitted
	30000.0, 2024-07-25,
	The proposed proprietary name / brand name
	Meco-Q 0.5mg/1ml
	Label Claim
	Each 1ml ampoule Contains; Mecobalamin.....0.5mg
	Reference to Finished product specifications
	As per Innovators Specification
	Proposed Pack Size
	3x10's=30's-As per SRO
	Shelf Life (Unit)
	2 Year(s)Protect from Light and Store below 30°C
	For generic drugs (me-too Status)
	Methycobal injection, M/s Hilton Pharma, Reg. No. 010313.
	Pharmacotherapeutic Group of (API)
	Vitamin B12 (Cyanocobalamin and analogues) ATC Code B03BA05.
	Name, address of Manufacturing site:
	Self Manufacturing

	Name & address of API manufacturer	Micro Orgo-Chem
	Detail of stability batches of drug product	03 batches having batch size of 1500 ampoules.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of Form 6 No. K-2092707551432 dated 12-07-2023 mentioning 100gm of Mecobalamin from M/s MICRO ORGO CHEM, India.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies are performed against comparator product i.e. Methycobal 500µg/1ml, B. No. 153339 Mfg. Date:04-2024 manufactured by M/s Hilton Pharma.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of 3 batches of drug substance as per Zone II is submitted. Accelerated 06 months and real time for 48 months.
	The status in reference regulatory authorities	PMDA JAPAN approved.
	GMP status of the firm	New DML issued dated 13-09-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of DML dated 17-09-2021 specifying Liquid injectable Vial & Ampoule (General) section.
	Evaluation Remarks	
	Case was approved in 347th meeting. While in decision of the Board, deferred for further deliberation was also mentioned inadvertently.	
64	Decision	
	Approved	
	Case Category	New Molecule/Formulation (Shahid Nawaz)
	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	(L5A-WG1-EMB6, 2025-02-03)
	Detail of Fee Submitted	75000.0, 2025-01-31,
	The proposed proprietary name / brand name	Axigra Tablet 100mg
	Label Claim	Each Film Coated Table Contains: Sildenafil citrate Equivalent to Sildenafil 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Selective inhibitor of cyclic guanosine monophosphate (cGMP) specific phosphodiesterase type 5 (PDE5) ATC code: G04BE03..
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceutical Limited
	Detail of stability batches of drug product	03 batches having batch size of 1200 Tablets each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of Form 6 No. DIL-C-F1COFC dated 12-11-2024 mentioning 2kg of Sildenafil Citrate USP from M/s Century Pharmaceuticals, India.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and PE studies are performed against innovator product i.e. Viagra 50mg Tablets, B. No. 3189819, Expiry date 07-2027 manufactured by Pfizer, UK and both reference and applied formulation have shown more than 85% release within 15 minutes in 0.1N HCl while in Acetate buffer & phosphate buffer value of F2 are in acceptable range.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of 3 batches of drug substance as per Zone IV-A is submitted. Accelerated 06 months and real time for 60 months.
	The status in reference regulatory authorities	Viagra 25mg, 50mg & 100mg (sildenafil) tablets, USFDA approved.
	GMP status of the firm	Firm has submitted copy of GMP Certificate No. 122/2024-DRAP(AD-61400297216) dated 04-07-2024 issued on the basis of inspection conducted on 03-07-2024.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-20/2006-Lic (Vol-II) dated 30-06-2020 mentioning Tablet section (General).
	Evaluation Remarks	
	Deferred for submission of six-month time point stability data along with raw data sheets and chromatograms.	Firm has submitted six-month time point stability data along with raw data sheets and chromatograms.
	Decision	
	Approved	
	Registration letter will be issued after verification of authenticity of submitted data by the panel constituted by the Chairman Registration Board.	
65	Case Category	New Molecule/Formulation (Shahid Nawaz)
	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	(SUA-L5X-8HQ2, 2025-02-03)
	Detail of Fee Submitted	75000.0, 2025-01-31,
	The proposed proprietary name / brand name	Axigra Tablet 25mg
	Label Claim	Each Film Coated Table Contains: Sildenafil citrate Equivalent to Sildenafil 25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Selective inhibitor of cyclic guanosine monophosphate (cGMP) specific phosphodiesterase type 5 (PDE5) ATC code: G04BE03.
	Name, address of Manufacturing site:	Self Manufacturing

Name & address of API manufacturer	Century Pharmaceutical Limited
Detail of stability batches of drug product	03 batches having batch size of 1200 Tablets each.
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of Form 6 No. DIL-C-F1COFC dated 12-11-2024 mentioning 2kg of Sildenafil Citrate USP from M/s Century Pharmaceuticals, India.
Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and PE studies are performed against innovator product i.e. Viagra 25mg Tablets, B. No. B592628U, Expiry date 12-2025 manufactured by Pfizer, UK and both reference and applied formulation have shown more than 85% release within 15 minutes in 0.1N HCl while in Acetate buffer & phosphate buffer value of F2 are in acceptable range.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of 3 batches of drug substance as per Zone IV-A is submitted. Accelerated 06 months and real time for 60 months.
The status in reference regulatory authorities	Viagra 25mg, 50mg & 100mg (sildenafil) tablets, USFDA approved.
GMP status of the firm	Firm has submitted copy of GMP Certificate No. 122/2024-DRAP(AD-61400297216) dated 04-07-2024 issued on the basis of inspection conducted on 03-07-2024.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-20/2006-Lic (Vol-II) dated 30-06-2020 mentioning Tablet section (General).
Evaluation Remarks	
Deferred for submission of six-month time point stability data along with raw data sheets and chromatograms.	Firm has submitted six-month time point stability data along with raw data sheets and chromatograms.
Decision	
Approved	
Registration letter will be issued after verification of authenticity of submitted data by the panel constituted by the Chairman Registration Board.	
66	Case Category
	New Molecule/Formulation (Shahid Nawaz)
	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
	(W7V-8YJ-XTVY, 2025-02-03)
	Detail of Fee Submitted
	75000.0, 2025-01-31,
	The proposed proprietary name / brand name
	Axigra Tablet 50mg
	Label Claim
	Each Film Coated Table Contains: Sildenafil citrate Equivalent to Sildenafil 50mg
	Reference to Finished product specifications
	United States Pharmacopeia
	Proposed Pack Size
	4's-As per SRO
	Shelf Life (Unit)
	24 Year(s)Store below 30°C

	For generic drugs (me-too Status)	Viagra Tablet 50mg
	Pharmacotherapeutic Group of (API)	Selective inhibitor of cyclic guanosine monophosphate (cGMP) specific phosphodiesterase type 5 (PDE5) ATC code: G04BE03.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceutical Limited
	Detail of stability batches of drug product	03 batches having batch size of 1200 Tablets each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of Form 6 No. DIL-C-F1COFC dated 12-11-2024 mentioning 2kg of Sildenafil Citrate USP from M/s Century Pharmaceuticals, India.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and PE studies are performed against innovator product i.e. Viagra 50mg Tablets, B. No. 3189819, Expiry date 07-2027 manufactured by Pfizer, UK and both reference and applied formulation have shown more than 85% release within 15 minutes in 0.1N HCl while in Acetate buffer & phosphate buffer value of F2 are in acceptable range.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of 3 batches of drug substance as per Zone IV-A is submitted. Accelerated 06 months and real time for 60 months.
	The status in reference regulatory authorities	Viagra 25mg, 50mg & 100mg (sildenafil) tablets, USFDA approved.
	GMP status of the firm	Firm has submitted copy of GMP Certificate No. 122/2024-DRAP(AD-61400297216) dated 04-07-2024 issued on the basis of inspection conducted on 03-07-2024.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-20/2006-Lic (Vol-II) dated 30-06-2020 mentioning Tablet section (General).
	Evaluation Remarks	
	Deferred for submission of six-month time point stability data along with raw data sheets and chromatograms.	Firm has submitted six-month time point stability data along with raw data sheets and chromatograms.
	Decision	
	Approved	
	Registration letter will be issued after verification of authenticity of submitted data by the panel constituted by the Chairman Registration Board.	
67	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	Bio-Labs(Pvt) Ltd Plot 145, Industrial Triangle, Kahuta Road (000296)
	Application Form Dy. No / Tracking ID & date of submission	(33V-81M-LDYQ, 2024-04-29)
	Detail of Fee Submitted	30000.0, 2023-11-29,
	The proposed proprietary name / brand name	Aquabio Ampoule
	Label Claim	Each ampoule contains: Water for Injection 2mL

Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	2ml ampoule-Controlled
Shelf Life (Unit)	2 Year(s)Store below 30C
For generic drugs (me-too Status)	Sterile water for injection 2ml Getz Pharma
Pharmacotherapeutic Group of (API)	Diluent
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	
Detail of stability batches of drug product	2000 ampoule 3 batches
Documents for the procurement of API with approval from DRAP (in case of Import)	Local production
Pharmaceutical Equivalence and Comparative Dissolution Profile	Water for injection 2ml Healthtek Pvt Ltd
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
The status in reference regulatory authorities	Ranbaxy (UK) Limited
GMP status of the firm	F.3-1912019-Addl. Dir. (QA & LT-I)7D dated 28.12.23
Evidence of approval of manufacturing facility	No. F. 1-12/89-Lic(Vol-III) dated 23 July 2012 mentioning ampoule section

Evaluation Remarks

Sr. No	Observation	Response
1	1.6.5: Valid copy of GMP certificate of the drug product & Substance manufacturer issued by concerned/relevant regulatory authority shall be submitted	F.3-1912019-Addl. Dir. (QA & LT-I)7D dated 28.12.23
2	3.2.S: Provide Detail of RO plant used for distilled water production.	Firm has submitted details of RO plant and distillation plant and layout of water filtration system
3	3.2.P.5.4: Batch Analysis: Result provided are not quantified only statement "complies" is written in all tests performed	Submitted
4	3.2. P.8.3 Stability Data: Result provided are not quantified only statement "complies" is written in all tests performed.	Submitted

Decision

Approved

68	Case Category	Priority As Per 257-M of RB (Tahir Waqas)
	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	(AR3-QV4-J6YM, 2024-09-24)
	Detail of Fee Submitted	75000.0, 9000.0 2024-09-02, 2025-05-07
	The proposed proprietary name / brand name	Cenova Tablets 50mg
	Label Claim	Each film-coated tablet contains: Cenobamate ... 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
Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect form sunlight and moisture.
For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	N03AX, Antiepileptics.
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	
Detail of stability batches of drug product	03 Batches, 6,666 Tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance Certificate from DRAP (I&E) Karachi for import of 4000grams API has been submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and CDP conducted against Ontozry Tablets 50mg.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Studies conducted on Zone IV by Drug Substance Manufacturer.
The status in reference regulatory authorities	Ontozry 50mg Tablets, EMA approved.
GMP status of the firm	Copy of GMP Certificate valid for 02 years from the date of Inspection (23-01-2023) has been submitted.
Evidence of approval of manufacturing facility	Section approval letter from Licensing Division for Tablet (General) Section has been submitted.

Evaluation Remarks

Case was deferred in 345th Meeting for submission of response to the following deficiencies: -

Deficiencies	Response of the Firm
a) Valid GMP of API Manufacturer.	Firm have referred to the API Manufacturing License of M/s Henan Jin Huaitang Biological Engineering Co., Ltd. (License No. YU20230200) https://yjj.henan.gov.cn/2023/07-13/2777876.html
b) Fee for revision of data.	Firm have submitted Fee of PKR 9,000/- as Pre-registration variation.
Registration Board further decided that the instant application will be considered along with 25mg strength.	Firm have stated that they have developed Cenobamate Tablets in four strengths. The 25mg and 150mg strengths are currently under development, wherein procurement of API for trial batch development & innovator samples for CDP & PE has been completed and they will be able to submit the same for registration approval instantly after completion of 6 months stability studies i.e. tentatively by December 2025. They have further submitted that for interim period the required initial dose of 25mg, as well as titration dose 150mg, can be effectively managed using available strengths. 25mg dose can be achieved by administering 12.5mg + 12.5mg. 150mg dose can be achieved by administering 100mg + 50mg.

Cenobamate Tablet is indicated for the adjunctive treatment of focal-onset seizures with or without secondary generalisation in adult patients with epilepsy who have not been adequately controlled despite a history of treatment with at least 2 anti-epileptic medicinal products.

Decision

Deferred

Registration Board did not accede to the firm's request and further decided that the instant application will be considered along with 25mg and 150mg strengths (as per innovator).

69	Case Category	Priority As Per 257-M of RB (Tahir Waqas)
	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	(BQX-G1Y-R3RW, 2024-10-08)
	Detail of Fee Submitted	75000.0, 9000.0 2024-08-12, 2025-05-07
	The proposed proprietary name / brand name	Cenova Tablets 12.5mg
	Label Claim	Each tablet contains: Cenobamate ... 12.5mg
	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
	Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect from sunlight and moisture
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	N03AX, Antiepileptics.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	03 Batches, 11,765 Tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance Certificate from DRAP (I&E) Karachi for import of 4000grams API has been submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and CDP conducted against Ontozry Tablets 12.5mg.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Studies conducted on Zone IV by Drug Substance Manufacturer.
	The status in reference regulatory authorities	Ontozry 12.5mg Tablets, EMA approved.
	GMP status of the firm	Copy of GMP Certificate valid for 02 years from the date of Inspection (23-01-2023) has been submitted.
	Evidence of approval of manufacturing facility	Section approval letter from Licensing Division for Tablet (General) Section has been submitted.
	Evaluation Remarks	
	Case was deferred in 345th Meeting for submission of response to the following deficiencies: -	
	Deficiencies	Response of the Firm
	a) Valid GMP of API Manufacturer.	Firm have referred to the API Manufacturing License of M/s Henan Jin Huaitang Biological Engineering Co., Ltd. (License No. YU20230200) https://yjj.henan.gov.cn/2023/07-13/2777876.html
	b) Fee for revision of data.	Firm have submitted Fee of PKR 9,000/- as Pre-registration variation.
	Registration Board further decided that the instant application will be considered along with 25mg strength.	Firm have stated that they have developed Cenobamate Tablets in four strengths. The 25mg and 150mg strengths are currently under development, wherein procurement of API for

trial batch development & innovator samples for CDP & PE has been completed and they will be able to submit the same for registration approval instantly after completion of 6 months stability studies i.e. tentatively by December 2025. They have further submitted that for interim period the required initial dose of 25mg, as well as titration dose 150mg, can be effectively managed using available strengths. 25mg dose can be achieved by administering 12.5mg + 12.5mg. 150mg dose can be achieved by administering 100mg + 50mg.

Cenobamate Tablet is indicated for the adjunctive treatment of focal-onset seizures with or without secondary generalisation in adult patients with epilepsy who have not been adequately controlled despite a history of treatment with at least 2 anti-epileptic medicinal products.

Decision

Deferred

Registration Board did not accede to the firm's request and further decided that the instant application will be considered along with 25mg and 150mg strengths (as per innovator).

70	Case Category	Priority As Per 257-M of RB (Tahir Waqas)
	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	(LM9-3VX-7SEG, 2024-09-10)
	Detail of Fee Submitted	75000.0, 9000.0 2024-09-02, 2025-05-07
	The proposed proprietary name / brand name	Cenova Tablets 100mg
	Label Claim	Each film-coated tablet contains: Cenobamate ... 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled, 14's-De-Controlled, 20's-De-Controlled, 28's-De-Controlled, 30's-De-Controlled
	Shelf Life (Unit)	2 Year(s) Store below 30°C. Protect from sunlight and moisture
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	N03AX, Antiepileptics.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	03 Batches, 3,333 Tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance Certificate from DRAP (I&E) Karachi for import of 4000grams API has been submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and CDP conducted against Ontozry Tablets 200mg.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Studies conducted on Zone IV by Drug Substance Manufacturer.
	The status in reference regulatory authorities	Ontozry 100mg Tablets, EMA approved.
	GMP status of the firm	Copy of GMP Certificate valid for 02 years from the date of Inspection (23-01-2023) has been submitted.

Evidence of approval of manufacturing facility		Section approval letter from Licensing Division for Tablet (General) Section has been submitted.
Evaluation Remarks		
Case was deferred in 345th Meeting for submission of response to the following deficiencies: -		
Deficiencies		Response of the Firm
a) Valid GMP of API Manufacturer.		Firm have referred to the API Manufacturing License of M/s Henan Jin Huaitang Biological Engineering Co., Ltd. (License No. YU20230200) https://yj.j.henan.gov.cn/2023/07-13/2777876.html
b) Fee for revision of data.		Firm have submitted Fee of PKR 9,000/- as Pre-registration variation.
Registration Board further decided that the instant application will be considered along with 25mg strength.		Firm have stated that they have developed Cenobamate Tablets in four strengths. The 25mg and 150mg strengths are currently under development, wherein procurement of API for trial batch development & innovator samples for CDP & PE has been completed and they will be able to submit the same for registration approval instantly after completion of 6 months stability studies i.e. tentatively by December 2025. They have further submitted that for interim period the required initial dose of 25mg, as well as titration dose 150mg, can be effectively managed using available strengths. 25mg dose can be achieved by administering 12.5mg + 12.5mg. 150mg dose can be achieved by administering 100mg + 50mg.
Cenobamate Tablet is indicated for the adjunctive treatment of focal-onset seizures with or without secondary generalisation in adult patients with epilepsy who have not been adequately controlled despite a history of treatment with at least 2 anti-epileptic medicinal products.		
Decision		
Deferred		
Registration Board did not accede to the firm's request and further decided that the instant application will be considered along with 25mg and 150mg strengths (as per innovator).		
71	Case Category	Priority As Per 257-M of RB (Tahir Waqas)
	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	(QRX-HP3-45UY, 2024-10-08)
	Detail of Fee Submitted	75000.0, 9000.0 2024-09-02, 2025-05-07
	The proposed proprietary name / brand name	Cenova Tablets 200mg
	Label Claim	Each film-coated tablet contains: Cenobamate ... 200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled, 14's-De-Controlled, 20's-De-Controlled, 28's-De-Controlled, 30's-De-Controlled
	Shelf Life (Unit)	2 Year(s) Store below 30°C. Protect from sunlight and moisture
	For generic drugs (me-too Status)	N/A

Pharmacotherapeutic Group of (API)	N03AX, Antiepileptics.
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	
Detail of stability batches of drug product	03 Batches, 1,666 Tablets each.
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance Certificate from DRAP (I&E) Karachi for import of 4000grams API has been submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and CDP conducted against Ontozry Tablets 200mg.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Studies conducted on Zone IV by Drug Substance Manufacturer.
The status in reference regulatory authorities	Ontozry 200mg Tablets, EMA approved.
GMP status of the firm	Copy of GMP Certificate valid for 02 years from the date of Inspection (23-01-2023) has been submitted.
Evidence of approval of manufacturing facility	Section approval letter from Licensing Division for Tablet (General) Section has been submitted.

Evaluation Remarks

Case was deferred in 345th Meeting for submission of response to the following deficiencies: -

Deficiencies	Response of the Firm
a) Valid GMP of API Manufacturer.	Firm have referred to the API Manufacturing License of M/s Henan Jin Huaitang Biological Engineering Co., Ltd. (License No. YU20230200) https://yjj.henan.gov.cn/2023/07-13/2777876.html
b) Fee for revision of data.	Firm have submitted Fee of PKR 9,000/- as Pre-registration variation.
Registration Board further decided that the instant application will be considered along with 25mg strength.	Firm have stated that they have developed Cenobamate Tablets in four strengths. The 25mg and 150mg strengths are currently under development, wherein procurement of API for trial batch development & innovator samples for CDP & PE has been completed and they will be able to submit the same for registration approval instantly after completion of 6 months stability studies i.e. tentatively by December 2025. They have further submitted that for interim period the required initial dose of 25mg, as well as titration dose 150mg, can be effectively managed using available strengths. 25mg dose can be achieved by administering 12.5mg + 12.5mg. 150mg dose can be achieved by administering 100mg + 50mg.

Cenobamate Tablet is indicated for the adjunctive treatment of focal-onset seizures with or without secondary generalisation in adult patients with epilepsy who have not been adequately controlled despite a history of treatment with at least 2 anti-epileptic medicinal products.

Decision

Deferred

Registration Board did not accede to the firm's request and further decided that the instant application will be considered along with 25mg and 150mg strengths (as per innovator).

Pharmaceutical Evaluation Cell (PEC)

Agenda of Adil Saeed (DD PEC-IX)

1.	Name, address of Applicant / Importer	M/s Mutabbar Pharma Flat No. E-1, 1 st Floor Agro Squire 47 Shadman Market Lahore..
	Details of Drug Sale License of importer	License No: 05-352-0063-037381D Address: Flat No E1, 1 st Floor Agro Squire Shadman Lahore. Address of Godown: NA Validity: 03-10-2020. Status: License to sell drugs as a distributor
	Name and address of marketing authorization holder (abroad)	Health Biotech Ltd Near Dream Hotel Nalagarh Road Baddi 173205 Distt Solan India.
	Name, address of manufacturer(s)	Health Biotech Ltd Near Dream Hotel Nalagarh Road Baddi 173205 Distt Solan India.
	Name of exporting country	India
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	CoPP: Not initially submitted GMP: copy of GMP certificate (No. HFW-H [Drugs] 185/05) issued by Health and Family Welfare Department Himachal Pradesh, dated 07-03-2020. The certificate is valid till 05-03-2023.
	Details of letter of authorization / sole agency agreement	Not initially submitted
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy No 36665: 06-11-2018
	Details of fee submitted	PKR 100,000/-: 06-11-2018
	The proposed proprietary name / brand name	DUROBSIN 50mg Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial Contains: Doxorubicin hydrochloride.....50mg
	Pharmaceutical form of applied drug	Freeze dried powder in amber color glass vial made of USP type I glass.
	Pharmacotherapeutic Group of (API)	Anthracyclines and related substances (L01DB01)
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	2394/-
	The status in reference regulatory authorities	Doxorubicin 2 mg/ml Concentrate for Solution for Infusion (MHRA Approved).
	For generic drugs (me-too status)	Adriablastine injection by pfizer
	Module-II (Quality Overall Summary)	Not submitted initially as per WHO template
	Name, address of drug substance	RPG Life Sciences Limited, Fermentation Division,

	manufacturer	2702/A G.I.D.C. Ankleshwar 393002 Dist Baruch Gujtay India.
	Module-III Drug Substance:	Not submitted initially
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Not submitted initially
	Module-III Drug Product:	Not submitted initially
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not submitted initially
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	30ml clear colourless glass vials type I
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted long term stability data of 3 batches for 24 months at 30±2°C, 65±5%RH and 6 months at 4°C±75%RH for three batches.
Evaluation by PEC		
	Shortcomings communicated	Response by the firm
	Provide valid drug sale license since the submitted DSL was valid till 03-10-2020	Firm has submitted copy of DSL which was valid till 03-10-2020. Firm has also submitted copy of Challan Form for submission of PKR 3000/- in National Bank of Pakistan dated 16-10-2020. The Challan form does not specify the purpose of payment and no evidence of submission of application for renewal of DSL is submitted. Furthermore, the payment is made after the due date.
	Provide original, legalized and valid certificate of pharmaceutical product since you have submitted copy of CoPP.	Original, Legalized CoPP (Certificate#. HFWH[Drugs] 185/05/18-81) dated 24-08-2019 issued by Health and Family Welfare Department Baddi, Himachal Pradesh. The CoPP declares free sale status of the applied product in exporting country. The CoPP also confirms the GMP status of the manufacturer through periodic inspections conducted once an year
	Submit letter of authorization / sole agency agreement from the product license holder (abroad) for the applied product.	Firm has submitted copy of Manufacturing and export agreement dated 7th February 2017. The agreement was valid for three years from the date of agreement. As per the agreement the address of Mutabbar Pharma is mentioned as 25 Taj Arcade 73, Jail Road Lahore, while the address of Mutabbar Pharma mentioned in the application and on DSL is Flat No. E-1, 1st Floor Agro Squire 47 Shadman Market Lahore. The agreement does not contains “Annexure A brand products” for which the agreement was made.
	Provide evidence of approval of applied formulation as (lyophilized) powder for injection in any reference regulatory authority adapted by Registration Board in its 275 th meeting.	Firm has submitted USP monograph of Doxorubicin hydrochloride for injection. But the evidence of approval of applied formulation in reference regulatory authorities is not submitted.
	Quality overall summary (QOS) in module 2 needs to be submitted as per WHO QOS - PD template or the template approved by Registration Board in its 293 rd meeting.	Firm has again submitted QOS which is not as per the WHO template.

Submit complete information of drug substance in section 3.2.S in module 3 as per the guidance document approved by Registration Board in its 296 th meeting.	Firm has submitted drug substance part of module 3. But firm has not submitted verification of analytical method for the drug substance in section 3.2.S.4.3 and stability study data of the drug substance.
Submit complete information of drug product in section 3.2.P in module 3 as per the numbering system approved as per CTD Form (5-F) promulgated vide SRO 713 (I) 2018 and the data requirement as per guidance document approved by Registration Board in its 296 th meeting.	Firm has submitted drug product part in module 3. But the firm has not submitted Pharmaceutical Equivalence, Process validation report, verification of analytical method and stability study data.
Submit data of pharmaceutical equivalence in section 3.2.P.2.2.1 as per the guidance document approved by Registration Board which states that “Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product shall be submitted and discussed”.	Firm has submitted pre-formulation study data. Firm has not provided results of pharmaceutical equivalence.
Submit data of compatibility in section 3.2.P.6 as per the guidance document approved by Registration Board which states that “Compatibility studies for the dry powder for injections and dry powder for suspension shall be performed as per the instructions provided in individual label of the drug product”.	Firm has submitted report of compatibility of the drug with excipients instead of providing compatibility of the drug product with the recommended diluent. Results of compatibility with the diluent is not submitted.
Submit batch analysis certificate of 3 batches of drug product in section 3.2.P.5.4 of module 3.	Firm has submitted COA of 3 batches of the 10mg strength instead of the applied product.
Submit copy of batch manufacturing record for the three batches for which stability studies have been performed.	Firm has submitted stability study data and process validation protocols and process validation report. Firm has not submitted copy of Batch Manufacturing Record (BMR) of the three stability batches.
Based on the response received by the firm and after evaluation, another letter of shortcoming was also issued on 31.12.2020 in which following observations were communicated to the firm. The Firm submitted its reply which was received in DRAP on 11-01-2021. The details of the response of the firm is provided below:	
Shortcomings communicated	Response by the firm
Provide valid Drug Sale License (DSL) since the submitted DSL was valid till 03-10-2020 and you have only submitted a copy of challan form dated 16.10.2020 without specifying the purpose of challan form. However, no evidence of submission of application for renewal of DSL is submitted. Furthermore, the payment on challan form is also made after the validity date of DSL.	Firm has submitted copy of application receipt for renewal of DSL submitted in primary and secondary healthcare department dated 07-01-2021. Firm has also submitted copy of fee challan form 32-A
Provide valid agreement between importer / applicant and manufacturer since the submitted agreement was valid till 6th February 2020. The address of Mutabbar Pharma is mentioned as 25 Taj Arcade 73, Jail Road Lahore, while the address of Mutabbar Pharma mentioned in the application and on DSL is Flat No. E-1, 1st Floor Agro Squire 47 Shadman Market Lahore. Furthermore, the	Firm has submitted scanned copy of exclusive distribution agreement dated 1 January 2021 between Health BioTech India and M/s Mutabbar Pharma. The newly submitted agreement contains the updated address of Mutabbar Pharma as mentioned in the DSL. The agreement also contains list of 4 products which are applied by Mutabbar Pharma.

agreement does not contains “Annexure A brand products” for which the agreement was made.	
Provide evidence of approval of applied formulation as (lyophilized) powder for injection in any reference regulatory authority adapted by Registration Board in its 275th meeting, since you have only submitted copy of USP monograph of Doxorubicin Hydrochloride for Injection while evidence of approval of such formulation could not be verified from USFDA.	Firm has not submitted evidence of approval of applied formulation as (lyophilized) powder for injection in any reference regulatory authority adapted by Registration Board in its 275th meeting
Quality Overall Summary (QOS) in module 2 needs to be submitted as per WHO QOS - PD template or the template approved by Registration Board as per the guidance document, since the submitted QOS is incomplete and is not as per WHO template.	Firm has submitted QOS as per WHO QOS-PD template.
Submit data of verification of analytical method for the drug substance in section 3.2.S.4.3 of module 3, as the USP General chapter Verification of Compendial Procedures <1226> and the CTD guidance document approved by Registration Board recommends verification of compendial analytical methods for the drug substance.	Firm has not submitted data of verification studies of analytical method of the drug substance.
Submit stability study data of 3 batches of the drug substance in section 3.2.S.7.3.	Firm’s representative have submitted that the drug product manufacturer has changed the source of drug substance. Firm has not submitted stability study data of 3 batches of the drug substance of new source in section 3.2.S.7.3.
Submit information in section in 3.2.P.1 regarding type of diluent, its composition, quantity or volume, specifications (as applicable) and regulatory status in Pakistan (as applicable) for the diluent which is to be provided along with the applied drug.	Firm has not submitted information regarding the type of diluent.
Submit pharmaceutical equivalence data in section 3.2.P.2.2.1 as per the guidance document which states that “Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator /reference/comparator product shall be submitted and discussed”.	Firm has not submitted data of pharmaceutical equivalence.
Submit data of compatibility of the drug product along with recommended diluents in section 3.2.P.6 as per the guidance document approved by Registration Board which states that “Compatibility studies for the dry powder for injections and dry powder for suspension shall be performed as per the instructions provided in individual label of the drug product”.	Firm has not submitted data of compatibility of drug product along with recommended diluent.

Submit process validation report and analytical method verification report of the drug product in relevant sections of module 3.	Firm has submitted report of validation of analytical procedures.	
Submit batch analysis certificate and stability study data of 3 batches of “Durobsin-50 Injection” in section 3.2.P.5.4 and section 3.2.P.8.3 of module 3.	Firm has not submitted batch analysis certificate and stability study data of 3 batches of “Durobsin-50 Injection	
Submit copy of batch manufacturing record for the three batches for which stability studies have been performed.	Firm has not submitted copy of batch manufacturing record for the three stability batches	
Firm was also advised vide letter dated 31st December, 2020 to appear before Registration Board on 13 th January 2021 through authorized person well conversant with registration application(s). Mr. Khawaja Umer CEO along with technical persons appeared before the Board on 13-01-2021. During the proceedings of the Board, firm representatives were asked about the shortcomings which were still present in their registration applications despite of 3 deficiencies letters issued to the applicant. The firm’s representatives agreed about deficiencies and responded that they will rectify the shortcomings when they will receive the relevant documents from their principle manufacturer.		
Decision of 297th RB meeting: Registration Board after hearing the representative of the firm and keeping in view the response submitted by the firm and after thorough deliberations decided to defer the case for following submissions: • Evidence of approval of applied formulation as (lyophilized) powder for injection in any reference regulatory authority adapted by Registration Board in its 275th meeting. • Complete data of the drug substance in section 3.2.S of module 3 for the new / revised source as per the Form 5F (CTD) guidance document issued by Registration Board, since the drug product manufacturer has changed the source of drug substance. • Complete data of the drug product developed and manufactured by using the new / revised source of drug substance in section 3.2.P of module 3 as per the Form 5F (CTD) guidance document issued by Registration Board, since the drug product manufacturer has changed the source of drug substance. • Quality overall Summary (QOS) as per WHO QOS-PD template or as per the template approved by Registration Board in its 296th meeting and available in Form 5F (CTD) guidance document approved by Registration Board. • Submission copy of batch manufacturing record for the three stability batches manufactured using the new / revised source of drug substance.		
Submission by the firm:		
S. No.	Shortcoming	Response
1.	Evidence of approval of applied formulation as (lyophilized) powder for injection in any reference regulatory authority adapted by Registration Board in its 275 th meeting.	Firm has submitted evidence of DOXORUBICIN HYDROCHLORIDE 2MG/ML Each 50 mg lyophilized vial contains 50 mg of Doxorubicin Hydrochloride, USP and 250 mg of Lactose Monohydrate, NF USFDA Approved.
2.	Complete data of the drug substance in section 3.2.S of module 3 for the new / revised source as per the Form 5F (CTD) guidance document issued by Registration Board, since the drug product manufacturer has changed the source of drug substance.	Firm has submitted complete 3.2.S in which API manufacturer is Sterling Biotech Limited Gujrat India.
3.	Complete data of the drug product developed and manufactured by using the new / revised source of drug substance in section 3.2.P of module 3 as per the Form 5F (CTD) guidance document issued by Registration Board, since the drug product manufacturer has changed the source of drug substance.	Firm has submitted complete 3.2.P module. • PE studies are conducted against Doxorubicin Injection by Pfizer • Stability study data of 3 batches is submitted at refrigerating conditions (2-8degree) for 24 months

4.	Quality overall Summary (QOS) as per WHO QOS-PD template or as per the template approved by Registration Board in its 296 th meeting and available in Form 5F (CTD) guidance document approved by Registration Board.	Submitted by the firm
5.	Submission copy of batch manufacturing record for the three stability batches manufactured using the new / revised source of drug substance.	Submitted by the firm

Decision of 345th RB: Deferred for clarification for performing stability studies as per refrigerating conditions, since the innovator's product is recommended for storage at room temperature.

Response of Firm:

The firm has submitted their response on eapp vide tacking ID AZ4-UVU-Z98X. The firm has a submitted a letter of product manufacturer wherein stability data of drug product is attached as under 3.2.P.8 Firm has Submitted Accelerated stability studies as per Zone IVb conditions whereas long term stability studies submitted re as per Zone-II conditions ($25 \pm 2^{\circ}\text{C}$ / $60 \pm 5\%\text{RH}$) up to 24 months

The drug product manufacturer has stated that innovator product is labelled for storage at room temperature ($25 \pm 2^{\circ}\text{C}$) in major markets, there formulation is lyophilized which inherently enhances stability compared to liquid formulations. They also confirm that short-term excursions up to 40°C for 3 months and 6 months showed no significant degradation.

Decision: Keeping in view the fact that firm has failed to complete the application regardless of communicating the deficiencies multiple times, therefore, Board rejected the case as the firm has not submitted stability studies as per requirement of Zone-IVa.

2.	Name, address of Applicant / Importer	M/s Gene-Tech Laboratories. B-246, Block 6, P.E.C.H.S, Karachi, Pakistan
	Details of Drug Sale License of importer	License No: 002 Address: 246-B, Block 6, P.E.C.H.S, Karachi, Pakistan Validity: 15-08-2022 Status: by way of wholesaler Address of Godown: N/A
	Name and address of marketing authorization holder (abroad)	M/s Exirnanosina, Unit 7, Fl. 4, No. 94, Fathi Shaghagi St., Jahanmehr St., Shahid Gornam Ave., Fatemi Sq., Tehran, Iran.
	Name, address of manufacturer(s)	M/s Exirnanosina, Pardis Science & Technology Park, Damavand Road, Tehran, I.R. Iran
	Name of exporting country	Iran
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate) • Original legalized COPP (Certificate# 665/113187) issued by Iran Food & Drug Administration dated 21-02-2021. • Free Sale status: The COPP endorses the free sale status of the applied product in Iran. • GMP status: The COPP endorses the GMP status of the manufacturer. • Firm has submitted Legalized GMP certificate (Certificate No. 665/44522) issued by Iran Food & Drug Administration dated 09-02-2022 for M/s Exirnanosina, Pardis Science & Technology Park, Damavand Road, Tehran, I.R. Iran	
	Details of letter of authorization / sole agency agreement • Original Legalized Sole Agency Declaration (NOC) issued dated 18-07-2021 by M/s Exirnanosina in name of M/s Gene-Tech Laboratories for SinaDoxosome Injection, has been submitted.	

• Another agreement between the M/s Zhejiang Hengdian Apeola I&E Co., & M/s Shandong Luoxin Pharmaceutical Group Stock Co; Ltd has also been submitted declaring M/s Zhejiang Hengdian Apeola I&E Co the formal sole distributor of the applied product in Pakistan	
Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose Only
Dy. No. and date of submission	Dy.No 20055 dated 13-07-2022
Details of fee submitted	Rs.150,000/- dated 27-06-2022
The proposed proprietary name / brand Name	SinaDoxosome 20mg/ 10ml
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	(Injectable Nanoliposomal Doxorubicin Hydrochloride) Each 10ml Vial Contains: Doxorubicin HCl.....20mg
Pharmaceutical form of applied drug	Powder for injection
Pharmacotherapeutic Group of (API)	L01DB01 — Anthracycline topoisomerase inhibitor
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack size	1's
Proposed unit price	As per SRO
The status in reference regulatory authorities	Approved by US FDA
For generic drugs (me-too status)	Doxulip 20mg Injection of M/s Revive Pharmakon, Lahore (Reg.087684)
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
Name, address of drug substance manufacturer	M/s Synbias Pharma Ltd., Kreplischikov Street 181, 83085, Donetsk, Ukraine
Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form,

		anufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 25°C ± 2°C / 60 ± 5% RH for 24 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 6 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative analysis Studies against the reference product of Caelyx injection has been submitted.
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies of the drug product.
	Container closure system of the drug product	Type I glass vial
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. The accelerated stability study data is conducted at 25°C ± 2°C / 60% ± 5% RH for 6 months. The real time stability study data is conducted at 5°C ± 3°C for 18 months.
	The product was considered by the Registration Board in its 330th meeting and deferred for submission of reply for below mentioned shortcomings. The firm has now submitted the response which is tabulated below:	
	Remarks of Evaluator:	
Section#	Observations	Firm's response
	A contract agreement has been submitted b/w Nano Daru Pajuhan Pardis Iran and Genetech laboratories Karachi. This need to be clarified because another sole agency authorization in your name has also been submitted by the manufacturer i.e. M/s Exirnanosina Company.	Copy of letter by the M/s Exirnanosina, Unit 7, F1. 4, No. 94, Fathi Shaghagi St., Jahanmehr St., Shahid Gornam Ave., Fatemi Sq., Tehran, Iran wherein they have submitted clarification that they are separate entity which specialize in the production and distribution of Doxorubicin whereas Nano Daru Pajuhan Pardis Iran is separate company and both of them have no connection and affiliation with each other.
1.3.5	Copy of valid DSL of the applicant shall be submitted.	Firm has submitted copy of DSL by way of whole sale vide No. 0311 dated 08.02.2023 issued on 31.01.2023 and is valid till 30.01.2028. New License has been issued to the firm.
1.5.9	Evidence of approval / registration / marketing status of the applied formulation in the same composition,	Firm has submitted reference of product of Janssen Inc., Canada (Caelyx (Pegylated Liposomal Doxorubicin Hydrochloride Injection) sterile aqueous suspension for intravenous infusion).

	salt form and dosage form in one of the reference regulatory authority specified by Registration Board shall be submitted.	
2.3	Information submitted in Table for literary references for drug product is not correct. Revised information shall be submitted along with reference from pharmacopoeia.	The firm has submitted the references of specifications for the API and excipients
3.2.S.2.1	Details of drug substance manufacturer declared in section 1.6.5 are different from that declared in section 3.2.S.2.1.	The firm now submitted they are getting API from M/s Synbias Pharma AG Switzerland which is manufactured by M/s Gemini PharmChem Mannheim GmbH Germany. As evidence copy of GMP certificate issued by the German Authorities is submitted.
3.2.S.4.1	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by M/s Exirnanosina shall be submitted.	The firm has submitted the required Information
3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the M/s Exirnanosina) shall be submitted.	The firm has submitted the required information
3.2.S.4.4	Provide results of analysis of relevant batch(es) of Drug Substance performed by M/s Exirnanosina used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance /Active Pharmaceutical Ingredient manufacture.	The firm has submitted the required information.
3.2.P.1	Qualitative composition of applied formulation is different from that of the innovator drug product. Clarification shall be submitted in this regard.	The firm clarified that applied qualitative formulation is same as the Innovator product.
3.2.P.2.2.1	Justification shall be submitted for the limit & results of pH test applied in pharmaceutical equivalence studies with reference to pharmacopoeial monograph.	The pH range is 6.0-6.8 as per specifications and CoA certificate of analysis submitted by the firm which is same as reference product.
3.2.P.2.5	Submit compatibility studies with the proposed diluent for dilution.	The firm submitted compatibility studies with dextrose 5% solution for injection which indicates that product is stable for 24 hrs after reconstitution when stored in refrigerator at 2-8 °C
3.2.P.5.1	• Justification need to be submitted for referring the USP monograph	The firm submitted the in house specifications with pH limits, impurities

	because the applied liposomal formulation is not available in the same. • Justification shall be submitted for the limit of pH test with reference to Innovator product • Justification shall be submitted for not including test of related substance in drug product specifications with reference to pharmacopoeial monograph. • Justification shall be submitted for variation of limit of Endotoxin test with reference to Innovator product	and endotoxin limits in line with the reference product.
3.2.P.5.4	The copies of complete analysis of at least two batches shall be provided.	The firm has stability data sheets of three batches rather the batch analysis details.
3.2.P.8.3	• Justification shall be submitted for the limit & results of pH test reported in the stability studies. • Justification shall be submitted for not performing test of related substances in stability studies. • Significant change in the results of Assay test has been reported in the accelerated stability studies of batch no. SD00209601. Justification shall be submitted in this regard. • Out of specification results for of Assay test has been reported in the accelerated stability studies of batch no. SD00209602. Justification shall be submitted in this regard. • Long term stability studies of 18months has been submitted only whereas long term stability study shall be submitted till claimed shelf life.	❖ As liposomal doxorubicin hydrochloride is not in any pharmacopeia, the applied pH I in the limit of the innovator drugs product (Caelyx) and the method of analysis is form pharmacopeia general chapter. ❖ Since the updated reference method of the product is BP, the impurity test has been added to new specification. ❖ According to stability studies the product I stable for 3 months under accelerate conditions (25±3°C, %±5 R.H) due to reduction of assay in month 6. ❖ According to stability studies the product I stable for 3 months under accelerate condition (25±3°C, %±5 R.H) due to reduction of assay in month 6. ❖ The product shelf life is the same as innovator drug (Caelyx) which is 18 months.
Remarks: As per innovator the identified CQAs of the finished product were appearance, identification of doxorubicin, identification of lipids, pH, osmolality, particulate matter, particle size distribution, zeta potential, assay, related substances, lipid content, lipid degradants, encapsulation efficiency, free drug, drug to lipid ratio, sulfate and ammonium ion concentration, colour, sterility and bacterial endotoxin.		
Decision in 331st meeting: Deferred for submission of following data: Identification of lipids, osmolality, particle size distribution, zeta potential, lipid content, lipid degradants, encapsulation efficiency, free drug, drug to lipid ratio and sulfate and ammonium ion concentration.		
Remarks of Evaluator: The firm has now submitted revised specifications for the tests mentioned above required by the Board however Drug Product part of dossier is required to confirm the manufacturing and testing of the product as per submitted specifications.		
Decision of 336th RB: Deferred for submission of product specifications data as per CTD section 3.2.P.5 (Proposed Specifications, Analytical Procedures, Analytical Method Validation Studies, Batch Analysis Data, Justification of Specifications).		
Evaluation by PEC-IX		

Firm has submitted their response on eapp vide tracking ID E13-NS2-S8H5 wherein same old letter of product manufacturer dated 22.07.2023 is submitted where in reply to previous deficiencies was submitted.

The firm has not submitted complete 3.2.P.5 part in compliance to decision of 336th RB, (Analytical Procedures, Analytical Method Validation Studies, Batch Analysis Data, Justification of Specifications not submitted). Further detailed manufacturing method is also not submitted.

Decision: Keeping in view the fact that firm has failed to complete the application regardless of communicating the deficiencies multiple times, the board rejected the case for following:-

- i. Incomplete Analytical Procedures,
- ii. Incomplete Analytical Method without Validation Studies,
- iii. Incomplete Batch Analysis Data, and
- iv. Justification of proposed Specifications.

3.	Name, address of Applicant / Marketing Authorization Holder	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Name, address of Manufacturing site.	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5 Dy. No 5607 dated 07-02-2019 Rs.20,000/-
	Details of fee submitted	PKR 30,000/- : 42386964353
	The proposed proprietary name / brand name	Rubidox P 50mg/25ml Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Doxorubicin hydrochloride...2mg (as liposomal pegylated)
	Pharmacotherapeutic Group of (API)	Anthracyclines and related substances
	Reference to Finished product specifications	Innovator Specifications.
	The status in reference regulatory authorities	USFDA (Doxil Liposomal)
	For generic drugs (me-too status)	Nagun 50 Injection of M/s. Ghani Brothers registered in import (Reg. no. 072574)
	Proposed Pack size	1's(25ml): As per SRO
	GMP Status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Terminal sterilization not mentioned • Packaging material not mentioned submit separate application for diluent
	Previous Decision of Registration Board (M-296)	Deferred for the following: • Submit justification on scientific grounds for not performing terminal sterilization of applied formulation.

		• Mention type of primary packaging material of applied formulation whether it is type I, II, or III glass container..
	Response of the Firm	• Firm informed that they import ready to fill sterile bulk solution for infusion. • Firm submitted that filling of product done under aseptic condition and prior to filling solution has been filtered for sterilization. • Primary packaging material is Glass vial Type-I.
	Decision of 316th meeting: Deferred for clarification regarding availability of diluent whether, it will be procured or it will be self manufactured. In case of self manufacturing of diluent by M/s Rotex Pharma Pvt Ltd., firm shall submit manufacturing process along with detail of manufacturing area in which the diluent will be manufactured. Submission by the firm: • The firm has stated that no diluent is applied and there is no requirement for any diluent as well. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/050718Orig1s060lbl.pdf (Accessed on 21/07/2022 at 1:50pm).	
	Decision of 320th RB: The Board was apprised that the applied product is in liposomal dispersion and the liposomal carriers used in the applied formulation have a complex composition and also product is pegylated. The Board after deliberation regarding complexity of manufacturing method decided to defer the case for detail of manufacturing technique and facility including the detail of equipments used in the manufacturing of the applied product.	
	Remarks of PEC-IX: The firm vide tracking ID XPZ-QPM-29M8 has submitted their response on eapp. R&I submission of 12.10.2022 is attached. The firm has stated that they will procure ready to fill bulk from M/s Praxis Pharma S.A Argentina. No steps of liposomal manufacturing will be carried out in their facility. Firm has attached a copy of Certificate of Medicine in Bulk Manufacture for “Export”	
	Decision: Deferred for submission of evidence that:- - same product of M/s Praxis Pharma S.A Argentina is freely available in market of any RRA, - legalized COPP from that RRA and - fee for import registration.	
4.	Name, address of Applicant / Marketing Authorization Holder	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Name, address of Manufacturing site.	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5 Dy. No.25484; 21-12-2017 ; Rs.20,000/- (21-12-2017)
	Details of fee submitted	Rs.20,000/- (21-12-2017)

	The proposed proprietary name / brand name	Primus 5mg dispersible tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each dispersible tablet contains: Everolimus....5mg
	Pharmacotherapeutic Group of (API)	Protein Kinase inhibitor
	Reference to Finished product specifications	Innovator Specifications.
	The status in reference regulatory authorities	AFINITOR DISPERZ TABLET FOR ORAL SUSPENSION. USFDA Approved
	For generic drugs (me-too status)	Could not be confirmed
	Proposed Pack size	10's, 30's, 50's, 60's, 90's, As per SRO
	GMP Status	Last Inspection report 17-3-2017 The panel concluded that the company is following GMP guidelines
	Remarks of the Evaluator.	Me-too status could not be confirmed.
	Previous Decision of Registration Board (M-278)	Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm and confirmation of pharmacological group
	Response of the Firm	The firm vide tracking ID XPZ-QPM-29M8 has submitted their response on eapp. Firm has submitted that Product Afinitor by Novartis Reg No. 069519 is Registered in Pakistan. Further product of genome is approved in 281 st meeting
	Decision: Deferred for further deliberation on processing and data requirement for such cases.	
5.	Name, address of Applicant / Marketing Authorization Holder	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Name, address of Manufacturing site.	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5 Dy.No. 5609 dated 07-02-2019 Rs.20,000/- Dated 07-02-2019
	Details of fee submitted	Dy.No. 5609 dated 07-02-2019 Rs.20,000/- Dated 07-02-2019
	The proposed proprietary name / brand name	Trexam 100mg Powder for Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Pemetrexed Disodium Hemipentahydrate Eq to Pemetrexed.....100mg
	Pharmacotherapeutic Group of (API)	Anticancer, Antifolate agent

Reference to Finished product specifications	MFG Specifications.
The status in reference regulatory authorities	ALMITA of USFDA Approved
For generic drugs (me-too status)	Alimta 100mg Injectable Of Eli Lilly
Proposed Pack size	As per SRO
GMP Status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections “Overall evaluation of the Inspection report is rated as Good”.
Remarks of the Evaluator.	Dry Powder Vial (Oncology) available.
Previous Decision of Registration Board (M-293 rd RB)	Deferred for confirmation of required manufacturing facility / section from Licensing Division. (M-293)
Evaluation by PEC Firm change dosage form from dry powder to concentrate for solution for infusion Submitted new dossier along submission of fee of Rs: 15000/- Deposit slip no# 1932292, Dated: 25-08-2020 and fee of Rs:5000/- Deposit slip no # 2034745, Dated: 13-10-2020	
New Label Claim	Trexam 100mg Concentrate for solution for infusion
Composition	Each Vial of 4ml Contains: Pemetrexed Disodium Hemipentahydrate Eq to Pemetrexed.....100mg
Finished product Specifications	Mfg Specs
Approval status of product in Reference Regulatory Authorities	Pemetrexed 25 mg/ml concentrate for solution for infusion of MHRA approved (4ml contains 100mg)
Me-too status (with strength and dosage form)	Not Found
Remarks of the Evaluatoriv	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. Liquid Vial SVP (Oncology) available.
Decision of 297th RB: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / metoo status) alongwith registration number, brand name and name of firm.	
Evaluation by PEC-IX: The firm vide tracking ID XPZ-QPM-29M8 has submitted their response on eapp. Firm has stated that Product Alimta 100mg Injection of M/s Eli lilly is registered in Pakistan. Product Alimta 100mg (USFDA Approved) is lyophilized powder which needs to be reconstituted before use. Firm has applied for liquid injection. Pemetrexed 10 mg/ml solution for infusion (ready to used solution) is MHRA Approved. (100mg/10ml, 500mg/50ml and 1000mg/100ml strengths are approved in MHRA)	
Decision: Deferred for further deliberation on processing and data requirement for such cases.	

6.	Name, address of Applicant / Marketing Authorization Holder	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Name, address of Manufacturing site.	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5 Dy.No. 5605 dated 07-02-2019 Rs.20,000/- Dated 07-02-2019
	Details of fee submitted	Dy.No. 5605 dated 07-02-2019 Rs.20,000/- Dated 07-02-2019
	The proposed proprietary name / brand name	Trexam 500mg Powder for Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Pemetrexed Disodium Hemipentahydrate Eq to Pemetrexed.....500mg
	Pharmacotherapeutic Group of (API)	Anticancer, Antifolate agent
	Reference to Finished product specifications	MFG Specifications.
	The status in reference regulatory authorities	ALMITA of USFDA Approved
	For generic drugs (me-too status)	Alimta 100mg Injectable Of Eli Lilly
	Proposed Pack size	As per SRO
	GMP Status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections “Overall evaluation of the Inspection report is rated as Good”.
	Remarks of the Evaluator.	Dry Powder Vial (Oncology) available.
	Previous Decision of Registration Board (M-293 rd RB)	Deferred for confirmation of required manufacturing facility / section from Licensing Division. (M-293)
	Evaluation by PEC Firm change dosage form from dry powder to concentrate for solution for infusion Submitted new dossier along submission of fee of Rs: 15000/- Deposit slip no# 1932292, Dated: 25-08-2020 and fee of Rs:5000/- Deposit slip no # 2034745, Dated: 13-10-2020	
	New Label Claim	Trexam 500mg Concentrate for solution for infusion
	Composition	Each Vial of 4ml Contains: Pemetrexed Disodium Hemipentahydrate Eq to Pemetrexed.....100mg
	Finished product Specifications	Mfg Specs
	Approval status of product in Reference Regulatory Authorities	Pemetrexed 25 mg/ml concentrate for solution for

		infusion of MHRA approved (4ml contains 100mg)
	Me-too status (with strength and dosage form)	Not Found
	Remarks of the Evaluator ^{iv}	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. Liquid Vial SVP (Oncology) available.
	Decision of 297th RB: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / metoo status) alongwith registration number, brand name and name of firm.	
	Evaluation by PEC-IX: The firm vide tracking ID XPZ-QPM-29M8 has submitted their response on eapp. Firm has stated that Product Maclimta 500mg Injection of M/s Macter and Pemosh 500mg Injection Reg No. 095569 of M/s AJ Mirza. Maclimta is powder for solution for injection Product Alimta 500mg (USFDA Approved) is lyophilized powder which needs to be reconstituted before use. Firm has applied for liquid injection. Pemetrexed 10 mg/ml solution for infusion (ready to used solution) is MHRA Approved. (100mg/10ml, 500mg/50ml and 1000mg/100ml strengths are approved in MHRA)	
	Decision: Deferred for further deliberation on processing and data requirement for such cases.	
7.	Name, address of Applicant / Marketing Authorization Holder	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Name, address of Manufacturing site.	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5 Dy.No. 5588 dated: 07/02/2019 Rs.20,000/-
	Details of fee submitted	Dy.No. 5588 dated: 07/02/2019 Rs.20,000/-
	The proposed proprietary name / brand name	Gemnil 1g Injection Lyophilized Powder for Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Gemcitabine as HCL..... 1gm
	Pharmacotherapeutic Group of (API)	Anticancer,
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	GEMZAR (gemcitabine) for injection, Lyophilized powder (200mg/vial & 1gm/vial) by M/s Lilly USA, LLC, USFDA Approved.

	For generic drugs (me-too status)	ONCOGEM 1gm injection by M/s AJ MIRZA PHARMA (PVT) LTD., (Imported) Reg. No. 45672
	Proposed Pack size	As per SRO
	GMP Status	Following additional sections were approved vide letter No.F.1-53/2003-Lic.(Vol-I) dated 13 th June, 2017. ☐ ☐ Tablet (oncology) ☐ ☐ Capsule (oncology) ☐ ☐ Liquid vial SVP (oncology) ☐ ☐ Liquid Ampoule SVP (Oncology) Dry powder vial (oncology) ☐ ☐ Capsule (Ceph) ☐ ☐ Dry [powder for oral suspension (ceph) ☐ ☐ Dry Powder vial (ceph) ☐ ☐ Dry Powder vial (Ceph)
	Remarks of the Evaluator.	
	Decision of 322nd Meeting: Registration Board discussed that the applied formulation is approved in reference regulatory authorities as Lyophilized Powder for Injection as well as Solution for Injection. Considering the submission from the applicant that they had applied for solution for injection, the Board deferred the case for confirmation of applied dosage form from the initially submitted dossier	
	Firm's response: Firm vide its letter no. Rotex/20/184 dated 07-03-2020 has submitted that "we have applied Gemnil 1gm injection & Gemnil 200mg as liquid injection (solution for injection) to be manufactured in our approved Liquid vial SVP (Oncology) section. The reference product approved in TGA is a solution for injection of 26.3ml vial & 5.3ml for 1gm and 200mg injection respectively.	
	Decision of 344th RB: Deferred for presentation of the case by company's representative along with relevant documents in upcoming Registration Board meeting.	
	Evaluation by PEC-IX: The firm vide tracking ID XPZ-QPM-29M8 has submitted their response on eapp. The firm has again stated that they had applied for liquid injection to be manufactured in their Liquid Vial SVP (oncology) Section. Firm has submitted copies of old Form-5 submitted at time of application, in that Form 5 solution for infusion is applied.	
	Decision: Deferred for further deliberation on processing and data requirement for such cases.	
8.	Name, address of Applicant / Marketing Authorization Holder	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Name, address of Manufacturing site.	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5 Dy.No. 5600 dated: 07/02/2019 Rs.20,000/-

Details of fee submitted	Dy.No. 5600 dated: 07/02/2019 Rs.20,000/-
The proposed proprietary name / brand name	Gemnil 200mg Injection Powder for Injection
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Gemcitabine as HCL.....200mg
Pharmacotherapeutic Group of (API)	Anticancer,
Reference to Finished product specifications	USP
The status in reference regulatory authorities	GEMZAR (gemcitabine) for injection, Lyophilized powder (200mg/vial & 1gm/vial) by M/s Lilly USA, LLC, USFDA Approved.
For generic drugs (me-too status)	ONCOGEM 200mg injection by M/s AJ MIRZA PHARMA (PVT) LTD., (Imported) Reg. No. 45671
Proposed Pack size	As per SRO
GMP Status	Following additional sections were approved vide letter No.F.1-53/2003-Lic.(Vol-I) dated 13 th June, 2017. ☐ ☐ Tablet (oncology) ☐ ☐ Capsule (oncology) ☐ ☐ Liquid vial SVP (oncology) ☐ ☐ Liquid Ampoule SVP (Oncology) Dry powder vial (oncology) ☐ ☐ Capsule (Ceph) ☐ ☐ Dry [powder for oral suspension (ceph) ☐ ☐ Dry Powder vial (ceph) ☐ ☐ Dry Powder vial (Ceph)
Remarks of the Evaluator.	
Decision of 322nd Meeting: Registration Board discussed that the applied formulation is approved in reference regulatory authorities as Lyophilized Powder for Injection as well as Solution for Injection. Considering the submission from the applicant that they had applied for solution for injection, the Board deferred the case for confirmation of applied dosage form from the initially submitted dossier	
Firm's response: Firm vide its letter no. Rotex/20/184 dated 07-03-2020 has submitted that "we have applied Gemnil 1gm injection & Gemnil 200mg as liquid injection (solution for injection) to be manufactured in our approved Liquid vial SVP (Oncology) section. The reference product approved in TGA is a solution for injection of 26.3ml vial & 5.3ml for 1gm and 200mg injection respectively.	
Decision of 344th RB: Deferred for presentation of the case by company's representative along with relevant documents in upcoming Registration Board meeting.	
Evaluation by PEC-IX: The firm vide tracking ID XPZ-QPM-29M8 has submitted their response on eapp. The firm has again stated that they had applied for liquid injection to be manufactured in their Liquid Vial SVP (oncology) Section. Firm has submitted copies of old Form-5 submitted at time of application, in that Form 5 solution for infusion is applied.	
Decision: Deferred for further deliberation on processing and data requirement for such cases.	

Import & Vet Section-I

1.	Name and address of manufacturer / Applicant	M/s. Archard Pharmaceuticals Pvt Ltd PlotNo27-28/B Small Industrial Estate Bhimber AJK
	Brand Name +Dosage Form + Strength	Arch Fortyl Oral Powder
	Composition	Each gram Contains: Fosfomycin Calcium.....200mg Tylosin as Tartrate.....50mg Fructose 1,6 disphosphate.....180mg Sodium Phosphate.....150mg Magnesium Phosphate 100mg Sodium chloride QS to make 1000mg
	Diary No. Date of R& I & fee	Dy.No 3276 dated 20.02.2024 Rs.30,000/- dated 20.02.2024
	Pharmacological Group	Antistress in action
	Type of Form	Form 5
	Finished product Specification	(As per Innovators Specification)
	Pack size & Demanded Price	100g,250g, 500g, 1kg; Decontrolled
	Me-too status	Fofact Powder of M/s Univet . (Reg. No. 075626)
	GMP status	Firm submitted inspection report dated 22-12-2023
	Remarks of the Evaluator ^x	
Decision: Approved		
2.	Name and address of manufacturer / Applicant	M/s Bioskills Pharmaceuticals, 4-Km Tamboly, GT Road, Sadhoke, District Gujranwala.
	Brand Name +Dosage Form + Strength	NORSTINSKILL-50 Veterinary <i>Liquid</i>
	Diary No. Date of R& I & fee	Dy. No:18662 (02-07-2021), Rs.30,000/-
	Composition	Each 100 ml Liquid contains Norfloxacin 20gm Colistin Sulphate 50 MIU
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	<i>Manufacturer's Specifications</i>
	Pack Size & Demanded Price	100ml,250ml 500ml, 1L, 2.5L ,Decontrolled
	Approval status of product in Reference Regulatory Authorities	NA
	Me-too Status	Colinor Liquid (VET), Reg No: 071066 by M/S Attabak Pharma
	GMP Status	First Inspection for Grant of license conducted on 18/02/2021, Panel unanimously approved for grant of license.
	Remarks of the Evaluator.	
Decision: On the recommendation of Expert Working Group on Veterinary Drugs to Issue show cause notices to all registered veterinary drugs containing Norfloxacin and recommended to de-register all formulations containing ciprofloxacin and Norfloxacin for veterinary use due to potential of AMR and in the best public health interest, hence Registration Board decided to defer the application accordingly. Recommendation of Sub-committee:		

	After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter.	

3.	Name and address of manufacturer / Applicant	M/s Bioskills Pharmaceuticals, 4-Km Tamboly, GT Road, Sadhoke, District Gujranwala.
	Brand Name +Dosage Form + Strength	NORSTINSKILL-60 Veterinary <i>Liquid</i>
	Diary No. Date of R& I & fee	Dy. No:18660 (02-07-2021), Rs.30,000/-
	Composition	Each 100 ml Liquid contains Norfloxacin 20gm Colistin Sulphate 60 MIU
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	<i>Manufacturer's Specifications</i>
	Pack Size & Demanded Price	100ml,250ml 500ml, 1L, 2.5L ,Decontrolled
	Approval status of product in Reference Regulatory Authorities	NA
	Me-too Status	Nor-C Liquid (VET), Reg No: 071056 By M/S Attabak Pharma
	GMP Status	First Inspection for Grant of license conducted on 18/02/2021, Panel unanimously approved for grant of license.
	Remarks of the Evaluator.	
	Decision: On the recommendation of Expert Working Group on Veterinary Drugs to Issue show cause notices to all registered veterinary drugs containing Norfloxacin and recommended to de-register all formulations containing ciprofloxacin and Norfloxacin for veterinary use due to potential of AMR and in the best public health interest, hence Registration Board decided to defer the application accordingly. Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use	
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter.		

4.	Name and address of manufacturer / Applicant	M/s Bioskills Pharmaceuticals, 4-Km Tamboly, GT Road, Sadhoke, District Gujranwala.
	Brand Name +Dosage Form + Strength	NORFENSIN SKILL Veterinary <i>Liquid</i>
	Diary No. Date of R& I & fee	Dy. No:18656 (02-07-2021), Rs.30,000/-
	Composition	Each 100 ml Liquid contains Norfloxacin 20gm Guaifenesin 20gm Aminophylline 8gm
	Pharmacological Group	Antibiotic / Bronchodilator
	Type of Form	Form-5
	Finished Product Specification	<i>Manufacturer's Specifications</i>
	Pack Size & Demanded Price	100ml,250ml 500ml, 1L, 2.5L ,Decontrolled
	Approval status of product in Reference Regulatory Authorities	NA

Me-too Status	NOR+AG Liquid (VET) Reg No : 058968 By M/S Biogen Pharmaceutical
GMP Status	First Inspection for Grant of license conducted on 18/02/2021, Panel unanimously approved for grant of license.
Remarks of the Evaluator.	
Decision: On the recommendation of Expert Working Group on Veterinary Drugs to Issue show cause notices to all registered veterinary drugs containing Norfloxacin and recommended to de-register all formulations containing ciprofloxacin and Norfloxacin for veterinary use due to potential of AMR and in the best public health interest, hence Registration Board decided to defer the application accordingly. Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use	
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter.	

Import cases

5.	Name and address of Applicant	M/s. Mustafa Brothers:186-D Peoples colony No.1. Faisalabad-38090 Pakistan
	Detail of Drug Sale License	Valid ti:21.06.2027
	Name and address of Manufacturer	M/s Bimeda-MTC Animal Health Inc. 420 Beaverdale Road Cambridge, Ontario Canada N3C 2W4
	Name and address of marketing authorization holder	M/s Bimeda-MTC Animal Health Inc. 420 Beaverdale Road Cambridge, Ontario Canada N3C 2W4
	Name of exporting country	Canada
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No.3234 Dated0:20.02.2024
	Fee including differential fee	Rs:150,000 Dated 10.11.2023, 03-06-2025 Rs. 150,000/-
	Brand Name +Dosage Form + Strength	Bimectin 1% Injectable solution 50ml
	Composition	Each 5ml contains:- Ivermectin 1% in 250mL(Ivermectin 10mg/ML)
	Finished Product Specification	USP
	Pharmacological Group	Antibacterial and Corticosteroid
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	50ml
	International availability	Canada
	Me-too status	available
	Detail of certificates attached	1. Original legalized CoPP of Certificate 81113 dated 12.01.2023 issued by Health Canada 2. LOA Submitted.
	Remarks of the Evaluator (Sarfraz)	

Decision: Approved		
6.	Name and address of Applicant	M/s. Mustafa Brothers:186-D Peoples colony No.1. Faisalabad-38090 Pakistan
	Detail of Drug Sale License	Valid ti:21.06.2027
	Name and address of Manufacturer	M/s Bimeda-MTC Animal Health Inc. 420 Beaverdale Road Cambridge, Ontario Canada N3C 2W4
	Name and address of marketing authorization holder	M/s Bimeda-MTC Animal Health Inc. 420 Beaverdale Road Cambridge, Ontario Canada N3C 2W4
	Name of exporting country	Canada
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No.3233 Dated0:20.02.2024
	Fee including differential fee	Rs:150,000 Dated 10.11.2023, Differential fee Rs150,000/- challan 030134448
	Brand Name +Dosage Form + Strength	Flunazine Injectable Solution
	Composition	Each ml contains:- Flunixin as Flunixin aeglumine.....50mg
	Finished Product Specification	USP
	Pharmacological Group	Antibacterial and Corticosteroid
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	Not demanded
	International availability	Canada
	Me-too status	Available
	Detail of certificates attached	1. Original legalized CoPP of Certificate 81114 dated 12.01.2023 issued by Health Canada 2. LOA Submitted.
	Remarks of the Evaluator	
Decision: Approved		

7.	Name and address of Applicant	M/s Qualivet Pharma, Office address: 1st Floor, B-16, Block A, Kazimabad, Near Masjid-e-Hira, Model Colony, Karachi-75100, Pakistan Godown Address: No. 5/15, Golden Town, Survey No. 79, Malir Halt, Karachi, Pakistan
	Detail of Drug Sale License	Name: M/s Qualivet Pharma Address: No. 5/15, Golden Town, Survey No. 79, Malir Halt, Karachi, Validity: 14-10-2022. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Zoopan-Produtos Pecuários S.A. Rua Da Liberdade, 77, 2050-023 Aveiras De Baixo, Portugal
	Name and address of marketing authorization holder	M/s Zoopan-Produtos Pecuários S.A. Rua Da Liberdade, 77, 2050-023 Aveiras De Baixo, Portugal
	Name of exporting country	Portugal
	Type of Form	Form-5A

Diary No. & Date of R& I	Dy.No 24712 Dated 07-09-2021
Fee including differential fee	Rs : 150,000 Dated 26-08-2021 (slip No.0859549907)
Brand Name +Dosage Form +Strength	Micorep Water Soluble Powder
Composition	Each gram contains: Tylosin Tartrate...100mg Doxycycline Hyclate...100mg Bromhexine Chlorhydrate...3.50mg
Finished Product Specification	Inhouse
Pharmacological Group	Antibacterial/ Expectorant, mucolytic
Shelf life	24 months
Demanded Price	Decontrolled
Pack size	100gm, 500gm and 1000gm
International availability	N/A
Me-too status	Could not be confirmed
Detail of certificates attached	➤ Unattested photocopy of CoPP No. 208/CMVPT/2018 certified by The General Directorate of Food and Veterinary confirming the free sale status in exporting country as well as GMP status of the manufacturer ➤ Photocopy of declaration (not legalized) dated 10-08-2021 of sole and exclusive distribution; valid for 5 years
Remarks of the Evaluator	The firm has not provided stability studies data as per zone-IV-A conditions. Shortcomings: • Provide copy of valid DSL • Provide notarized original valid Letter of Authorization/ Sole agency certificate since already submitted is copy not even legalized. • Provide legalized original valid CoPP since already submitted is unattested copy. • Provide 06 months accelerated and real time stability studies data upto claimed shelf life as per zone IV-A conditions. • Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
Decision of 330th meeting: Deferred for following: • copy of valid DSL • notarized original valid Letter of Authorization/ Sole agency certificate. • legalized original valid CoPP • 06 months accelerated and real time stability studies data upto claimed shelf life as per zone IV-A conditions • evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, . Updated status: The firm has submitted the following: • legalized original valid CoPP No. 617/CMVPT/2022 dated 04-10-2022 issued by Direção-Geral da Alimentação e Veterinária confirming the GMP and free sale status in Portugal. • original valid Letter of Authorization/ Sole agency certificate dated 10-08-2021 valid for 5 years • copy of DSL valid till 14-10-2024	

	• Provided 06 months accelerated and 24 months' real time stability studies data as per zoneIV-A conditions. Shortcomings: Generic /RRA approval status. Decision of 333rd meeting: Deferred for evidence of approval status in RRA or evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. Updated status: The firm has submitted copies of registration letters in Portugal, Malta and Greece. (approval status could not be confirmed in Malta and Greece) Decision: Deferred for the confirmation of Metoo/RRA. Remarks: Product is confirmed from official website of EMA in veterinary drug database. Submitted for consideration of the Board please.
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter.	

Case No.02 Registratiton of M/s. Inshal Pharmaceutical Industries, Rawat, Islamabad.

Below mentioned case was discuss in 239th meeting of Registration Board held on 12th September, 2013 and decided as follows:

8.	M/s. Inshal Pharmaceutical Industries, Rawat, Islamabad.	Asper Shell Water Soluble Powder Each 1000g contains:- Vitamin C..... 200g Acetyl Salicylic Acid.....67g (NSAIDS + Supplement). Generic 043537 SALI-C POWDER	Decontrolled 30g 50g 100g 250g 500g 1 Kg 5 Kg 10Kg	02 years	Deferred, for PSI by panel comprising of Area FID and A.Q.Javed Iqbal Member RB.
9.	M/s. Inshal Pharmaceutical Industries, Rawat, Islamabad.	Adekshell Water Soluble Powder Each 1000g contains:- Vitamin A.....20 MIU Vitamin D.....2 MIU Vitamin E.....6g Vitamin K3.....5g (Multivitamins).	Decontrolled 30g 50g 100g 250g 500g 1 Kg 5 Kg 10Kg	02 years	Deferred, for PSI by panel comprising of Area FID and A.Q.Javed Iqbal Member RB.

Recommendation of Sub-committee:

After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.

Firm requested for registration of mentioned product as per current policy.

Decision: Approved.

Imported veterinary products deferred in different meeting

10.	Name and address of Applicant	M/s Atzan Pharmaceuticals, 13-E, Commercial Area, Aziz Bhatti Town, Sargodha, Pakistan
	Detail of Drug Sale License	Name: M/s Atzan Pharmaceutical
		Address: 13-E, Commercial Area, Aziz Bhatti Town, Sargodha, Pakistan. Validity: 14 April, 2020. Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Farma Vet OOD. 40 Otets Paisiy Street, Shumen 9700, Bulgaria
	Name and address of marketing authorization holder	M/s Farma Vet OOD. 40 Otets Paisiy Street, Shumen 9700, Bulgaria
	Name of exporting country	Bulgaria
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 32615 Dated 08-12-2020

Fee including differential fee	Rs : 1,00,000 Dated 08-12-2020
Brand Name +Dosage Form + Strength	Permethrin Pharma Insecticide Shampoo
Composition	Each 100ml contains: Permethrin...1g
Finished Product Specification	Inhouse
Pharmacological Group	Pyrethrines
Shelf life	2 Years
Demanded Price	Decontrolled
Pack size	100ml, 250ml
International availability	N/A
Me-too status	Could not be confirmed
Detail of certificates attached	➤ Original Legalized Free Sale Certificate issued by Bulgarian Food Safety Agency at the Ministry of Agriculture, Food and Forestry confirms free sale status of the applied product in exporting country. Date of issuance: 13-04-2020 ➤ Original legalized GMP certificate No. 102/2019/GMP issued on 29-05-2019 by Bulgarian Food Safety Agency Ministry of Agriculture, Food and Forestry Bulgaria. (Original in Tylofarm-Water Soluble Powder dossier) ➤ Copy of Letter of Authorization dated 05-03-2020 (Original in Tylofarm- Water Soluble Powder dossier)
Remarks of the Evaluator ^{XXV}	6 months accelerated and 24 months long term stability studies data has been submitted as per zone-IV-A conditions. Shortcomings: • Provide valid copy of DSL • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
Decision of 326th meeting: Deferred for following: • valid copy of DSL • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Label in accordance with The Drugs (Labeling and Packing) Rules, 1986	
Updated status: The firm has submitted the following: • copy of DSL valid till 07-11-2027 • Label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Link for verification of approval status of Permethrin Pharma in EU; authorized in Bulgaria (https://medicines.health.europa.eu/veterinary/en/search-medicines?keys=permethrin)	
Decision of 336th meeting: Deferred for availability of the said formulation in three EU countries, any	

	reference country or PICs member country or ML-4 country.	
	Updated status: The firm has submitted the reference of Lyclar Crème Rinse 1% w/w cutaneous solution for hair application, registered in Ireland. Our formulation is also a cutaneous solution used as shampoo for dogs for removing/ killing lice from their hair. Remarks/shortcomings: The reference formulation approved in Ireland is for human use. Decision: Deferred for submission of evidence of approval of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or in any RRA. Firm reply: The firm has submitted the reference of Lyclar Crème Rinse 1% w/w cutaneous solution for hair application, registered in Ireland. Our formulation is also a cutaneous solution used as shampoo for dogs for removing/ killing lice from their hair.	
	Decision: Referred to sub-committee on veterinary drugs.	
11.	Name and address of Applicant	M/s Atzan Pharmaceuticals, 13-E, Commercial Area, Aziz Bhatti Town, Sargodha, Pakistan
	Detail of Drug Sale License	Name: M/s Atzan Pharmaceutical Address: 13-E, Commercial Area, Aziz Bhatti Town, Sargodha, Pakistan. Validity: 14 April, 2020. Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Farma Vet OOD. 40 Otets Paisiy Street, Shumen 9700, Bulgaria
	Name and address of marketing authorization holder	M/s Farma Vet OOD. 40 Otets Paisiy Street, Shumen 9700, Bulgaria
	Name of exporting country	Bulgaria
	Type of Form	Form-5A
	Diary No. & Date of R&I	Dy.No 24241 Dated 17-09-2020
	Fee including differential fee	Rs : 1,00,000 Dated 17-09-2020
	Brand Name +Dosage Form + Strength	Gentamast F-Intramammary Suspension
	Composition	Each Gram Contains: Gentamicin Sulphate...10,000 IU (0.0167gm)
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibacterial
	Shelf life	2 Years
	Demanded Price	Decontrolled
	Pack size	10gm
	International availability	N/A
	Me-too status	Could not be confirmed
	Detail of certificates attached	➤ Original Legalized Free Sale Certificate issued by Bulgarian Food Safety Agency at the Ministry of Agriculture, Food and Forestry

		confirms free sale status of the applied product in exporting country. Date of issuance: 13-04-2020 ➤ Original legalized GMP certificate No. 102/2019/GMP issued on 29-05-2019 by Bulgarian Food Safety Agency Ministry of Agriculture, Food and Forestry Bulgaria. (Original in Tylofarm- Water Soluble Powder dossier) ➤ Copy of Letter of Authorization dated 05-03-2020 (Original in Tylofarm- Water Soluble Powder dossier)
	Remarks of the Evaluator ^X	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Provide valid copy of DSL • Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. ➤ 6 months accelerated and 24 months long term stability studies data has been submitted as per zone-IV-A conditions.
	Decision of 326th meeting: Deferred for following: • valid copy of DSL • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Label in accordance with The Drugs (Labeling and Packing) Rules, 1986	
	Updated status: The firm has submitted the following: • copy of DSL valid till 07-11-2027 • Label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Link for verification of approval status of Gentamast F-Intramammary Suspension in EU; authorized in Bulgaria (https://medicines.health.europa.eu/veterinary/en/search-medicines?keys=gentamast)	
	Decision: Deferred for availability of the said formulation in three EU countries, any reference country or PICs member country or ML-4 country. Firm reply: Product is available in official website of EMA.	
	Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter.	
12.	Name and address of Applicant	M/s Atzan Pharmaceuticals, 13-E, Commercial Area, Aziz Bhatti Town, Sargodha, Pakistan
	Detail of Drug Sale License	Name: M/s Atzan Pharmaceutical Address: 13-E, Commercial Area, Aziz Bhatti Town, Sargodha, Pakistan. Validity: 14 April, 2020. Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Vietnam Sakan Technology Development & Investment Joint Stock Company, Lot D1-D4, Dong Tho Industrial Complex, Yen Phong District, Bac Ninh Province, Vietnam

Name and address of marketing authorization holder	M/s Vietnam Sakan Technology Development & Investment Joint Stock Company, Lot D1-D4, Dong Tho Industrial Complex, Yen Phong District, Bac Ninh Province, Vietnam
Name of exporting country	The Socialist Republic of Vietnam
Type of Form	Form-5A
Diary No. & Date of R& I	Dy.No 12409 Dated 18-07-2019
Fee including differential fee	Rs : 1,00,000 Dated 18-07-2019
Brand Name +Dosage Form + Strength	Amoxi 50 S Powder
Composition	Each 100g contains: Amoxicillin Trihydrate...50g
Finished Product Specification	Inhouse
Pharmacological Group	Antibiotic
Shelf life	24 months
Demanded Price	Decontrolled
Pack size	20gm, 50gm, 100gm
International availability	N/A
Me-too status	Not provided
Detail of certificates attached	➤ Original Legalized Free Sale Certificate No. 351/2019/QLT-CFS issued by Ministry of Agriculture and Rural development department of Animal Health 15/78 GiaiPhong Street- DongDa-HaNoi- Vietnam Date of issuance: 03-05-2019 ➤ Original legalized GMP certificate No. 07/17/GCN-GMP issued on 06-06-2016 and valid for 5 years. (scope of submitted GMP certificate does not cover beta lactam production line.) ➤ Letter of Authorization/Sole Agency Certificate is not provided.
Remarks of the Evaluator ^x	- Letter of Authorization (LOA) is not provided, Provide legalized valid original LOA. - Scope of submitted GMP certificate does not cover production lines of beta lactam oral powder,

	provide legalized original valid relevant GMP certificate. • Amoxicillin Trihydrate ...50gm/100gm is mentioned in label claim on form-5A and FSC, while the referred generic product contains Amoxicillin as Trihydrate 50gm/100gm. Submit evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm; or revise label claim in line with reference product and submit full fee of registration for revision of label claim/ master formula. • Provide valid copy of DSL • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. ➤ 6 months accelerated and 24 months long term stability studies data has been submitted as per zone-IV-A conditions.
Decision of 322nd meeting: Deferred for following: • Original legalized valid Letter of Authorization (LOA) • Legalized original valid relevant GMP certificate with scope covering beta lactam production line. • Valid copy of DSL • Finished product specifications in the light of decision taken in 267th meeting of Registration Board. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
Updated status: The firm has submitted the following: • copy of DSL valid till 07-11-2027 • Original legalized Letter of Authorization (LOA) dated 01-06-2019 for the applied product. • Copy of legalized GMP certificate No. 23/22/GCN-GMP dated 25-07-2022 with scope covering beta lactam production line, valid for 5 years. • Metoo status: Rymox-50 Water Soluble Powder of M/s Zumars Pharma Fty (Pvt) Ltd., Karachi. (Reg. No. 069665) Shortcomings: • clarification of the manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise.	
Decision: Deferred for clarification of the manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise. Firm reply: Firm inform that there is division in Cephalosporin & Penicillin production lines for oral powder formulation in Beta-Lactam antibiotics production unit.	

Decision: Approved.

The firm shall submit fee for specification correction before the issuance of registration letter.
Panel shall verify the division in Cephalosporin & Penicillin production lines for oral powder formulation in Beta-Lactam antibiotics production unit.

Case No.03 Registration of M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad.

13.	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	Euromint Liquid
	Composition	Each ml Contains: Vitamin A...30,000,000 IU Menthol...50gm Eucalyptus...50gm Peppermint...40gm
	Diary No. Date of R& I & fee	Dy.No 6159 dated 15-05-2019 Rs.20,000/- dated 15-05-2019
	Pharmacological Group	Supplement/ counterirritative
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 150ml, 200ml, 450ml, 500ml, 1Liter, 2.5Liter, 5Liter, 10Liter and 20Liter; Decontrolled
	Me-too status	Fenetime Oral Solution of M/s Biogen Pharma, Rawat. (Reg. No. 063815)
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator ^X	• Oral Liquid (General) section confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML. • The firm has submitted fee Rs. 7,500/- for revision of finished product specifications via deposit slip no 041403599512. • The firm has submitted that Vitamin A Palmitate 1.7MIU/gram • Initially the firm has applied for formulation containing Vitamin A 30,000,000 IU, Menthol...50gm, Eucalyptus...50gm, Peppermint...40gm/ml. However, the referred generic product contains same quantities as applied per liter. Now the firm has submitted following revised formulation as per reference product Each Liter Contains: Vitamin A...30,000,000 IU Menthol...50gm

		Eucalyptus...50gm Peppermint...40gm Shortcomings: ➤ Balance Fee Rs. 22,500/- for revision of formulation
	Decision: Referred to committee for review of formulation in grey area as product contains ingredients regulated as H&OTC product. Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.	
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter.		

Sub-committee on veterinary drugs recommendations		
1.	Name and address of manufacturer/ Applicant	M/s. Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur.
	Brand Name + Dosage Form + Strength	Oxyfen LA Injection
	Composition	Oxytetracycline.....100mg Ketoprofen.....30mg
	Diary No. Date of R & I & fee	Dy. No 12153 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.
	Pharmacological Group	Broad Spectrum Antibiotic
	Type of Form	Form – 5
	Finished product Specification	Innovator
	Pack size & Demanded Price	100ml, type II glass vial.
	Approval status of product in Reference Regulatory Authorities	Not Applicable
	Me-too status	Oxyfen LA injection, 071091, SELMORE PHARMACEUTICALS, LAHORE.
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as “ In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing , machinery/equipment , material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection”: Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin)

		Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)
Remarks of the Evaluator	• Master Formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Firm did not mention per ml composition. • Pack Size, container and closure is not provided. • Evidence of me-too status of product already registered in Pakistan.	• Firm has submitted fee challan No.4713859323 dated 16-06-2022 of 30000/= along with revised form -5 with revised per label claim as under: Each ml contains: Oxytetracycline as Dihydrate.....200 mg Ketoprofen.....30mg • Firm has also submitted revised Form- 5, Manufacturing method, master formulation, Pack size, and finished product specification. • However, Composition of me - too is as under; Oxytetracycline...200 mg Ketoprofen...30mg
Decision: Registration Board referred the case to Expert Working Group for review of formulation.		
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved		
2.	Name and address of manufacturer / Applicant	M/s. Noble Pharma, Plot No. B-1 Old Industrial Area, Mirpur, Azad Kashmir
	Brand Name +Dosage Form + Strength	Nobiket Injection
	Composition	Each ml contains:- Ketoprofen.....100mg
	Diary No. Date of R& I & fee	Dy.No 16592 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Analgesic
	Type of Form	Form 5
	Finished product Specification	BP Vet Specifications
	Pack size & Demanded Price	50ml; Decontrolled

	Me-too status	Dinalgen Injection of M/s Mylab (Pvt) Ltd. Bahawalpur. (Reg. No.074012)
	GMP status	Panel inspection of M/s Noble Pharma, Azad Kashmir has been carried out on 09-02-2022. It was observed to do a lot of improvements in HVAC, Pharmaceutical Quality systems including documentation and other quality related areas. The firm submitted improvements in these areas. A detailed report would be submitted later on after verification of same through onsite inspection.
	Remarks of the Evaluator ^X	• Approval of Veterinary Liquid Vial Injection (General) section confirmed vide letter No.F. 5-2/2007-Lic dated 08-07-2015 • Firm has claimed BP Vet specifications without submitting fee for inclusion of finished product specifications.
Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.		
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved		
3.	Name and address of manufacturer / Applicant	M/s. Elko Organization Pvt Ltd., Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	El-Keto Injection 100mg/ml
	Composition	Each ml contains:- Ketoprofen.....100mg
	Diary No. Date of R& I & fee	Dy.No 5559 dated 08-05-2019 Rs.20,000/- dated 08-05-2019
	Pharmacological Group	NSAID, Analgesic, Antipyretic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Ketoject Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)
	GMP status	Not submitted
	Remarks of the Evaluator ^X	• Latest cGMP inspection report (conducted within the period of last three years) is required. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.

		• Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Fee Rs. 7,500/- for revision of finished product specifications. • Undertaking as per 251st meeting of Registration Board has not been provided.
Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.		
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter		
4.	Name and address of manufacturer / Applicant	M/s. Elko Organization Pvt Ltd., Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Ketoproline Injection
	Composition	Each ml contains:- Oxytetracycline.....200mg Ketoprofen.....30mg
	Diary No. Date of R& I & fee	Dy.No 5556 dated 08-05-2019 Rs.20,000/- dated 08-05-2019
	Pharmacological Group	Antibiotic, Antipyretic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Could not be confirmed
	GMP status	Not submitted
	Remarks of the Evaluator ^x	• Latest cGMP inspection report (conducted within the period of last three years) is required. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Revise label claim/master formula in terms of salt form in line with reference product

		and adjust its weight as per salt factor in master formula accordingly. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Full fee of registration for revision of label claim/ master formula, and finished product specifications. • Lidocain HCl is included in list of excipients mentioned in master formula and outline of method of manufacture while the same has not been reflected in label claim, clarify. • Undertaking as per 251st meeting of Registration Board has not been provided.
Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.		
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter.		
5.	Name and address of manufacturer / Applicant	M/s. Manhattan Pharma, 209/3-B, Sector 5, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Ketocam-100 Injection
	Composition	Each ml contains:- Ketoprofen.....100mg
	Diary No. Date of R& I & fee	Dy.No 28433 dated 27-12-2019 Rs.20,000/- dated 27-12-2019
	Pharmacological Group	Anti-inflammatory
	Type of Form	Form 5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	100ml vial; Decontrolled
	Me-too status	Ketorise Injection (100ml) of M/s. Biorise Pharmaceuticals Multan. (Reg. No. 113398)
	GMP status	Inspection conducted on 15-12-2021 concludes good level of GMP compliance.
	Remarks of the Evaluator ^X	Sterile Liquid Injectable (General) section confirmed vide letter No. F. 2-2/92-Lic (Vol-II) dated 30-06-2020. Shortcomings: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status), with the applied fill volume/ pack size, alongwith registration number, brand name and name of firm.

		The firm has claimed BP Vet specifications while the official monograph of applied formulation does not exist in BP.
Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.		
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved		
6.	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	Fenoxy Injection
	Composition	Each ml contains:- Oxytetracycline HCl.....200mg Ketoprofen 30mg
	Diary No. Date of R& I & fee	Dy.No 5140 dated 20-03-2020 Rs.20,000/- dated 20-03-2020
	Pharmacological Group	Antibiotic/NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer’s Specifications
	Pack size & Demanded Price	50ml, 100ml: Decontrolled
	Me-too status	Vetoxy-K Injection (50ml) of M/s. Mallard Pharmaceutical (Pvt) Ltd., Multan. (Reg. No. 109240) Ketocin Injection (100ml) of M/s A & K Pharmaceutical, Faisalabad. (Reg. No. 102101)
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator ^x	Liquid injectable (General) section confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML renewal - Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier.
Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.		
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter.		

7.	Name and address of manufacturer / Applicant	M/s. Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Vetpro 10% Injection 20ml
	Composition	Each ml contains:- Ketoprofen.....100mg
	Diary No. Date of R& I & fee	Dy.No 3194 dated 02-03-2020 Rs.20,000/- dated 27-02-2020
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	20ml: Decontrolled
	Me-too status	Ketoject Injection (20ml) of M/s. Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 043141)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
Remarks of the Evaluator ^x		Liquid injection (General) section confirmed vide panel inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 report for renewal of DML.
Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.		
Recommendation of Sub-committee:		
After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved		
8.	Name and address of manufacturer / Applicant	M/s. Noble Pharma, B-1 Old Industrial Area, Mirpur, Azad Kashmir
	Brand Name +Dosage Form + Strength	Nobioxy-K Injection
	Composition	Each ml contains:- Oxytetracycline HCl...20mg Ketoprofen.....3mg
	Diary No. Date of R& I & fee	Dy.No 10157 dated 06-05-2020 Rs.20,000/- dated 06-05-2020
	Pharmacological Group	Antibacterial and anti-inflammatory
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml vial: Decontrolled
	Me-too status	Could not be confirmed in the applied strength
	GMP status	Panel inspection of M/s. Noble Pharma, Azad Kashmir has been carried out on 09-02-2022. It was observed to do a lot of improvements in HVAC, Pharmaceutical Quality systems including documentation and other quality related areas. The firm submitted improvements in these areas. A detailed report would be submitted later on after verification of same through onsite inspection.

Remarks of the Evaluator ^X		Approval of Veterinary Liquid Vial injection (General) section confirmed vide letter No.F. 5-2/2007-Lic dated 08-07-2015. Shortcomings: - Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. - Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier.
Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.		
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter		
9.	Name and address of manufacturer / Applicant	M/s. Vetz Pharmaceutical (Pvt) Ltd, Plot # Q-1, S.I.T.E, Kotri, Sindh.
	Brand Name +Dosage Form + Strength	Oxyvetz Super Injection 100ml
	Composition	Each ml contains:- Oxytetracycline HCl.....200mg Ketoprofen.....30mg
	Diary No. Date of R& I & fee	Dy.No 13140 dated 09-06-2020 Rs.20,000/- dated 09-06-2020
	Pharmacological Group	Antibacterial/ NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Oxyfen LA Injection (100ml) of M/s Selmore Pharmaceutical (Pvt) Ltd., Lahore. (Reg. No. 071091)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator ^X	Sterile Liquid Injection (Veterinary) Section confirmed from panel inspection report conducted on 11-04-2015 for grant of DML. Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.
Recommendation of Sub-committee:		

After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved.		
The firm shall submit fee for specification correction before the issuance of registration letter.		
10.	Name and address of manufacturer / Applicant	M/s. Leads Pharma Pvt Ltd., Plot No. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Profenol Injection 50ml
	Composition	Each ml contains:- Ketoprofen 100mg
	Diary No. Date of R& I & fee	Dy.No 14854 dated 25-06-2020 Rs.20,000/- dated 24-06-2020
	Pharmacological Group	Analgesic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	KETO-P Injection (50ml) of M/s Star Laboratories (Pvt) Ltd., Lahore (Reg. No. 063625)
	GMP status	GMP of relevant section
	Remarks of the Evaluator ^X	• Injectable section confirmed vide letter No. F.1-26/93-Lic (Vol. I) (M-205) dated 30-04-2007. • Shortcomings: • Latest GMP inspection report (conducted within the period of last three years).
Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.		
Recommendation of Sub-committee:		
After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved.		
The firm shall submit fee for specification correction before the issuance of registration letter.		
11.	Name and address of manufacturer / Applicant	M/s. Leads Pharma Pvt Ltd., Plot No. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Profenol Injection 100ml
	Composition	Each ml contains:- Ketoprofen 100mg
	Diary No. Date of R& I & fee	Dy.No 14857 dated 25-06-2020 Rs.20,000/- dated 24-06-2020
	Pharmacological Group	Analgesic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	KETO-P Injection (100ml) of M/s. Star Laboratories (Pvt) Ltd., Lahore (Reg. No. 063625)
	GMP status	GMP of relevant section

Remarks of the Evaluator ^X		Injectable section confirmed vide letter No. F.1-26/93-Lic (Vol. I) (M-205) dated 30-04-2007. Shortcomings: - Latest GMP inspection report (conducted within the period of last three years).
Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.		
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter.		
12.	Name and address of manufacturer / Applicant	M/s. Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Fenoxy L-A Injection 100ml
	Composition	Each ml contains:- Oxytetracycline as HCl...200mg Ketoprofen 30mg
	Diary No. Date of R& I & fee	Dy.No 30034 dated 10-11-2020 Rs.20,000/- dated 10-11-2020
	Pharmacological Group	Antibacterial/ NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Ketocin Injection (100ml) of M/s A & K Pharmaceutical, Faisalabad. (Reg. No. 102101)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator ^X	Approval of Liquid injectable (veterinary) section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML.
Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.		
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter.		
13.	Name and address of manufacturer / Applicant	M/s. Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Fenoxy L-A Injection
	Composition	Each ml contains:- Oxytetracycline as HCl.....200mg Ketoprofen 30mg
	Diary No. Date of R& I & fee	Dy.No 30037 dated 10-11-2020 Rs.20,000/- dated 10-11-2020
	Pharmacological Group	Antibacterial/ NSAID

	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Pro Cycline Injection (50ml) of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 111328)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator ^X	Approval of Liquid injectable (veterinary) section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML.
Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.		
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter.		
14.	Name and address of manufacturer / Applicant	M/s. Intervac Pvt. Limited, 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Oxy-Pro Injection
	Composition	Each ml contains:- Oxytetracycline HCl.....200mg Ketoprofen 30mg
	Diary No. Date of R& I & fee	Dy.No 27128 dated 14-10-2020 Rs.20,000/- dated 14-10-2020
	Pharmacological Group	Antibacterial/NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Pro Cycline Injection (50ml) of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 111328)
	GMP status	cGMP Inspection conducted on 08-10-2020 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator ^X	Liquid Injectable (General) (Veterinary) section confirmed vide letter No. F.1-37/2004-Lic (Vol-I) dated 04-10-2019.
Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.		
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter.		
15.	Name and address of manufacturer / Applicant	M/s. Vetz Pharmaceutical (Pvt) Ltd, Plot # Q-1, S.I.T.E, Kotri, Sindh.

	Brand Name +Dosage Form + Strength	Oxy-K LA Injection
	Composition	Each ml contains:- Oxytetracycline.....200mg Ketoprofen 30mg
	Diary No. Date of R& I & fee	Dy.No 32484 dated 07-12-2020 Rs.20,000/- dated 07-12-2020
	Pharmacological Group	Antibacterial/ Anti-inflammatory
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Pro Cycline Injection (50ml) of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 111328)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator ^X	Sterile Liquid Injection (Veterinary) Section confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
	Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.	
	Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter	
16.	Name and address of manufacturer / Applicant	M/s. Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Oxy KP Injection
	Composition	Each ml contains:- Oxytetracycline HCl.....200mg Ketoprofen 30mg
	Diary No. Date of R& I & fee	Dy.No 2828 dated 25-01-2021 Rs.20,000/- dated 22-01-2021
	Pharmacological Group	Antibacterial/NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml, 20ml, 30ml, 50ml, 100ml; Decontrolled
	Me-too status	Oxyfen LA Injection (10ml, 20ml, 30ml, 50ml, 100ml) of M/s Selmore Pharmaceutical (Pvt) Ltd., Lahore. (Reg. No. 071091)
	GMP status	Panel unanimously recommends the grant of additional sections based on inspection dated 17-02-2022
	Remarks of the Evaluator ^X	Approval of Liquid Injection Section (General-Veterinary) confirmed vide panel inspection report

		dated 29-11-18 and 01-01-2019, for issuance of GMP certificate. Shortcomings: 1. The firm has applied for Oxytetracycline HCl...200mg and Ketoprofen...30mg, while the referred generic product contains Each ml contains:- Oxytetracycline (as HCl)....200mg Ketoprofen.....30mg Submit evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board; or revise formulation in line with reference product. 2. Separate registration is granted to separate pack size/ fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier. 3. Latest GMP inspection report conducted within the period of last three years.
		Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter.		
17.	Name and address of manufacturer / Applicant	M/s. Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Oxkit Injection
	Composition	Each ml contains:- Oxytetracycline as HCl...200mg Ketoprofen.....30mg
	Diary No. Date of R&I & fee	Dy.No 194 dated 01-01-2021 Rs.20,000/- dated 19-11-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml; Decontrolled
	Me-too status	Oxyfen LA Injection (10ml, 20ml, 30ml, 50ml, 100ml) of M/s

		Selmore Pharmaceutical (Pvt) Ltd., Lahore. (Reg. No.071091)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator X	1. Liquid Injection (General) section confirmed vide panel inspection report based on inspection dated 08- 07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. Shortcomings: 2. Separateregistrationisgrantedtoseparatepacksize/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a singleapplication.Soclarificationisrequiredfor which pack size/ fill volume you want to apply thisdossier. 3. Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specificationin the light of decision taken in 267th meeting of Registration Board.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved		
18.	Name and address of manufacturer / Applicant	M/s. Univet Pharmaceuticals, 14-km, Adyala Road, Post Office Dahgal, Rawalpindi.
	Brand Name +Dosage Form + Strength	Kerofen-10% Injection
	Composition	Each ml contains:- Ketoprofen 100mg
	Diary No. Date of R& I & fee	Dy.No 7660 dated 09-03-2021 Rs.20,000/- dated 09-03-2021
	Pharmacological Group	NSAID/Analgesic
	Type of Form	Form-5
	Finished product Specification	BP (Vet) Specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Ketoject Injection (10ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)
	GMP status	Panel inspection conducted on 01-12-2020 for renewal of

		DML
	Remarks of the Evaluator ^X	Shortcomings: 3. Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.		
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved.		
19.	Name and address of manufacturer / Applicant	M/s. Univet Pharmaceuticals, 14-km, Adyala Road, Post Office Dahgal, Rawalpindi.
	Brand Name +Dosage Form + Strength	Kerofen-10% Injection
	Composition	Each ml contains: Ketoprofen 100mg
	Diary No. Date of R& I & fee	Dy.No 7656 dated 09-03-2021 Rs.20,000/- dated 09-03-2021
	Pharmacological Group	NSAID/Analgesic
	Type of Form	Form-5
	Finished product Specification	BP (Vet) Specifications
	Pack size & Demanded Price	20ml; Decontrolled
	Me-too status	Ketoject Injection (20ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)
	GMP status	Panel inspection conducted on 01-12-2020 for renewal of DML
	Remarks of the Evaluator ^X	Shortcomings: 5. Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/ manufacturing facility.
Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.		
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved		
20.	Name and address of manufacturer / Applicant	M/s. Univet Pharmaceuticals, 14-km, Adyala Road, Post Office Dahgal, Rawalpindi.

	Brand Name +Dosage Form + Strength	Kerofen-10% Injection
	Composition	Each ml contains:- Ketoprofen.....100mg
	Diary No. Date of R& I & fee	Dy.No 7618 dated 09-03-2021 Rs.20,000/- dated 09-03-2021
	Pharmacological Group	NSAID/Analgesic
	Type of Form	Form-5
	Finished product Specification	BP (Vet) Specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Ketoject Injection (50ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)
	GMP status	Panel inspection conducted on 01-12-2020 for renewal of DML
	Remarks of the Evaluator ^X	Shortcomings: 7. Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.		
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use .		
Decision: Approved		
21.	Name and address of manufacturer / Applicant	M/s. Univet Pharmaceuticals, 14-km, Adyala Road, Post Office Dahgal, Rawalpindi.
	Brand Name +Dosage Form + Strength	Kerofen-10% Injection
	Composition	Each ml contains:- Ketoprofen.....100mg
	Diary No. Date of R& I & fee	Dy.No 7649 dated 09-03-2021 Rs.20,000/- dated 09-03-2021
	Pharmacological Group	NSAID/Analgesic
	Type of Form	Form-5
	Finished product Specification	BP (Vet) Specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Ketoject Injection (100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)
	GMP status	Panel inspection conducted on 01-12-2020 for renewal of DML

	Remarks of the Evaluator ^X	Shortcomings: 9. Approval of section/manufacturing facility bythe Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.		
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved		
22.	Name and address of manufacturer / Applicant	M/s. Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Ketogen Injection
	Composition	Each ml contains:- Ketoprofen.....100mg
	Diary No. Date of R& I & fee	Dy.No 18474 dated 01-07-2021 Rs.30,000/- dated 28-06-2021 (slip No. 2916250106)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer’s specifications
	Pack size & Demanded Price	100ml vial: Decontrolled
	Me-too status	Ketorise Injection (100ml) of M/s Biorise Pharmaceuticals, Multan. (Reg. No.113398)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
Remarks of the Evaluator ^X	Shortcomings: • Approval of Injectable (General) Veterinary section by CLB	
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter.		
23.	Name and address of manufacturer / Applicant	M/s. Lucky Core Industries Limited, 45-KM, off Multan Road, Lahore. (Formerly, ICI Pakistan Limited Life Sciences)
	Brand Name +Dosage Form + Strength	Proxifen Injection
	Composition	Each ml contains:- Ketoprofen.....100mg
	Diary No. Date of R& I & fee	Dy.No 20432 dated 27-07-2021 Rs.30,000/- dated 26-07-2021 (slip No. 70534384404)
	Pharmacological Group	NSAID

	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Ketoject Injection (20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)
	GMP status	cGMP certificate dated 30-03-2021 based on inspection conducted on 10-11-2020.
	Remarks of the Evaluator ^X	• Liquid Injectable (SVP) Veterinary section granted vide letter No. F.1-41/2007-Lic dated 10-07-2017 • The firm shall submit revised form-5 with its new title along with fee Rs. 30,000/- for change of title of the firm.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
	Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.	
	Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter.	
24.	Name and address of manufacturer / Applicant	M/s. Lucky Core Industries Limited, 45-KM, off Multan Road, Lahore. (Formerly, ICI Pakistan Limited Life Sciences)
	Brand Name +Dosage Form + Strength	Proxifen Injection
	Composition	Each ml contains: Ketoprofen.....100mg
	Diary No. Date of R& I & fee	Dy.No 20431 dated 27-07-2021 Rs.30,000/- dated 26-07-2021 (slip No. 82678962247)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	20ml; Decontrolled
	Me-too status	Ketoject Injection (20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)
	GMP status	cGMP certificate dated 30-03-2021 based on inspection conducted on 10-11-2020.
	Remarks of the Evaluator ^X	• Liquid Injectable (SVP) Veterinary section granted vide letter No. F.1-41/2007-Lic dated 10-07-2017 • The firm shall submit revised form-5 with its new title along with fee Rs. 30,000/- for change of title of the firm.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	

Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter.		
25.	Name and address of manufacturer / Applicant	M/s. Lucky Core Industries Limited, 45-KM, off Multan Road, Lahore. (Formerly, ICI Pakistan Limited Life Sciences)
	Brand Name +Dosage Form + Strength	Proxifen Injection
	Composition	Each ml contains:- Ketoprofen.....100mg
	Diary No. Date of R& I & fee	Dy.No 20433 dated 27-07-2021 Rs.30,000/- dated 26-07-2021 (slip No. 77703107862)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Ketoject Injection (20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)
	GMP status	cGMP certificate dated 30-03-2021 based on inspection conducted on 10-11-2020.
	Remarks of the Evaluator ^X	• Liquid Injectable (SVP) Veterinary section granted vide letter No. F.1-41/2007-Lic dated 10-07-2017 • The firm shall submit revised form-5 with its new title along with fee Rs. 30,000/- for change of title of the firm.
Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.		
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter.		
26.	Name and address of manufacturer / Applicant	M/s. ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Isketo Injection
	Composition	Each ml contains:- Ketoprofen...100mg
	Diary No. Date of R& I & fee	Dy.No 22609 dated 17-08-2021 Rs.30,000/- dated 06-07-2021 (slip No. 77983104)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml: Decontrolled

	Me-too status	Ketoexel 100 Injection (10ml) Of M/s Mediexcel Pharmaceuticals, Islamabad. (Reg. No. 106694)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator ^x	Liquid Injection (Veterinary) section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter.		
27.	Name and address of manufacturer / Applicant	M/s. ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Isketo Injection
	Composition	Each ml contains:- Ketoprofen.....100mg
	Diary No. Date of R& I & fee	Dy.No 22604 dated 17-08-2021 Rs.30,000/- dated 06-07-2021 (slip No. 10792384591)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Ketoexel 100 Injection (50ml) Of M/s Mediexcel Pharmaceuticals, Islamabad. (Reg. No. 106695)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator ^x	Liquid Injection (Veterinary) section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021.
		Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter		
28.	Name and address of manufacturer / Applicant	M/s. ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Isketo Injection
	Composition	Each ml contains:- Ketoprofen.....100mg

	Diary No. Date of R& I & fee	Dy.No 22605 dated 17-08-2021 Rs.30,000/- dated 06-07-2021 (slip No. 718116033117)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Ketoexel 100 Injection (100ml) Of M/s Mediexcel Pharmaceuticals, Islamabad. (Reg. No. 106696)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator ^X	Liquid Injection (Veterinary) section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs decided to keep under review the above formulation for veterinary use.		
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter.		
29.	Name and address of manufacturer / Applicant	M/s. Epoch Pharmaceuticals, Plot # 83-85, Sector 15, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Ketolin Injection Vet I/M, S/C
	Composition	Each ml injection contains:- Oxytetracycline as HCl.....200mg Ketoprofen.....30mg
	Diary No. Date of R& I & fee	Dy.No.3474 dated 22-01-2019; Rs.20,000/- Dated 22-01-2019
	Pharmacological Group	Anti- infective/ NSAIDs
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10ml, 100ml & Decontrolled
	Me-too status	Keto- Oxy La Injection M/s International Pharma Labs, Defence Road, Lahore 094412
	GMP status	Last GMP inspection was conducted on 28-09-2020 And the report concludes: “In compliance to decision of 276 th meeting of CLB, contravention of the Drugs Act, 1976 rules made there under, non-compliance of GMP conditions and non-compliance of conditions of the Drug Manufacturing License, you are hereby ordered to Show Cause Notice in writing as to why the following proceeding may not be initiated against you. a) Cancellation/Suspension of DML of Liquid Injectable/Sterile area. b) Prosecution in the Drug Court.

		c) Any other action taken by the concerned Board.
	Remarks of the Evaluator	GMP status is not compliant.
	Decision of 297th meeting: Deferred for updated status of GMP of the firm from QA & LT division as inspection report submitted by firm does not conclude GMP compliant status	
	Updated status: The firm has submitted cGMP certificate dated 20-12-2022 based on inspection conducted on 21-11-2022	
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter.		
30.	Name and address of manufacturer / Applicant	M/s. Sanna Laboratories, 1019-B, P.S.I.E, Sargodha Road, Faisalabad.
	Brand Name +Dosage Form + Strength	Ketosan-10 Injection
	Composition	Each ml contains:- Ketoprofen.....100mg
	Diary No. Date of R& I & fee	Dy.No 4642 dated 18-02-2022 Rs.30,000/- dated 15-02-2022 (slip No. 225878235554)
	Pharmacological Group	Analgesic, Antipyretic and NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Ketorise Injection (50ml) of M/s Biorise Pharmaceuticals, Multan. (Reg. No. 113397)
	GMP status	
	Remarks of the Evaluator ^x	Oral Liquid (Non-Antibiotic/ Antibiotic) (Veterinary) Section confirmed from panel inspection report conducted on 10-01-2019 for grant of cGMP certificate. Shortcomings: Latest GMP inspection report conducted within the period of last three years.
Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters, and for submission of the following: ☐ ☐ Latest GMP inspection report conducted within a period of last three years.		
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter.		
31.	Name and address of manufacturer / Applicant	M/s. Sanna Laboratories, 1019-B, P.S.I.E, Sargodha Road, Faisalabad.
	Brand Name +Dosage Form + Strength	Ketosan-10 Injection

	Composition	Each ml contains:- Ketoprofen.....100mg
	Diary No. Date of R& I & fee	Dy.No 4643 dated 18-02-2022 Rs.30,000/- dated 15-02-2022 (slip No. 1711292825)
	Pharmacological Group	Analgesic, Antipyretic and NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Ketorise Injection (100ml) of M/s Biorise Pharmaceuticals, Multan. (Reg. No. 113398)
	GMP status	
	Remarks of the Evaluator ^X	Oral Liquid (Non-Antibiotic/ Antibiotic) (Veterinary) Section confirmed from panel inspection report conducted on 10-01-2019 for grant of cGMP certificate. Shortcomings: Latest GMP inspection report conducted within the period of last three years.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters, and for submission of the following: ☐ ☐ Latest GMP inspection report conducted within a period of last three years.	
	Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.	
	Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter.	
32.	Name and address of manufacturer / Applicant	M/s. Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Vetpro 100 Injection
	Composition	Each ml contains:- Ketoprofen...100mg
	Diary No. Date of R& I & fee	Dy.No 5088 dated 23-02-2022 Rs.30,000/- dated 14-02-2022 (slip No. 5098129909)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	20ml: Decontrolled
	Me-too status	Catoprofen Injection (20ml) of M/s Hilton Pharma (Pvt) Ltd., Korangi, Karachi. (Reg. No.101472)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator ^X	Liquid Injection (General)section confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML.

	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter		
33.	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	Ketox Injection
	Composition	Each ml contains:- Ketoprofen.....100mg
	Diary No. Date of R& I & fee	Dy.No 8911 dated 07-04-2022 Rs.30,000/- dated 06-04-2022 (slip No.7263589648)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml, 20ml, 50ml, 100ml, 450ml, 500ml: Decontrolled
	Me-too status	Ketoject Injection (10ml, 20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator ^x	• Liquid injectable (General) section confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML renewal. • Shortcomings: • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status), in the applied pack size, alongwith registration number, brand name and name of firm. • Approval of relevant manufacturing facility (LVP).
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters, and for submission of the following: • Choice of one pack size • Approval of relevant manufacturing facility (LVP).	

	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status), in the 450ml and 500ml pack sizes, alongwith registration number, brand name and name of firm.																								
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.																									
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter																									
34.	<table border="1"> <tr> <td>Name and address of manufacturer / Applicant</td><td>M/s. Izfaar Pharmaceutical Industries, 542-A, Sundar Industrial Estate, Lahore.</td></tr> <tr> <td>Brand Name +Dosage Form + Strength</td><td>Ketoxay LA Injection</td></tr> <tr> <td>Composition</td><td>Each ml contains:- Oxytetracycline as HCl.....mg Ketoprofen.....30mg</td></tr> <tr> <td>Diary No. Date of R& I & fee</td><td>Dy.No 17848 dated 20-06-2022 Rs.30,000/- dated 09-06-2022 (5592698150)</td></tr> <tr> <td>Pharmacological Group</td><td>Antibiotic/ Anti-inflammatory</td></tr> <tr> <td>Type of Form</td><td>Form 5</td></tr> <tr> <td>Finished product Specification</td><td>Innovator's specifications</td></tr> <tr> <td>Pack size & Demanded Price</td><td>100ml; Decontrolled</td></tr> <tr> <td>Me-too status</td><td>Ketocin Injection (100ml) of M/s A & K Pharmaceutical, Faisalabad. (Reg. No.102101)</td></tr> <tr> <td>GMP status</td><td>cGMP certificate dated 24-09-2021 based on inspection conducted on 02-07-2021.</td></tr> <tr> <td>Remarks of the Evaluator^X</td><td>Veterinary Liquid Injection (General) section confirmed vide letter No. F. 1-29/2007-Lic (M-236) dated 23-09-2014.</td></tr> <tr> <td colspan="2">Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.</td></tr> </table>	Name and address of manufacturer / Applicant	M/s. Izfaar Pharmaceutical Industries, 542-A, Sundar Industrial Estate, Lahore.	Brand Name +Dosage Form + Strength	Ketoxay LA Injection	Composition	Each ml contains:- Oxytetracycline as HCl.....mg Ketoprofen.....30mg	Diary No. Date of R& I & fee	Dy.No 17848 dated 20-06-2022 Rs.30,000/- dated 09-06-2022 (5592698150)	Pharmacological Group	Antibiotic/ Anti-inflammatory	Type of Form	Form 5	Finished product Specification	Innovator's specifications	Pack size & Demanded Price	100ml; Decontrolled	Me-too status	Ketocin Injection (100ml) of M/s A & K Pharmaceutical, Faisalabad. (Reg. No.102101)	GMP status	cGMP certificate dated 24-09-2021 based on inspection conducted on 02-07-2021.	Remarks of the Evaluator ^X	Veterinary Liquid Injection (General) section confirmed vide letter No. F. 1-29/2007-Lic (M-236) dated 23-09-2014.	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Name and address of manufacturer / Applicant	M/s. Izfaar Pharmaceutical Industries, 542-A, Sundar Industrial Estate, Lahore.																								
Brand Name +Dosage Form + Strength	Ketoxay LA Injection																								
Composition	Each ml contains:- Oxytetracycline as HCl.....mg Ketoprofen.....30mg																								
Diary No. Date of R& I & fee	Dy.No 17848 dated 20-06-2022 Rs.30,000/- dated 09-06-2022 (5592698150)																								
Pharmacological Group	Antibiotic/ Anti-inflammatory																								
Type of Form	Form 5																								
Finished product Specification	Innovator's specifications																								
Pack size & Demanded Price	100ml; Decontrolled																								
Me-too status	Ketocin Injection (100ml) of M/s A & K Pharmaceutical, Faisalabad. (Reg. No.102101)																								
GMP status	cGMP certificate dated 24-09-2021 based on inspection conducted on 02-07-2021.																								
Remarks of the Evaluator ^X	Veterinary Liquid Injection (General) section confirmed vide letter No. F. 1-29/2007-Lic (M-236) dated 23-09-2014.																								
Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.																									
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.																									
Decision: Approved																									
35.	<table border="1"> <tr> <td>Name and address of manufacturer / Applicant</td><td>M/s. Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.</td></tr> <tr> <td>Brand Name +Dosage Form + Strength</td><td>Ketonol Injection</td></tr> <tr> <td>Composition</td><td>Each ml contains:- Ketoprofen.....100mg</td></tr> <tr> <td>Diary No. Date of R& I & fee</td><td>Dy.No 18192 dated 22-06-2022 Rs.30,000/- dated 22-06-2022 (slip No. 99613018)</td></tr> <tr> <td>Pharmacological Group</td><td>Analgesic, anti-inflammatory agent</td></tr> <tr> <td>Type of Form</td><td>Form 5</td></tr> <tr> <td>Finished product Specification</td><td>BP specifications</td></tr> <tr> <td>Pack size & Demanded Price</td><td>10ml,: Decontrolled</td></tr> <tr> <td>Me-too status</td><td>Ketoject Injection (10ml, 100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)</td></tr> <tr> <td>GMP status</td><td></td></tr> <tr> <td>Remarks of the Evaluator^X</td><td>Shortcomings:</td></tr> </table>	Name and address of manufacturer / Applicant	M/s. Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.	Brand Name +Dosage Form + Strength	Ketonol Injection	Composition	Each ml contains:- Ketoprofen.....100mg	Diary No. Date of R& I & fee	Dy.No 18192 dated 22-06-2022 Rs.30,000/- dated 22-06-2022 (slip No. 99613018)	Pharmacological Group	Analgesic, anti-inflammatory agent	Type of Form	Form 5	Finished product Specification	BP specifications	Pack size & Demanded Price	10ml,: Decontrolled	Me-too status	Ketoject Injection (10ml, 100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)	GMP status		Remarks of the Evaluator ^X	Shortcomings:		
Name and address of manufacturer / Applicant	M/s. Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.																								
Brand Name +Dosage Form + Strength	Ketonol Injection																								
Composition	Each ml contains:- Ketoprofen.....100mg																								
Diary No. Date of R& I & fee	Dy.No 18192 dated 22-06-2022 Rs.30,000/- dated 22-06-2022 (slip No. 99613018)																								
Pharmacological Group	Analgesic, anti-inflammatory agent																								
Type of Form	Form 5																								
Finished product Specification	BP specifications																								
Pack size & Demanded Price	10ml,: Decontrolled																								
Me-too status	Ketoject Injection (10ml, 100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)																								
GMP status																									
Remarks of the Evaluator ^X	Shortcomings:																								

		• Approval of relevant manufacturing facility • Latest GMP inspection report conducted within the period of last three years.
Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters, and for submission of the following: • Approval of relevant manufacturing facility • Latest GMP inspection report conducted within the period of last three years.		
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved		
36.	Name and address of manufacturer / Applicant	M/s. Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Ketonol Injection
	Composition	Each ml contains:- Ketoprofen 100mg
	Diary No. Date of R& I & fee	Dy.No 18193 dated 22-06-2022 Rs.30,000/- dated 22-06-2022 (slip No. 96071888)
	Pharmacological Group	Analgesic, anti-inflammatory agent
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	100ml,: Decontrolled
	Me-too status	Ketoject Injection (10ml, 100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)
	GMP status	
	Remarks of the Evaluator ^X	Shortcomings: • Approval of relevant manufacturing facility • Latest GMP inspection report conducted within the period of last three years.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters, and for submission of the following: • Approval of relevant manufacturing facility • Latest GMP inspection report conducted within the period of last three years.	
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved		
37.	Name and address of manufacturer / Applicant	M/s. Symans Pharmaceuticals (Private) Limited, 10km Sheikhpura Road, Lahore.
	Brand Name +Dosage Form + Strength	Ketosym Injection
	Composition	Each ml contains:- Ketoprofen 100mg
	Diary No. Date of R& I & fee	Duplicate dossier submitted which was confirmed from R&I section, DRAP

		Dy.No 987 dated 28-04-2017 Rs.20,000/- dated 28-04-2017
	Pharmacological Group	Anti haematozoan
	Type of Form	Form 5
	Finished product Specification	Manufacturer’s specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	De-Trox 340 Injection (50ml) of M/s Biorise Pharmaceuticals, Multan. (Reg. No. 113397)
	GMP status	Panel inspection report for renewal of DML dated 28-10-2019 and 02-10-2020 recommends renewal of DML
	Remarks of the Evaluator ^x	• Liquid Injectable section vial Veterinary (General) confirmed vide panel inspection report for renewal of DML dated 28-10-2019 and 02-10-2020
Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters, and for submission of the following: • Fee Rs. 7500/- for change of finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.		
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter		
38.	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	Ketozon Injection
	Composition	Each ml contains:- Ketoprofen 100mg
	Diary No. Date of R& I & fee	Dy. No. 23386 dated 20-09-2023 Rs.30,000/- dated 19-09-2023 (Slip No. 1721722586)
	Pharmacological Group	Analgesic
	Type of Form	Form 5
	Finished product Specification	As per Innovator’s Specification
	Pack size & Demanded Price	10ml, Decontrolled
	Me-too status	Ketoject Injection (10ml) of M/s. Selmore Pharmaceuticals (Reg. No. 043141)
	GMP status	New DML
	Remarks of the Evaluator ^x	
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter		

39.	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	Ketozon Injection
	Composition	Each ml contains:- Ketoprofen 100mg
	Diary No. Date of R& I & fee	Dy. No. 23387 dated 20-09-2023 Rs.30,000/- dated 19-09-2023 (Slip No. 4078198612)
	Pharmacological Group	Analgesic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specification
	Pack size & Demanded Price	20ml, Decontrolled
	Me-too status	Ketoject Injection (20ml) of M/s. Selmore Pharmaceuticals (Reg. No. 043141)
	GMP status	New DML
	Remarks of the Evaluator ^X	
Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.		
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter.		
40.	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	Ketozon Injection
	Composition	Each ml contains:- Ketoprofen 100mg
	Diary No. Date of R& I & fee	Dy. No. 23388 dated 20-09-2023 Rs.30,000/- dated 19-09-2023 (Slip No. 81146079242)
	Pharmacological Group	Analgesic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specification
	Pack size & Demanded Price	50ml, Decontrolled
	Me-too status	Ketoject Injection (50ml) of M/s. Selmore Pharmaceuticals (Reg. No. 043141)
	GMP status	New DML
	Remarks of the Evaluator ^X	
Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.		
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter.		
41.	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	Ketozon Injection

	Composition	Each ml contains:- Ketoprofen 100mg
	Diary No. Date of R& I & fee	Dy. No. 23389 dated 20-09-2023 Rs.30,000/- dated 19-09-2023 (Slip No. 783772489377)
	Pharmacological Group	Analgesic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specification
	Pack size & Demanded Price	100ml, Decontrolled
	Me-too status	Ketoject Injection (100ml) of M/s. Selmore Pharmaceuticals (Reg. No. 043141)
	GMP status	New DML
	Remarks of the Evaluator ^X	
Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.		
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved		
42.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Oxyket L.A Injection
	Composition	Each ml contains:- Oxytetracycline as HCl.....200mg Ketoprofen 30mg
	Diary No. Date of R& I & fee	Dy.No 20537 dated 20-07-2022 Rs.30,000/- dated 18-07-2022 (slip No. 76930089)
	Pharmacological Group	Antibiotic/NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Oxyfen LA Injection of M/s Selmore Pharmaceutical (Pvt) Ltd., Lahore.(Reg. No. 071091)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator ^X	• Liquid Injection (General)section confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. • Target species: Honeybees, livestock, cattle, poultry, fish
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved		

43.	Name and address of manufacturer / Applicant	M/s. SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad. Manufacturer: M/s Bio-Labs Pvt. Ltd., Plot No. 145 Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	SB Fen Injection 100ml
	Composition	Each ml contains:- Ketoprofen.....100mg
	Diary No. Date of R& I & fee	Dy.No 19925 dated 07-07-2022 Rs.75,000/- dated 22-06-2022 (slip No. 3428744475)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Ketoject Injection (10ml, 20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)
	GMP status	M/s Bio-Labs: cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021 M/s SB pharma: GMP inspection report dated 26-09-2019 & 07-10-2019 concludes acceptable level of cGMP compliance.
Remarks of the Evaluator ^X		Liquid Injection (General)section confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. Target species: Dogs, cats, horses, small animals, other large animals, birds, exotic animals Shortcomings: Address of the applicant mentioned on DML is Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad while that on form-5 is 48-C, Satellite Town, Chandani Chowk, Rawalpindi, clarify.
Decision: Deferred for following: - Review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters. - Clarification regarding address of the applicant - DML status of the applicant from Licensing Division, DRAP		
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter		
44.	Name and address of manufacturer / Applicant	M/s. SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad. Manufacturer: M/s Bio-Labs Pvt. Ltd., Plot No. 145 Industrial Triangle, Kahuta Road, Islamabad.

	Brand Name +Dosage Form + Strength	SB Fen Injection
	Composition	Each ml contains:- Ketoprofen.....100mg
	Diary No. Date of R& I & fee	Dy.No 19924 dated 07-07-2022 Rs.75,000/- dated 22-06-2022 (slip No. 61279267300)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Ketoject Injection (10ml, 20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)
	GMP status	M/s Bio-Labs: cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021 M/s SB pharma: GMP inspection report dated 26-09-2019 & 07-10-2019 concludes acceptable level of cGMP compliance.
	Remarks of the Evaluator ^x	Liquid Injection (General)section confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. Target species: Dogs, cats, horses, small animals, other large animals, birds, exotic animals Shortcomings: Address of the applicant mentioned on DML is Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad while that on form-5 is 48-C, Satellite Town, Chandani Chowk, Rawalpindi, clarify.
	Decision: Deferred for following: - Review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters. - Clarification regarding address of the applicant - DML status of the applicant from Licensing Division, DRAP	
	Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.	
	Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter	
45.	Name and address of manufacturer / Applicant	M/s. Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Ketozar Injection
	Composition	Each ml contains:- Ketoprofen.....100mg
	Diary No. Date of R& I & fee	Dy.No 19941 dated 07-07-2022 Rs.30,000/- dated 06-07-2022 (slip No. 6011027756)
	Pharmacological Group	NSAID
	Type of Form	Form 5

	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Ketoject Injection (10ml, 20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No.043141)
	GMP status	GMP inspection report dated 29-07-2022 concludes that the firm was GMP compliant on the day of inspection.
	Remarks of the Evaluator ^x	Veterinary Liquid Injection (General) section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. Target species: Beef heifers, beef steers, beef calves 2 months of age and older, beef bulls, replacement dairy heifers, dairy bulls
Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.		
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved.		
46.	Name and address of manufacturer / Applicant	M/s. Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Ketozar Injection
	Composition	Each ml contains:- Ketoprofen.....100mg
	Diary No. Date of R& I & fee	Dy.No 19942 dated 07-07-2022 Rs.30,000/- dated 06-07-2022 (slip No. 1077717717)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Ketoject Injection (10ml, 20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No.043141)
	GMP status	GMP inspection report dated 29-07-2022 concludes that the firm was GMP compliant on the day of inspection.
	Remarks of the Evaluator ^x	Veterinary Liquid Injection (General) section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. Target species: Beef heifers, beef steers, beef calves 2 months of age and older, beef bulls, replacement dairy heifers, dairy bulls
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee:		

After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved		
47.	Name and address of manufacturer / Applicant	M/s. Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Ketozar Injection 100ml
	Composition	Each ml contains:- Ketoprofen.....100mg
	Diary No. Date of R& I & fee	Dy.No 19943 dated 07-07-2022 Rs.30,000/- dated 06-07-2022 (slip No. 97238058)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Ketoject Injection (10ml, 20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No.043141)
	GMP status	GMP inspection report dated 29-07-2022 concludes that the firm was GMP compliant on the day of inspection.
	Remarks of the Evaluator ^x	Veterinary Liquid Injection (General) section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. Target species: Beef heifers, beef steers, beef calves 2 months of age and older, beef bulls, replacement dairy heifers, dairy bulls
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee:		
After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved		
48.	Name and address of manufacturer / Applicant	M/s. Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Ketostrep LA Injection
	Composition	Each ml contains:- Oxytetracycline as HCl.....200mg Ketoprofen.....30mg
	Tracking Id, date & fee	P6S-L4W-ZBWZ dated 26-02-2024 Rs 30,000/- dated 22-02-2024 (Slip No. 470625527)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Ketocin Injection of M/s A & K Pharmaceutical, Faisalabad. (Reg. No.102101)
	GMP status	New Section

	Remarks of the Evaluator	
Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.		
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved		
49.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Ketostrep LA Injection
	Composition	Each ml contains:- Oxytetracycline as HCl.....200mg Ketoprofen.....30mg
	Tracking Id, date & fee	AA3-ZDD-L7QM dated 29-02-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 30271366088)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	20ml; Decontrolled
	Me-too status	Oxyfen LA Injection of M/s Selmore Pharmaceutical (Pvt) Ltd., Lahore (Reg. No. 071091)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved		
50.	Name and address of manufacturer / Applicant	M/s. Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Ketostrep LA Injection
	Composition	Each ml contains:- Oxytetracycline as HCl.....200mg Ketoprofen.....30mg
	Tracking Id, date & fee	RH9-5JL-5NG3 dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 95106582745)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Pro Cycline Injection of M/s Kayans Pharmaceuticals, Rawalpindi. (Reg. No. 111328)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	

Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved		
51.	Name and address of manufacturer / Applicant	M/s. Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLAFENIK Injection
	Composition	Each ml contains:- Ketoprofen 100mg
	Tracking Id, date & fee	ZB1-8UN-L1LA dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 0893442558)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Ketoject Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 043141)
	GMP status	New Section
	Remarks of the Evaluator	
Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.		
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved.		
The firm shall submit fee for specification correction before the issuance of registration letter		
52.	Name and address of manufacturer / Applicant	M/s. Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLAFENIK Injection
	Composition	Each ml contains:- Ketoprofen 100mg
	Tracking Id, date & fee	Z91-16X-2WWA dated 29-02-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 33091851175)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Ketoject Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 043141)
	GMP status	New Section
	Remarks of the Evaluator	
Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.		
Recommendation of Sub-committee:		

After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved.		
The firm shall submit fee for specification correction before the issuance of registration letter.		
53.	Name and address of manufacturer / Applicant	M/s. Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLAFENIK Injection
	Composition	Each ml contains:- Ketoprofen.....100mg
	Tracking Id, date & fee	BGU-193-6QQ1 dated 29-02-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 667493224)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	20ml; Decontrolled
	Me-too status	Ketoject Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 043141)
	GMP status	New Section
	Remarks of the Evaluator	
Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.		
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved.		
The firm shall submit fee for specification correction before the issuance of registration letter.		
54.	Name and address of manufacturer / Applicant	M/s. Prix Pharmaceutica Pvt Ltd. Plot No 5, Pharmacy, 30-km Multan Road, Lahore (DML No. 000587) Veterinary Liquid Injectable Section
	Brand Name +Dosage Form + Strength	Ketoflame 10 Injection
	Composition	Each ml contains:- Ketoprofen.....100mg
	Diary No. Date of R& I & fee	Dy.No 34223 dated 31-12-2021; Rs.30,000/- vide Deposit Slip No. 930536178837
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	20ml; Decontrolled
	Me-too status	Ketoject 10% Injection Reg. No. 043141 M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (10ml,20ml,50ml,100ml)
	GMP status	Not provided
	Remarks of the Evaluator ^{xxiii} .	Latest GMP inspection report against inspection conducted within the last three years is required.

Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters, and for submission of the following: • Latest GMP inspection report conducted within a period of last three years • The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes. Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter		
55.	Name and address of manufacturer / Applicant	M/s. Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Fento Injection
	Composition	Each ml contains:- Ketoprofen.....100mg
	Diary No. Date of R& I & fee	Dy.No 3920 dated 10-02-2023 Rs.30,000/- dated 07-02-2023 (slip No. 280841152826)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	20ml; Decontrolled
	Me-too status	Catoprofen Injection of M/s Hilton Pharma (Pvt) Ltd., Karachi. (Reg. No.101472)
	GMP status	cGMP certificate dated 09-12-2019 based on inspection conducted on 08-11-2019.
	Remarks of the Evaluator	Veterinary Liquid Injection (General) section confirmed vide letter No. F. 1-51/2004-Lic dated 07-02-2014
Decision: Referred to Sub-Committee on Veterinary Drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters. Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved		
56.	Name and address of manufacturer / Applicant	M/s. Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Fento Injection
	Composition	Each ml contains:- Ketoprofen.....100mg
	Diary No. Date of R& I & fee	Dy.No 3921 dated 10-02-2023 Rs.30,000/- dated 30-01-2023 (slip No. 355336486)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	50ml; Decontrolled

	Me-too status	Catoprofen Injection of M/s Hilton Pharma (Pvt) Ltd., Karachi. (Reg. No.101473)
	GMP status	cGMP certificate dated 09-12-2019 based on inspection conducted on 08-11-2019.
	Remarks of the Evaluator	Veterinary Liquid Injection (General) section confirmed vide letter No. F. 1-51/2004-Lic dated 07-02-2014
Decision: Referred to Sub-Committee on Veterinary Drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters. Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved		
57.	Name and address of manufacturer / Applicant	M/s. Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Oxy Ket Injection
	Composition	Each ml contains:- Oxytetracycline.....200mg Ketoprofen.....30mg
	Diary No. Date of R& I & fee	Dy.No 4017 dated 13-02-2023 Rs.30,000/- dated 10-02-2023 (slip No. 799416121208)
	Pharmacological Group	Antibacterial & NSAID
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Pro Cycline Injection of M/sKayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 111328)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	Liquid Injectable General (Veterinary) Section confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Referred to Sub-Committee on Veterinary Drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters. Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.	
	Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter	
58.	Name and address of manufacturer / Applicant	M/s. Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Oxy Ket Injection
	Composition	Each ml contains:- Oxytetracycline.....200mg

		Ketoprofen.....30mg
	Diary No. Date of R& I & fee	Dy.No 4013 dated 13-02-2023 Rs.30,000/-dated 10-02-2023 (slip No. 215688653102)
	Pharmacological Group	Antibacterial & NSAID
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml,: Decontrolled
	Me-too status	Pro Cycline Injection of M/sKayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 111329)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	Liquid Injectable General (Veterinary) Section confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Referred to Sub-Committee on Veterinary Drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters. Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.	
Decision: Approved		
59.	Name and address of manufacturer/ Applicant	M/s.Biorise Pharmaceuticals, 19-Km, Lahore Road Multan.
	Brand Name + Dosage Form + Strength	Ketorise Injection
	Composition	Each ml contains:- Ketoprofen.....100mg
	Diary No. Date of R&I & fee	Dy.No 27357 dated 21-11-2023 Rs30,000/-dated 20-11-2023 (slip No.99545777)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	BPV specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Hansi Pro 10% Injection (10ml) of M/sD-Haans Pharmaceuticals, Bhimber, Azad Kashmir (Reg.No.114838)
	GMP status	DML granted on 02-06-2021
	Remarks of the Evaluator	Liquid Injection vial section (General) Veterinary confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021. Target Species: Cattle, horses Shortcomings: Latest GMP inspection report (conducted within the period of last three years).
Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and submission of latest GMP inspection report conducted within the period of last three years.		

Recommendation of Sub-committee:

After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.

Decision: Approved

60.	Name and address of manufacturer/ Applicant	M/s. Izfaar Pharmaceutical Pvt. Ltd., 542-A&B, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Ketozar Injection
	Composition	Each ml contains:- Ketoprofen 100mg
	Diary No. Date of R&I & fee	Dy. No 29890 dated 29-12-2023 Rs 30,000/- dated 28-12-2023
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	20ml; Decontrolled
	Me-to status	Hansi Pro 10% Injection (100ml) of M/s D-Haans Pharmaceuticals, Bhimber, Azad Kashmir. (Reg. No. 114840)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	Veterinary Liquid Injection (General) section confirmed vide letter No. F.1-29/2007-Lic(M-236) dated 23-09-2014. Target species: Cattle, sheep, goat, poultry

Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and submission of latest GMP inspection report conducted within the period of last three years.

Recommendation of Sub-committee:
After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.

Decision: Approved.**The firm shall submit fee for specification correction before the issuance of registration letter**

61.	Name and address of manufacturer/ Applicant	M/s. Zakfas Pharmaceuticals Pvt. Ltd., 12-Km, Bosan Road, Multan.
	Brand Name + Dosage Form + Strength	Ketofosb Injection
	Composition	Each ml contains:- Ketoprofen 100mg
	Diary No. Date of R&I & fee	Dy. No 1303 dated 22-01-2024 Rs 30,000/- dated 18-01-2024
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-to status	Hansi Pro 10% Injection of M/s D-Haans Pharmaceuticals, Bhimber, Azad Kashmir. (Reg. No. 114839)
	GMP status	Panel inspection report for renewal of DML dated 15-06- 2021 recommends renewal of DML

Remarksofthe Evaluator		VeterinaryLiquidinjection(General)section confirmed vide panel inspection report for renewal of DML dated 15- 06-2021 Shortcomings: LatestGMPinspectionreportconductedwithinthe period of last three years.
Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and submission of latest GMP inspection report conducted within the period of last three years. Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter		
62.	Nameandaddressofmanufacturer/ Applicant	M/s.ZakfasPharmaceuticalsPvt.Ltd.,12-Km,BosanRoad, Multan.
	BrandName+DosageForm+ Strength	Clofen Injection
	Composition	Each ml contains:- Oxytetracycline.....200mg Ketoprofen 30mg
	DiaryNo.Dateof R&I&fee	Dy.No1310dated22-01-2024Rs30,000/-dated18-01-2024
	PharmacologicalGroup	Antibiotic& NSAID
	Typeof Form	Form5
	Finishedproduct Specifications	Innovator'sspecifications
	Packsize&DemandedPrice	100ml:Decontrolled
	Me-toostatus	Pro Cycline Injection (100ml) of M/s Kayans Pharmaceuticals,Rawat,Rawalpindi.(Reg.No.111329)
	GMPstatus	PanelinspectionreportforrenewalofDMLdated15-06-2021recommendsrenewalofDML
	Remarksofthe Evaluator	VeterinaryLiquidinjection(General)section confirmed vide panel inspection report for renewal of DML dated 15- 06-2021 Targetspecies: Cattle,buffalo,sheep,goat Shortcomings: Latest GMP inspection report conducted within the period of last three years.
Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and submission of latest GMP inspection report conducted within the period of last three years. Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter		
63.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Febrol Injection 50ml

	Composition	Each ml contains:- Aceclofenac.....25mg
	Diary No. Date of R& I & fee	Dy.No 7567 dated 29-05-2019 Rs.20,000/- dated 27-05-2019
	Pharmacological Group	NSAID/Antipyretic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1 x 50ml vial; As per SRO
	Me-too status	Vetafenac-Super Injection of M/s S.J. & G. Fazul Ellahie (Pvt) Limited, Karachi. (Reg. No. 046569)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator ^x	- Approval of Liquid injectable (veterinary) section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML. - Firm has revised finished product specification from inhouse to “as per innovator's specifications” along with the fee of Rs. 7,500/- via deposit slip no 4746891203.
Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.		
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter		
64.	Name and address of manufacturer / Applicant	M/s. Intervac Pvt. Limited, 18-Km, Lahore Sheikhpura Road, Sheikhpura, Pakistan.
	Brand Name +Dosage Form + Strength	Fevofas Injection
	Composition	Each ml contains:- Aceclofenac.....25mg
	Diary No. Date of R& I & fee	Dy.No 16419 dated 02-09-2019 Rs.20,000 dated 30-08-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Clofenac Injection (50ml) of M/s. Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 088082)
GMP status	cGMP Inspection conducted on 08-10-2020 concluded satisfactory level of GMP compliance.	

	Remarks of the Evaluator ^X	• Liquid Injectable (General) (Veterinary) Section confirmed vide letter No. F.1-37/2004-Lic (Vol-I) dated 04-10-2019.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
	Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.	
	Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter	
65.	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	Diclostar Injection
	Composition	Each ml contains:- Aceclofenac Sodium eq. to Aceclofenac...25mg
	Diary No. Date of R& I & fee	Dy.No 18062 dated 19-09-2019 Rs.20,000 dated 19-09-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10ml, 20ml, 50ml, 100ml, 450ml, 500ml: Decontrolled
	Me-too status	Clofenac Injection (50ml) of M/s. Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 088082)
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator ^X	• Liquid injectable (General) section confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML renewal • Initially, multiple pack sizes (10ml, 20ml, 50ml, 100ml, 450ml, 500ml) of injectable dosage form were demanded in a single application. Now, the firm has demanded 50ml pack size. • Firm has mentioned salt form while the reference formulation is Each ml contains: Aceclofenac.....25mg • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter		
66.	Name and address of manufacturer / Applicant	M/s. Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Evonac Injection
	Composition	Each ml contains:- Aceclofenac.....25mg
	Diary No. Date of R& I & fee	Dy.No 21637 dated 23-10-2019 Rs.20,000 dated 21-10-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10ml, 50ml,: Decontrolled
	Me-too status	Vetafenac-Super Injection (50ml) of M/s. S.J. & G. Fazul Ellahie (Pvt) Limited, Karachi. (Reg. No. 046569)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator ^x	Liquid Injection (General) (Veterinary) Section confirmed vide letter No. F. 1-31/2010-Lic (Vol-I) dated 13-02-2020. Initially, multiple pack sizes (10ml, and 50ml) of injectable dosage form were demanded in a single application. Now, the firm has demanded 50ml pack size.
Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.		
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter		
67.	Name and address of manufacturer / Applicant	M/s. Mylab Pvt Ltd. Khankah Sharif Bahawalpur.
	Brand Name +Dosage Form + Strength	Hi-Fenac Injection
	Composition	Each ml contains:- Aceclofenac as Sodium.....25mg
	Diary No. Date of R& I & fee	Dy.No 21534 dated 22-10-2019 Rs.20,000/- dated 22-10-2019
	Pharmacological Group	NSAID

	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Vetafenac-Super Injection (50ml) of M/s. S.J. & G. Fazul Ellahie (Pvt) Limited, Karachi. (Reg. No. 046569)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator ^x	Liquid injection (General) Veterinary section confirmed vide letter No. F. 1-45/2009-Lic dated 27-08-2012. Shortcomings: - Firm has mentioned salt form while the reference formulation is Each ml contains: Aceclofenac.....25mg - Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.		
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter		
68.	Name and address of manufacturer / Applicant	M/s. Mylab Pvt Ltd. Khankah Sharif Bahawalpur.
	Brand Name +Dosage Form + Strength	Afonac Injection
	Composition	Each ml contains:- Aceclofenac As Sodium.....25mg
	Diary No. Date of R& I & fee	Dy.No 32402 dated 31-01-2020 Rs.20,000/- dated 31-01-2020
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	20ml vial,: Decontrolled
	Me-too status	Aceclovetz Injection (20ml) of M/s. Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 088160)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator ^x	Liquid injection (General) Veterinary section confirmed vide letter No. F. 1-45/2009-Lic dated 27-08-2012. Shortcomings:

		- Firm has mentioned sodium salt of Aceclofenac while the reference formulation is Each ml contains: Aceclofenac.....25mg - Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.		
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter.		
69.	Name and address of manufacturer / Applicant	M/s. Leads Pharma Pvt Ltd., Plot No. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Lefenac Injection
	Composition	Each ml contains:- Aceclofenac.....25mg
	Diary No. Date of R& I & fee	Dy.No 18240 dated 29-06-2021 Rs.30,000/- dated 28-06-2021
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10ml,50ml, 100ml: Decontrolled
	Me-too status	Registered with 10ml, 20ml and 50ml fill volume/pack sizes
	GMP status	GMP of relevant section
	Remarks of the Evaluator ^x	Liquid Injection Vet (General) section confirmed vide panel inspection report for renewal of DML based on inspection conducted on 25-02-2020. Shortcomings: - Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier. - Evidence of applied formulation/drug already approved by DRAP (generic / me-too status), with same fill volume/ pack size as applied, alongwith registration number, brand name and name of firm

	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter.		
70.	Name and address of manufacturer / Applicant	M/s. Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Clofenac Injection
	Composition	Each ml contains:- Aceclofenac Sodium eq. to Aceclofenac...25mg
	Diary No. Date of R& I & fee	Dy.No 26574 dated 09-10-2020 Rs.20,000/- dated 08-10-2020
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Afonac Injection (10ml) of M/s Mylab (Pvt) Ltd, Bahawalpur (Reg. No. 095656)
	GMP status	cGMP certificate dated 27-02-2023 based on inspection dated 24-01-2023 & 25-01-2023
	Remarks of the Evaluator ^x	Liquid Injectable Vial-I General (Veterinary) and Liquid Injectable Vial-II General (Veterinary) section confirmed vide panel inspection report for grant of additional sections based on inspection dated 14-03-2022. Shortcomings: - Firm has mentioned salt form while the reference formulation is Each ml contains: Aceclofenac.....25mg - Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Referred to EWGon veterinary drugs to review environment safety requirements	
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter.		
71.	Name and address of manufacturer / Applicant	M/s. Moreno Iglisias Research Labs (Pvt) Ltd., 21 Km, Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Acemore 2.5% Injection
	Composition	Each ml contains:- Aceclofenac.....25mg

Diary No. Date of R& I & fee	Dy. No. 27420 dated 22-11-2023 Rs 30,000/- dated 16-11-2023 (Slip No. 475994345360)
Pharmacological Group	Anti-pyretic/ Analgesic/ Anti-inflammatory
Type of Form	Form 5
Finished product Specification	Manufacturer's specifications
Pack size & Demanded Price	50ml; Decontrolled
Me-too status	I-Acefenac Injection (50ml) of M/s International Pharma Labs. Lahore. (Reg. No. 094437)
GMP status	Additional section
Remarks of the Evaluator ^X	Target species: Horse, camel, cattle, buffaloes, sheep, goats, dogs, cats
Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.	
Decision: Approved. The firm shall submit fee for specification correction before the issuance of registration letter.	

Import & Vet Section-II

Case No.01: - REQUEST FOR CORRECTION OF TYPOGRAPHIC ERROR ON XARELTO 15MG TABLET REGISTRATION NO. 072549 (BATCH NUMBER BXKHE11) ON SECONDARY PACKAGING.

M/s Bayer Pakistan Pvt. Ltd. inform that during our recent routine check, a typographic error was observed in the brand name in Urdu on the secondary packaging (unit carton) of our imported product, Xarelto 15mg Tablet contains: Rivaroxaban...15mg (Batch No. BXK4E11). Details of typo error as follows:

Correct brand name in Urdu (same already printed on primary packaging)	Incorrect brand name printed in on secondary packaging due to typo error
Xarelto 15mg Tablet	Xarelto 20mg Tablet

Therefore, upon identifying this typo error, they immediately took the following actions:

- Stopped the sales of impacted packs.
- Assessed the impact and potential risk.

As per firm's assessment:

- Only one batch is impacted, i.e., Batch No. BXK4E11, and this error appears only at one place in the brand name in Urdu on the secondary packaging. The brand name in Urdu on the primary packaging is correctly printed, and the brand name in English (bold text) on both primary and secondary packaging is also correct (pack images attached).
- There is no contamination of any ingredient, molecule, or foreign particle.
- The tablets are genuine, contains claimed amount of API as per approved specifications.

- d) There is no compromise on product efficacy, potency, or quality considering this typo is only at one place and the same information is correctly printed in both English and Urdu on primary packaging, as well as in English on Secondary packaging (bold text). Also, 15. is properly embossed on each tablet.
- e) Inventory Status of Impacted Batch:
- The status of the packs is as follows:

Quantity Imported: 15,072 packs

Quantity Unsold: 13,879 packs

Quantity Sold to Distributors: 1,192 packs

Quantity Returned*: 857 packs

Firm has submitted following supporting documents:

- Application with a fee of Rs.12,000/-
- Copy of registration letter & last renewal.
- Specimen of artwork before and after masking and re-printing.

Firm request your office to allow us to correct this typo on the secondary packaging through masking and re -printing at the manufacturing facility of Novartis located at C-21, S.I.T.E ., Karachi, Pakistan. A copy of the DML and the agreement between Bayer Pakistan and Novartis is submitted.

Decision:

Registration Board approved the firm's request to perform inkjet printing of correct brand name "Xarelto 15mg Tablet" on outer folding boxes only for one time for the product Xarelto 15mg (Batch No. BXK4E11) for remaining quantities at facility of Novartis located at C-21, S.I.T.E ., Karachi, Pakistan. Other terms and conditions will remain the same.

Case.No.02: REQUEST OF M/S NOVARTIS PHARMA (PAKISTAN) LIMITED, KARACHI FOR DE-REGISTRATION OF REGISTERED PRODUCTS.

M/s Novartis Pharma (Pakistan) Limited, 15 West Wharf, Dockyard Road, Karachi has submitted request for de-registration of following registered imported product as per details mentioned alongside.

S. No	Product(s) Name	Reg. No.	Reason for De-Reg. (stated by firm)	Alternative Registered Product
1.	Tacrosan 0.5mg Capsule. Each capsule contains: - Tacrolimus 0.5mg (as tacrolimus monohydrate).	078163	The Sandoz group portfolio has been divested and we do not want to continue mentioned products as per global directives.	1. Taclekin 0.5mg, 1mg & 5mg Capsule M/s Navegal Pharma. 2. Inograf 0.5mg, 1mg & 5mg Capsule M/s Platinum Pharma Pvt Ltd. 3. Imunol 1mg M/s Saffron.

2.	Tacrosan 1mg Capsule. Each capsule contains: - Tacrolimus 1mg (as tacrolimus monohydrate).	078164	-do-	4. Arilio 0.5mg, 1mg & 5mg Capsule M/s Sami Pharmaceuticals, Pvt Ltd.
3.	Tacrosan 5mg Capsule. Each capsule contains: - Tacrolimus 5mg (as tacrolimus monohydrate).	078165	-do-	5. Tacmus 0.5mg, 1mg & 5mg Capsule M/s Schazoo Pharmaceuticals Labs. 6. Graftil 0.5mg, 1mg & 5mg Capsule M/s Bio-Labs, Pvt Ltd. 7. Tacgraf 0.5mg, 1mg & 5mg Capsule M/s CCL Pharma.

Firm has submitted following supporting documents:

- Application with a fee Rs.7500/- for each product
- Copy of registration letter & last renewal.
- Alternate brand names.
- Justification.
- An undertaking that:
 - No case is pending at any forum / court of law regarding this product.
 - Provided information/ documents are true/ correct.

Decision:

Registration Board acceded the firm's request for de-registration of following imported products:

S. No	Product(s) Name	Reg. No.
1.	Tacrosan 0.5mg Capsule. Each capsule contains: - Tacrolimus 0.5mg (as tacrolimus monohydrate)	078163
2.	Tacrosan 1mg Capsule. Each capsule contains: - Tacrolimus 1mg (as tacrolimus monohydrate).	078164
3.	Tacrosan 5mg Capsule. Each capsule contains: - Tacrolimus 5mg (as tacrolimus monohydrate).	078165

Case.No.03: REQUEST OF M/S NOVARTIS PHARMA (PAKISTAN) LIMITED, KARACHI FOR DE-REGISTRATION OF REGISTERED PRODUCTS.

M/s Novartis Pharma (Pakistan) Limited, 15 West Wharf, Dockyard Road, Karachi has submitted request for de-registration of following registered imported product as per details mentioned alongside.

S. No	Product(s) Name	Reg. No.	Reason for De-Reg. (stated by firm)	Alternative Registered Product

1.	Exforge 320/5mg Tablets. Each film coated tablet contains:- Valsartan 320mg. Amlodipine 5mg	069545	Products have been discontinued from more than a decade, and we have no future plan for their marketing. furthermore, their approved MPR not viable. Thus, we are not able to continue mentioned products as per global directives.	1. Amodip-V, M/s Masss Pharma. 2. Amstan, M/s Getz Pharma. 3. Avcard, M/s Hilton Pharma. 4. Avscar, Pharmevo. 5. Dioplus, Atco Labs. 6. Extor, Searle Pakistan. 7. Lodis, Tabros Pharma. 8. Newday Werrick. 9. Nuwasc, Wilson. 10. Valsar-M, Helix Pharma. 11. Valtec AM, Tabros Pharma.
2.	Exforge 320/10mg Tablets. Each film coated tablet contains:- Valsartan 320mg. Amlodipine 10mg	069546		
3.	Sandimmun Neoral Soft Gelatin Capsules. Each Capsule Contains: Cyclosporin....10mg	020500		1. Consupren, M/s Universal Enterprises. 2. Neocyspin, M/s Biocare Pharma.
4.	Sandimmun Neoral 50mg Capsules. Each soft gelatin capsule Capsule Contains: Cyclosporin....50mg	081779		3. Scots Cyclosporin, M/s Scotmann Pharma.
5.	Zometa Powder Each vial contains: Zoledronic acid 4mg	027365		1. Edonax, M/s Ferozsons Labs 2. Zoldic, M/s Consolidated Chemical Laboratories Pvt Ltd.
6.	Zometa 4mg/5ml concentrate for solution for infusion Each vial contains: Zoledronic acid 4mg/5ml	031390		3. Zoldria, AJ Mirza Pharma. 4. Zoledron, M/s Scotmann Pharma.

Firm has submitted following supporting documents:

- Application with a fee Rs.7500/- for each product
- Copies of registration letters & last renewal.
- Alternate brand names.
- Justification.
- An undertaking that:
 - No case is pending at any forum / court of law regarding this product.
 - Provided information/ documents are true/ correct.

Decision:

Registration Board acceded the firm's request for de-registration of following imported products:

S. No	Product(s) Name	Reg. No.
1.	Exforge 320/5mg Tablets. Each film coated tablet contains:- Valsartan 320mg. Amlodipine 5mg	069545

2.	Exforge 320/10mg Tablets. Each film coated tablet contains:- Valsartan 320mg. Amlodipine 10mg	069546
3.	Sandimmun Neoral Soft Gelatin Capsules. Each Capsule Contains: Cyclosporin....10mg	020500
4.	Sandimmun Neoral 50mg Capsules. Each soft gelatin capsule Capsule Contains: Cyclosporin....50mg	081779
5.	Zometa Powder Each vial contains: Zoledronic acid 4mg	027365
6.	Zometa 4mg/5ml concentrate for solution for infusion Each vial contains: Zoledronic acid 4mg/5ml	031390

Case.No.04: REQUEST OF M/S GLAXOSMITHKLINE PAKISTAN LIMITED, KARACHI FOR DE-REGISTRATION OF REGISTERED PRODUCTS.

M/s Glaxosmithkline Pakistan Limited, 35 West Wharf, Dockyard Road, Karachi has submitted request for de-registration of following registered imported product as per details mentioned alongside.

S. No	Product(s) Name	Reg. No.	Reason for De-Reg. (stated by firm)	Alternative Registered Product
1.	Augmentin Injectable Each vial contains:- 1gm amoxicillin as amoxicillin sodium and 200mg clavulanic acid as potassium clavulanate	011523	- Suitable therapeutic alternatives and advance therapies are available in the market. - Better / new molecules to cater the same portfolio are also in the market.	1. Calamox Injection, M/s Bosch Pharma. 2. Co-Amoxi, M/s Macter Pharma. 3. Zamoclav, M/s Zafa Pharma.
2.	Augmentin Injection Each vial contains:- 500mg amoxicillin as amoxicillin sodium and 100mg clavulanic acid as potassium clavulanate	010338	Virtually there is no demand of this product in local market.	

Firm has submitted following supporting documents:

- Application with a fee Rs.10,000/- for each product
- Copies of registration letters & last renewal.
- Alternate brand names.
- Justification.
- An undertaking that:
 - No case is pending at any forum / court of law regarding this product.

- ii. Provided information/ documents are true/ correct.

Decision: Registration Board referred the case for views of DRAP's CLSD Committee.

Case.No.05: REQUEST OF M/S PFIZER PAKISTAN LIMITED, KARACHI FOR WITHDRAWAL OF REGISTRATION APPLICATION.

M/s Pfizer Pakistan Limited, 12 Dockyard Road, West Wharf, Karachi has submitted request for withdrawal of registration application of following approved imported product in 320th meeting of Registration Board, the reason for the withdrawal is due solely to a Pfizer business decision and it is not related to any safety, tolerability, efficacy or quality concern. Details are as under.

Name of Product	Name of Importer, Product License Holder / Manufacturer
PAXLOVID 150 mg/100mg Film-Coated Tablets Each Pink Coloured Film coated tablet contains: Nirmatrelvir.....150mg Each White Coloured Film coated tablet contains: Ritonavir.....100mg	M/s Pfizer Pakistan Limited,12 Dockyard Road West Wharf, Karachi. Product License Holder: M/s Pfizer Limited Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom Manufacturer: Ritonavir Tablets Bulk Tabs. Manufacturer, Testing and Release: M/s. Hetero Labs Limited, Unit-III, 22-110, Industrial Development Area, Jeedimetla, Hyderabad-500055, Telangana, India Nirmatrelvir Tablets Manufacturer, Primary Packaging, Secondary Packaging, Testing, Stability, Release of co-packs: Pfizer Manufacturing Deutschland GmbH Betriebsstätte Freiburg, Mooswaldallee 1, 79090 Freiburg, Germany
Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad and verification of local storage facility. - Firm shall submit the fee of Rs. 7,500 for revision of specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. - Firm will provide Quality Overall summary (QOS) on the basis of which MHRA has accorded Emergency Use Authorization before issuance of Registration letter.	

Decision: Registration Board referred the case for views of DRAP's CLSD Committee.

Case.No.06: REQUEST OF M/S FEROSONS LABORATORIES LTD, AMANGARH NOWSHERA FOR DE-REGISTRATION OF REGISTERED PRODUCT.

M/s Ferozsos Laboratories Limited, P.O., Ferozsos, Amangarh Nowshera has submitted request for de-registration of following registered imported product as per details mentioned alongside.

S. No	Product(s) Name	Reg. No.	Reason for De-Reg. (stated by firm)	Alternative Registered Product
1.	Truvada Tablets Each tablet contains:- Emtricitabine....200mg Tenofovir Disoproxil Fumarate 300mg equivalent to 245mg of tenofovir disoproxil	072544	Gilead Sciences, Inc. the marketing authorization holder of the product, hereby notifies request to withdraw the following marketing authorization in Pakistan and cease all further regulatory activity related to this marketing authorization. This is a voluntary withdrawal and does not pertain to any safety, efficacy or quality issue.	1. Epivir, M/s Genome Pharma. 2. Tenofo-EM, M/s Getz Pharma.

Firm has submitted following supporting documents:

- Copies of registration letters & last renewal.
- Alternate brand names.
- Justification.
- An undertaking that:
 - No case is pending at any forum / court of law regarding this product.
 - Provided information/ documents are true/ correct.

Decision:

Registration Board acceded the firm's request for de-registration of following imported products:

S. No	Product(s) Name	Reg. No.
1.	Truvada Tablets Each tablet contains:- Emtricitabine....200mg Tenofovir Disoproxil Fumarate 300mg equivalent to 245mg of tenofovir disoproxil	072544

Case.No.07: REQUEST OF M/S NOVARTIS PHARMA (PAKISTAN) LIMITED, KARACHI FOR DE-REGISTRATION OF REGISTERED PRODUCTS.

M/s Novartis Pharma (Pakistan) Limited, 15 West Wharf, Dockyard Road, Karachi has submitted request for de-registration of following registered imported product as per details mentioned alongside.

S. No	Product(s) Name	Reg. No.	Reason for De-Reg. (stated by firm)	Alternative Registered Product
1.	Exafal Tablets. Each tablet contains:- Artemether 20mg. Lumefantrine...120mg	025230	The Sandoz group portfolio has been divested and we do not want to continue	1. A-Fantrine, M/s Atco Labs. 2. Akilum, M/s Glitz Pharma. 3. Alar, M/s Searle Pakistan. 4. Altamal, M/s Hisun Pharma.

2.	Exafal Dispersible Tablets. Each dispersible tablet contains:- Artemether 20mg. Lumefantrine .120mg	071000	mentioned products as per global directives.	5. Altelum, Genera Pharma. 6. Amalar, Bloom pharma. 7. A-Mether, Rasco Pharma. 8. Antamol, Pfizer Labs Ltd. 9. Antimal, Pharnevo. 10. Arceva, Sami Pharma

Firm has submitted following supporting documents:

- Application with a fee Rs.75,00/- for each product
- Copies of registration letters & last renewal.
- Alternate brand names.
- Justification.
- An undertaking that:
 - No case is pending at any forum / court of law regarding this product.
 - Provided information/ documents are true/ correct.

Decision:

Registration Board acceded the firm's request for de-registration of following imported products:

S. No	Product(s) Name	Reg. No.
1.	Exafal Tablets. Each tablet contains:- Artemether 20mg. Lumefantrine...120mg	025230
2.	Exafal Dispersible Tablets. Each dispersible tablet contains:- Artemether 20mg. Lumefantrine .120mg	071000

Case.No.08: REQUEST OF M/S NOVARTIS PHARMA (PAKISTAN) LIMITED, KARACHI FOR DE-REGISTRATION OF REGISTERED PRODUCTS.

M/s Novartis Pharma (Pakistan) Limited, 15 West Wharf, Dockyard Road, Karachi has submitted request for de-registration of following registered imported product as per details mentioned alongside.

S. No	Product(s) Name	Reg. No.	Reason for De-Reg. (stated by firm)	Alternative Registered Product
1.	Zykadia 150mg hard gelatin capsules. Each capsule contains:- Ceritinib 150mg.	088399	That this decision has been taken due to business non viability. Moreover, this product is registered but not currently marketed in Pakistan.	Not provided

Firm has submitted following supporting documents:

- Application with a fee Rs.75 00/- for each product
- Copies of registration letters & last renewal.
- Alternate brand names.

- d. Justification.
- e. An undertaking that:
 - i. No case is pending at any forum / court of law regarding this product.
 - ii. Provided information/ documents are true/ correct.

Decision: Registration Board referred the case for views of DRAP's CLSD Committee.

Case.No.09: **REQUEST OF M/S NOVARTIS PHARMA (PAKISTAN) LIMITED, KARACHI FOR DE-REGISTRATION OF REGISTERED PRODUCTS.**

M/s Novartis Pharma (Pakistan) Limited, 15 West Wharf, Dockyard Road, Karachi has submitted request for de-registration of following registered imported product as per details mentioned alongside.

S. No	Product(s) Name	Reg. No.	Reason for De-Reg. (stated by firm)	Alternative Registered Product
1.	Emadine sterile ophthalmic solution 0.05% contains:- Emedastine Difumarate...0.0884% (equivalent to 0.05% emedastine)	091916	That this decision has been taken due to business non viability. Moreover, this product is registered but not currently marketed in Pakistan.	1. Emeda, M/s Bosch Pharma. 2. Alaway, Innvotek Pharma. 3. Ematrex, Winbrain Pharma

Firm has submitted following supporting documents:

- a. Application with a fee Rs.7500/- for each product
- b. Copies of registration letters & last renewal.
- c. Alternate brand names.
- d. Justification.
- e. An undertaking that:
 - i. No case is pending at any forum / court of law regarding this product.
 - ii. Provided information/ documents are true/ correct.

Decision:

Registration Board acceded the firm's request for de-registration of following imported products:

S. No	Product(s) Name	Reg. No.
1.	Emadine sterile ophthalmic solution 0.05% contains:- Emedastine Difumarate...0.0884% (equivalent to 0.05% emedastine)	091916

Case.No.10: **REQUEST OF M/S NOVARTIS PHARMA (PAKISTAN) LIMITED, KARACHI FOR DE-REGISTRATION OF REGISTERED PRODUCTS.**

M/s Novartis Pharma (Pakistan) Limited, 15 West Wharf, Dockyard Road, Karachi has submitted request for de-registration of following registered imported product as per details mentioned alongside.

S. No	Product(s) Name	Reg. No.	Reason for De-Reg. (stated by firm)	Alternative Registered Product

1.	Sandostatin 0.2mg/ml vial Each 5ml vial contains:- Octreotide.....1mg	086484	That this decision has been taken due to business non viability. Moreover, this product is registered but not currently marketed in Pakistan.	1. Jintrotide, M/s Accurate Medical Suppliers. 2. Jintide, M/s Accurate Medical Suppliers. 3. Asterotide, Aster Life Sciences. 4. Sanotide, M/s CCL Pharma. 5. Octreotide, Revive Healthcare. 6. Hatide, M/s Hygeia.

Firm has submitted following supporting documents:

- Application with a fee Rs.7500/- for each product
- Copies of registration letters & last renewal.
- Alternate brand names.
- Justification.
- An undertaking that:
 - No case is pending at any forum / court of law regarding this product.
 - Provided information/ documents are true/ correct.

Decision:

Registration Board acceded the firm's request for de-registration of following imported products:

S. No	Product(s) Name	Reg. No.
1.	Sandostatin 0.2mg/ml vial Each 5ml vial contains:- Octreotide.....1mg	086484

Case.No.11: REQUEST OF M/S NOVARTIS PHARMA (PAKISTAN) LIMITED, KARACHI FOR DE-REGISTRATION OF REGISTERED PRODUCTS.

M/s Novartis Pharma (Pakistan) Limited, 15 West Wharf, Dockyard Road, Karachi has submitted request for de-registration of following registered imported product as per details mentioned alongside.

S. No	Product(s) Name	Reg. No.	Reason for De-Reg. (stated by firm)	Alternative Registered Product
1.	Sandostatin LAR 10mg Injection Each vial contains:- Octreotide acetate...10mg	027323	Product was never marketed after its initial registration, furthermore, its approved MRP is not viable. Thus we are not able to continue mentioned product as per global directives.	1. Asterotide, M/s Hoffman Health Pakistan Ltd. 2. Hatide, M/s Hygeia. 3. Jintrotide, M/s Accurate Medical Suppliers.

Firm has submitted following supporting documents:

- Application with a fee Rs.7500/- for each product
- Copies of registration letters & last renewal.
- Alternate brand names.
- Justification.
- An undertaking that:
 - No case is pending at any forum / court of law regarding this product.
 - Provided information/ documents are true/ correct.

Decision:

Registration Board acceded the firm's request for de-registration of following imported products:

S. No	Product(s) Name	Reg. No.
1.	Sandostatin LAR 10mg Injection Each vial contains:- Octreotide acetate...10mg	027323

Case.No.12: REQUEST OF M/S NOVARTIS PHARMA (PAKISTAN) LIMITED, KARACHI FOR DE-REGISTRATION OF REGISTERED PRODUCTS.

M/s Novartis Pharma (Pakistan) Limited, 15 West Wharf, Dockyard Road, Karachi has submitted request for de-registration of following registered imported product as per details mentioned alongside.

S. No	Product(s) Name	Reg. No.	Reason for De-Reg. (stated by firm)	Alternative Registered Product
1.	Afinitor 2mg dispersible Tablets Each dispersible tablet contains: Everolimus.....2mg	088396	Product was never marketed after its initial registration, furthermore, its approved MRP is not viable. Thus we are not able to continue mentioned product as per global directives.	1. Evrilus 10mg, M/s Navegal Pharma. 2. Everus 10mg, M/s Pharmasol. 3. Everus 5mg, M/s Pharmasol.
2.	Afinitor 3mg dispersible Tablets Each dispersible tablet contains: Everolimus.....3mg	088397		
3.	Afinitor 5mg dispersible Tablets Each dispersible tablet contains: Everolimus.....5mg	088398		
4.	Afinitor 2.5mg Tablets Each tablet contains: Everolimus.....2.5mg	078105		

Firm has submitted following supporting documents:

- Application with a fee Rs.7500/- for each product
- Copies of registration letters & last renewal.
- Alternate brand names.

- d. Justification.
- e. An undertaking that:
 - i. No case is pending at any forum / court of law regarding this product.
 - ii. Provided information/ documents are true/ correct.

Decision:

Registration Board acceded the firm's request for de-registration of following imported products:

S. No	Product(s) Name	Reg. No.
1.	Afinitor 2mg dispersible Tablets Each dispersible tablet contains: Everolimus.....2mg	088396
2.	Afinitor 3mg dispersible Tablets Each dispersible tablet contains: Everolimus.....3mg	088397
3.	Afinitor 5mg dispersible Tablets Each dispersible tablet contains: Everolimus.....5mg	088398
4.	Afinitor 2.5mg Tablets Each tablet contains: Everolimus.....2.5mg	078105

Case No.13

1	Name, address of Applicant / Importer	M/s AMGOMED Office # 4, First Floor Ghausia Plaza, Jinnah Avenue Blue area Islamabad Pakistan
	Details of Drug Sale License of importer	License No: DSL-ISB-1881 M/s Amgommed office # 4, First floor Ghausia Plaza, Jinnah Avenue Blue area Islamabad Address of Godown: Office number 5, First floor Rose-I plaza, I-8 Markaz Islamabad. Validity: 21-03-2026
	Name and address of marketing authorization holder (abroad)	M/s DEVA Holding A.S. Halkalı Merkez Mah. Basın Ekspres Cad. No: 1 34303 Küçükçekmece - ISTANBUL/TURKEY
	Name, address of manufacturer(s)	M/s DEVA Holding A.S. Çerkezköy Organize Sanayi Bölgesi Karaagaç Mah. Fatih Bulvarı No: 26 Kapaklı - TEKIRDAG/TURKEY.
	Name of exporting country	Turkey

Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	COPP: Firm has attached copy of original, legalized COPP certificate (No. 2020/1389) dated 22-05-2020 issued by Republic of TURKEY MEDICINE AND MEDICAL DIVICES AGENCY For: CARBODEX 450MG/45ML SOLUTION FOR I.V INFUSION Name of dosage form of Product: CARBODEX 450MG/45ML SOLUTION FOR I.V INFUSION Active ingredient and amount per unit: CARBOPLATIN 450G /45ML The applied product is available for free sale in the market of exporting country. The facilities and operations conform to WHO-GMP.
Details of letter of authorization / sole agency agreement	Details of letter of authorization / sole agency agreement: Copy of Original legalized letter of authorization is attached whereby M/s DEVA HOLDING A.S. Turkey authorized M/s Amgomed to apply for registration, for marketing, distribution and sale of below mentioned product; CARBODEX 450MG/45ML SOLUTION FOR I.V INFUSION (CARBOPLATIN)
Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
Dy. No. and date of submission	Dy. No. 30 - 09 -2020
Details of fee submitted	PKR 300,000 /- Challan No. 83588479 & Challan No. 58246940982

The proposed proprietary name / brand name	CARBODEX 450MG/45ML SOLUTION FOR I.V INFUSION (CARBOPLATIN)
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: 450 mg/45 ml Solution for IV Infusion
Pharmaceutical form of applied drug	Solution for IV Infusion
Pharmacotherapeutic Group of (API)	Antineoplastic agents (Platinum compounds) , Alkylating agen, cytotoxic ATC-code: L01XA02
Reference to Finished product specifications	B.P Specification
Proposed Pack size	1 Vial
Proposed unit price	1's MRP as per SRO
The status in reference regulatory authorities	Carboplatin 450mg/45ml, concentrate for solution for infusion by M/s Accord Healthcare Limited, MHRA Approved
For generic drugs (me-too status)	Kemocarb Injection 450/45ml M/s Atco Laboratories Limited Head Office/Factory B-18, S.I.T.E., Karachi-75700, Pakistan.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Name, address of drug substance manufacturer	Name and Address of the manufacturer: SICOR DE MEXICO S.A de C.V Av. San Rafael No.35 Parque Industrial Lerma Lerma, Edo. de Mexico C.P 52000 Mexico.
Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of API at accelerated as well as real time conditions. Accelerated stability studies are conducted at 40 ±2°C / 75 ±5% RH for 6 months.

		Long term stability studies are conducted at 25 ±2°C / 60 ±5% RH for a maximum of 5 years.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted data of Pharmaceutical Equivalence: Carbodex 10mg / ml (450 mg/45 ml) Solution for I.V. Infusion product comparable in formulation, concentration and administration with the reference innovator product of DBL Carboplatin Injection 10mg / ml (450mg /45ml) (Hospira H0216 76AD)
	Analytical method validation/verification of product	The firm has submitted relevant data including analytical method validation for the drug product including the impurities
	Container closure system of the drug product	Carbodex 450 mg/45 ml Solution for I.V. Infusion is 50 ml, amber colored Type I glass vial sealed with Type I grey bromobutyl coated rubber stopper and aluminum cap with blue plastic flip-off component.
	Stability study data of drug product, shelf life and storage conditions	Long -Term Stability Studies 18Months Storage conditions: 30°C ± 2°C, 65 ± 5 % RH Accelerated Stability Studies Storage conditions: 40°C ± 2°C, 75 ± 5 % RH
Evaluation by PEC:		

Decision:

Approved as per policy of inspection of manufacturer abroad. Registration letter will be issued upon submission of Original & Legalized CoPP and Letter of Authorization.

Case No.14. CANCELLATION OF DRUG MANUFACTURING LICENSES BY CENTRAL LICENSING BOARD.

The Central Licensing Board has cancelled Drug Manufacturing Licenses of following firms. Details are as under:

Sr. No.	Name of Firm	DML No.	Meeting No. of CLB	Letter dated
1.	M/s Westmont Pharmaceuticals Industry, Mini Industrial Estte, GT	DML#000631 (Formulation).	-	16-09-2024

	Road, Gujar khan, Rawalpindi	Duration from 19-06-2018 to 18-06-2023 renewal not received DML is invalid		
2.	M/s Bio Fine Pharmaceuticals (Pvt) Ltd, 74-Industrial Estate, Multan	DML#000334 (Formulation). Duration from 19-07-2024 to 18-07-2029 renewal received after sixty days of the expiry of period of validity of License DML is invalid	-	09-12-2024
3.	M/s Agror Pharma, Plot No.4, Street No.SS-4, National Industrial Zone, Rawat.	DML#000791 (Formulation). Duration from 03-02-2024 to 02-02-2029 No response was received from firm DML is invalid	-	16-12-2024
4.	M/s Munawar Pharma (Pvt) Ltd, 31-KM, Ferozpur Road, Lahore	DML#000334 (Formulation). Duration from 12-01-2024 to 11-01-2029 No response was received from firm DML is invalid		16-12-2024
5.	M/s Caylex Pharmaceuticals (Pvt) Ltd, 10-Km, Main Raiwind Road, Lahore	DML#000451 (Formulation). Suspend for 03 months	309 th meeting of CLB	13-06-2025
Decision: Central Licensing Board considered facts, your reply decided as under: “No one appeared on behalf of the firm before the Board. The Board after perusal of record and facts decided to suspend the DML No. 000541 (formulation) of M/s Caylex Pharmaceuticals (Pvt) Ltd, 10-Km, Main Raiwind Road, Lahore for 03 months for fulfilment of codal formalities under section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (Licensing, Registering & Advertising) rules, 1976 for not complying the provisions of Rule 5 (2A), 16 and 19 of the Drugs (Licensing, Registering & Advertising) rules, 1976.				
6.	M/s. Novex Pharma, Plot No.54, Street No.S-6, National Industrial Zone, Rawat.	DML#000898 (Formulation). Suspend till the completion of codal formalities	309 th meeting of CLB	13-06-2025
Decision: Central Licensing Board considered facts, your reply decided as under: “Mr. Khurram Shahzad (Director) and Mr. Abdul Aleem (QC Incharge) appeared and represented the firm before the Board. They contended that they will submit all the required documents including updated nothing due certificate regarding CRF. The Board after perusal of record and facts decided to suspend the DML No. 000898 (formulation) of M/s Novex Pharma, Plot No.54, Street No.S-6, National Industrial Zone, Rawat till fulfilment of codal formalities under section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (Licensing,				

Registering & Advertising) rules, 1976 for not complying the provisions of Rule 5 (2A) of the Drugs (Licensing, Registering & Advertising) rules, 1976. The Board also authorized the Chairman CLB for revocation of DML suspension in case of completion of the application.				
7.	M/s. Humayun International Pharma (Pvt) Ltd, 20-KM, Satiana Road, Faisalabad.	DML#000443 (Formulation). Stands cancelled	309 th meeting of CLB	03-06-2025
Decision: Central Licensing Board considered facts, your reply decided as under: “Mr. Nadeem Abbas appeared and represented the firm before the Board. However, Mr. Nadeem Abbas did not present the required documents and he contended that unit is non-functional since 2022. The Board after perusal of record and facts decided to cancel the Drug Manufacturing License No. 000443 (by way of formulation) of M/s Humayun International Pharma (Pvt) Ltd, 20-KM, Satiana Road, Faisalabad under section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (Licensing, Registering & Advertising) rules, 1976 for not complying the provisions of Rule 5 (2A), 16 and 19 of the Drugs (Licensing, Registering & Advertising) rules, 1976.				

Proceedings of 348th Meeting:

Registration Board was apprised that in 307th meeting of the Board, case regarding suspension of DML was discussed with Mr. Amar Latif, Deputy Director (Legal Affairs Division, DRAP). He informed that suspension of DML is for a specified period and is temporary in nature. The suspension is terminated at the end of specified period or earlier on the rectification of deficiencies, which formed basis of suspension, to the satisfaction of the CLB. Since the firm cannot continue manufacturing operations during the suspension of DML, there is no need to suspend registration of drugs.

Decision:

Keeping in view the aforementioned explanation given by Deputy Director (Legal Affairs Division, DRAP), Registration Board noted the information regarding suspension of drug manufacturing license of M/s Caylex Pharmaceuticals (Pvt) Ltd and M/s. Novex Pharma.

Furthermore, keeping in view the decisions taken by the Central Licensing Board regarding cancellation of DMLs of above-mentioned firms, Registration Board decided to cancel all the registered drugs w.e.f. date of cancellation of DML, in the name of following firms;

- 1. M/s Westmont Pharmaceuticals Industry, Mini Industrial Estte, GT Road, Gujar khan, Rawalpindi.**
- 2. M/s Bio Fine Pharmaceuticals (Pvt) Ltd, 74-Industrial Estate, Multan.**
- 3. M/s Agror Pharma, Plot No.4, Street No. SS-4, National Industrial Zone, Rawat.**
- 4. M/s Munawar Pharma (Pvt) Ltd, 31-KM, Ferozpur Road, Lahore.**
- 5. M/s. Humayun International Pharma (Pvt) Ltd, 20-KM, Satiana Road, Faisalabad.**

Case No. 01: Standardization of formulation as per RRA

- i. **M/s. Crystolite Pharmaceuticals, Plot No. 1& 2, S-2, National Industrial Zone Rawat, Islamabad**

The Registration Board in its 336th Meeting held on 4th - 6th June, 2024 had approved following product of **M/s. Crystolite Pharmaceuticals, Islamabad:**

Product details	Decision of the 336th meeting of Registration Board
Dalofen 25mg/ml solution for Injection or Infusion Each 1ml ampoule contains: Diclofenac Sodium... 25mg Manufacture's specification 1ml x 5's, 1ml x10's ; As per SRO	Approved with following label; Each 1ml ampoule contains; Diclofenac Sodium...25mg Letter shall be issued after submission of fee of Rs. 30,000/-

Registration letter was **withheld** for confirmation of Me-Too of 1ml ampoule. The firm has submitted the fee of Rs.30,000/- vide fee challan No. 120712529538 paid on **09-07-2024** (DRAP R&I dated **18-09-2024**) along with the request for correction in label claim as under:

Sr. No.	Approved Label claim by RB in its 336th meeting	Requested Label claim
01.	Dalofen 25mg/ml solution for Injection or Infusion Each 1ml ampoule contains: Diclofenac Sodium... 25mg Manufacture's specification	Dalofen 25mg/ml solution for Injection or Infusion Each 3ml ampoule contains: Diclofenac Sodium... 75mg (As per Innovator's Specifications)

The demanded label claim is approved by UK-MHRA (Econac 75 mg/3 ml Solution for Injection; One ampoule contains 75 mg Diclofenac sodium in 3 ml injectable solution). The generic is also approved for M/s Searle Company Limited, Karachi i.e. **Defnac Injection 75mg/3ml** with Registration No. **053338**.

Decision: **Registration Board decided to approve the correction in above product with following details.**

**Dalofen 25mg/ml solution for Injection or Infusion
Each 3ml ampoule contains:
Diclofenac Sodium... 75mg
(As per Innovator's Specifications)**

Item No. VI Division of Biological Evaluation & Research

**Minutes of Supplementary Agenda of 348th Meeting of Registration
Board Division of Biological Evaluation & Research**

S. No.	Category Summary of Cases	No. of Cases
1.	Registration Applications of Vaccines (Human)	19
2.	Registration Applications of Monoclonal Antibodies (Human)	08
3.	Registration Applications of Misc. Biological Products (Human)	09
4.	Registration Applications of Veterinary Biological Products	23
Total		59

Agenda Item No 1
Registration Applications of Vaccines

1.	Meningococcal vaccines	2
2.	Influenza vaccines	4
3.	Tetanus Toxoid	3
4.	Malaria Vaccine	2
5.	Human Papillomavirus (HPV)	1
6.	Polio Vaccines	2
7.	Enterovac vaccine	1
8.	MMR vaccine	1
9.	Hepatitis Vaccines	3
	Total	19

Meningococcal vaccines

- Meningococcal vaccines containing **unconjugated purified capsular polysaccharides (A, C, Y and W)** have been available since the 1970s and are still used to immunize travelers and at risk individuals. **Conjugated vaccine** containing polysaccharide chemically conjugated to a protein carrier such as the non-toxic diphtheria toxin CRM 197 or tetanus toxoid are also now available. Vaccines can be formulated as bivalent (groups A and C) or tetravalent (groups A, C, Y, and W135) OR pentavalent. The vaccine approved in reference regulatory authorities as declared by RB are all Conjugated vaccines.
- **Polysaccharide-protein conjugate vaccines, which are more immunogenic and effective in preventing nasopharyngeal carriage of the bacteria and thus its transmission.**
- They are available in monovalent (A or C), quadrivalent (A, C, W, Y), or combination (serogroup C and Haemophilus influenzae type b) formulations.
- For each country the choice of vaccine depends on the locally prevalent serogroup(s) of N. meningitidis (or serosubtype in case of serogroup B). Conjugate vaccines are preferred over polysaccharide vaccines due to their potential for herd protection and their increased immunogenicity, particularly in children.

Meningococcal ACYWX (Polysaccharide conjugate) 1 Dose
Deferred Case (M-345)
Exporting Country (India)

Case # 01		
Name, address of Applicant / Importer	Ms Hoffmann Human Health Pakistan Ltd., 1st 32-Babar Block New Garden Town Lahore.	
Details of Drug Sale License of importer	Type of License: To Sell Drugs as a Distributor Address: 1st Floor, 32 Babar Block, New Garden Town, Lahore. Valid up to: 29-11-2028	
Name and address of marketing authorization holder (abroad)	M/s Serum Institute of India Pvt. Ltd. Address : 212/2 Hadapsar, Pune- 411 0028, Dist: Pune-Zone 3, INDIA	
Name, address of manufacturer(s)	M/s Serum Institute of India Pvt. Ltd. Address : 212/2 Hadapsar, Pune- 411 0028, INDIA	
Name of exporting country	India	
Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	<u>Scanned Copy of Free Sale Certificate</u> Certificate No:6111434 Dated:14-02-2023 Does not provide free sale status in exporting country.	
	Validity:13-02-2024 Firms Response The product is WHO prequalified so please exempt the provision of availability of product in the country of origin. We are sending herewith WHO certification for your perusal. Valid GMP certificate not submitted.	
Details of letter of authorization / sole agency agreement	<u>Scanned Copy of Letter of Authorization</u> M/s Serum Institute of India Pvt. Ltd. Address : 212/2 Hadapsar, Pune- 411 0028, INDIA authorize Ms Hoffmann Human Health Pakistan Ltd.,1st 32-Babar Block New Garden Town Lahore.(1 dose, 5 Dose) Validity: 30-04-2025	
Status of the applicant	Importer	
Status of application	New Drug Product	
Intended use of pharmaceutical product	Domestic sale	

For imported products, specify one the these	Finished Pharmaceutical product import										
Dy. No. and date of submission	Tracking ID: LM6-UJ5-QMNZ Application Number: 16076 Date:25-09-2024										
Details of fee submitted	Challan Number: 4898164288 Paid Date: 2024-04-09 Rs 75,000/- Challan Number: 0404640745 Remaining fee: Rs. 225,000										
The proposed proprietary name / brand name	MenFive vaccine										
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each dose of 0.5ml contains: N. meningitidis group A polysaccharide Conjugated to TT 5 µg N. meningitidis group C polysaccharide Conjugated to CRM197 5 µg N. meningitidis group Y polysaccharide Conjugated to CRM197 5 µg N. meningitidis group W polysaccharide Conjugated to CRM197 5 µg N. meningitidis group X polysaccharide Conjugated to TT 5 µg Purified Tetanus Toxoid (TT) 7.8 to 33.4 µg Recombinant CRM197 (cross-reactive material 197, a nontoxic mutant of diphtheria toxin) protein 11.7 to 50.1 µg										
Clinical Indication	MenFive is indicated for active immunization of individuals aged 1-85 years against invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, Y, W, and X.										
Dosage form of applied drug	Lyophilized Powder for injection										
Route of Administration	IM										
Pharmacotherapeutic Group of (API)	ATC Code: J07AH04 Meningococcal vaccines										
Finished product specifications	Inhouse										
Proposed Pack size	Pack of 50 vials										
Proposed unit price	-										
Shelf life	36										
Storage conditions	Store in a refrigerator (+2°C to +8°C). Protect from light										
The status in reference regulatory authorities	<u>WHO Pre-Qualified Vaccine</u> Vaccine type Menigococcal ACYWX (Polysaccharide conjugate) Commercial Name MenFive™ Manufacturer Serum Institute of India Pvt. Ltd. URL http://www.seruminstitute.com/ Responsible NRA Central Drugs Standard Control Organization Country India URL www.cdsco.nic.in Prequalification Prequalification Status: Current Effective Date: 06/07/2023										
For generic drugs (me-too status)	NA										
Meningococcal A Tetanus Toxoid (Men A-TT) Bulk Conjugate, Men A TT Conjugate Bulk, NmCV5-A-Conjugate Bulk											
Name, address of drug substance manufacturer	<table border="1"> <caption>Table 1: MenA-TT Conjugate Bulk Drug Substance Manufacturer</caption> <thead> <tr> <th>Manufacturer Name</th><th>Manufacturer Address</th></tr> </thead> <tbody> <tr> <td>Serum Institute of India Pvt. Ltd.</td><td>212/2 Hadapsar, Pune 411028, Maharashtra, INDIA</td></tr> <tr> <td></td><td>Telephone: +91-20-26993900</td></tr> <tr> <td></td><td>Fax: +91-20-26993921</td></tr> <tr> <td></td><td>E-mail: parag.nagarkar@seruminstitute.com</td></tr> </tbody> </table>	Manufacturer Name	Manufacturer Address	Serum Institute of India Pvt. Ltd.	212/2 Hadapsar, Pune 411028, Maharashtra, INDIA		Telephone: +91-20-26993900		Fax: +91-20-26993921		E-mail: parag.nagarkar@seruminstitute.com
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	Telephone: +91-20-26993900										
	Fax: +91-20-26993921										
	E-mail: parag.nagarkar@seruminstitute.com										
Module-III Drug Substance:	The manufacturing of Men-A-TT Conjugate Bulk Drug Substance used in the Drug product Meningococcal (A, C, Y, W, X) Polysaccharide Conjugate Vaccine (Freeze Dried) i.e MenFive Vaccine (NmCV-5) consists of the following stages -Fermentation, Polysaccharide Purification,										

	Conjugation and Conjugate Purification. Strain details for Meningococcal Serogroup - A The source organism for generation of Cell substrate is Neisseria meningitidis A Strain M1027. The strain was isolated at Chicago, USA. The isolate was transferred to NIH in 1937. The strain M1027 derived from this isolate was freeze dried in Bethesda, Maryland in 1957.										
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Based upon the results of the stability study #1, MenA-TT Conjugate Bulk Drug Substance can be stored in Ultra low density polyethylene Hyclone (media bag) for 18 months at $\leq -20^{\circ}\text{C}$.										
MenX-TT Conjugate Bulk Drug Substance											
Name, address of drug substance manufacturer	Table 1: MenX-TT Conjugate Bulk Drug Substance Manufacturer <table border="1"> <thead> <tr> <th>Manufacturer Name</th><th>Manufacturer Address</th></tr> </thead> <tbody> <tr> <td>Serum Institute of India Pvt. Ltd.</td><td>212/2 Hadapsar, Pune 411028, Maharashtra, INDIA</td></tr> <tr> <td></td><td>Telephone: +91-20-26993900</td></tr> <tr> <td></td><td>Fax: +91-20-26993921</td></tr> <tr> <td></td><td>E-mail: parag.nagarkar@seruminstitute.com</td></tr> </tbody> </table>	Manufacturer Name	Manufacturer Address	Serum Institute of India Pvt. Ltd.	212/2 Hadapsar, Pune 411028, Maharashtra, INDIA		Telephone: +91-20-26993900		Fax: +91-20-26993921		E-mail: parag.nagarkar@seruminstitute.com
Manufacturer Name	Manufacturer Address										
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	Telephone: +91-20-26993900										
	Fax: +91-20-26993921										
	E-mail: parag.nagarkar@seruminstitute.com										
Module-III Drug Substance:	The manufacturing of Men-X-TT Conjugate Bulk Drug Substance used in the Drug Product Meningococcal (A, C, Y, W, X) Polysaccharide Conjugate Vaccine (Freeze Dried) i.e. NmCV-5 vaccine (MenFive™) consists of the following stages - Fermentation, Polysaccharide Purification, Conjugation and Conjugate Purification. Strain details for Meningococcal Serogroup - X The source organism for generation of cell bank is Neisseria meningitidis X Strain M8210. The strain was isolated at North Carolina, USA on 28.04.2001 from a human blood specimen. The strain was received by CBER, USFDA from the Centers for Disease Control, Atlanta, Georgia and transferred to SIPL in May 2012.										
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Meningococcal X-TT Conjugate Bulk Drug Substance is stable and remained within specification at real time (i.e. at or below -20°C) and accelerated ($2-8^{\circ}\text{C}$) conditions, hence 36 months retest period is assigned to Meningococcal X-TT Conjugate Bulk Drug Substance.										
N. meningitidis group C polysaccharide Conjugated to CRM197 5 µg N. meningitidis group Y polysaccharide Conjugated to CRM197 5 µg N. meningitidis group W polysaccharide Conjugated to CRM197 5 µg	Not Submitted.										
Module-III Drug Product: MenFive [Meningococcal (A, C, Y, W, X) Polysaccharide Conjugate Vaccine (Freeze-Dried)] Drug Product											
Manufacturer(s)	Table 1: MenFive [Meningococcal (A, C, Y, W, X) Polysaccharide Conjugate Vaccine (Freeze-Dried)] Drug Product Manufacturer <table border="1"> <thead> <tr> <th>Manufacturer Name</th><th>Manufacturer Address</th></tr> </thead> <tbody> <tr> <td>Serum Institute of India Pvt. Ltd.</td><td>212/2 Hadapsar, Pune 411028, Maharashtra, INDIA</td></tr> <tr> <td></td><td>Telephone: +91-20-26993900</td></tr> <tr> <td></td><td>Fax: +91-20-26993921</td></tr> <tr> <td></td><td>E-mail: parag.nagarkar@seruminstitute.com</td></tr> </tbody> </table>	Manufacturer Name	Manufacturer Address	Serum Institute of India Pvt. Ltd.	212/2 Hadapsar, Pune 411028, Maharashtra, INDIA		Telephone: +91-20-26993900		Fax: +91-20-26993921		E-mail: parag.nagarkar@seruminstitute.com
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	Telephone: +91-20-26993900										
	Fax: +91-20-26993921										
	E-mail: parag.nagarkar@seruminstitute.com										
Specification	The method and specifications in Table 1 are adopted from the following: - Inhouse - European Pharmacopoeia (Ph Eur) 10.0 Meningococcal A, C, W, Y conjugate vaccine.										
Container Closure System	Both single dose and five dose MenFive vaccine are filled in 3 mL, USP-Type I, clear tubular glass vial with 13 mm Bromo-butyl rubber stopper and 13 mm Flip-off aluminium seal.										
Stability data of drug product	On the basis of available real time (long term) stability data of 42 months for six batches manufactured for Phase I and Phase II clinical trial and 42 months real time stability data										

	of six batches manufactured for Phase III clinical trial (Phase 3 Africa and India Phase 2/3 Lot to lot consistency) along with Accelerated stability data of ten batches and High accelerated (Stressed) stability data of six batches indicating that Meningococcal A, C, Y, W, X Polysaccharide Conjugate Vaccine-Freeze dried (MenFive) is stable found within specification for 36 months at 2-8°C. Hence 36 months shelf life at 2-8°C can be assigned to Meningococcal A, C, Y, W, X Polysaccharide Conjugate Vaccine-Freeze dried (Men Five). Reconstitution Study (In Use Stability Study) MenFive [Meningococcal (A, C, Y, W, X) Polysaccharide Conjugate Vaccine (Freeze-Dried)] Drug Product (5 dose- 25mcg/dose -5 mcg of each antigen per dose) is found stable for 8 hours post reconstitution at +2-+8°C. Reconstituted Drug product batches shown to be stable for 8 hours and as per the regulatory requirement to cover atleast one immunization session i.e 6 hours (at 2-8°C)
Module-III Drug Product: Sodium Chloride Injection BP i.e. Diluent for Meningococcal (A, C, Y, W, X) Polysaccharide Conjugate Vaccine (Freeze Dried)	
Manufacturer 3.2.P.3.1	M/s Sovereign Pharma Pvt. Ltd. (SPPL) Survey No. 46/1-4, Kadaiya Village, Nani Daman – 396210, India.
Specifications 3.2.P.5.1	The analytical procedures along with acceptance criteria of Sodium Chloride Injection BP (0.9 % w/v) are as per the recent version of Pharmacopoeial method of analysis
Container Closure System	Presentation: Sodium Chloride Injection BP 0.09 % w/v is available in 1 mL (0.5 mL diluent for single dose of MenFive) and 3 mL (2.5 mL diluent for five dose of MenFive) in OPC Neutral Type-I glass ampoule for reconstitution of MenFive
Stability Summary and Conclusion 3.2.P.8.1 -	The stability studies performed on Sodium Chloride Injection BP 0.9%w/v batches are stable up to 24 months when stored in glass ampoule at 30 ± 2°C 65 ± 5% RH, +2°C to 8°C and 40 ± 2°C 75 ± 5% RH stability conditions and Stable up to 48 months when stored at 30 ± 2°C 65 ± 5% RH.
	Five preclinical studies contributed nonclinical pharmacology data: 1) Study 7, which evaluated the immunogenicity of Men X-TT with and without aluminium phosphate adjuvant in Swiss albino mice. 2) Study 1557-05389, which evaluated the immunogenicity of Men X-TT in candidate SIPL NmCV-5 presentation with and without aluminium phosphate adjuvant in BALB/c mice. 3) Study 13, which evaluated the immunogenicity of three candidate SIPL NmCV-5 formulations with aluminium phosphate adjuvant in comparison to Menveo® and Menactra® in New Zealand white rabbits. 4) Study 18-19, which evaluated the immunogenicity of SIPL NmCV-5 (clinical formulation) with and without aluminium phosphate adjuvant in New Zealand white rabbits. 5) Study PATH MVPP 2021/1, this study was to determine the immunogenicity of adjuvanted and non-adjuvanted pentavalent (A, C, W, Y and X) meningococcal polysaccharide conjugate vaccine (NmCV-5) formulations in female Sprague-Dawley rats of reproductive age following three intramuscular doses of 40% of a standard human dose (SHD) given on Day 1 (Dose 1), Day 15 (Dose 2) and Day 29 (Dose 3). Immunogenicity was quantified with regards to the presence of IgG antibodies to meningococcal serogroups A, C, W, Y and X polysaccharides (PS) in rat serum samples taken at three time points namely Day 1 (pre-immunisation), Day 22 (1 week post-dose 2) and Day 36 (1 week post-dose 3), in the study.
5.3 Clinical Study Reports	
5.3.1 Reports of Biopharmaceutic Studies	Biopharmaceutical studies are not relevant for vaccines, with the exception of vaccines with novel adjuvants, which is not the case for the NmCV-5 as it is unadjuvanted. Biopharmaceutical studies have therefore not been performed.
5.3.2 Reports of Studies Pertinent to Pharmacokinetics	This section is not applicable to Meningococcal (A,C,Y,W,X) Polysaccharide Conjugate Vaccine (Freeze-Dried)
using Human Biomaterials	
5.3.3 Reports of Human Pharmacokinetic (PK) Studies	This section is not applicable to Meningococcal (A,C,Y,W,X) Polysaccharide Conjugate Vaccine (Freeze-Dried)
5.3.4 Reports of Human Pharmacodynamic (PD) Studies	This section is not applicable to Meningococcal (A,C,Y,W,X) Polysaccharide Conjugate Vaccine (Freeze-Dried)
5.3.5.2 Reports of Efficacy and Safety Studies	The following study reports are provided with this section. Phase 1 Study: Study Title: A Phase 1, double blind, randomized, controlled study to evaluate the safety and immunogenicity of a new Meningococcal Conjugate Vaccine containing serogroups A, C, Y, W and X in healthy adults.
5.3.5.3 Study Reports of Uncontrolled Clinical Studies	Study Report No.: ACYWX-01/ VAC-046

5.3.5.4 Reports of Analyses of Data from More Than One Study	Phase 2 Study: Study Title: A Phase 2, Observer-blind, Randomized, Controlled Study to Evaluate the Safety and Immunogenicity of Two Formulations of Investigational Meningococcal Groups ACYWX Conjugate Vaccine, Administered to Healthy Malian Children 12-16 Months of Age Study Report No.: ACYWX-02 / CVIA058 Phase 3 Study: Study Title: A Phase 3, observer-blind, randomized, active controlled trial to assess the safety of an investigational meningococcal serogroups ACYWX conjugate vaccine (NmCV-5) and compare its Immunogenicity to a Licensed Meningococcal Serogroups ACYW Conjugate Vaccine (Menactra®), in Healthy Subjects 2 to 29 Years of Age Study Report No.: ACYWX-03, CVIA 071 Study Report No.: Study ACYWX-03, CVIA 071 Clinical Study Report Addendum Phase 2/3 Study: Study Title: A Phase 2/3, Randomized, Observer-blind, Controlled, Multi-Center Study TO Evaluate the Lot-to-Lot Consistency of SIIPL Meningococcal ACYWX Conjugate Vaccine (NmCV-5) and to Compare its Safety and Immunogenicity with that of Licensed Meningococcal ACYW Vaccine Menactra® in Healthy Individuals 18-85 Years of Age Study Report No.: ACYWX-04 Note: Phase 2/3 Study is completed and CSR report will be available in March-April 2022 for submission.
5.3.6 Reports of Post-Marketing Experience.	The Reports of Post-Marketing Experience for Meningococcal (A,C,Y,W,X) Polysaccharide Conjugate Vaccine (Freeze-Dried) are not available presently

Evaluation by BE&R

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	Form 5 F/Module 1	Separate registration applications for 1 dose and 5 doses are required. Clarification whether it is combo pack application or otherwise.
2.	1.3.4	Hard copy of original or notarized copy of Letter of Authorization. Hard copy of original, legalized and valid COPP for powder and diluent.
3.	1.5.5	Pharmacotherapeutic group of applied vaccine.
4.	1.5.6	Specify the reference to Pharmacopoeial specifications as per Drug Specification Rules 1978 and guidance document regarding application of Drug Product Specifications.
5.	1.5.9	Provide details of prevalence of serogroup X strain in Pakistan, country of origin or any other NRA.
6.	3.2.S.2 to 7	Complete and separate drug substance part of each monovalent bulk conjugates from S1 to S 7 .(A,C,W,X,Y)
7.	3.2.R	Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3.
8.	Module 4	Proper justification with evidence of reference guidelines were “Not applicable” has been mentioned for non-clinical study reports like safety pharmacology, drug interaction, pharmacokinetic, genotoxicity, carcinogenicity and other toxicity studies.
9.	Module 5 Clinical Data	e)Complete Clinical study reports (Phase1, Phase2 and Phase3) along with raw data or in the case of non-conductance of any required studies provide justification on the basis of reference guidelines. f)Updated Clinical studies with claimed indication. g) Risk Management Plan (RMP) h)Periodic Safety Update Report (PSUR)/Periodic Benefit-Risk Evaluation Report (PBRER) i)Adverse event following immunization report (summary of annual reports) in the country of origin or any other NRA.

Previous Decision of 345th Meeting:

- The Registration Board deferred the formulation for submission of the following requisite documents: Separate registration applications for 1 dose and 5 doses are required.
- Clarification whether it is combo pack application or otherwise.
- Hard copy of original or notarized copy of Letter of Authorization.
- Hard copy of original, legalized and valid COPP for powder and diluent.
- Pharmacotherapeutic group of applied vaccine.
- Specify the reference to Pharmacopoeial specifications as per Drug Specification Rules 1978 and guidance

document regarding application of Drug Product Specifications. • Provide details of prevalence of serogroup X strain in Pakistan, country of origin or any other NRA. • Complete and separate drug substance part of each monovalent bulk conjugates from S1 to S 7 ○ .(A,C,W,X,Y) • Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3. • Proper justification with evidence of reference guidelines were “Not applicable” has been mentioned for non-clinical study reports like safety pharmacology, drug interaction, pharmacokinetic, genotoxicity, carcinogenicity and other toxicity studies. • Complete Clinical study reports (Phase1, Phase2 and Phase3) along with raw data or in the case of non- conductance of any required studies provide justification on the basis of reference guidelines. • Updated Clinical studies with claimed indication. • Risk Management Plan (RMP) • Periodic Safety Update Report (PSUR)/Periodic Benefit-Risk Evaluation Report (PBRER) • Adverse event following immunization report (summary of annual reports) in the country of origin or any other NRA.			
Evaluation by BE&R			
S. No	Sections	Observations/Deficiencies/ Short-comings	Applicant Response
1.	Form 5 F/Module 1	a)Separate registration applications for 1 dose and 5 doses are required. b)Clarification whether it is combo pack application or otherwise.	a)Release consider this application for 1 dose however, we will apply for 5 doses presentation separately. b)hereby clarify that this is for combo pack application SIPL 15.02.2025: The standard pack size available for MenFive 1 dose and 5 dose is box of 50 vials. The diluent is also supplied in a pack of 50 ampoules as the secondary pack presentation.
2.	1.3.4	a)Hard copy of original or notarized copy of Letter of Authorization. b)Hard copy of original, legalized and valid COPP for powder and diluent	a)Hard copy of Authorization letter is available and it will be sent in original to your office. b)Hard copy of CoPP for Powder is available and it will be sent in original to your office c)Besides, as communicated through mail, the COPP for the diluent is awaited to be issued by the FDA. Once, the same is obtained, can be provided
3.	1.5.5	Pharmacotherapeutic group of applied vaccine.	Following is Pharmacotherapeutic group: Pharmacotherapeutic group: J07AH – Meningococcal vaccines (ATC Code: J07AH) Meningococcal vaccines fall under the ATC (Anatomical Therapeutic Chemical) classification system as J07AH, which includes bacterial vaccines specifically designed to protect against Neisseria meningitidis infections.

4.	1.5.6	Specify the reference to Pharmacopoeial specifications as per Drug Specification Rules 1978 and guidance document regarding application of Drug Product Specifications.	WHO Prequalification: The MenFive vaccine is WHO-prequalified, meeting international quality, safety, and efficacy standards. Manufacturer's Specifications: The product is manufactured in compliance with WHO guidelines and GMP standards, with specifications set by the manufacturer being Meningococcal A, C, Y, W, X Polysaccharide conjugate vaccine manufactured for the first time and no guidance was available for Meningococcal Multivalent vaccine in either Pharmacopoeia or WHO. Reference to Pharmacopoeial Specifications: The available recognized pharmacopoeia for Multivalent Meningococcal A, C, Y, W Polysaccharide conjugate vaccine viz. European Pharmacopoeia (Ph. Eur.) is referenced for the drug product specifications, which is available for specifically serotypes A, C, Y, and W. Therefore, the product specification referred to complies with in-house and Ph. Eur. specifications. There is currently no specific pharmacopoeial monograph for this Meningococcal Multivalent A, C, Y, W, X combination vaccine. However, individual monographs exist for certain (serogroup A and C) meningococcal serogroups in pharmacopoeias as well as WHO. WHO-prequalified vaccines follow WHO TRS (Technical Report Series) and vaccine evaluation guidelines. Regulatory Consideration: WHO-prequalified vaccines are widely accepted based on manufacturer specifications when no pharmacopoeial monograph is available.
5.	1.5.9	Provide details of prevalence of serogroup X strain in Pakistan, country of origin or any other NRA.	Neisseria meningitidis, the bacterium responsible for invasive meningococcal disease (IMD), is classified into several serogroups, with A, B, C, W, Y, and X being the most notable. In Pakistan, serogroup A has historically been the primary cause of meningococcal outbreaks. For instance, a significant serogroup A epidemic occurred in Karachi in 1988, resulting in 112 cases with an 11% overall mortality rate. Regarding serogroup X, there is limited data on its prevalence in Pakistan. The absence of reported cases suggests that serogroup X is either rare or underreported in the country. Globally, serogroup X has been responsible for outbreaks between 2006 and 2010 in countries such as Kenya, Niger, and Togo.

			Furthermore, vaccination of Hajj and Umrah pilgrims is essential during their visit to Saudi Arabia. Saudi health authorities mandate vaccination against	
			meningococcal disease to prevent outbreaks among large gatherings of international travelers. Ensuring broad vaccine coverage against multiple serogroups, including serogroup X, is crucial for protecting pilgrims and reducing disease transmission.	
6.	3.2.S.2 to 3.2.S.7	Complete and separate drug substance part of each monovalent bulk conjugates from S1 to S 7 .(A,C,W,X,Y)	Complete and separate drug substances part of each monovalent bulk conjugates from S1 to S6 (A,C,W,X,Y) are attached herewith in Module 3 and remaining from S7 to S11 are attached herewith as Annex 1	
7.	3.2.R	Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3.	Regarding copies of BMR from Serum Institute of India SIPL 15.02.2025: Summary Lot Protocols for Production and Testing are enclosed for MenFive stability batches used in Phase III clinical studies as well as commercial scale batches.	
8.	Module 4 Non-Clinical Data	Proper justification with evidence of reference guidelines were “Not applicable” has been mentioned for non-clinical study reports like safety pharmacology, drug interaction, pharmacokinetic, genotoxicity, carcinogenicity and other toxicity studies.	For justification SIPL 15.02.2025: The same will be provided shortly.	
9.	Module 5 Clinical Data	a) Complete Clinical study reports (Phase1, Phase2 and Phase3) along with raw data or in the case of non- conductance of any required studies provide justification on the basis of reference guidelines. b) Updated Clinical studies with claimed indication. c) Submit following details for clinical evaluation in tabular form:	a) Regarding complete clinical study reports b) SIPL 15.02.2025: Complete clinical study reports are shared in submitted Module 5. c) Please refer submitted section 2.7 Clinical Summary of Module 2. This includes the requisite details in tabular format. Please let us know if any additional information is required. d) The Risk Management Plan is enclosed in CTD dossier	
		• Dose • Clinical development phase • Study design • Number of subjects • Age Schedule • Route of administration of the vaccine d) Risk Management Plan (RMP) e) Periodic Safety Update Report (PSUR)/Periodic Benefit-Risk Evaluation Report(PBRER) f) Adverse event following immunization report	e) The PSURs for last one year are enclosed in CTD dossier f) Please refer to the enclosed PSURs in CTD dossier	

		(summary of annual reports) in the country of origin or any other NRA.		
Remarks by BE&R Division Recommended for approval on the basis of WHO PQ Status and submission of following two documents: - Stability data of drug product of commercial batches till claimed shelf life. - Drug substance part of C-CRM197and W-CRM197 - COPP with combo pack. - Proper justification with evidence of reference guidelines were “Not applicable” has been mentioned for non-clinical study reports like safety pharmacology, drug interaction, pharmacokinetic, genotoxicity, carcinogenicity and other toxicity studies				
Previous Decision of 347th Meeting The Registration Board deferred the case for the submission of the following documents: Stability data of drug product of commercial batches till claimed shelf life. Drug substance part of C-CRM197and W-CRM197. COPP with combo pack. Proper justification with evidence of reference guidelines were “Not applicable” has been mentioned for non-clinical study reports like safety pharmacology, drug interaction, pharmacokinetic, genotoxicity, carcinogenicity and other toxicity studies.				
Evaluation by BE&R				
Sr. No.	Deficiencies	Response		
1)	Stability data of drug product of commercial batches till claimed shelf life.	MenFive was launched recently in September 2022. WHO PQ approval is received in July 2023. Complete stability data for claimed shelf life is available for clinical batches. The same has been enclosed in the submitted dossier. Stability data for commercial batches is on-going. Stability data for 1 dose commercial batches: 3 batches; 6 months long term, 6 months accelerated for 1 batch and 3 months accelerated for 2 batchesThe stability study for commercial batches of 1 dose presentation was initiated recently. <i>As this vaccine is WHO-prequalified with a shelf life of 36 months, we kindly request you to consider this product for conditional acceptance. We hereby undertake that, upon completion of the ongoing studies on commercial batches, we will submit the relevant data without any further delay.</i>		
2)	Drug substance part of C-CRM197and W-CRM197.	Drug Substance part of C-CRM197 is attached as Annex 3 and W-CRM197 is attached as Annex 4 for your perusal.		
3)	COPP with combo pack.	Our principal has applied COPP for dilute and hopefully it will be issued within next week. As soon as the same received we hereby assure you that we will submit to your office without any further delay.		
4)	Proper justification with evidence of reference guidelines were “Not applicable” has been mentioned for non-clinical study reports like safety pharmacology, drug interaction, pharmacokinetic, genotoxicity, carcinogenicity and other toxicity studies.	Reference guidelines of WHO Expert Committee on Biological Standardization are attached as Annexure 5 which reflect that testing / non clinical trial is not required for vaccine; A		
Conclusion: The product is approvable based on its WHO Prequalification (PQ) status; however, still deficient for the submission of stability data for commercial batches and the Certificate of Pharmaceutical Product (COPP). For combo pack.				
Decision of 348th Meeting The Registration Board approved the single dose vial formulation on the basis of WHO Prequalification (PQ) status as per current policy for inspection of manufacturers abroad notified vide Letter No.3-2/2005-Reg-I /Vol-II dated July 6, 2022. Registration letter will be issued on submission of stability data for commercial batches and the Certificate of Pharmaceutical Product (COPP) for combo pack.				

Meningococcal ACYWX (Polysaccharide conjugate) 5 Dose
Deferred Case-347

Case # 02

Name, address of Applicant / Importer	Ms Hoffmann Human Health Pakistan Ltd., 1st 32-Babar Block New Garden Town Lahore.
Details of Drug Sale License of importer	Type of License: To Sell Drugs as a Distributor Address: Ist Floor, 32 Babar Block, New Garden Town, Lahore. Valid up to: 29-11-2028
Name and address of Marketing authorization holder (abroad)	M/s Serum Institute of India Pvt. Ltd. Address : 212/2 Hadapsar, Pune- 411 0028, Dist: Pune-Zone 3, INDIA
Name, address of manufacturer(s)	M/s Serum Institute of India Pvt. Ltd. Address : 212/2 Hadapsar, Pune- 411 0028, INDIA
Name of exporting country	India
Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	<u>Scanned Copy of Free Sale Certificate</u> Certificate No:6111434 Dated:14-02-202023 Does not provide free sale status in exporting country. Validity:13-02-2024 Firms Response The product is WHO prequalified so please exempt the provision of availability of product in the country of origin. We are sending herewith WHO certification for your perusal. Valid GMP certificate not submitted.
Details of letter of authorization / sole agency agreement	<u>Scanned Copy of Letter of Authorization</u> M/s Serum Institute of India Pvt. Ltd. Address : 212/2 Hadapsar, Pune- 411 0028, INDIA authorize Ms Hoffmann Human Health Pakistan Ltd.,1st 32-Babar Block New Garden Town Lahore.(1 dose, 5 Dose) Validity: 30-04-2025
Status of the applicant	Importer
Status of application	New Drug Product
Intended use of pharmaceutical product	Domestic sale
For imported products, specify one the these	Finished Pharmaceutical product import
Dy. No. and date of submission	Tracking ID:1ZW-P83-JWUA Application Number:90928 Date:21-04-2024
Details of fee submitted	Challan Number: 1473102786 Division: Biological Evaluation & Registration Paid Fee: 300000.
The proposed proprietary name / brand name	MenFive vaccine
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each dose of 0.5ml contains: N. meningitidis group A polysaccharide Conjugated to TT 5 µg N. meningitidis group C polysaccharide Conjugated to CRM197 5 µg N. meningitidis group Y polysaccharide Conjugated to CRM197 5 µg N. meningitidis group W polysaccharide Conjugated to CRM197 5 µg N. meningitidis group X polysaccharide Conjugated to TT 5 µg Purified Tetanus Toxoid (TT) 7.8 to 33.4 µg Recombinant CRM197 (cross-reactive material 197, a nontoxic mutant of diphtheria toxin) protein 11.7 to 50.1 µg
Clinical Indication	MenFive is indicated for active immunization of individuals aged 1-85 years against invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, Y, W, and X.
Dosage form of applied	Lyophilized Powder for injection
drug	
Route of Administration	IM
Pharmacotherapeutic Group of (API)	ATC Code: J07AH04 Meningococcal vaccines
Finished product	Inhouse

specifications					
Proposed Pack size	Pack of 50 vials				
Proposed unit price	-				
Shelf life	36				
Storage conditions	Store in a refrigerator (+2°C to +8°C). Protect from light				
The status in reference regulatory authorities	WHO Pre-Qualified Vaccine Vaccine type Menigococcal ACYWX (Polysaccharide conjugate) Commercial Name MenFive™ Manufacturer Serum Institute of India Pvt. Ltd. URL http://www.seruminstitute.com/ Responsible NRA Central Drugs Standard Control Organization Country India URL www.cdsco.nic.in Prequalification Prequalification Status: Current Effective Date: 06/07/2023				
For generic drugs (me-too status)	NA				
Meningococcal A Tetanus Toxoid (Men A-TT) Bulk Conjugate, Men A TT Conjugate Bulk, NmCV5-A-Conjugate Bulk					
Name, address of drug substance manufacturer	Table 1: MenA-TT Conjugate Bulk Drug Substance Manufacturer <table border="1"> <thead> <tr> <th>Manufacturer Name</th><th>Manufacturer Address</th></tr> </thead> <tbody> <tr> <td>Serum Institute of India Pvt. Ltd.</td><td> 212/2 Hadapsar, Pune 411028, Maharashtra, INDIA Telephone: +91-20-26993900 Fax: +91-20-26993921 E-mail: parag.nagarkar@seruminstitute.com </td></tr> </tbody> </table>	Manufacturer Name	Manufacturer Address	Serum Institute of India Pvt. Ltd.	212/2 Hadapsar, Pune 411028, Maharashtra, INDIA Telephone: +91-20-26993900 Fax: +91-20-26993921 E-mail: parag.nagarkar@seruminstitute.com
Manufacturer Name	Manufacturer Address				
Serum Institute of India Pvt. Ltd.	212/2 Hadapsar, Pune 411028, Maharashtra, INDIA Telephone: +91-20-26993900 Fax: +91-20-26993921 E-mail: parag.nagarkar@seruminstitute.com				
Module-III Drug Substance:	The manufacturing of Men-A-TT Conjugate Bulk Drug Substance used in the Drug product Meningococcal (A, C, Y, W, X) Polysaccharide Conjugate Vaccine (Freeze Dried) i.e MenFive Vaccine (NmCV-5) consists of the following stages -Fermentation, Polysaccharide Purification, Conjugation and Conjugate Purification. Strain details for Meningococcal Serogroup - A The source organism for generation of Cell substrate is Neisseria meningitidis A Strain M1027. The strain was isolated at Chicago, USA. The isolate was transferred to NIH in 1937. The strain M1027 derived from this isolate was freeze dried in Bethesda, Maryland in 1957.				
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Based upon the results of the stability study #1, MenA-TT Conjugate Bulk Drug Substance can be stored in Ultra low density polyethylene Hyclone (media bag) for 18 months at $\leq -20^{\circ}\text{C}$.				
MenX-TT Conjugate Bulk Drug Substance					
Name, address of drug substance manufacturer	Table 1: MenX-TT Conjugate Bulk Drug Substance Manufacturer <table border="1"> <thead> <tr> <th>Manufacturer Name</th><th>Manufacturer Address</th></tr> </thead> <tbody> <tr> <td>Serum Institute of India Pvt. Ltd.</td><td> 212/2 Hadapsar, Pune 411028, Maharashtra, INDIA Telephone: +91-20-26993900 Fax: +91-20-26993921 E-mail: parag.nagarkar@seruminstitute.com </td></tr> </tbody> </table>	Manufacturer Name	Manufacturer Address	Serum Institute of India Pvt. Ltd.	212/2 Hadapsar, Pune 411028, Maharashtra, INDIA Telephone: +91-20-26993900 Fax: +91-20-26993921 E-mail: parag.nagarkar@seruminstitute.com
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Serum Institute of India Pvt. Ltd.	212/2 Hadapsar, Pune 411028, Maharashtra, INDIA Telephone: +91-20-26993900 Fax: +91-20-26993921 E-mail: parag.nagarkar@seruminstitute.com				
Module-III Drug Substance:	The manufacturing of Men-X-TT Conjugate Bulk Drug Substance used in the Drug Product Meningococcal (A, C, Y, W, X) Polysaccharide Conjugate Vaccine (Freeze Dried) i.e. NmCV-5 vaccine (MenFive™) consists of the following stages - Fermentation, Polysaccharide Purification, Conjugation and Conjugate Purification. Strain details for Meningococcal Serogroup - X The source organism for generation of cell bank is Neisseria meningitidis X Strain M8210. The strain was isolated at North Carolina, USA on 28.04.2001 from a human blood specimen. The strain was received by CBER, USFDA from the Centers for Disease Control, Atlanta, Georgia and transferred to SIPL in May 2012.				
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Meningococcal X-TT Conjugate Bulk Drug Substance is stable and remained within specification at real time (i.e. at or below -20°C) and accelerated (2-8°C) conditions, hence 36 months retest period is assigned to Meningococcal X-TT Conjugate Bulk Drug Substance.				
N. meningitidis group C polysaccharide Conjugated to	Not Submitted.				

CRM197 5 µg									
N. meningitidis group Y polysaccharide Conjugated to CRM197 5 µg	Not Submitted.								
N. meningitidis group W polysaccharide Conjugated to CRM197 5 µg	Not Submitted.								
Module-III Drug Product: MenFive [Meningococcal (A, C, Y, W, X) Polysaccharide Conjugate Vaccine (Freeze-Dried)] Drug Product									
Manufacturer(s)	<table><tr><th colspan="2">Table 1: MenFive [Meningococcal (A, C, Y, W, X) Polysaccharide Conjugate Vaccine (Freeze-Dried)] Drug Product Manufacturer</th></tr><tr><th>Manufacturer Name</th><th>Manufacturer Address</th></tr><tr><td>Serum Institute of India Pvt. Ltd.</td><td>212/2 Hadapsar, Pune 411028, Maharashtra, INDIA Telephone: +91-20-26993900 Fax: +91-20-26993921 E-mail: parag.nagarkar@seruminstitute.com</td></tr></table>			Table 1: MenFive [Meningococcal (A, C, Y, W, X) Polysaccharide Conjugate Vaccine (Freeze-Dried)] Drug Product Manufacturer		Manufacturer Name	Manufacturer Address	Serum Institute of India Pvt. Ltd.	212/2 Hadapsar, Pune 411028, Maharashtra, INDIA Telephone: +91-20-26993900 Fax: +91-20-26993921 E-mail: parag.nagarkar@seruminstitute.com
Table 1: MenFive [Meningococcal (A, C, Y, W, X) Polysaccharide Conjugate Vaccine (Freeze-Dried)] Drug Product Manufacturer									
Manufacturer Name	Manufacturer Address								
Serum Institute of India Pvt. Ltd.	212/2 Hadapsar, Pune 411028, Maharashtra, INDIA Telephone: +91-20-26993900 Fax: +91-20-26993921 E-mail: parag.nagarkar@seruminstitute.com								
Specification	The method and specifications in Table 1 are adopted from the following: • Inhouse • European Pharmacopoeia (Ph Eur) 10.0 Meningococcal A, C, W, Y conjugate vaccine.								
Container Closure System	Both single dose and five dose MenFive vaccine are filled in 3 mL, USP-Type I, clear tubular glass vial with 13 mm Bromo-butyl rubber stopper and 13 mm Flip-off aluminium seal.								
Stability data of drug product	On the basis of available real time (long term) stability data of 42 months for six batches manufactured for Phase I and Phase II clinical trial and 42 months real time stability data of six batches manufactured for Phase III clinical trial (Phase 3 Africa and India Phase 2/3 Lot to lot consistency) along with Accelerated stability data of ten batches and High accelerated (Stressed) stability data of six batches indicating that Meningococcal A, C, Y, W, X Polysaccharide Conjugate Vaccine-Freeze dried (MenFive) is stable found within specification for 36 months at 2-8°C. Hence 36 months shelf life at 2-8°C can be assigned to Meningococcal A, C, Y, W, X Polysaccharide Conjugate Vaccine-Freeze dried (Men Five). Reconstitution Study (In Use Stability Study) MenFive [Meningococcal (A, C, Y, W, X) Polysaccharide Conjugate Vaccine (Freeze-Dried)] Drug Product (5 dose- 25mcg/dose -5 mcg of each antigen per dose) is found stable for 8 hours post reconstitution at +2-+8°C. Reconstituted Drug product batches shown to be stable for 8 hours and as per the regulatory requirement to cover atleast one immunization session i.e 6 hours (at 2-8°C)								
Module-III Drug Product: Sodium Chloride Injection BP i.e. Diluent for Meningococcal (A, C, Y, W, X) Polysaccharide Conjugate Vaccine (Freeze Dried)									
Manufacturer 3.2.P.3.1	M/s Sovereign Pharma Pvt. Ltd. (SPPL) Survey No. 46/1-4, Kadaiya Village, Nani Daman – 396210, India.								
Specifications 3.2.P.5.1	The analytical procedures along with acceptance criteria of Sodium Chloride Injection BP (0.9 % w/v) are as per the recent version of Pharmacopoeial method of analysis								
Container Closure System	Presentation: Sodium Chloride Injection BP 0.09 % w/v is available in 1 mL (0.5 mL diluent for single dose of MenFive) and 3 mL (2.5 mL diluent for five dose of MenFive) in OPC Neutral Type-I glass ampoule for reconstitution of MenFive								
Stability Summary and Conclusion 3.2.P.8.1 -	The stability studies performed on Sodium Chloride Injection BP 0.9%w/v batches are stable up to 24 months when stored in glass ampoule at 30 ± 2°C 65 ± 5% RH, +2°C to 8°C and 40 ± 2°C 75 ± 5% RH stability conditions and Stable up to 48 months when stored at 30 ± 2°C 65 ± 5% RH.								
Module 4 (Non-clinical / Safety)									
4.2 Study Reports									
4.2.1	Pharmacology		Provided Below:						
	4.2.1.1	Primary Pharmacodynamic s							
	4.2.1.2	Secondary Pharmacodynamic s							

		Five preclinical studies contributed nonclinical pharmacology data: 1) Study 7, which evaluated the immunogenicity of Men X-TT with and without aluminium phosphate adjuvant in Swiss albino mice. 2) Study 1557-05389, which evaluated the immunogenicity of Men X-TT in candidate SIIPL NmCV-5 presentation with and without aluminium phosphate adjuvant in BALB/c mice. 3) Study 13, which evaluated the immunogenicity of three candidate SIIPL NmCV-5 formulations with aluminium phosphate adjuvant in comparison to Menveo® and Menactra® in New Zealand white rabbits. 4) Study 18-19, which evaluated the immunogenicity of SIIPL NmCV-5 (clinical formulation) with and without aluminium phosphate adjuvant in New Zealand white rabbits. 5) Study PATH MVPP 2021/1, this study was to determine the immunogenicity of adjuvanted and non-adjuvanted pentavalent (A, C, W, Y and X) meningococcal polysaccharide conjugate vaccine (NmCV-5) formulations in female Sprague-Dawley rats of reproductive age following three intramuscular doses of 40% of a standard human dose (SHD) given on Day 1 (Dose 1), Day 15 (Dose 2) and Day 29 (Dose 3). Immunogenicity was quantified with regards to the presence of IgG antibodies to meningococcal serogroups A, C, W, Y and X polysaccharides (PS) in rat serum samples taken at three time points namely Day 1 (pre-immunisation), Day 22 (1 week post-dose 2) and Day 36 (1 week post-dose 3), in the study.	
	4.2.1.3	Safety Pharmacology	NA
	4.2.1.4	Pharmacodynamic Drug Interactions	NA
4.2.2	Pharmacokinetics		NA
4.2.3	Toxicology		
	4.2.3.1	Single-Dose Toxicity (in order by species, by route)	Discussions and conclusion A series of GLP toxicology studies were performed in vivo in animal models (rats, guinea pigs) and in vitro in prokaryotic and eukaryotic cells to evaluate the toxicity and mutagenicity, respectively, of a potential manufacturing process-related contaminant 4- pyrrolidinopyridine (4-PP) in the SIIPL NmCV-5 product. A repeated-dose good laboratory practice (GLP) toxicology study was performed in rabbits; no abnormal toxicity was observed. This rabbit study also had an immunogenicity component; vaccination with adjuvanted and nonadjuvanted NmCV-5 at a 5µg dose level per PS conjugate in the vaccine was highly immunogenic in all rabbits for all five meningococcal serogroups (A, C, Y, W, X) represented in the vaccine.
	4.2.3.2	Repeat-Dose Toxicity (in order by species, by route, by duration; including supportive	A Repeat Intramuscular Toxicity Study of NmCV-5 Vaccine in New Zealand White Rabbits Followed by a 6-Week Recovery
	4.2.3.3	Genotoxicity	NA
		Carcinogenicity (including	NA
	4.2.3.4	supportive toxicokinetics evaluations)	
	4.2.3.5	Reproductive and Developmental Toxicity (including range- finding studies and supportive toxicokinetics evaluations) (If modified study designs are used, the following sub-headings should be	4.2.3.5.1 Fertility and early embryonic development There were no NmCV-5 effects on maternal necropsy observations, embryo-fetal survival, or fetal weight. There were no NmCV-5-related fetal external, visceral, or skeletal malformations or variations. Please Reproductive and Developmental Toxicity Study in enclosed in 4.2 Study reports (Study ID: study #20274277) 4.2.3.5.2 Embryo-fetal development There were no NmCV-5 effects on maternal necropsy observations, embryo-fetal survival, or fetal weight. There were no NmCV-5-related fetal external, visceral, or skeletal malformations or variations. Please refer Reproductive and

		modified accordingly.)	Developmental Toxicity Study in enclosed in 4.2 Study reports (Study ID: study #20274277) 4.2.3.5.3 Prenatal and postnatal development, including maternal function All maternal clinical signs that were observed were considered unrelated to NmCV-5 because:1) the observation occurred at similar incidences in the control group; 2) the observation was limited to the control group; and/or 3) the observation was considered a common finding in this species and strain of laboratory animal. Please refer Reproductive and Developmental Toxicity Study in enclosed in 4.2 Study reports (Study ID: study #20274277)
	4.2.3.6	Local Tolerance	
5.2 Tabular Listing of All Clinical Studies			
5.3 Clinical Study Reports			
5.3.1 Reports of Biopharmaceutic Studies		Biopharmaceutical studies are not relevant for vaccines, with the exception of vaccines with novel adjuvants, which is not the case for the NmCV-5 as it is unadjuvanted. Biopharmaceutical studies have therefore not been performed.	
5.3.2 Reports of Studies Pertinent to Pharmacokinetics using Human Biomaterials		This section is not applicable to Meningococcal (A,C,Y,W,X) Polysaccharide Conjugate Vaccine (Freeze-Dried)	
5.3.3 Reports of Human Pharmacokinetic (PK) Studies		This section is not applicable to Meningococcal (A,C,Y,W,X) Polysaccharide Conjugate Vaccine (Freeze-Dried)	
5.3.4 Reports of Human		This section is not applicable to Meningococcal (A,C,Y,W,X) Polysaccharide Conjugate Vaccine (Freeze-Dried)	
Pharmacodynamic (PD) Studies			
5.3.5.5 Reports of Efficacy and Safety Studies		The following study reports are provided with this section. Phase 1 Study: Study Title: A Phase 1, double blind, randomized, controlled study to evaluate the safety and immunogenicity of a new Meningococcal Conjugate Vaccine containing serogroups A, C, Y, W and X in healthy adults. Study Report No.: ACYWX-01/ VAC-046 Phase 2 Study: Study Title: A Phase 2, Observer-blind, Randomized, Controlled Study to Evaluate the Safety and Immunogenicity of Two Formulations of Investigational Meningococcal Groups ACYWX Conjugate Vaccine, Administered to Healthy Malian Children 12-16 Months of Age Study Report No.: ACYWX-02 / CVIA058 Phase 3 Study: Study Title: A Phase 3, observer-blind, randomized, active controlled trial to assess the safety of an investigational meningococcal serogroups ACYWX conjugate vaccine (NmCV-5) and compare its Immunogenicity to a Licensed Meningococcal Serogroups ACYW Conjugate Vaccine (Menactra®), in Healthy Subjects 2 to 29 Years of Age Study Report No.: ACYWX-03, CVIA 071 Study Report No.: Study ACYWX-03, CVIA 071 Clinical Study Report Addendum Phase 2/3 Study: Study Title: A Phase 2/3, Randomized, Observer-blind, Controlled, Multi- Center Study TO Evaluate the Lot-to-Lot Consistency of SIIPL Meningococcal ACYWX Conjugate Vaccine (NmCV-5) and to Compare its Safety and Immunogenicity with that of Licensed Meningococcal ACYW Vaccine Menactra® in Healthy Individuals 18-85 Years of Age	
5.3.5.6 Study Reports of Uncontrolled Clinical Studies			
5.3.5.7 Reports of Analyses of Data from More Than One Study			

	Study Report No.: ACYWX-04 Note: Phase 2/3 Study is completed and CSR report will be available in March-April 2022 for submission.
5.3.6 Reports of Post- Marketing Experience.	The Reports of Post-Marketing Experience for Meningococcal (A,C,Y,W,X) Polysaccharide Conjugate Vaccine (Freeze-Dried) are not available presently

Remarks by BE&R Division

- Recommended for approval on the basis of WHO PQ Status and requirement by Haj Pilgrims and submission of following two documents:
- Stability data of drug product of commercial batches till claimed shelf life.
- Drug substance part of C-CRM197and W-CRM197
- COPP with combo pack.
- Proper justification with evidence of reference guidelines were “Not applicable” has been mentioned for non- clinical study reports like safety pharmacology, drug interaction, pharmacokinetic, genotoxicity, carcinogenicity and other toxicity studies

Decision of 347th meeting:

The Registration Board deferred the case for submission of the following documents:

- **Stability data of drug product of commercial batches till claimed shelf life.**
- **Drug substance part of C-CRM197and W-CRM197.**
- **COPP with combo pack.**
- **Proper justification with evidence of reference guidelines were “Not applicable” has been mentioned for non-clinical study reports like safety pharmacology, drug interaction, pharmacokinetic, genotoxicity, carcinogenicity and other toxicity studies.**

Sr. No.	Deficiencies	Response
1)	Stability data of drug product of commercial batches till claimed shelf life.	Complete stability data for claimed shelf life is available for clinical batches. The same has been enclosed in the submitted dossier. Stability data for commercial batches is on-going. Please find below the status of commercial stability reports being attached with this reply as Annexure 1 (for single dose) and Annexure 2 (for multi dose). a) Stability data for 5 dose commercial batches: 3 batches; 24 months long term, 6 months accelerated The long-term stability study is on-going, and results for the 36 months' interval would be available by mid-2025.
2)	Drug substance part of C-CRM197and W-CRM197.	Drug Substance part of C-CRM197 is attached as Annex 3 and W-CRM197 is attached as Annex 4 for your perusal.
3)	COPP with combo pack.	Our principal has applied COPP for dilute and hopefully it will be issued within next week. As soon as the same received we hereby assure you that we will submit to your office without any further delay.
4)	Proper justification with evidence of reference guidelines were “Not applicable” has been mentioned for non-clinical study reports like safety pharmacology, drug interaction, pharmacokinetic, genotoxicity, carcinogenicity and other toxicity studies.	Reference guidelines of WHO Expert Committee on Biological Standardization are attached as Annexure 5 which reflect that testing / non clinical trial is not required for vaccine; A

Conclusion:

The product is approvable based on its WHO Prequalification (PQ) status; however, still deficient for the submission of stability data for commercial batches and the Certificate of Pharmaceutical Product (COPP) for combo pack.

Decision of 348th Meeting

The Registration Board approved the 5 dose vial formulation on the basis of WHO Prequalification (PQ) status for only institutional supply as per current policy for inspection of manufacturers abroad notified vide Letter No.3-2/2005-Reg-I /Vol-II dated July 6, 2022. Registration letter will be issued on submission of stability data for commercial batches and Certificate of Pharmaceutical Product (COPP) for combo pack.

Influenza Vaccine

Recommended composition of influenza virus vaccines for use in the 2025-2026 northern hemisphere influenza season

: The WHO recommends that **trivalent** vaccines for use in the 2025-2026 northern hemisphere influenza season contain the following:
Egg-based vaccines

- an A/Victoria/4897/2022 (H1N1)pdm09-like virus;
- an A/Croatia/10136RV/2023 (H3N2)-like virus; and
- a B/Austria/1359417/2021 (B/Victoria lineage)-like virus.

Cell culture-, recombinant protein- or nucleic acid-based vaccines

- an A/Wisconsin/67/2022 (H1N1)pdm09-like virus;
- an A/District of Columbia/27/2023 (H3N2)-like virus; and
- a B/Austria/1359417/2021 (B/Victoria lineage)-like virus.

The recommendation for the B/Yamagata lineage component of quadrivalent influenza vaccines remains unchanged from previous recommendations:

- a B/Phuket/3073/2013 (B/Yamagata lineage)-like virus.

What is the position of WHO on the B/Yamagata lineage vaccine component? The continued absence of confirmed detection of naturally occurring B/Yamagata lineage viruses after March 2020 is indicative of a very low risk of infection by B/Yamagata lineage viruses. Consistent with previous recommendations (WHO September 2024 recommendation, February 2024 recommendation, and September 2023 recommendation), it remains the opinion of the WHO influenza vaccine composition advisory committee that inclusion of a B/Yamagata lineage antigen in quadrivalent influenza vaccines is no longer warranted, and every effort should be made to exclude this component as soon as possible. National or regional authorities should make decisions regarding the transition to trivalent influenza vaccines in their jurisdictions.

Vaccination

Time: October

**(Influenza Vaccine (Split Virion), Inactivated, Quadrivalent
Deferred Case (M-347)
Exporting Country (China)**

Case # 3

	Name, address of Applicant / Importer	M/s. ImmunoWell (Pvt) Ltd, No. 473, Street No. 7, Block J-2, Johar Town, Lahore, Pakistan
	Details of Drug Sale License of importer	License No. 05-352-0066-100098D Address: 473, Street No. 7, Block J-2, Johar Town, Lahore, Pakistan Validity: 17-Nov-2027 Status: License to sell, stock & exhibit for sale, distributor registered products on behalf of licensed pharmaceuticals manufacturer as his authorized agent on the premises
	Name and address of marketing authorization holder (abroad)	M/s. ImmunoWell (Pvt) Ltd, No. 473, Street No. 7, Block J-2, Johar Town, Lahore, Pakistan
	Name, address of manufacturer(s)	M/s. Shanghai Institute of Biological Products Co., Ltd. Address: No. 758 Guangfeng Road, Fengxian District, Shanghai, China
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Firm has submitted original Apostilled CoPP No. Shanghai 20220253, issued on 02-03-2021, issued by Shanghai Municipal Medical Products Administration, China. Apostilled GMP Inspection Report issued by Beijing Medical Products Administration, China.
	Details of letter of authorization / sole agency agreement	Firm has submitted Authorization Letter with product specific brand name FluLing Quad, according to the letter, M/s. Shanghai Institute of Biological Product appoints ImmunoWell(Pvt) Ltd with address 473, Street No. 7, Block J-2, Johar Town, Lahore, Pakistan. It's representative for sole purpose of registration of the said product.
	Status of the applicant	Importer
	Status of application	Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale
	For imported products, specify one of these	Finished Pharmaceutical product import
	Dy. No. and date of submission	Tracking ID No.LRS-TBA-A741
		Dated: 29-07-2024
	Details of fee submitted	Rs.300, 000/- via e-deposit slip No.9840117677, dated: 24-07-2024
	The proposed proprietary name / brand name	FluLing Quad.
	Strength / concentration of drug of Active	Each single dose of PFS of 0.5ml contains: 15mcg hemagglutinins per strain: A/Victoria/4897/2022(H1N1)pdm09-like virus.....15 µg of hemagglutinin A/Thailand/8/2022 (H3N2)-like virus 15 µg of hemagglutinin

Pharmaceutical ingredient (API) per unit	B/Austria/1359417/2021 (B/Victoria lineage)-like virus..15 µg of hemagglutinin B/Phuket/3073/2013 (B/Yamagata lineage)-like virus....15 µg of hemagglutinin
Dosage form of applied drug	Prefilled Syringe (PFS)
Pharmacotherapeutic Group of (API)	Vaccine
Reference to Finished product specifications	Chinese Pharmacopeia European Pharmacopeia /WHO specification
Proposed Pack size	0.5ml/dose/ Prefilled Syringe
Proposed unit price	As per DRAP Policy
Shelf Life	12 months
Storage Conditions	2-8°C
The status in reference regulatory authorities	1. Influvac Tetra by Abbott Biologicals B.V., The Netherlands 2. Influenza Vaccine by Sanofi Aventis France
For generic drugs (me-too status)	
Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to introduction, nomenclature, structure, general properties, solubilities, physical form, Manufacture: manufacturers, description of manufacturing process and controls, controls of materials,
	control of critical steps and intermediates, process validation and /or evaluation, manufacturing process development, Elucidation of structure and other characteristics, impurities, specifications, Analytical procedures and its validation, batch analysis, justification of specification , reference standard or materials, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its Description and composition of the drug product, pharmaceutical development, manufacture, batch formula, description of manufacturing process and process control, control of critical steps and intermediates, process evaluation and/or evaluation, control of excipients, control of drug product, specifications, analytical procedures and its validation, batch analysis, characterization of impurities and justification of specification, reference standard, container closure system and stability studies of drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
Name, address of drug substance manufacturer	M/s. Shanghai Institute of Biological Products Co., Ltd. Address: No. 758 Guangfeng Road, Fengxian District, Shanghai, China
Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and process controls. control of materials, control of critical steps and intermediates, Process Validation and/or evaluation, manufacturing process development, characterization, impurities and Elucidation of structure and other characteristics, control of Drug Substance: specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	In accordance with the "9001 Guideline for the Stability Testing of Drug Substances and Preparations" in <i>Chinese Pharmacopoeia</i> 2020 (Volume IV), the stability study of monovalent virus bulk of influenza vaccine
	was conducted, including influencing factor test (high temperature test), Influencing factor test (photostability test), accelerated stability and long-term stability testing. The stability study was used to evaluate the effect of different storage conditions on the stability of the monovalent virus bulk of influenza vaccine, and finally the shelf life of monovalent virus bulk of influenza vaccine was determined.
Module-III Drug Product:	Firm has submitted data of drug product including its description, & composition of the drug product, pharmaceutical development, manufacturer, batch formula, description of manufacturing process and process control, control of critical steps and intermediates, process validation and/or evaluation, control of excipients, control of drug product: specifications, analytical procedures, validation of analytical procedures, batch analysis, characterization of impurities, justification of specifications, reference standard or materials, container closure system and stability.
Container closure system of the drug product	Pre-filled syringe is used as primary packaging material, and the suppliers are Shandong WEGO Prefills Pharmaceutical Packaging Co., Ltd. and Becton Dickinson France SAS. Becton Dickinson Medical Devices (Shanghai) Co., Ltd. and Guangzhou BrunsLab Co., Ltd. were entrusted to conduct

		the compatibility study of the primary packaging material to comprehensively investigate the test results of effect of the primary packaging material on the drug and the effect of the drug on the primary packaging material. The primary packaging material had no significant effect on the Influenza Vaccine (Split Virion), Inactivated, Quadrivalent, and the Influenza Vaccine (Split Virion), Inactivated, Quadrivalent had no significant effect on the primary packaging material. Influenza Vaccine (Split Virion), Inactivated, Quadrivalent is well compatible with the primary packaging material provided by the two suppliers.
	Stability study data of drug product, shelf life and storage conditions	Influencing factor test was conducted for final products. The results of high temperature test showed: (1) Hemagglutinin content: After the final products were placed at $40 \pm 2^{\circ}\text{C}$ /protected from light for 5 days, the hemagglutinin content of each type of final products decreased significantly, the hemagglutinin content of final products on Day 1, 2 and 3 met the specification, and the hemagglutinin content of three batches of final products on Day 5 was lower than the specification (the hemagglutinin content of each type of influenza virus strain in each 1 mL should be not less than 80% of the labeled amount), that is, the corresponding value was 24 $\mu\text{g/mL}$. The study was terminated. (2) During
		the investigation period, the appearance, filling volume and pH of the three batches of final products met the specification.
		The results of photostability test showed: (1) Hemagglutinin content: After the final products were placed at $25 \pm 2^{\circ}\text{C}/4500 \text{ lx} \pm 500 \text{ lx}$ for 15 days, the hemagglutinin content of each type of final products decreased significantly, the hemagglutinin content of final products on Day 3 and 7 met the specification, and the hemagglutinin content of three batches of final products on Day 12 was lower than the specification (the hemagglutinin content of each type of influenza virus strain in each 1 mL should be not less than 80% of the labeled amount), that is, the corresponding value was 24 $\mu\text{g/mL}$. The study was terminated. (2) By the 12-day node, the appearance, filling volume and pH of the three batches of final products met the specification.
		Accelerated stability testing was performed on the final product, (1) Hemagglutinin content: With the extension of the hold time at 25°C , the overall virus showed a slow downward trend in the final product, which was within the specification. (2) The slope of the decline trend of hemagglutinin content in the final product was similar, and the decline trend of hemagglutinin in each type of the final product was more consistent after change. (3) The appearance, filling volume and pH of the process investigation nodes of Day 7, 14 and 21 met the specification. (4) After the storage under 25°C for 28 days, the full test items still met the in-house specification.
		Long-term stability testing was performed on the final product, (1) Hemagglutinin content: With the extension of the storage time under $2-8^{\circ}\text{C}$, the overall hemagglutinin content showed a slow downward trend in the final product, which was within the specification. (2) The slope of the decline trend of hemagglutinin content in the final product was similar, and the decline slope was similar. (3) The long-term stability study of samples have all been completed and all results met the specifications.
		In summary, the stability of the vaccine and its influencing factors were fully investigated through the photostability test, high-temperature test, accelerated stability test and long-term stability test of the final product. According to the previous stability test data and stability results, the shelf life of the vaccine finished product is 12 months.
Module 4 (non-clinical/Safety)		
Pharmacology		The BALB/c mice were immunized with different doses of Influenza Vaccine
		(Split Virion), Inactivated, Quadrivalent to evaluate the immunogenicity of the product.
		Influenza Vaccine (Split Virion), Inactivated, Quadrivalent were diluted with PBS to a concentration of 15 μg , 1.5 μg , 0.15 μg and 0.015 μg hemagglutinin solution and immunized the BALB/c mice respectively. To compare Influenza Vaccine (Split Virion), Inactivated, Quadrivalent with Influenza Vaccine (Split Virion), Inactivated, the study also used Influenza Vaccine (Split Virion), Inactivated (containing B/Vic) as a control. The vaccine was diluted with PBS to a concentration of 15 μg , 1.5 μg , 0.15 μg and 0.015 μg hemagglutinin solution and immunized the BALB/c mice respectively; the PBS group was served as negative control group; the unimmunized mice were used as blank control group. On day 21 after immunization, serum samples were collected from mice to detect the specific IgG antibodies based on different influenza virus strain antigens contained in the vaccine.
		The results showed that immunizing BALB/c mice with Influenza Vaccine (Split Virion), Inactivated, Quadrivalent could induce good immunogenicity.
		The specific antibody titers for H1N1, H3N2, and B/Yam produced by mice immunized with different doses of Influenza Vaccine (Split Virion), Inactivated, Quadrivalent were comparable to those of the

		same dose of Influenza Vaccine (Split Virion), Inactivated, while the antibodies for B/Vic antigen were significantly higher than those of the same dose of Influenza Vaccine (Split Virion), Inactivated (p < 0.05).
Toxicology		
4.2.3.1	Single dose Toxicity	CD-1 mice were used to evaluate the acute toxicity of the vaccine. Sodium chloride injection was used as the negative control group, and Influenza Vaccine (Split Virion), Inactivated, Quadrivalent produced at the new site (1 dose/animal, 0.5ml/dose) and the original site (1 dose/animal, 0.5ml/dose) was used as the experimental group. The test results showed that no death or dying phenomenon was observed in the experimental group, and no abnormality was found in the clinical observation of animals in each group. There were no vaccine-related abnormal changes in body weight and food intake. At the end of the observation period, no abnormality was found in the gross observation of animals in each group, so no histopathology examination was performed. Under the test conditions, CD-1 mice were given single intramuscular injection of Influenza Vaccine (Split Virion), Inactivated, Quadrivalent produced at the new site and the original site, and no vaccine related abnormal changes were found. The maximum tolerable dose (MTD) was 1 dose per animal, which was equivalent to 1 clinical intended dose.
4.2.3.2	Repeat-dose Toxicity	Not applicable.
4.2.3.3	Genotoxicity	Not applicable.
4.2.3.4	Carcinogenicity	Not applicable.
(including supportive toxicokinetics evaluation)		
4.2.3.5	Reproductive and Developmental Toxicity (including range-finding studies and supportive toxicokinetics evaluations) (if modified study designs are used, following sub-headings should be modified accordingly.) Not applicable	
4.2.3.6	Local Tolerance	New Zealand rabbits were used to evaluate the local tolerance of the vaccine. Sodium chloride injection was used as the negative control group, and Influenza Vaccine (Split Virion), Inactivated, Quadrivalent produced at the new site (1 dose/animal, 0.5ml/dose) and the original site (1 dose/animal, 0.5ml/dose) was used as the experimental group. The test results showed that no vaccine-related abnormalities were observed in animal clinical studies. No obvious abnormal pathological changes were observed at the administration site. At the end of administration, there was slight infiltration of inflammatory cells at the administration site. There was no significant difference in the irritation between the Influenza Vaccine (Split Virion), Inactivated, Quadrivalent produced at the new site and the original site.
Module -V		
5.3	Clinical Study Reports	
	5.3.1	Report of Biopharmaceutic Studies Not Applicable.
	5.3.2	Reports of Studies Pertinent to tests using Human Biomaterials Not Applicable.
	5.3.3	Reports of Human Pharmacokinetics (PK) Studies Not Applicable.
	5.3.4	Reports of Human Pharmacodynamic (PD) Studies Not Applicable.
	5.3.5	Reports of Efficacy and Safety Studies 5.3.5.2 Study Reports of 5.3.5.1.1 A randomized, double-blind, parallel-controlled phase III clinical study to evaluate the immunogenicity and safety of Influenza Vaccine (Split Virion), Inactivated, Quadrivalent in the population aged 3 years and above. Clinical study report: "Clinical Study Report - Open-Label Phase I and Randomized, Double-blind, Influenza Vaccine (Split Virion), Inactivated, Trivalent Active Comparator-Controlled Phase III Clinical Study of Influenza Vaccine (Split Virion), Inactivated, Quadrivalent in the Population Aged 3 Years and Above" (Version No.: V1.0) Refer to Attachment 5.3.5.1.1 for details. 5.3.5.1.2 A randomized, double-blind, parallel-controlled phase II clinical study to evaluate the immunogenicity and safety of Influenza Vaccine (Split Virion), Inactivated,

			Uncontrolled Clinical Studies. 5.3.5.3 Reports of Analyses of Data from More Than One Study	Quadrivalent in the population aged 6-35 months. Clinical study report: “Final Report of Open-label Phase I and Randomized, Double-blind, Parallel-controlled Phase II Clinical Study to Evaluate the Safety of Influenza Vaccine (Split Virion), Inactivated, Quadrivalent in the Population Aged 6-35 Months (Version No.: V2.0). 5.3.5.2 Study Reports of Uncontrolled Clinical Studies 5.3.5.2.1 An open-label phase I clinical study to evaluate the safety of Influenza Vaccine (Split Virion), Inactivated, Quadrivalent in the population aged 3 years and above. Clinical study report: "Clinical Study Report - Open-label Phase I and Randomized, Double-blind, Influenza Vaccine (Split Virion), Inactivated, Trivalent Active Comparator- Controlled Phase III Clinical Study of Influenza Vaccine (Split Virion), Inactivated, Quadrivalent in the Population Aged 3 Years and Above" (Version No.: V1.0) 5.3.5.2.2 An open-label Phase I clinical study to evaluate the safety of Influenza Vaccine (Split Virion), Inactivated, Quadrivalent in the population aged 6-35 months. Clinical study report: “Final Report of Open-Label Phase I and Randomized, Double-Blind, Parallel-Controlled Phase II Clinical Study to Evaluate the Immunogenicity and Safety of Influenza Vaccine (Split Virion),
		5.3.7	Case Report Forms and Individual Patient Listing	Not Applicable

Previous Decision of 345th Meeting:

The Registration Board deferred the applied formulation for submission of the following documents:

- i. Original, legalized and valid COPP mentioning the composition of vaccine as per WHO recommended strains 2024-2025.
- ii. Hard copy of original or notarized copy of letter of authorization.
- iii. Documents/evidence for acceptable shipping conditions for both finished product and drug substance and formulated bulk (for importing bulks for filling and domestic production) & proof of shipping validation.
- iv. Comparison of Chinese specifications with EP specifications.
- v. The reference of already registered product containing 2024-2025 strain needs to be submitted.
- vi. Provide SMPC. Two package inserts are provided which mentions IM and indications which is not in line with clinical data.
- vii. The clinical indications (in adults and children from 6 months of age) which is different than SRA.
- viii. The vaccine in trials is given by subcutaneous route whereas Package leaflet mentions IM route.
- ix. Drug substance part of each monovalent virus bulk containing data of recommended strains for the year 2024- 2025 northern hemisphere influenza seasons as per (EMA/CHMP/BWP/99698/2007 Rev. 2).
- x. Drug product part (Final bulk Filling) as per WHO recommended strains for the year 2024-2025 containing data of recommended strains for the year 2024-2025 northern hemisphere influenza season as per (EMA/CHMP/BWP/99698/2007 Rev. 2).
- xi. Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3.
- xii. Risk Management Plan (RMP).
- xiii. Periodic Safety Update Report (PSUR)/Periodic Benefit-Risk Evaluation Report (PBRER).
- xiv. Adverse event following immunization report (summary of annual reports).
- xv. Product-specific effectiveness and safety studies.
- xvi. The reactogenicity profile of influenza vaccines of WHO recommended strains for the year 2024-2025.in the population indicated for vaccine (including children).
- xvii. Scientific justification in the light reference guidelines is required for conducting Phase 4 studies on target population (aged 3-8 years) with subject size (380), route of administration(SC) whereas, PI mentions indication (6 months and above), route of administration (IM) and recommended subject size (3000 as per guidelines).

Evaluation by BE& R Division

Sr. No	Sections	Observations/Deficiencies/	Applicants Response	Evaluator Remarks

		Shortcomings		
1.	1.3.1	Name of marketing authorization holder abroad.	Shanghai Institute of Biological Products Co., Ltd.	Mentioned by the applicant
2.	1.3.3	a) Original, legalized and valid COPP mentioning the composition of vaccine, as provided COPP is invalid b) Hard copy of original or notarized copy of letter of authorization.	SIBP will re-apply to the Shanghai Municipal Drug Administration for CoPP, and it will take about one and a half months for the processing. e-copy of Apostilled Authorization Letter is already submitted along with CTD dossier, original, hard copy will be submitted with new CoPP.	eCOPP submitted but strains are still not mentioned on the COPP. It mentions. Active ingredients are hemagglutinins of various influenza viruses used in that year.; 0.5ml per container. 0.5ml per single human dose containing 15µg of hemagglutinin of each types of flu virus strain recommended by WHO of the current year. The COPP is for the year 2025. COPP NO. No.Shanghai20250094
3.	1.4.2	Documents/evidence for acceptable shipping conditions for both finished product and drug substance and formulated bulk (for importing bulks for filling and domestic production) & proof of shipping validation.	SIBP QIV vaccine is acceptable for transport at 2 to 8 °C, protected from light. SIBP QIV have been done the stability study before marketing and every time when switching the influenza virus. Those data can prove that SIBP QIV meet the requirement under the storage condition. Documents will be provided	Cold Chain Insulated Container Verification Report submitted by Hangzhou Ruhr New Material Technology Co., Ltd.
4.	1.5.2	Complete strength/concentration of applied vaccine.	This product is a split virion vaccine prepared by inoculating chicken embryos with influenza A and B virus strains recommended by the World Health Organization (WHO) through concentrating, lysing, inactivating and purifying the cultured and harvested virus solution. It is a slightly opalescent liquid. active ingredients: hemagglutinin of various influenza viruses used in that year. Every 0.5 mL of this product contains: A/Victoria/4897/2022(H1N1)pdm09 like virus 15 µg of hemagglutinin A/Thailand/8/2022 (H3N2)- like virus 15 µg of hemagglutinin B/Austria/1359417/2021 (B/Victoria lineage)-like virus	Complete strength/concentration of applied vaccine submitted.
			15 µg of hemagglutinin B/Phuket/3073/2013 (B/Yamagata lineage)-like virus 15 µg of hemagglutinin Excipients: sodium chloride, sodium dihydrogen phosphate, disodium hydrogen phosphate, formaldehyde. Strength: Each syringe is 0.5ml, each single human dose is 0.5ml, containing 15mg of hemagglutinin of each H1N1	

			influenza virus, H3N2 influenza virus, B/V influenza virus and B/Y influenza virus.	
5.	1.5.6	Specify reference to specification along with relevant monograph as you have specified Chinese/EP and WHO specifications and comparison of specs.	QIV from SIBP is produced and released follow the current edition of Chinese Pharmacopoeia	As per rules EP Specs will be granted.
6.	1.5.8	The reference of already registered product containing 2024-2025 strain including the following details needs to be submitted. - Brand name - Manufacturer/Registration holder	Influenza Vaccine (Split Virion) manufactured by SINOVAC Registration Holder: Sind Medical Stores, Karachi. Registration No.115151	This submission is optional.
		Registration number		
7.	1.5.9	List of RRA where the product is already licensed and the date of approval.	SIBP QIV was approved and marketing in P.R. China, Date of approval 2022.11.22 Approval number: National approval number : GYZZ S20210007 SIBP QIV is registered in China only so far. In Pakistan registration is in process.	Same strains are approved in Netherlands.
8.	1.5.14	Provide SMPC. Two package inserts are provided which mentions IM and indications which is not in line with clinical data. The clinical indications (in adults and children from 6 months of age) which is different than SRA. The vaccine in trails is given by subcutaneous route whereas Package leaflet mentions IM route.	The vaccine used in the trial was actually administered via intramuscular injection, which was a mistake in the clinical summary report (3- 8 years). In fact, the vaccination route we mentioned in the pre- market research and instructions is intramuscular injection. We have made the necessary corrections.	No supporting document submitted to prove premarket research studies included route of administration IM. However, declaration has been submitted by the applicant. No fee submitted in case of correction. The clinical indications (in adults and children from 6 months of age) which is different than SRA. NO RRA evidence submitted. However. Declaration has been submitted by the applicant that this clinical indication is approved by NMPA.

9.	3.2.S.2 to 3.2.S.7	Complete drug substance part of each monovalent virus bulk from S1 to S 7 containing data of recommended	According to China National Medical Products Administration (NMPA), relevant guidelines and science research, switching the influenza virus will not change the manufacture	The recommend of WHO influenza virus, SIBP carried out the establishment of three- level virus lot, passage stability study, quality control testing and stability study of bulk, quality control testing and stability study of finished product.
		strains for the year 2024-2025 northern hemisphere influenza season as provided data is of southern hemisphere 2021 -2022.	process, specification, and control testing methods etc. The manufacture process, specification and control testing methods do not change between the influenza vaccine which use the 2024 2025 WHO recommend virus and the clinical trial stage, process validation stage and marketing production stage.	For details, see remarks of Evaluator.
10.	3.2.P.2 to 3.2.P.8	Complete drug product part P 1 to P 8(Final bulk Filling) as per WHO recommended strains for the year 2024-2025.	Follow the relevant guidelines and routine operation in the industry, after replacing the strains recommended by WHO every year, SIBP establishes the third-level seed lot (master seed lot, primary seed lot and working seed lot) and issues it for production after it is qualified; The generic stability of the strain was studied. ✓ For bulk, each sub- type of bulk will proceed continuous stability studies every year for at least three batches. If the virus changed,accelerated stability studies will be proceeded for three batches besides the continuous stability studies. ✓ For finished products, the stability studies shall be done for the first three batches for every year, if the virus changed, the accelerated stability studies shall be proceeded simultaneously.	
			Therefore, follow the recommend of WHO influenza virus, SIBP carried out the establishment of three-level virus lot, passage stability study, quality control testing and stability study of bulk, quality control testing and stability study of finished product.	
11.	3.2.R	Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3.	Documents will be provided after Chinese holidays.	BMR of following three batches submitted by the applicant ✓ 202403001 ✓ 202403002 ✓ 202403003
12.	Module 4	a)Complete non-clinical studies pertinent to recommended strains	The split vaccine is a mature production process for influenza virus vaccines. It was approved for the prevention of influenza virus	- To support seasonal strain updates there is no need to provide non-clinical/clinical data. Vaccine performance should be monitored by means of product-specific effectiveness

	Non-Clinical Data	and justification for not performing complete pharmacodynamics studies like protective studies, passive immune transfer studies, safety pharmacology studies, repeat dose toxicity studies, safety studies, development and reproductive toxicity studies. b) Proper justification with	infection. in the human population as early as the 1970s [1, 2]. The safety and immunogenicity of influenza virus vaccines of this process and formulation have been widely recognized worldwide. The formulation of the SIBP influenza virus split vaccine is consistent with the formulation of the international guidelines (refer to the influenza vaccine official position paper released by the WHO in 2022). This series product was first approved for marketing in China in 2002 and has been continuously	studies and enhanced safety surveillance. The reactogenicity profile of influenza vaccines after annual strain updates should be investigated in the population indicated for each vaccine (including children if applicable) in order to confirm acceptable tolerability of the newly recommended strain(s).
		evidence of reference guidelines were “Not applicable” has been mentioned for non-clinical study reports.	produced and sold to date, with a large cumulative sale. Unlike completely novel drugs, whose safety in animals or humans is unknown. This product has completed comprehensive clinical trial (refer to the clinical research report) and has been vaccinated on a large scale in the real world. Its safety and immunogenicity have been proven in the human body (for details, see the clinical research report and post marketing adverse reaction monitoring data). Therefore, during the process of registration and declaration of the quadrivalent influenza virus split vaccine in China, based on the prior experience of non-clinical and clinical research of influenza virus split vaccines worldwide, referring to the vaccine non-clinical research guidelines issued by the WHO, and in accordance with the requirements of the (NMPA), non-clinical studies such as single-dose administration tests, local tolerance tests, and allergy tests have been carried out. No additional toxicological studies are required. The above research results and data have all been provided to your bureau. In addition, in terms of	

			pharmacodynamics research, usually animal pharmacodynamics studies include humoral immunity and cellular immunity. Split	
			vaccines are generally considered to mainly stimulate humoral immune responses. Therefore, in the pharmacodynamics research, immunogenicity studies based on the detection of humoral immune indicators have been carried out. Influenza virus vaccines have classic serological evaluation criteria to assess the immunogenicity of vaccines. NMPA, EMA, and FDA have all issued clinical guidelines for influenza virus vaccines. The antibody level against the influenza hemagglutinin antigen in the body of subjects after vaccination is the main criterion for evaluating the effectiveness of the vaccine, namely hemagglutinin inhibitory antibody and it is considered that when the antibody level is $\geq 1:40$, it reaches the protective level and is used as an evaluation index for the protective effect of the vaccine. Therefore, in the non-clinical pharmacodynamics research of this product, the hemagglutinin inhibitory antibody level against the influenza hemagglutinin antigen in the serum of animals after vaccination with the vaccine was used to evaluate the immunogenicity of the vaccine. [1] Gross PA, Ennis FA. Influenza vaccine: split- product versus whole virus	
			types--How do they differ? N Engl J Med. 1977;296:567-8. [2] Kim YH, Hong KJ, Kim H, Nam JH. Influenza vaccines: Past, present, and future. Rev Med Virol. 2022;32:e2243.	
	Module 5 Clinical Data	Complete Clinical study reports along with raw data for the WHO recommended strains for the year 2024-2025 as	For influenza vaccine manufacturer globally, the influenza vaccine will be produced follow the WHO recommend virus, no extra clinical trial will be needed aiming at the specific influenza virus for that year. As we can see	- To support seasonal strain updates there is no need to provide non-clinical/clinical data. Vaccine performance should be monitored by means of product-specific effectiveness studies and enhanced safety surveillance. The reactogenicity profile of influenza vaccines after annual strain

		per international guidelines. • Proper justification with evidence of reference guidelines were “Not applicable” has been mentioned for non-clinical study reports. • Risk Management Plan (RMP) for the WHO recommended strains for the year 2024-2025. Periodic Safety Update Report (PSUR)/Periodic Benefit-Risk Evaluation Report (PBRER) for the WHO recommended strains for the year 2024-2025. • Adverse event following immunization	that FDA, EMA do not require additional clinical trial just because switching the virus (FDA: 21 CFR 601.2, EMA: Reg. (EC) No. 1234/2008 Article 18), neither do China NMPA. For SIBP, we produce the QIV with the influenza virus follow the WHO recommend, and the QIV manufacture process, specification will not change. The clinical trial report show that SIBP QIV is safety. and efficacy follow the SIBP manufacture process and specification For question (CDE), SIBP do have a PV department and mature management. For QIV, SIBP do not amend the SOP and related documents solely due to changes in the influenza viruses. Therefore, SIBP will provide: C) common version of QIV marketing risk management plan D) latest QIV PSUR E) latest QIV Summary of the annual report	updates should be investigated in the population indicated for each vaccine (including children if applicable) in order to confirm acceptable tolerability of the newly recommended strain(s). (Not submitted) Risk Management Plan submitted. PSUR report submitted. AFIR report Submitted. F Clarification for route of administration not provided.
		report (summary of annual reports) in the country of origin or any other NRA. • f) Scientific justification is required for conducting Phase 4 studies on target population (aged 3-8 years) with subject size (380), route of administration(SC) whereas, PI mentions indication (6 months and above), route of administration (IM) and recommended subject size (3000 as per guidelines)	F) f As a newly launched product of our company, the quadrivalent influenza virus split vaccine is required by the approval conclusion of the Drug Registration Certificate issued by the National Medical Products Administration to conduct research on evaluating the safety and immunogenicity of the quadrivalent influenza vaccine after vaccination with different immunization programs in the 3-8-year-old population Therefore, we conducted this Phase 4 clinical study to evaluate the immunogenicity and safety of different dose regimens of QIV in healthy participants aged 3 to 8 years old. We calculated the sample size based on the main purpose of the study.	
Remarks by BE&R Division				

The applicant response has been evaluated and found still deficient for the following:

- i. COPP mentioning the annual strains of 2024-2025.(COPP has been submitted for the year 2025)
- ii. Fee for correction in clinical report along with evidence that vaccine used in the trial was actually administered via intramuscular injection, which was a mistake in the clinical summary report (3-8 years).
- iii. Reactogenicity profile (short-term, expected side effects) after strain update

Recommended for approval on submission of above cited documents.**Decision of 347th Meeting :**

Deferred for submission of the following documents:

- i. Requisite fee for typographical error correction in clinical report from SC to IM along with evidence that vaccine used in the trial was actually administered via intramuscular route.
- ii. Reactogenicity profile (short-term, expected side effects) after strain update

Remarks of the Evaluator

Sr No.	Shortcomings	Response	Remarks
1)	Requisite fee for typographical error correction in clinical report from SC to IM along with evidence that vaccine used in the trial was actually administered via intramuscular route.	Attachment 1 Requisite fee challan Attachment 2 Informed Consent Form-Chinese and Informed Consent Form English	Applicant has submitted Phase IV studies as an evidence and requisite fee as per SRO.
2)	Reactogenicity profile (short-term, expected side effects) after strain update	Reactogenicity profile (short-term, expected side effects) after strain update. WHO position paper of influenza vaccine	The adverse reaction rate of QIV in 2023 was 2.864 per 10,000, and in 2024 it was 2.805 per 10,000. The incidence rates of QIV in the past two years have been far lower than the range of adverse reaction frequencies stated in the instructions, and also much lower than the point of World Health Organization (as per the WHO's 2022 influenza vaccine position paper, mild pain at the injection site is common (60–80%) of recipients); systemic symptoms include low-grade fever (2–10%*)

Conclusion

Influenza viruses continuously change and evolve. The periodic replacement of the virus strains contained in influenza vaccines is therefore necessary to keep the vaccines effective. The WHO recommends that trivalent vaccines for use in the 2025-2026 northern hemisphere influenza season contain the following:

Egg-based vaccines

- an A/Victoria/4897/2022 (H1N1)pdm09-like virus;
- an A/Croatia/10136RV/2023 (H3N2)-like virus; and
- a B/Austria/1359417/2021 (B/Victoria lineage)-like virus.

The applicant is required to update the strains through a pre-registration variation application, along with the corresponding updates to the relevant CTD modules, in accordance with the EMA Guideline on Influenza Vaccines – Submission and Procedural Requirements (Rev. 2) (EMA/56793/2014 Rev. 2).

Decision of 348th Meeting:

The Registration Board deferred the case to update the strains as per WHO recommendation for 2025-2026 northern hemisphere influenza vaccines and submit updated Module 3 with submission of requisite fee.

Influenza Vaccine (Split Virion), Inactivated, Quadrivalent**Deferred Case M-347****Exporting Country(China)****Case No.4**

Name, address of Applicant / Importer	M/s :Immunonet Pharma (Pvt) Limited Address: 14-Airline Society, Lahore
Details of Drug Sale License of importer	License No: 05-352-0066-102283D Address: 14-Airline Society, Lahore Address of go-down: N/A Validity: 23-01-2028
Name and address of marketing authorization holder (abroad)	M/s : Changchun Institute of Biological Products Co., Ltd. Manufacturing Address: No.1616,Chuangxin Road, High-Tech Development Zone, Changchun City P.R. China

	Registration Address: No.1616,Chuangxin Road, High-Tech Development Zone, Changchun City P.R. China								
Name, address of manufacturer(s)	M/s: Changchun Institute of Biological Products Co., Ltd. Manufacturing Address: No.1616,Chuangxin Road, High-Tech Development Zone, Changchun City P.R. Chin								
Name of exporting country	China								
Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	COPP Certificate No.20230014 Date of License Issue=11-03-2020 Valid Date= 23-02-2025 Free Sale Certificate: COPP states that the product is freely available in country of origin. GMP Declaration Certificate Certificate No.2020S00115								
Details of letter of authorization / sole agency agreement	Changchun Institute of Biological Products Co., Ltd. a company manufacturing pharmaceutical and biological products, whose principal place of business is located at No. 1616, Chuangxin Road, High-Tech Development Zone, Changchun City, P. R. China , does hereby authorize Immunonet Pharma Pvt. Ltd., at 14-Airline Society, Lahore Pakistan, Postal Code 54000, for the purpose of registration or post registration variation approvals with the Drug Regulatory Authority of Pakistan, Marketing, Selling, Quoting and Distribution in private & public sectors of our following product in Pakistan. This Authorization shall be effective for five years from the date of issuance of this letter.								
Status of the applicant	☒ Importer								
Status of application	☒ Generic Drug Product (GDP)								
Intended use of pharmaceutical product	☒ Domestic sale								
For imported products, specify one the these	☒ Finished Pharmaceutical product import								
Dy. No. and date of submission	Dy. No. 20020985361 Dated: 12-12-2023								
Details of fee submitted	Rs. 150000/- Dated 12/12/2023								
The proposed proprietary name / brand name	Influenza Vaccine (Split Virion), Inactivated, Quadrivalent								
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Hemagglutinin (HA) derived from each type of influenza virus strain in the current year. Each 0.5ml of this medicinal product contains: A/Guandong - Maonan/ SWL1536/2019(H1N1)pd,09-like 15µg HA virus A/Hong Kong/2671/2019(H3N2)-like virus B/Washington/02/2019 (B/Victoria lineage)-like virus 15µg HA B/Phuket/3073/2013 (B/Yamagata lineage)-like virus 15µg HA								
Dosage form of applied drug	Suspension for Injection								
Pharmacotherapeutic Group of (API)	ATC classification: J07BB02								
Reference to Finished product specifications	Chinese Specifications								
Proposed Pack size	0.5ml/syringe,1 syringe/carton								
Proposed unit price	Retail price as per SRO								
Shelf Life	12 months								
Storage Conditions	2-8C								
The status in reference regulatory authorities	Influenza Vaccine (Spilt Virion), Inactivated, Quadrivalent manufacturer has been registered in China. The registration situation of Influenza Vaccine (Spilt Virion), Inactivated, Quadrivalent is as follow: <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 33%;">Country</th><th style="width: 33%;">Registration No.</th><th style="width: 33%;">Date of Registration/Last Renewal</th></tr> <tr> <td>People's Republic of China</td><td>GYZZ S20000029</td><td>February 25th , 2020</td></tr> </table>			Country	Registration No.	Date of Registration/Last Renewal	People's Republic of China	GYZZ S20000029	February 25 th , 2020
Country	Registration No.	Date of Registration/Last Renewal							
People's Republic of China	GYZZ S20000029	February 25 th , 2020							
For generic drugs (me-too status)	N/A								
Drug Substance: IIV 4 monovalent bulk									
Name, address of drug substance manufacturer	M/s : Changchun Institute of Biological Products Co., Ltd. Manufacturing Address: No.1616,Chuangxin Road, High-Tech Development Zone, Changchun City P.R. China								
General Information	The manufacture of IIV 4 monovalent bulk mainly includes virus seed passage, virus inoculation, harvest, purification, disruption, re-purification, and inactivation. Critical								

		intermediates include allantoic fluid harvest, concentrated virus suspension, purified virus suspension, purified virus suspension obtained from chromatography, purified disrupted-virion suspension, inactivated disrupted-virion suspension, purified suspension of inactivated disrupted-virions, and monovalent bulk. The monovalent bulk is a slightly opalescent liquid.
	Specifications	Reference not provided.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	(1) Stability studies at 37 °C for 28 days: contents of hemagglutinin and protein met the requirements of specification. (2) Accelerated stability study at 25 °C for 6 months: contents of hemagglutinin and protein met the requirements of specification. (3) Long-term study at 2-8 °C for 12 months: contents of hemagglutinin and protein met the requirements of specification.
	Drug Product:	
	Description	Injection, Strength: 0.5 mL/pre-filled syringe for a single dose (adults and children aged over three years), which shall contain 15 µg of hemagglutinin for each type of influenza strains. Compared to clinical samples, the proposed formula of IIV 4 for commercialization used the same excipients except that the virus strain is changed according to the annual information released by the WHO. The drug product is a preparation made from strains of influenza virus type A and type B (abbreviated as flu) recommended by WHO, which are inoculated to embryonated chicken eggs before incubation. Viral suspension is then harvested, purified, disrupted, re-purified, and inactivated. The product is a slightly opalescent liquid. The preparation quantity is 200 L -250 L for each batch of final bulk, with the batch size of 330,000 -420,000 of syringes for finished products.
	Analytical method validation/verification of product	P53-1 Identification P53-2 Determination of free formaldehyde content P53-3 Determination of gentamicin residue P53-4 Determination of hemagglutinin content P53-5 Determination of protein content P53-6 Determination of ovalbumin content P53-7 Method of suitability of sterility test P53-8 Bacterial endotoxin test P53-9 Leak-HS Microleak Sealing Tester
	Container closure system of the drug product	The pre-filled syringe is employed as the container closure system of the drug product commonly used for vaccines.
	Stability study data of drug product, shelf life and storage conditions	Three process validation batches of drug product were subjected to stability studies performed at 37 °C for 21 days, at 25 °C for six months (accelerated stability studies), and at 2 - 8 °C for 18 months (long-term stability studies). The shelf life of the product was determined to be 12 months.
	Module-IV	Single-dose toxicity 2.4.4.1.1 Toxicity Test in ICR mice During the study period, no dead or dying animal was observed. No abnormality was observed in the clinical observation compared with animals of the same gender in the negative reference group. No statistically significant difference was observed in body weights of animals in the UV 4 group. No significant difference was observed in food consumption. Results of pathological gross anatomy and macroscopic observation showed no abnormal changes in the main organs or tissues. The results showed that there was no apparent toxicity after a single intramuscular injection of 1 dose/animal in ICR mice. The maximum tolerated dose (MTD) in mice was greater than or equal to 1 dose/animal
	Module-V	To evaluate the efficacy of Influenza Vaccine (Split Virion), Inactivated, Quadrivalent, CCIBP conducted "A Randomized, Double-blind, Active-controlled Phase III Clinical Trial Evaluating the Immunogenicity and Safety of Influenza Vaccine (Split Virion), Inactivated, Quadrivalent (IIV4) in Adults and Children Aged Over 3 Years" in China
S. No	Sections	Observations/Deficiencies/ Short-comings
	1.3.3	Original, legalized and valid COPP mentioning the composition of vaccine as per WHO recommended strains for the year 2024-2025.
	1.4.2	Documents/evidence for acceptable shipping conditions for both finished product and drug substance and formulated bulk (for importing bulks for filling and domestic

		production) & proof of shipping validation.
	1.5.2	Complete strength/concentration of applied vaccine.
	1.5.8	The reference of already registered product containing 2024-2025 strain including the following details needs to be submitted. • Brand name • Manufacturer/Registration holder • Registration number
	1.5.9	List of RRA where the product is already licensed and the date of approval.
	1.5.14	Provide SMPC as per WHO recommended strains for the year 2024-2025. Justification for the clinical indications “It is specially recommended for the population with a higher risk of influenza complications such as children, the elderly, the vulnerable and the ones who are living in influenza pandemic area” as no supporting clinical trial data has been submitted. Clarification is required for clinical indication as already approved indication of influenza virus in RRA is Prevention of influenza, especially in individuals who are at increased risk of complications in influenza. “Influvac is indicated in adults and children from 6 months of age”.
	3.2.S.2 to 3.2.S.7	Complete drug substance part of each monovalent virus bulk from S1 to S 7 containing data of recommended strains for the year 2024-2025 northern hemisphere influenza season as provided data is of 2020.
	3.2.P.2 to 3.2.P.8	Complete drug product part P 1 to P 8(Final bulk Filling) as per WHO recommended strains for the year 2024-2025.
	3.2.R	Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3.
	Module 4 Non-Clinical Data	Complete non-clinical studies pertinent to recommended strains of 2024-2025 and justification for not performing complete pharmacodynamics studies like protective studies, passive immune transfer studies, safety pharmacology studies, repeat dose toxicity studies, safety studies, development and reproductive toxicity studies. Complete study reports with English version. Proper justification with evidence of reference guidelines were “Not applicable” has been mentioned for non-clinical study reports.
	Module 5 Clinical Data	Complete Clinical study reports along with raw data for the WHO recommended strains for the year 2024-2025 as per international guidelines. The clinical data should be supporting clinical indications. In case of studies with comparator, provide the details of comparator product. Proper justification with evidence of reference guidelines were “Not applicable” has been mentioned for non-clinical study reports. Risk Management Plan (RMP) for the WHO recommended strains for the year 2024-2025. Periodic Safety Update Report (PSUR)/Periodic Benefit-Risk Evaluation Report (PBRER) for the WHO recommended strains for the year 2024-2025. Adverse event following immunization report (summary of annual reports) in the country of origin or any other NRA.

Decision of 345th Meeting:

The Registration Board deferred the case for the submission of the following documents:

- Original, legalized and valid COPP mentioning the composition of vaccine as per WHO recommended strains for the year 2024-2025.
- Documents/evidence for acceptable shipping conditions for both finished product and drug substance and formulated bulk (for importing bulks for filling and domestic production) & proof of shipping validation.
- Complete strength/concentration of applied vaccine.
- The reference of already registered product containing 2024-2025 strain.
- List of RRA where the product is already licensed and the date of approval.
- Provide SMPC as per WHO recommended strains for the year 2024-2025.
- Justification for the clinical indications “It is specially recommended for the population with a higher risk of influenza complications such as children, the elderly, the vulnerable and the ones who are living in influenza pandemic area” as no supporting clinical trial data has been submitted.
- Clarification is required for clinical indication as already approved indication of influenza virus in RRA is Prevention of influenza, especially in individuals who are at increased risk of complications in influenza. “Influvac is indicated in adults and children from 6 months of age”.

- Drug substance part of each monovalent virus bulk containing data of recommended strains for the year 2024-2025 northern hemisphere influenza seasons as per (EMA/CHMP/BWP/99698/2007 Rev. 2).
- Drug product part (Final bulk Filling) as per WHO recommended strains for the year 2024-2025 containing data of recommended strains for the year 2024-2025 northern hemisphere influenza season as per (EMA/CHMP/BWP/99698/2007 Rev. 2).
- Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3.
- Complete non-clinical studies pertinent to recommended strains of 2024-2025 and justification for not performing complete pharmacodynamics studies like protective studies, passive immune transfer studies, safety pharmacology studies, repeat dose toxicity studies, safety studies, development and reproductive toxicity studies. Complete non-clinical study reports with English version.
- Proper justification with evidence of reference guidelines were “Not applicable” has been mentioned for non-clinical study reports.
- Complete Clinical study reports for the WHO recommended strains for the year 2024-2025 or justification is required in the light of reference guidelines. The clinical data should be supporting clinical indications.
- In case of studies with comparator, provide the details of comparator product.
- Proper justification with evidence of reference guidelines were “Not applicable” has been mentioned for clinical study reports.
- Risk Management Plan (RMP) for the WHO recommended strains for the year 2024-2025.
- Periodic Safety Update Report (PSUR)/Periodic Benefit-Risk Evaluation Report (PBRER) for the WHO recommended strains for the year 2024-2025.
- Adverse event following immunization report (summary of annual reports).

Remarks of the Evaluator

S. No	Sections	Observations/Deficiencies/Short-comings	Responses from CCIBP	Remarks of Evaluator
1.	1.3.3	Original, legalized and valid COPP mentioning the composition of vaccine as per WHO recommended strains for the year 2024-2025.	Refer to Annex 1	Original, Apostille COPP submitted by the applicant but strains are not mentioned. The Applicant has applied for following strains: Each 0.5ml of this medicinal product contains: A/Guandong - Maonan/ SWL1536/2019(H1N1)pd,09-like 15µg HA virus A/Hong Kong/2671/2019(H3N2)-like virus B/Washington/02/2019 (B/Victoria lineage)-like virus 15µg HA B/Phuket/3073/2013 (B/Yamagata lineage)-like virus 15µg HA. COPP mentions both vial and syring. Clarification is required.
2.	1.4.2	Documents/evidence for acceptable shipping conditions for both finished product and drug substance and formulated bulk (for importing bulks for filling and domestic production) & proof of shipping validation.	The finished product shall be stored and transported at 2-8 °C. Refer to Annex 2 for the International Cold-chain Transportation Validation Protocol and Report. The bulk and final bulk of IIV4 will not be exported to Pakistan.	PQ of pallet incubator submitted by the applicant instead of shipping validation protocol.
3.	1.5.2	Complete strength/concentration of applied vaccine.	The strength of IIV4 is 0.5 mL/syringe. Active ingredient: Hemagglutinin (HA) derived from each type of influenza virus strain in the current year. Each 0.5 mL of this medicinal product contains (consider virus seeds listed for the Northern Hemisphere by WHO in	Strains has been revised without submission of variation fee.

			2024): A/Victoria/4897/2022 (H1N1) pdm09-like virus.....15µg HA A/Thailand/8/2022 (H3N2) -like virus.....15µg HA B/Austria/1359417/2021 (B/Victoria lineage) -like virus..... 15µg HA B/Phuket/3073/2013(B/Yamagata lineage) - like virus.....15µg HA								
4.	1.5.8	The reference of already registered product containing 2024-2025 strain including the following details needs to be submitted. Brand name Manufacturer/Registration holder Registration number	Influenza Vaccine (Split Virion), Inactivated, Quadrivalent Sinovac Biotech CO., LTD Reg: No 115151	-							
5.	1.5.9	List of RRA where the product is already licensed and the date of approval.	Influenza Vaccine (Split Virion), Inactivated, Quadrivalent manufactured is registered in China and Macao. The registration situation of Influenza Vaccine (Split Virion), Inactivated, Quadrivalent is as follows: <table><tr><th>Country</th><th>Date of registration</th></tr><tr><td>People’s Republic of China</td><td>March 11th, 2020</td></tr><tr><td>Macao</td><td>February 20th, 2024</td></tr></table>	Country	Date of registration	People’s Republic of China	March 11 th , 2020	Macao	February 20 th , 2024	List of RRA not provided.	
Country	Date of registration										
People’s Republic of China	March 11 th , 2020										
Macao	February 20 th , 2024										
6.	1.5.14	Provide SMPC as per WHO recommended strains for the year 2024-2025.	Refer to Annex 3- SmPC containing WHO recommended strains for the year 2024-2025.	Revised SMPC submitted but clinical data not incorporated in it.							
		Justification for the clinical indications "It is specially recommended for the population with a higher risk of influenza complications such as children,the elderly,the vulnerable and the ones who are living in influenza pandemic area"as no supporting clinical trial data has been submitted.	The submitted clinical trials of Changchun Company in Module 5 of CTD dossier have included the immunogenicity and safety data of this product. The influenza vaccine changes strains every year, but there is no need to conduct clinical trials based on different strains. The previously submitted clinical data is sufficient to demonstrate the safety and immunogenicity of this product, and the previous clinical data of this product has covered populations such as children and the elderly.	Only single dose toxicity studies submitted.							
		Clarification is required for clinical indication as already approved indication of influenza	This product to be registered now is	-Vaccine is for 3 years and above.							

		virus in RRA is Prevention of influenza, especially in individuals who are at increased risk of complications in influenza."Influvac is indicated in adults and children from 6 months of age".	for adults and children aged 3 years old and above, with a specification of 0.5mL/syringe. The other product with the specification of 0.25ml is for children with the age of 6-35 months old.		
7.	3.2.S.2 to 3.2.S.7	Complete drug substance part of each monovalent virus bulk from S1 to S7 containing data of recommended strains for the year 2024-2025 northern hemisphere influenza season as provided data is of 2020.	Refer to Annex 4	Revised S part submitted.	
8.	3.2.P.2 to 3.2.P.8	Complete drug product part P1 to P8 (Final bulk Filling) as per WHO recommended strains for the year 2024-2025.	Refer to Annex 4	Revised P part submitted.	
9.	3.2.R	Copy of Batch Manufacturing Record(BMR)for all the batches of drug product for which stability studies data is provided in Module 3. (BMR)。	Refer to Annex 5	Not provided.	
10.	Module 4 Non-Clinical Data	Complete non-clinical studies pertinent to recommended strains of 2024-2025 and justification for not performing complete pharmacodynamics studies like protective studies, passive immune transfer studies, safety pharmacology studies, repeat dose toxicity studies,safety studies, development and reproductive toxicity studies.	The data in Module 4 of submitted CTD dossier have included the non-clinical trials of Changchun Company of this product. The influenza vaccine changes strains every year, but there is no need to conduct non-clinical trials based on different strains. The previously submitted non-clinical data is sufficient to demonstrate the safety and immunogenicity of this product.	Single dose toxicity data submitted.	
		Complete study reports with English version.	Please refer to Annex 6- The English version of completed non-clinical study reports.	Submitted.	
		Proper justification with evidence of reference guidelines were "Not applicable "has been mentioned for non-clinical study reports. 。	Please refer to the highlighted parts of Annex 7- Updated Module 4 for the justifications of reference guidelines were "Not applicable "has been mentioned for non-clinical study reports.	Attached.	
11.	Module 5 Clinical Data	Complete Clinical study reports along with raw data for the WHO recommended strains for the year 2024-2025 as per international guidelines. The clinical data should be supporting clinical indications. In case of studies with comparator, provide the details of comparator product. Proper justification with evidence of reference guidelines	The submitted clinical trials of Changchun Company in Module 5 of CTD dossier have included the immunogenicity and safety data of this product. The influenza vaccine changes strains every year, but there is no need to conduct clinical trials based on different strains.	To evaluate the efficacy of Influenza Vaccine (Split Virion), Inactivated, Quadrivalent, CCIBP conducted "A Randomized, Double-blind, Active-controlled Phase III Clinical Trial Evaluating the Immunogenicity and Safety ofInfluenza Vaccine (Split Virion), Inactivated, Quadrivalent (IIV4) in Adults and Children Aged Over 3 Years" in China.	

		were "Not applicable"has been mentioned for non-clinical study reports. Risk Management Plan(RMP)for the WHO recommended strains for the year 2024-2025.			
		The clinical data should be supporting clinical indications	The previously submitted clinical data is sufficient to demonstrate the safety and immunogenicity of this product, and the previous clinical data of this product has covered populations such as children and the elderly	-	
		In case of studies with comparator, provide the details of comparator product.	The comparators used in Phase III clinical trail are Influenza Vaccine (Split Virion), Inactivated (manufactured by Changchun Institute of Biological Products Co., Ltd. with the batch No. of S20170101) and Influenza Vaccine (Split Virion), Inactivated (manufactured by Changchun Institute of Biological Products Co., Ltd. with the batch No. of S20170103).	-Provided	
		Proper justification with evidence of reference guidelines were "Not applicable"has been mentioned for non-clinical study reports.	Please refer to the highlighted parts of Annex 4- Updated Module 4 for the justifications of "Not applicable"has been mentioned for non-clinical study reports.	-Provided	
		Risk Management Plan(RMP)for the WHO recommended strains for the year 2024-2025.	Please refer to Annex 8- Risk Management Plan.	Attached.	
		Periodic Safety Update Report (PSUR) / Periodic Benefit-Risk Evaluation Report (PBRER) for the WHO recommended strains for the year 2024-2025.	According to Chinese regulations, the data reporting period for the first submission of PSUR for this product is from March 11, 2020 to March 10, 2025. Currently, the data period for this product has not ended and there is no PSUR report yet.	Attached.	
		Adverse event following immunization report (summary of annual reports)in the country of origin or any other NRA.	There is no AEFI report submission requirement in China.	Not submitted.	

Remarks of Evaluation

Not recommended as revised COPP does not mention recommended strains, submission of fee for strain change, repeat dose toxicity, shipping validation, BMR is also required.

Decision 345th RB meeting:

The registration Board deferred the case for the submission of the following documents:

- i. Revised Form 5 F with WHO recommended strains for the year 2024-2025 along with submission of requisite fee.
- ii. Revised original, legalized and valid COPP with updated strains.

iii.	Updated Summary of Product Characteristics (SmPC), labeling, packaging, patient leaflets with updated strains and already available clinical data.
iv.	Updated Quality Overall Summary (QOS) with following revised sections as per WHO recommended strains for the year 2024-2025. a. 2.3.S.1.1 General Information → updated strain designation. b. 2.3.S.2 Manufacture → identify new virus seeds (e.g., CVVs). c. 2.3.P.1 Description and Composition → updated strain names. d. 2.3.P.5 Control of Drug Product → batch release data for new formulation. e. 2.3.P.8 Justification for absence due to routine nature of strain change.
v.	Stability data of drug product of commercial batches with updated strains or justification in the light of reference guidelines.
vi.	BMR of updated strains.
vii.	Reactogenicity profile after strain update.
viii.	Proof of shipping validation.

Conclusion

Influenza viruses continuously change and evolve. The periodic replacement of the virus strains contained in influenza vaccines is therefore necessary to keep the vaccines effective. The WHO recommends that trivalent vaccines for use in the 2025-2026 northern hemisphere influenza season contain the following:

Egg-based vaccines

- an A/Victoria/4897/2022 (H1N1)pdm09-like virus;
- an A/Croatia/10136RV/2023 (H3N2)-like virus; and
- a B/Austria/1359417/2021 (B/Victoria lineage)-like virus.

The applicant is required to update the strains through a pre-registration variation application, along with the corresponding updates to the relevant CTD modules, in accordance with the EMA Guideline on Influenza Vaccines – Submission and Procedural Requirements (Rev. 2) (EMA/56793/2014 Rev. 2).

Decision of 348th RB meeting:

Registered Board deferred the case for submission of following documents:

- i. Revised Form 5 F with WHO recommended strains for the year 2025-2026 along with submission of requisite fee.
- ii. Revised original, legalized and valid COPP mentioning recommended strains for the year 2025-2026.
- iii. Updated Summary of Product Characteristics (SmPC), labeling, packaging, patient leaflets with updated strains and already available clinical data.
- iv. Updated Quality Overall Summary (QOS) with following revised sections as per WHO recommended strains for the year 2024-2025.
 - a. 2.3.S.1.1 General Information → updated strain designation.
 - b. 2.3.S.2 Manufacture → identify new virus seeds (e.g., CVVs).
 - c. 2.3.P.1 Description and Composition → updated strain names.
 - d. 2.3.P.5 Control of Drug Product → batch release data for new formulation.
 - e. 2.3.P.8 Justification for absence due to routine nature of strain change.
- v. Stability data of drug product of commercial batches with updated strains or justification in the light of reference guidelines.
- vi. BMR of updated strains.
- vii. Reactogenicity profile after strain update.
- viii. Proof of shipping validation.

Quadrivalent Influenza Vaccine Deferred Case:M-345 Exporting Country (Korea)		
Case # 5		
	Name, address of Applicant / Importer	M/s Amson Vaccines & Pharma (Pvt.) Ltd. Plot No. 115, Industrial Triangle, Kahuta Road, Islamabad.
	Details of Drug Sale	FORM-11 (DISTRIBUTION LICENSE) Computerized ID: DHO-ISB-1352
	License of importer	License No: DHO-ISB-1352 Address: 115 Industrial triangle Kahuta Road Islamabad. Validity: 01-12-2025 Certifying Authority: Ministry Of National Health Services Regulations And Coordination District Health Office

	Islamabad
Name and address of marketing authorization holder (abroad)	GC Biopharma Corp, (Hwasun Plant) 40 Sadan-gil, Hwasun-eup, Hwasun-gun, Jeollanam-do, 519-955, Republic of Korea
Name, address of manufacturer(s)	GC Biopharma Corp, (Hwasun Plant) 40 Sadan-gil, Hwasun-eup, Hwasun-gun, Jeollanam-do, 519-955, Republic of Korea Phone Number: +82-61-379-2100 Fax Number: +82 -61-379-2166
Name of exporting country	Republic of Korea
Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Scanned Copy Apostille COPP Certificate No:2023-A1-1492 COPP is not as per WHO recommended strains for the year 2024-2025.
Details of letter of authorization / sole agency agreement	SOLE AGENCY CERTIFICATE We, GC Biopharma Corp., established and reputable manufacturer of the below mentioned product having factory at, 40 Sandan-gil, Hwasun-eup, Hwasun-gun, Jeollanam-do, do hereby confirm that we have appointed Amson Vaccine & Pharma (Pvt) Ltd, 115, Industrial Triangle as our sole agent and exclusive distributor in Pakistan for registration, import, promotion, and marketing of the below mentioned product in Pakistan. 1. GC FLU Quadrivalent pre-filled syringe inj. Date of Validity: 22nd October 2026
Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
Dy. No. and date of submission	Tracking ID: G44-QU4-1B4T Application Number:3509 Receiving Date: 13-05-2024
Details of fee submitted	Challan Number: 2560048368 Division: Biological Evaluation & Registration Paid Fee: 300000.0 Paid Date: 2024-02-20 Fee Head: Registration of Any Other Biological Drug for Import
The proposed proprietary name / brand name	GC FLU Pre-filled syringe injection 0.5 ml.
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	1 pre-filled syringe 0.5 mL contains, Purified Inactivated Influenza Virus Antigen Type A [A/Victoria/4897/2022 IVR-238 (H1N1)] 15 µg Purified Inactivated Influenza Virus Antigen Type A [A/Darwin/9/2021 SAN-010 (H3N2)] - 15 µg Purified Inactivated Influenza Virus Antigen Type B [B/Austria/1359417/2021 BVR-26] --- 15 µg Purified Inactivated Influenza Virus Antigen Type B [B/Phuket/3073/2013] -- ----- 15 µg

		This vaccine complies with the WHO recommendations (Northern Hemisphere) for 2023-2024 season.
Therapeutic Indications		Prophylaxis against influenza caused by influenza A subtype viruses and type B viruses in persons aged 6 months and older.
Route of Administration		IM
Dosage form of applied drug		Pre-filled syringe containing colourless or slightly whitish liquid.
Pharmacotherapeutic Group of (API)		Vaccine for Influenza
Finished product specifications		European Pharmacopeia
Proposed Pack size		1's
Proposed unit price		As per SRO
Shelf life		12 Months
Storage conditions		2°C -8°C
The status in reference regulatory authorities		WHO prequalified in Vial (2022 Season) Vaccine type Influenza, seasonal (Quadrivalent) Commercial Name GC FLU Quadrivalent inj. Manufacturer GC Biopharma Corp. URL http://www.globalgreencross.com/eng/company/company.do Responsible NRA Ministry of Food and Drug Safety Country Republic of Korea URL http://www.mfds.go.kr/eng/index.do Prequalification Prequalification Status Current Effective Date 21/12/2016 Product description Pharmaceutical Form Liquid: ready to use Presentation Vial Number of Doses 1 Diluent Not Applicable Route of Administration Intramuscular Shelf Life 12 months Storage Temperature 2-8°C Vaccine Vial Monitor Type 7 Secondary Packaging a) Single dose carton [Dimensions: 2.5 x 2.5 x 4.5 cm]; b) Carton of 10 vials (10 doses) [Dimensions: 8.8 x 3.6 x 4.4 cm] Tertiary Packaging Box of 3000 single doses cartons
For generic drugs (me-too status)		Brand name: Influvac Tetra Manufacturer: Abbott Bio Netherland (Registration No: 107910)
Drug Substance Part: Monovalent Bulk		
Name, address of drug substance manufacturer		M/s GC Biopharma Corp. (Hwasun Plant) 40, Sandan-gil, Hwasun-eup, Hwasun-gun, Jeollanam-do, Korea
General Information and Manufacturing		General Properties

	GC3110A drug substance is split, inactivated influenza type A (H1N1 and H3N2) and influenza type B (Yamagata and Victoria) monovalent bulks. The monovalent bulks consist of purified inactivated split viruses that are prepared from working seeds of the four strains of influenza virus, which are grown individually in embryonated healthy flock (non-SPF) eggs. Since circulating virus strains are different every year, virus antigens in GC3110A are changed every year as recommended by WHO. Recommended influenza virus strains since 2013/2014 northern hemisphere are provided. Manufacturing the monovalent bulk (DS) consist of purified inactivated split viruses that are prepared from working seeds of the four strains of influenza virus, type A (H1N1 and H3N2) and type B (Yamagata, Victoria), which are cultivated individually in embryonated healthy flock (non-SPF) eggs. Each virus containing fluid that is harvested from the eggs is partially clarified, concentrated and ultracentrifugated in a linear sucrose gradient, then treated with Octoxinol 10 (Triton X-100), a non-ionic surfactant, to disrupt the virus particles. The monovalent split virus pool is inactivated by formalin, followed by a sterile filtration step.									
Specifications	1. Most of specifications are satisfying the requirement of European Pharmacopoeia (Ph.Eur) unless otherwise specified.									
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Long-term stability testing (2 – 8°C) was conducted for 3 batches of GC3110A (A/H1N1, A/H3N2, B/Yamagata, B/Victoria) manufactured at Hwasun Plant. Acceptable test results were obtained when stored for up to 24 months (for B/Brisbane/60/2008, up to 27 months).									
Module-III Drug Product: GC3110A drug product is purified, inactivated monovalent bulk of four virus antigen type (A/H1N1, A/H3N2, B/Yamagata and B/Victoria).										
Manufacturer	GC Biopharma Corp. (Hwasun Plant) 40, Sandan-gil, Hwasun-eup, Hwasungun, Jeollanam-do, 58141, Korea Final bulk and drug product manufacturing, packaging, release testing, stability testing and storage/distribution of the drug product									
Specifications	Most of specifications are satisfying the requirement of European Pharmacopoeia (Ph.Eur) unless otherwise specified. The analytical methods have been developed and validated, when appropriate to support the current specifications.									
Container closure system of the drug product	GC3110A final bulk is stored in a single-use 50 L Flexboy® bag (EVA, ethylene vinyl acetate copolymer) manufactured by Sartorius same as monovalent bulk solution (DS). 1mL prefilled syringe Type I glass (borosilicate) Stainless Steel Needle 1mL prefilled syringe plunger rod Polystyrene Rubber stopper Chlorobutyl Rubber									
Stability study data of drug product	Stability Results and Conclusions Acceptable test results were obtained when GC3110A final bulk was stored for up to 12 months and when GC3110A drug product (0.5 mL) were stored for up to 12 months.									
Non-clinical (Module-IV)										
<table><tr><td colspan="3">Module 4 (Non-clinical / Safety)</td></tr><tr><td>4.2</td><td colspan="2">Study Reports</td></tr><tr><td>4.2.1</td><td>Pharmacology</td><td></td></tr></table>		Module 4 (Non-clinical / Safety)			4.2	Study Reports		4.2.1	Pharmacology	
Module 4 (Non-clinical / Safety)										
4.2	Study Reports									
4.2.1	Pharmacology									

		4.2.1.1	Primary Pharmacodynamics	1Immunogenicity assessment conducted in the reproductive and developmental toxicity study (under GLP compliance) was conducted under non-GLP condition by GCC. The objective of this study was to confirm the immunogenicity and protection efficacy of quadrivalent inactivated influenza vaccine (split virion, GC3110A) after challenge with A/California/07/09 A/Panama/2007/99(H3N2). In conclusion, GC3110A showed sufficient immunogenicity in this ferret model and protection against H1N1 virus in nasal wash and lung tissue. Protection studies are not performed. Justification is required. Passive immune transfer studies are not performed. Justification is required.	
		4.2.1.2	Secondary Pharmacodynamics	NA	
		4.2.1.3	Safety Pharmacology	As described in the Note for Guidance on Preclinical Pharmacological and Toxicological Testing of Vaccines (CPMP/465/95), undesirable pharmacological activity affecting physiological functions (such as central nervous system, respiratory system, cardiovascular system and kidney function) was not observed in repeat dose toxicity study in rabbits . Accordingly, separate safety pharmacology study was not conducted. .	
		4.2.1.4	Pharmacodynamic Drug Interactions	NA	
	4.2.2	Pharmacokinetics		NA	
	4.2.3	Toxicology			
		4.2.3.1	Single-Dose Toxicity (in order by species, by route)	As described in Guideline on Nonclinical Evaluation of Biopharmaceuticals (MFDS, 2004.9, single-dose toxicity study was replaced by repeated-dose toxicity study.	
		4.2.3.2	Repeat-Dose Toxicity (in order by species, by route, by duration; including supportive	Repeat Dose Toxicity Study of GC3110A Administered by Intramuscular Injection to Rabbits. GC3110A: Reproductive and Developmental Toxicity Study by Intramuscular Administration in Sprague-Dawley Rats Repeat Dose Toxicity Study of GC3110A Administered by Intramuscular Injection to Rabbits	
		4.2.3.3	Genotoxicity	NA	
		4.2.3.4	Carcinogenicity (including supportive toxicokinetics evaluations)	NA	
		4.2.3.5	Reproductive and Developmental Toxicity (including range-finding studies and supportive toxicokinetics evaluations) (If modified study designs are used, the following sub-headings should be modified accordingly.)	NA	
		4.2.3.6	Local Tolerance	NA	
Clinical (Module-V)					
	Sr. No.	Name		Comments	

		5.2 Tabular Listing of All Clinical Studies	
		5.3 Clinical Study Reports	
	5.3.1 Reports of Biopharmaceutic Studies	Biopharmaceutics studies do not apply to this class of products. Therefore clinical studies that describe the release and systemic availability of GC Flu pre filled syringes injection have not been performed.	
	5.3.2 Reports of Studies Pertinent to Pharmacokinetics using Human Biomaterials	Pharmacokinetics and product metabolism studies do not apply to this class of drug	
	5.3.3 Reports of Human Pharmacokinetic (PK) Studies	Pharmacokinetics and product metabolism studies do not apply to this class of drug	
	5.3.4 Reports of Human Pharmacodynamic (PD) Studies		
	5.3.5 Reports of Efficacy and Safety Studies 5.3.5.2 Study Reports of Uncontrolled Clinical Studies 5.3.5.3 Reports of Analyses of Data from More Than One Study		
	5.3.6 Reports of Post-Marketing Experience.	Periodic safety updated reports has been submitted	
	5.3.7 Case Report Forms and Individual Patient Listings	-	
S. No	Sections	Observations/Deficiencies/ Short-comings	
1.	1.3.3	a) Multiple COPPs have been provided in the Module 1. Clarification is required. Provide hard copy of Original, legalized and valid COPP mentioning the composition of vaccine as per WHO recommended strain 2024-2025. b) The verification number mentioned on COPP is not readable. c) Hard copy of original or notarized copy of letter of authorization.	
2.	1.4.2	Documents/evidence for acceptable shipping conditions for both finished product and drug substance and formulated bulk (for importing bulks for filling and domestic production) & proof of shipping validation.	
3.	1.5.2	The concentration of vaccine doesnot provide any data about strains used in the vaccine. The excipient details should be provided in relevant section instead of section 1.5.2.	
4.	1.5.5	Pharmacotherapeutic group is required in relevant section.	
5.	1.5.6	The specifications mentioned in this section are both EP and WHO. Comparison of specs is required along with monograph.	
6.	1.5.8	The reference of already registered product containing 2024-2025 strain including the following details needs to be submitted. - Brand name - Manufacturer/Registration holder - Registration number	
7.	1.5.9	a) List of RRA where the product is already licensed and the date of approval. b) Evidence of approval / registration / marketing status of the applied formulation in the same composition and dosage form in one of the reference regulatory authority specified by Registration Board.	
8.	1.5.14	a) SMPC of WHO recommended strains for the year 2024-2025 is required. b) The therapeutic indication(6 months and older) should be in line with submitted clinical data.	
9.	3.2.S.2 to 3.2.S.7	a) Complete drug substance part of each monovalent virus bulk from S1 to S 7 containing data of recommended strains for the year 2024-2025 northern hemisphere influenza season as provided data is of 2013/2014 strains.	
10.	3.2.P.2 to 3.2.P.8	b) Complete drug product part P 1 to P 8(Final bulk Filling) as per WHO recommended strains for the year 2024-2025. c) The drug part is of 30 µg/mL of each four strain whereas, the applied strength is 15 µg/mL d) Evidence of EP monograph and comparability of provided specifications with EP. e) 120% excessive overage has been added. Justification is required w.r.t specification and comparator product.	

11.	3.2.R	Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3.
12.	Module 4 Non-Clinical Data	a) Complete non-clinical studies pertinent to recommended strains and justification for not performing complete pharmacodynamics studies like protective studies, passive immune transfer studies, safety pharmacology, safety studies, development and reproductive toxicity studies. b) Submit single dose/repeat dose toxicity and local tolerance studies of WHO recommended strains 2024-2025. c) Proper justification with evidence of reference guidelines were “Not applicable” has been mentioned for non-clinical study reports.
13.	Module 5 Clinical Data	a) Complete Clinical study reports along with raw data for the WHO recommended strains for the year 2024-2025 as per international guidelines. b) Provide evidence of published clinical study reports if any. c) Provide details of comparator product (along with strains) against which clinical studies have been performed. d) Justification is required for comparison of quadrivalent vaccine with Trivalent vaccine w.r.t to SRA guidelines. e) Reports of post marketing. f) Proper justification with evidence of reference guidelines were “Not applicable” has been mentioned for non-clinical study reports. g) Risk Management Plan (RMP) for the WHO recommended strains for the year 2024-2025. h) Periodic Safety Update Report (PSUR)/Periodic Benefit-Risk Evaluation Report(PBRER) for the WHO recommended strains for the year 2024-2025. i) Adverse event following immunization report (summary of annual reports) in the country of origin or any other NRA. j) Submit raw data for all clinical study reports.

Decision of 345th Meeting:

The Registration Board deferred the case for the submission of the following documents:

- i. Multiple COPPs have been provided in the Module 1. Clarification is required.
- ii. Provide hard copy of Original, legalized and valid COPP mentioning the composition of vaccine as per WHO recommended strain 2024-2025.
- iii. The verification number mentioned on COPP is not readable.
- iv. Hard copy of original or notarized copy of letter of authorization.
- v. Documents/evidence for acceptable shipping conditions for both finished product and drug substance and formulated bulk (for importing bulks for filling and domestic production) & proof of shipping validation.
- vi. The concentration of vaccine does not provide any data about strains used in the vaccine.
- vii. The excipient details should be provided in relevant section instead of section 1.5.2.
- viii. Pharmacotherapeutic group is required in relevant section.
- ix. The specifications mentioned in this section are both EP and WHO. Comparison of specs is required along with monograph.
- x. The reference of already registered product containing 2024-2025 strain including the following details needs to be submitted.
- xi. List of RRA where the product is already licensed and the date of approval.
- xii. Evidence of approval / registration / marketing status of the applied formulation in the same composition and dosage form in one of the reference regulatory authority specified by Registration Board.
- xiii. SMPC of WHO recommended strains for the year 2024-2025 is required.
- xiv. The therapeutic indication (6 months and older) should be in line with submitted clinical data.
- xv. Drug substance part of each monovalent virus bulk containing data of recommended strains for the year 2024-2025 northern hemisphere influenza seasons as per (EMA/CHMP/BWP/99698/2007 Rev. 2).
- xvi. Drug product part (Final bulk Filling) as per WHO recommended strains for the year 2024-2025 containing data of recommended strains for the year 2024-2025 northern hemisphere influenza season as per (EMA/CHMP/BWP/99698/2007 Rev. 2).
- xvii. The drug part is of 30 µg/mL of each four strain whereas, the applied strength is 15 µg/mL.
- xviii. Evidence of EP monograph and comparability of provided specifications with EP.
- xix. 120% excessive overage has been added. Justification is required w.r.t specification and comparator product.
- xx. Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3.
- xxi. Justification for not performing complete pharmacodynamics studies like protective studies, passive immune transfer studies, safety pharmacology, safety studies, development and reproductive toxicity studies.
- xxii. Submit single dose/repeat dose toxicity and local tolerance studies of WHO recommended strains 2024-2025.
- xxiii. Proper justification with evidence of reference guidelines were “Not applicable” has been mentioned for non-clinical and clinical study reports.
- xxiv. Complete Clinical study reports along with raw data for the WHO recommended strains for the year 2024-2025 as per international guidelines or justification is required in the light of reference guidelines.

xxv.	Provide evidence of published clinical study reports if any.
xxvi.	Provide details of comparator product (along with strains) against which clinical studies have been performed.
xxvii.	Justification is required for comparison of quadrivalent vaccine with Trivalent vaccine w.r.t to SRA guidelines.
xxviii.	Reports of post marketing is required.
xxix.	Proper justification with evidence of reference guidelines were “Not applicable” has been mentioned for clinical study reports.
xxx.	Risk Management Plan (RMP) for the WHO recommended strains for the year 2024-2025.
xxxi.	Periodic Safety Update Report (PSUR)/Periodic Benefit-Risk Evaluation Report (PBRER) for the WHO recommended strains for the year 2024-2025.
xxxii.	Adverse event following immunization report (summary of annual reports) in the country of origin or any other NRA.

Decision of 345th Meeting:

The Registration Board deferred the case for the submission of the following documents:

Shortcomings	Response	
1) Multiple COPPs have been provided in the Module 1. Clarification is required.	The hardcopy of original, legalized and valid CoPP mentioning the composition of vaccine as per WHO recommended strain 2024-2025NH can be found in the Attachment #1.3.3 QIV PFS_24-25NH_CPP_apostilled.	
2) Provide hard copy of Original, legalized and valid COPP mentioning the composition of vaccine as per WHO recommended strain 2024-2025.		
3) The verification number mentioned on COPP is not readable.	The verification number of above CPP is QFGC-G895-RZ6L-91QA	
4) Hard copy of original or notarized copy of letter of authorization.	-	
5) Documents/evidence for acceptable shipping conditions for both finished product and drug substance and formulated bulk (for importing bulks for filling and domestic production) & proof of shipping validation.	To validate shipping condition of finished product, a shipping validation was conducted with using simulated temperature chamber under the longest transportation route of shipping to Honduras Tegucigalpa, the most remote country from which we release. - Transportation route : GC Biopharma Corp manufacturing site in Hwasun to Honduras Tegucigalpa - Duration : approximately 218 hours (9 days) As we applied new drug registration process of GCFLU Quadrivalent pre-filled syringe inj. to export only the finished product to Pakistan, not drug substance or final bulk, we would like to submit the transport validation report that was performed based on the finished product. Shipping validation of finished product was already included in the previously submitted CTD 3.2.P.7, but for your better understanding, please find enclosed Attachment #1.4.2_Shipping validation report.	

6)	The concentration of vaccine does not provide any data about strains used in the vaccine.	The information regarding the concentration used and strains used in the Vaccine has been updated.	
7)	The excipient details should be provided in relevant section instead of section 1.5.2.	-	
8)	Pharmacotherapeutic group is required in relevant section.	The Pharmacotherapeutic group has been specified in accordance with CTD guidelines and included in relevant section of Module 1.	
9)	The specifications mentioned in this section are both EP and WHO. Comparison of specs is required along with monograph.	The specification method has been aligned with PH. Eur. Specification and the relevant monograph has been provided in the CTD section	
10)	The reference of already registered product containing 2024-2025 strain including the following details needs to be submitted.	Abbott Bio Netherland Influvac Tetra 0.5ml	
11)	List of RRA where the product is already licensed and the date of approval.	GCFLU Quadrivalent pre-filled syringe inj. has been internationally recognized for its safety and effectiveness and has been registered in the following countries listed below Nepal, Iran, Georgia, Guatemala, Ukraine.	
12)	Evidence of approval / registration / marketing status of the applied formulation in the same composition and dosage form in one of the reference regulatory authority specified by Registration Board.	In case of GCFLU Quadrivalent inj, which is manufactured based on the exact same drug substance and excipients with GCFLU Quadrivalent pre-filled syringe inj, is as follows. Since the difference between GC FLU Quadrivalent inj. and GCFLU Quadrivalent pre-filled syringe inj. is only in the container (vial/syringe) it is filled in, therefore, the registration status of GCFLU Quadrivalent inj. is also provided below for reference. In regard to WHO, which grants WHO-PQ approval only for vial formulations of vaccine, GCFLU Quadrivalent inj. received WHO-PQ approval in 2016. Please refer to the Attachment #1.5.9 WHO PQ approval of GCFLU Quadrivalent inj. (vial). Please find SmPC of WHO Recommended strain for the year 2024-2025 in the Attachment #1.5.14 QIV PFS_SmPC_24-25NH_V3.6 The therapeutic indications is confirmed as follow “prophylaxis against influenza caused by	
13)	SMPC of WHO recommended strains for the year 2024-2025 is required.		
14)	The therapeutic indication (6 months and older) should be in line with submitted clinical data.		

	influenza A subtype viruses and type B viruses in prerson aged 6 months and older" based on the performed clinical study.	
15) Drug substance part of each monovalent virus bulk containing data of recommended strains for the year 2024-2025 northern hemisphere influenza seasons as per (EMA/CHMP/BWP/99698/2007 Rev. 2).	Previously submitted CTD were written based on the season at the time of approval in Korea. After obtaining approval of related products, we are planning to update the strain information in CTD as of the most recent season at that time of approval in Pakistan. Please find enclosed Attachment #3.2.S to 3.2.P.8 Justification letter for more detailed information.	
16) Drug product part (Final bulk Filling) as per WHO recommended strains for the year 2024-2025 containing data of recommended strains for the year 2024-2025 northern hemisphere influenza season as per (EMA/CHMP/BWP/99698/2007 Rev. 2).	Previously submitted CTD were written based on the season at the time of approval in Korea. After obtaining approval of related products, we are planning to update the strain information in CTD as of the most recent season at that time of approval in Pakistan. Please find enclosed Attachment #3.2.S to 3.2.P.8 Justification letter for more detailed information.	
17) The drug part is of 30 µg/mL of each four strain whereas, the applied strength is 15 µg/mL.	We hereby declare that the correct amount for drug part is 30 ug/mL (=15ug/0.5mL) for each four strains.	
18) Evidence of EP monograph and comparability of provided specifications with EP.	Based on the previously submitted CTD 3.2.P.5.1 specification, the specification following EP	
19) 120% excessive overage has been added. Justification is required w.r.t specification and comparator product.	Excessive amount of hemagglutinin (120%) is added under consideration of test method variation and loss during storage. Based on the results of retrospective evaluation, excessive addition of hemagglutinin in formulation of final bulk (hemagglutinin overage of 120%) was justified. In addition, no safety issue was observed in non-clinical and clinical studies conducted with such drug products manufactured with hemagglutinin overage (120%). Detailed test results are described below. Retrospective evaluation of hemagglutinin contents based on the reduction rate from stability data 12 months stability studies of hemagglutinin content of GC3110A drug product (0.5 mL pre-filled syringe) which is formulated to have 120% overage of theoretical amount (15 µg/0.5mL) are conducted as shown in the table below. All test results are met for acceptance criteria	

	(Lower confidence limit $\geq$ 80% of stated quantity for each strain) for 12 month.	
20)	Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3.	All the batches of drug product for which stability studies data is provided in Module 3 is as below and summary of batch results are provided in the CTD 3.2.P.8.3 and they are all acceptable
21)	Justification for not performing complete pharmacodynamics studies like protective studies, passive immune transfer studies, safety pharmacology, safety studies, development and reproductive toxicity studies.	For seasonal influenza vaccine, there is no requirement to perform and submit non-clinical or clinical data for the recommended strain every year.
22) 23)	Submit single dose/repeat dose toxicity and local tolerance studies of WHO recommended strains 2024-2025. Proper justification with evidence of reference guidelines were "Not applicable" has been mentioned for non-clinical and clinical study reports.	For seasonal influenza vaccine, there is no requirement to perform and submit non-clinical or clinical data for the recommended strain every year. Reference guidelines that were referred to were written in the 4.3 Literature References in the Module 4 of CTD. The list of reference guidelines and reference were as below. Please find Attachment #4_4.3 Literature references_v1.0
24)	Complete Clinical study reports along with raw data for the WHO recommended strains for the year 2024-2025 as per international guidelines or justification is required in the light of reference guidelines.	For seasonal influenza vaccine, there is no requirement to perform and submit non-clinical or clinical data for the recommended strain every year
25)	Provide evidence of published clinical study reports if any.	Attachment #5_a Published Adult CSR_QIV PFS - Attachment #5_b Published Elderly CSR_QIV PFS - Attachment #5_c Published Children CSR_QIV PFS - Attachment #5_d Published Infant CSR_QIV PFS
26)	Provide details of comparator product (along with strains) against which clinical studies have been performed.	GCFLU Pre-filled Syringe inj. - A/California/7/2009 NYMC X-181(H1N1) -A/Texas/50/2012 NYMC X-223A(H3N2) - B/Massachusetts/02/2012 NYMC BX-51B(Yamagata lineage)
27)	Justification is required for comparison of quadrivalent vaccine with Trivalent vaccine w.r.t to SRA guidelines.	A non-inferiority trial for an influenza vaccine aims to demonstrate that the new vaccine is not significantly worse than a reference vaccine. This type of trial is often used when a new vaccine is being compared to an existing, established vaccine, and the goal is to show that the new vaccine provides a similar level of protection and safety. Globally, it is assumed

	that demonstration of non-inferior immune responses should translate into broadly comparable protection against influenza. For example, EMA (European Medicine Agency) also recommends to confirm the non-inferior immunogenicity in the influenza vaccine in the guideline on Influenza vaccine . Through several non-inferiority clinical trial of GC FLU Quadrivalent pre filled syringe inj., the non-inferiority was confirmed with compared to the approved control drug, GC FLU pre-filled syringe inj. and It was confirmed that GC FLU Quadrivalent pre filled syringe inj. is as effective as the already approved trivalent vaccine in preventing influenza virus infection. From a safety perspective, the Quadrivalent vaccine, which contains one more strain, is more likely to cause adverse reaction than the trivalent vaccine. However, it is also confirmed that GC FLU Quadrivalent pre filled syringe inj. is as safe as B and no safety issue have been confirmed.	
28)	Reports of post marketing is required.	PBRER_QIV PFS_v9.0
29)	Proper justification with evidence of reference guidelines were “Not applicable” has been mentioned for clinical study reports.	Please see the Attachment #5_f Literature reference
30)	Risk Management Plan (RMP) for the WHO recommended strains for the year 2024-2025.	Please see the Attachment #5_f Literature reference
31)	Periodic Safety Update Report (PSUR)/Periodic Benefit-Risk Evaluation Report (PBRER) for the WHO recommended strains for the year 2024-2025.	Please see the Attachment #5_f Literature reference
32)	Adverse event following immunization report (summary of annual reports) in the country of origin or any other NRA.	There isn't any separate AE following immunization report. All the related safety concern are reported in the submitted RMP and PBRER for each Attachment #5_e PBRER_QIV PFS_v9.0 and Attachment #5_g RMP_QIV PFS_v2.0

Conclusion

The applicant is required to update the strains through a pre-registration variation application, along with the corresponding updates to the relevant CTD modules, in accordance with the Guideline on Influenza Vaccines – Submission and Procedural Requirements (Rev. 2) (EMA/56793/2014 Rev. 2).

Decision of 348th Meeting:

The Registration Board deferred the case for the submission of following documents:

- Update the strains through a pre-registration variation, along with the corresponding updates to the relevant CTD module 1,

Module 2 and Module 3 with requisite fee.
• Hard copy of Original, legalized and valid COPP mentioning the composition of vaccine as per WHO recommended strain 2025-2026.
• Clinical studies of PFS.
• Reactogenicity Profile after strain update.
• Risk Management Plan (RMP) for the WHO recommended strains for the year 2024-2025.
• Periodic Safety Update Report (PSUR)/Periodic Benefit-Risk Evaluation Report (PBRER) for the WHO recommended strains for the year 2024-2025.
• Adverse event following immunization report (summary of annual reports) in the country of origin or any other NRA.

(Influenza Vaccine (Split Virion), Inactivated, Trivalent) New Case Exporting Country (China)	
Case No. 6	
Name, address of Applicant / Importer	Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila Rawalpindi
Details of Drug Sale License of importer	License No: 01-374-0006-118530D Valid up to: 15.08.2029
Name of exporting country	China
Name and address of marketing authorization holder (abroad)	Hualan Biological Vaccine Inc. Address: Jia No.1-1, Hualan Ave., Xinxiang 453003, Henan, China.
Name, address of manufacturer(s)	Hualan Biological Vaccine Inc. Address: Jia No.1-1, Hualan Ave., Xinxiang 453003, Henan, China.
Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	COPP Certificate No: No.Henan20250080 Validity: 31st Dec.2025 Certifying Authority: Henan Medical Products Administration Free Sale Status: Yes GMP Status: Yes Not as per WHO recommendations.
Details of letter of authorization / sole agency agreement	June 12, 2025 Subject: Letter of Authorization We, Hualan Biological Vaccine Inc., a manufacturer incorporated under the laws of People's Republic of China with a registered representative office at Jia No.1-1, Hualan Ave., Xinxiang 453003, Henan, China, hereby authorize: M/s. Lab Diagnostic Systems (SMC) Pvt Ltd Head office: 111 Hall Road Westridge 1, Rawalpindi Warehouse: Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi, Punjab
Status of the applicant	Importer
Status of application	Human-Import Form 5-F
For imported products, specify one the these	Finished Drug Product
Dy. No. and date of submission	Tracking ID: 2NU-DXU-H2TB Application Number: 105388 Date of Receiving: 27-06-2024
Details of fee submitted	Challan Number: 858185121 Division: Biological Evaluation & Registration Paid Fee: 300,000 Paid Date: 2025-06-16
The proposed proprietary name / brand name	VIRIONZA
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	The vaccine 0.5ml contains: A/Guangdong-Maonan/SWL1536/2019 (H1N1) pdm09-like virus ...15µg hemagglutinin A/Hong Kong/2671/2019 (H3N2)-like virus.....15µg hemagglutinin B/Washington/02/2019 (B/Victoria lineage)-like virus.....15µg hemagglutinin Excipients: Na2HPO4, NaH2PO4, NaCl.
Adjuvant (if any)	NA
Dosage form of applied drug	Injection

Indication/Target Disease	It is indicated for active immunization against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine for prophylaxis of the Influenza caused by the contained vaccine strain.
Target Population	The vaccine is approved for use in vulnerable people and high risk population for influenza complications, such as children over 3 years of age, the elderly, the weak and people in influenza epidemic areas. Each 0.25ml syringe (for pediatric use) or 0.5ml syringe/vial (for adult use) contains 7.5µg or 15µg of hemagglutinin from each strain, respectively
Route of Administration	Intramuscular
Pharmacotherapeutic Group of (API)	Flu Vaccine
Finished product specifications	Chinese Pharmacopeia
Proposed Pack size	1's
Proposed unit price	As per SRO
Shelf life	12 Months
Storage conditions	Store and ship at 2-8°C, protected from light.
The status in reference regulatory authorities/Name of NRA	Brand Name: Flublok Manufactured by: Sanofi Pasteur Inc Packing: 0.5 mL prefilled syringe UFDA Approved
For generic drugs (me-too status)	Brand Name: Influvac Tetra Marketed by: Abbott Laboratories (Pakistan) Ltd. Packing: 0.5ml syringe
Drug Substance (Bulk of Influenza Vaccine (Split Virion), Inactivated)	
General Information	Bulk of Influenza Vaccine (Split Virion), Inactivated
Name, address of drug substance manufacturer	Hualan Biological Bacterin Co., Ltd. Jia No.1-1, Hualan Avenue, Xinxiang, Henan, China
Manufacturing Process	Bulk of influenza vaccine (split virion), inactivated, of our company is produced through inoculating the influenza A and influenza B viral strains which are recommended by WHO into the chick embryos, culturing the virion, collecting the allantoic fluid containing virus after cooling embryos and then adding formaldehyde to inactivate virus after pre-filtration, clarification filter (microfiltration) and sterilization filter; adding Triton X-100 into inactivated monovalent virus solution for lysis after undergoing ultrafiltration and concentration, sucrose density gradient centrifugation and molecular sieve chromatography: taking ultrafiltration to remove the split agent and adding sterilization filter to get monovalent bulk. In the process of bulk of influenza vaccine (split virion), inactivated, there are relevant process control to the corresponding production process
Characterization	Hemagglutinin: it is columnar form that combined with receptor on the surface of red blood cell in human and animals such as birds, pigs and guinea pigs to cause coagulation that is hemagglutinin. After hemagglutinin proteolysis is divided into 2parts: heavy chain and light chain, the latter can combine with sialic acid receptor on the host cell membrane and the former can help the fusion of the virus envelope with the host cell membrane. Hemagglutinin plays an important role in the process of virus entering a cell. HA has immunogenicity and anti-Hemagglutinin antibody can neutralize influenza virus.
Control of drug Substance	This section includes specifications to ensure the vaccine meets required quality standards, such as virus titer and HA content. It outlines the analytical procedures used for testing the vaccine's identity, purity, and potency, with validated methods to ensure consistency. The section also includes batch analyses to verify that each production batch complies with the specifications. Additionally, it provides justifications for the chosen specifications, ensuring they are scientifically grounded and comply with regulatory standards.
Stability	Batch number: B2-A3201602001、B2-A3201602002、B2-A3201603003、B2-Bv201603001、B2-Bv201603002、B2-Bv201603003), and retain 1 batch of H1N1 (batch number: B2-A1201601001) to do stability study. Place in the 2 ~ 8 °C conditions for 24 months (bulk validity is 18 months), and validate at the 0,3rd, 6th, 9th ,12th ,18th ,24th months respectively. 24 months of detection have been completed, and hemagglutinin content overall decline, but are within the regulation restriction, in line with company quality standards. Visual inspection, bacterial endotoxin test and sterility test are in line with regulations.

Drug Substance (Each Monovalent strain)	
General Information	Not provided.
Name, address of drug substance manufacturer	Not provided.
Manufacturing Process	Not provided.
Characterization	Not provided.
Control of drug Substance	Not provided.
Stability	Not provided.
Drug Product (Name)	
Composition	The vaccine 0.5ml contains: A/Guangdong-Maonan/SWL1536/2019 (H1N1) pdm09-like virus ...15µg hemagglutinin A/Hong Kong/2671/2019 (H3N2)-like virus.....15µg hemagglutinin B/Washington/02/2019 (B/Victoria lineage)-like virus.....15µg hemagglutinin Excipients: Na ₂ HPO ₄ , NaH ₂ PO ₄ , NaCl.
Formulation	The formulation of the VIRIONZA Influenza Vaccine (split virion, inactivated) consists of the active ingredient, hemagglutinin (HA) derived from H1N1 , H3N2 , and B influenza strains, which is crucial for the vaccine's effectiveness. For the pediatric dose, each 0.25ml syringe contains 7.5µg of HA from each strain, while the adult dose (0.5ml syringe or vial) contains 15µg per strain. The excipients used include sodium chloride (NaCl) , sodium dihydrogen phosphate (NaH₂PO₄) , and disodium hydrogen phosphate (Na₂HPO₄) , which act as stabilizers and maintain the pH balance. The vaccine is formulated as a slightly opalescent liquid, ensuring stability in the buffer solution
Manufacturing	The manufacturing process of the VIRIONZA Influenza Vaccine (split virion, inactivated) involves several key steps to ensure the production of a high-quality vaccine. These steps include: 1. Pre-Incubation Candling: The eggs are selected from healthy chicken flocks and incubated for 9-11 days. Eggs are then inspected for viability using candling. 2. Inoculation: The selected eggs are inoculated with the appropriate influenza virus strains (H1N1, H3N2, and B). The virus is diluted and injected into the eggs using automated virus inoculation machinery. The inoculation volume is strictly controlled. 3. Virus Cultivation: The inoculated eggs are transferred to a virus cultivation room, where the virus grows in the allantoic fluid of the eggs. 4. Post-Inoculation Candling: After cultivation, eggs are inspected again to ensure the embryos are developing properly. Unqualified embryos are discarded, while the healthy ones are sent back for further cultivation. 5. Egg Cooling: Once the virus cultivation process is complete, the embryos are cooled at 2-8°C to prepare them for harvest. 6. Virus Harvesting: The allantoic fluid containing the virus is harvested using an automatic virus harvester, and any residual contaminants are removed through a series of filtration steps. 7. Filtration and Inactivation: The harvested virus solution undergoes pre-filtration (5µm), microfiltration (0.45µm), and sterilization filtration. Formaldehyde is added to inactivate the virus, ensuring it is non-infectious. 8. Ultrafiltration and Concentration: The inactivated virus is then concentrated using ultrafiltration, and further purified using sucrose density gradient centrifugation and molecular sieve chromatography. 9. Virus Splitting: Triton X-100 is introduced to split the virus particles, breaking them into smaller components. The excess Triton X-100 is removed through another round of ultrafiltration. 10. Sterilization Filtration: The final vaccine formulation is sterilized using 0.2µm filtration to ensure it is free from microbial contamination. 11. Filling and Inspection: The monovalent bulk is filled into vials or pre-filled syringes under sterile conditions. The product undergoes lamp inspection to detect any defects or foreign materials. 12. Storage: The final product is stored at 2-8°C to maintain its stability and efficacy.
Specifications	Chinese Pharmacopoeia (As per Innovator's Specifications)

Container Closure	The container closure system for the VIRIONZA Influenza Vaccine (split virion, inactivated) involves two types of packaging materials designed to ensure the stability and sterility of the vaccine: 1. Pre-filled Syringes: The vaccine is also packaged in pre-filled syringes, which are sealed using brominated butyl rubber stoppers.
Stability	The stability studies for the VIRIONZA Influenza Vaccine include both long-term and accelerated tests at various temperatures: but no details on container closure system has been provided. Stability Summary: 1. Accelerated Stability Studies: ○ 37°C and 25°C accelerated tests were conducted, with batches like 201207A017, 201207A022, and 201207B013 studied at various time points (0, 7, 14, 21, 30 days at 37°C and 0, 45, 90, 193 days at 25°C). ○ Tests included parameters like pH, HA content, protein content, bacterial endotoxins, and formaldehyde levels. Results showed that while HA content slightly decreased over time, it remained within acceptable limits. 2. Long-Term Stability Studies: ○ These were conducted under 2-8°C conditions for extended periods, typically for 18 months. The HA content showed a gradual decrease, but remained within the acceptable range, and other stability indicators (pH, endotoxins, etc.) showed no significant deviations. 3. Post-Marketing Stability: ○ The vaccine undergoes continuous stability testing post-marketing, with one batch tested annually unless significant production changes occur. This study also includes testing for factors such as packaging material changes or production process updates.
Viral Safety Evaluation	The VIRIONZA Influenza Vaccine has undergone a thorough adventitious agents safety evaluation to ensure that the vaccine is free from any unintended or harmful agents that could affect its safety or efficacy. This includes testing for the presence of exogenous avian leucosis virus, exogenous avian adenovirus, and mycoplasma contamination, with all tests returning negative results, confirming the absence of these potential contaminants. Additionally, a sterility test is performed on every batch to confirm that the vaccine remains free from microbial contamination, which is crucial for maintaining its safety during use.
Module 4- Nonclinical Reports	
Pharmacology: Primary Pharmacodynamic (PD) studies Immunogenicity studies humoral as well as cellular immune responses (depending on reagents availability), and dose-range testing of antigen. Protection Studies Passive immune transfer Studies	Primary Pharmacodynamics: The influenza vaccine (split virion) was tested in SPF mice to evaluate its immunogenicity. The vaccine samples were tested using different dilutions (1:25 to 1:3125), and the results showed that the vaccine triggered robust immune responses, with high antibody titers (e.g., HI titers of 1:3840 for H1N1 strain) across all tested dilutions, confirming its effectiveness in inducing immunity Secondary Pharmacodynamics: Not applicable for the vaccine, as the primary mechanism is immune stimulation Safety Pharmacology: The safety of the vaccine is supported by decades of use with flu vaccines. The vaccine shows reduced side effects compared to whole-virus vaccines due to its refined purification process, which minimizes the presence of other proteins, such as ovalbumin
Toxicology: Repeat-dose (IM) in animals one animal species of relevance (e.g. rats, ferrets, rabbits, etc.) possible the number of doses and time intervals foreseen in clinical settings; dosing intervals may be shorter (e.g. an interval of 2-3 weeks) considering species-specific differences in the kinetics of the immune response Local tolerance (site histology)	Single dose toxicity Studies. Acute toxicity test for Triton X.

Reproductive & developmental studies	
Module 5 – Clinical Study Reports Immunogenicity Criteria for Split-Virus Influenza Vaccine (Age >3 years) HI Seroconversion Rate ≥40% HI Seroprotection Rate (titer ≥1:40) ≥70% Geometric Mean Fold Rise (GMFR) ≥2.5	
Biopharmaceutics Not applicable for vaccines.	Not applicable for vaccines, as their action is primarily immune stimulation rather than systemic absorption and metabolism
Clinical Efficacy & Safety ☐ Phase I/II:	Phase I/II: These studies were conducted to evaluate dose-ranging and immunogenicity in both adults and infants. Results showed a significant immune response, with measurable antibody production after vaccination
Phase III: Post-marketing:	Phase III studies not performed on children 3 years and above. Phase IV studies on 3 years and above. Rando mized, parallel controlled test Pasteur Biological Products Co., Ltd. Name: Inactivated influenza vaccine (split, virion) Strength:15ug HA/0.5ml/ Piece Batch no.: 20080832 Control vaccine 2: Production unit: Shanghai GSK Strength: 15ug HA/0.5ml/ Piece Batch no.: XFLUA406A 1 Randaomized Parallel control test.
Integrated Summaries ISS & ISE support consistent efficacy and safety across age groups and populations.	The Integrated Summaries (ISS & ISE) for the VIRIONZA Influenza Vaccine support consistent efficacy and safety across various age groups and populations. The Phase III clinical trial demonstrated a robust seroconversion rate of over 90%, with H1N1, H3N2, and B strains achieving high antibody response across children, adults, and elderly individuals. Additionally, the seroconversion rate for different age groups ranged from 83.9% to 96.7% for H1N1, from 56.7% to 77.6% for H3N2, and from 80.2% to 91.9% for the B strain. These data show no significant statistical difference in efficacy between groups, confirming that the vaccine maintains consistent performance across diverse demographic groups. Furthermore, post-marketing surveillance data continuously confirms the long-term efficacy and low incidence of adverse events, reinforcing the vaccine's safety profile. These studies validate that the vaccine provides effective protection while maintaining a favorable safety record, aligning with EU and FDA specifications
Miscellaneous Documents in Compliance to WHO Requirements ✓ A statement by the Applicant to confirm whether the product has been rejected, withdrawn from the markets/countries. ✓ Information on the type of the product if was produced using a GMO technology, ☐ Evidence of valid GMP certificate. ✓ Acceptable shipping condition for both finished product and Drug Substance and Formulated Bulks (for importing bulks for filling and domestic production). ✓ Proof of Shipping validation. ✓ A copy template of lot summary protocol in compliance with WHO-recommended format (identified as per specific WHO TRS). ✓ A copy of labels (vial and carton).	

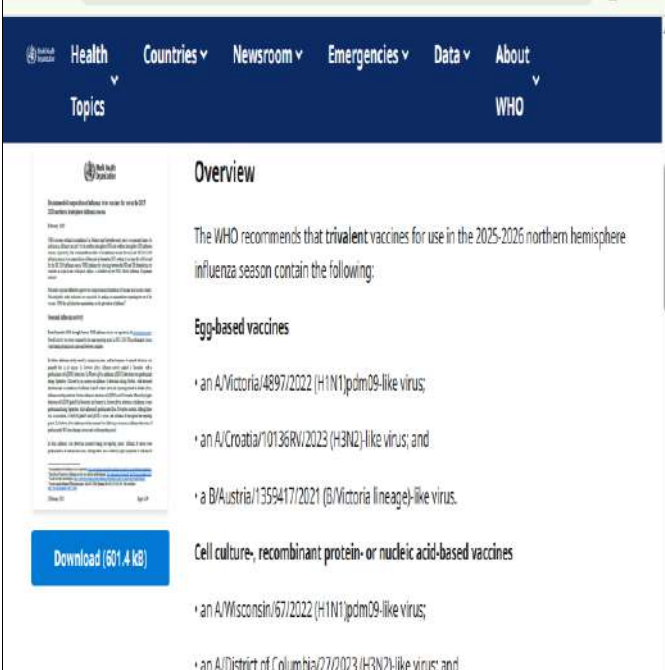
DEFECIENCIES	RESPONSE	Remarks of evaluator
The strains mentioned on Form 5 F are not as per WHO recommended strains for 2024-2025.	Updated Form 5-F is attached.	Submitted
The Form 5 F is not as per Final guidance document for Biological products.	Updated Form 5-F is attached.	The Form 5 F is not as per Final guidance document for Biological products available on DRAP website.
The specifications are not as per DRAP	Our product complies with Chinese Pharmacopeia	Submitted

requirement Reference of specifications should be from any of the following:
USP , BP, Int. Ph. ,• JP
,• Pharmacopoeia of any Reference Regulatory Authority

ChP vs. BP Comparison Table – Influenza Vaccine (Inactivated, Split Virion)

Test Item	Chinese Pharmacopoeia (ChP)	British Pharmacopoeia (BP)	Comment
Identity Test	SRID using antigen/antiserum to confirm strain specificity	SRID or equivalent immunoassay to confirm identity	Equivalent
Appearance	Slightly opalescent liquid; no abnormal substances (by light inspection)	Clear or slightly opalescent; free from visible particles (visual inspection)	Equivalent
Filling Quantity	Not less than stated volume; measured using reference cylinder	Not less than the labeled volume; volumetric check	Equivalent
pH Value	7.0–7.6 (release), 7.0–7.8 (shelf life); measured via potentiometry	6.5–7.8; measured using potentiometric method	Slight range variation; acceptable
Free Formaldehyde	≤ 20 µg/mL; colorimetric method	≤ 0.02 mg/mL (20 µg/mL); colorimetric method	Same limit
HA Content	31–37 µg/mL (release); shelf life: 80–120% of label claim, ≥80% CI; SRID method	≥15 µg per strain per dose; must remain within acceptable variation throughout shelf life; SRID	Equivalent (SRID-based)
Total Protein	≤400 µg/mL; ≤4× HA content; Lowry method	Not always specified in BP, but limits applied in WHO guidance (≤400 µg/mL commonly followed)	Equivalent (may require justification)
Ovalbumin Content	≤80 ng/mL (release); ≤120 ng/mL (shelf); ELISA method	BP usually aligns with WHO limit: ≤1 µg/dose; more stringent ChP is acceptable	ChP is stricter

	Sterility	Direct inoculation or membrane filtration; incubation 14 days	Must comply with BP sterility test; typically direct inoculation	Equivalent
	Bacterial Endotoxins	≤10 EU/mL; turbidimetric kinetic LAL method	≤100 EU/dose; LAL method	ChP is stricter
	Abnormal Toxicity	In vivo test in mice and guinea pigs (per historical pharmacopoeia method)	No longer a BP requirement; replaced by in vitro tests and process validation (in line with ICH Q5E)	
	Osmolality	255–300 mOsmol/kg (release); 280 ± 65 mOsmol/kg (shelf); cryoscopic method	240–320 mOsmol/kg (typically); acceptable range per WHO/BP	Equivalent
Hard copy of COPP and LOA.	The COPP can be verified online. The manufacture is shipping the original legalized LOA, will submit once received.			LOA not received yet
The COPP does not mention strains as per WHO recommendation for the current year. The strains mentioned on COPP are as follow: Hemagglutinin of various influenza virus strains in current year. The vaccine 0.5ml contains: A/ Victoria/4897/2022 (H1N1)pdm09-like virus..... ...15µg hemagglutinin A/Croatia/ 10136RV/2023 (H3N2)-like virus.....	The strains mentioned on COPP is as per year 2025-26. Evidence is attached below.			-

.....15µg hemagglutinin B/Austria /1359417/2021 (B/Victoria lineage)-like virus.....15µg Submit original, legalized/ apostilled COPP.	 The WHO recommends that trivalent vaccines for use in the 2025-2026 northern hemisphere influenza season contain the following: Egg-based vaccines • an A/Victoria/4897/2022 (H1N1)pdm09-like virus; • an A/Croatia/10136RV/2023 (H3N2)-like virus; and • a B/Austria/1359417/2021 (B/Victoria lineage)-like virus. Cell culture, recombinant protein- or nucleic acid-based vaccines • an A/Wisconsin/67/2022 (H1N1)pdm09-like virus; • an A/District of Columbia/27/2023 (H3N2)-like virus; and	
Drug substance part of each monovalent virus bulk containing data of recommended strains for the year 2024-2025 northern hemisphere influenza seasons as per (EMA/CHMP/BWP/996 98/2007 Rev. 2).	Our product contains Strains as per year 2025-26. We are preparing the separate drug substance part for each strain.	Drug substance part not provided yet.
Drug product part (Final bulk Filling) as per WHO recommended strains for the year 2024-2025 containing data of recommended strains for the year 2024-2025 northern hemisphere influenza season as per (EMA/CHMP/BWP/996 98/2007 Rev. 2).	Our product contains Strains as per year 2025-26. The vaccine 0.5ml contains: A/Victoria/4897/2022 (H1N1)pdm09-like virus.....15µg hemagglutinin A/Croatia/10136RV/2023 (H3N2)-like virus.....15µg hemagglutinin B/Austria/1359417/2021 (B/Victoria lineage)-like virus.....15µg The influenza vaccine presented in the current submission is in full alignment with the WHO recommended strains for the 2025–2026 Northern Hemisphere season. As per the latest WHO guidance (February 2025), the following strains are recommended for egg-based trivalent vaccines: A/Victoria/4897/2022 (H1N1)pdm09-like	Updated drug product part (final bulk filling) as per WHO recommended strains for the year 2025-2026 is still required.

	A/Croatia/10136RV/2023 (H3N2)-like (Updated strain per Feb 2025 WHO recommendation) B/Austria/1359417/2021 (B/Victoria lineage)-like	
SMPC of WHO recommended strains for the year 2024-2025 is required as only leaflet has been provided.	Attached	Submitted
Documents/evidence for acceptable shipping conditions for both finished product and drug substance and formulated bulk (for importing bulks for filling and domestic production) & proof of shipping validation.	Attached	Not provided yet.
Section 2.3A and 2.3.R not provided.	These sections are optional to submit as per ICH-M4Q guideline. We have still asked the manufacturer to provide details on this section. We will submit that once received.	Not provided yet.
Submit BMR for each batch.	Manufacture has shared QC reports. Attached.	BMR still required.
Repeat dose toxicity not performed. Justification is required.	Justification for not performing Repeat Dose Toxicity: WHO Guidance on Nonclinical Evaluation of Vaccines According to the WHO Guidelines on Nonclinical Evaluation of Vaccines (TRS No. 927, 2005): <i>“Repeat dose toxicity studies are not required for vaccines consisting of well-characterized antigens (such as inactivated or subunit vaccines) combined with established adjuvants and excipients, particularly when the vaccine is similar to already licensed vaccines and administered in a limited number of doses.”</i> (WHO TRS 927, Annex 1, Section 4.2.1) Our vaccine is a split virion, inactivated trivalent influenza vaccine, composed of well-characterized	Not verified from Who TRS 927,2005. Applicant may be advised to attach evidence.

	HA antigens from WHO-recommended strains, and does not contain a novel adjuvant or excipient. 2. Single-Dose Seasonal Schedule The product is designed for once-yearly administration (or two doses for naïve pediatric patients), and thus does not pose cumulative systemic toxicity risk typically associated with multi-dose schedules. This limited exposure is explicitly cited in the WHO guideline as a justification for waiving repeat-dose studies.	
Phase 1 and II studies not submitted/performed. Clarification is required.	Clarification: According to the original 2007 version of the Registration Management Measures, vaccines for which national drug standards are available are only required to undergo Phase III clinical trials. Thus, Phase I and II studies have not been conducted for our product, Influenza Vaccine (Split Virion), Inactivated.	Submit reference in the light of international guidelines.
Phase III studies not performed on recommended age group > 3 years.	we would like to submit the following justifications: Phase IV (Post-Marketing) Clinical Studies involving large populations aged ≥3 years and older have been conducted and submitted. These studies have confirmed the vaccine's real-world safety, tolerability, and immunogenicity in the recommended population. Evidence: https://ichgcp.net/clinical-trials-registry/NCT01511744?utm_source The product shares an identical formulation and manufacturing process with Hualan's WHO-prequalified vaccine, which is approved for use in similar age groups in multiple countries.	Submit extrapolation studies.
Provide the name of strains on which Phase III and Phase IV studies have been performed.	The vaccine 0.5ml contains: A/Victoria/4897/2022 (H1N1)pdm09-like virus.....15µg hemagglutinin A/Croatia/10136RV/2023 (H3N2)-like virus.....15µg hemagglutinin B/Austria/1359417/2021 (B/Victoria lineage)-like virus.....15µg	Provide evidence of use of WHO recommended strains in Phase III and Phase IV studies.

	The influenza vaccine presented in the current submission is in full alignment with the WHO recommended strains for the 2025–2026 Northern Hemisphere season. As per the latest WHO guidance (February 2025), the following strains are recommended for egg-based trivalent vaccines: A/Victoria/4897/2022 (H1N1)pdm09-like A/Croatia/10136RV/2023 (H3N2)-like (Updated strain per Feb 2025 WHO recommendation) B/Austria/1359417/2021 (B/Victoria lineage)-like	
Risk Management Plan (RMP) for the WHO recommended strains for the year 2024-2025.	Attached	
Periodic Safety Update Report (PSUR)/Periodic Benefit-Risk Evaluation Report (PBRER) for the WHO recommended strains for the year 2024-2025.	Attached	Periodic Safety Update Report (PSUR)/Periodic Benefit-Risk Evaluation Report (PBRER) for the WHO recommended strains for the year 2024-2025 is not provided.
Adverse event following immunization report (summary of annual reports) in the country of origin or any other NRA.	Attached	
Provide evidence of published clinical study reports if any.	Below mentioned links are the evidence of published clinical study reports: https://ctv.veeva.com/study/phase-iv-clinical-trial-of-an-inactivated-influenza-split-vaccine?utm_source https://ctv.veeva.com/study/clinical-trial-of-inactivated-influenza-vaccine-05ml-formulation?utm_source	
The reactogenicity profile of influenza vaccines of WHO recommended strains	• We have provided Phase III and Phase IV clinical study reports for our Influenza Vaccine (Split Virion, Inactivated), which demonstrate the safety, immunogenicity, and effectiveness of the	The reactogenicity profile of influenza vaccines of WHO recommended strains for the year 2024-2025.in the

for the year 2024-2025.in the population indicated for vaccine (including children).	vaccine in the target population, including both adults and children. These studies were conducted in compliance with Good Clinical Practice (GCP) guidelines. • Furthermore, a similar vaccine formulation manufactured by Hualan Biological Vaccine Inc. has received WHO Prequalification (WHO-PQ), confirming its compliance with global standards for quality, safety, and efficacy. The WHO-PQ assessment process includes rigorous evaluation of clinical data and manufacturing quality.	population indicated for vaccine (including children) not provided yet.
Update the strains as per 2025-2026 through a pre-registration variation application, along with the corresponding updates to the relevant CTD modules, in accordance with the Guideline on Influenza Vaccines – Submission and Procedural Requirements (Rev. 2) (EMA/56793/2014 Rev. 2).	we have paid the fee of 9,000/- as pre-registration variation charges for the variance to the registration application (except those specified) for VIRIONZA (Influenza Vaccine, Split Virion) related to the <i>*strain update for the 2025–2026 northern hemisphere influenza season</i> . The payment was made through Challan No. 1082570737 , dated July 2, 2025 .	Copy of challan required.

Decision of 348th RB meeting:

Registration Board deferred the case for submission of following;

- The reactogenicity profile of influenza vaccines of WHO recommended strains for the year 2024-2025 in the population indicated for vaccine (including children).
- Copy of paid fee challan for pre-registration variation.
- Periodic Safety Update Report (PSUR)/Periodic Benefit-Risk Evaluation Report (PBRER) for the WHO recommended strains for the year 2024-2025.
- Evidence of use of WHO recommended strains in Phase III and Phase IV studies.
- Phase III studies not performed on recommended age group > 3 years. Submit extrapolation studies.
- Submit reference of not performing phase I and phase II studies in the light of International guidelines.
- Submit reference of not performing Repeat dose toxicity studies in the light of International guidelines.
- Section 2.3A and 2.3.R not provided.
- Original or notarized LOA in hard copy is required.
- Drug substance part of each monovalent virus bulk containing data of recommended strains for the year 2024-2025 northern hemisphere influenza seasons as per (EMA/CHMP/BWP/99698/2007 Rev. 2).

- **BMR of each batch is required.**
- **The Form 5 F is not as per Final guidance document for Biological products available on DRAP website.**

Tetanus Vaccine

- Tetanus is acquired through infection of a cut or wound with the spores of the bacterium *Clostridium tetani*, and most cases occur within 14 days of infection. Tetanus cannot be transmitted from person to person.
- Tetanus can be prevented through immunization with tetanus-toxoid-containing vaccines (TTCV). However, people who recover from tetanus do not have natural immunity and can be infected again.
- The majority of reported tetanus cases are birth-associated among newborn babies and mothers who have not been sufficiently vaccinated with TTCV.
- WHO recommends that an individual receives 6 doses (3 primary plus 3 booster doses) of TTCV. The 3-dose primary series should begin as early as 6 weeks of age, with subsequent doses given with a minimum interval of 4 weeks between doses. The 3 booster doses should preferably be given during the second year of life (12–23 months), at 4–7 years of age, and at 9–15 years of age. Ideally, there should be at least 4 years between booster doses. There are many kinds of vaccines used to protect against tetanus, all of which are combined with vaccines for other diseases:
 - ✓ diphtheria and tetanus (DT) vaccines
 - ✓ diphtheria, tetanus, and pertussis (whooping cough) (DTaP) vaccines
 - ✓ tetanus and diphtheria (Td) vaccines
 - ✓ tetanus, diphtheria, and pertussis (Tdap) vaccines.

Adsorbed Tetanus Toxoid Vaccine 0.5ml (10 Dose)

New Product

Exporting Country (Indonesia)

Case No. 7

Name, address of Applicant / Importer	M/s Amson Vaccines & Pharma (Pvt.) Ltd. Plot No. 115, Industrial Triangle, Kahuta Road, Islamabad.
Details of Drug Sale License of importer	License No: DHO-ISB-1352 Address: 154 Industrial triangle Kahuta Road Islamabad. Validity: 01-12-2025
Name of exporting country	Indonesia
Name and address of marketing authorization holder (abroad)	PT. BIO FARMA Jl. Pasteur No. 28 Bandung, 40161, Barat, Indonesia
Name, address of manufacturer(s)	PT. BIO FARMA Jl. Pasteur No. 28 Bandung, 40161, Barat, Indonesia
Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	COPP with QR Code Certificate No: No. ST.03.05.35.352A.05.25.000181 Validity: 29-05-2027 Certifying Authority: Address of certifying authority : Directorate of Safety, Quality, and Export-Import Control of Drugs, Narcotics, Psychotropics, Precursors, and Addictive Substances Indonesian Food and Drug Authority (Indonesian FDAGMP Status: : Facilities and operations confirms GMP status
Details of letter of authorization / sole agency agreement	Scanned Copy of LOA (validity:31-12-2028) Firm has submitted Letter of Authorization from PT. BIO FARMA (PERSERO). According to the letter, the firm authorizes “Amson Vaccine & Phrama Pvt Ltd” for the said product and officially authorized to submit application to Drug Regulatory Authority of Pakistan.
Status of the applicant	Importer
Status of application	Generic Drug Product (GDP)
For imported products, specify one the these	Finished Pharmaceutical product import
Dy. No. and date of submission	Duplicate Dossier R&I Date: 02-Sep-2022

	Application Number:
Details of fee submitted	Challan Number: PKR.1,50,000/- Division: Biological Evaluation & Registration Paid Fee: 14-07-2022 Paid Date: 659330528
The proposed proprietary name / brand name	Tetanus Toxoid Vaccine (10 Dose)
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each dose (0.5 ml) of vaccine contains: Purified tetanus toxoid 10 Lf (≥ 40 IU) Aluminum phosphate as Al^{3+} 0.33 mg Thimerosal 0.05 mg
Adjuvant (if any)	Aluminum phosphate 1.50 mg (equivalent to 0.33 mg Al^{3+}) Thimerosal 0.05 mg
Dosage form of applied drug	Suspension for Injection
Indication/Target Disease	TT immunization for the prevention of tetanus/neonatal tetanus, to maintain the immunity of women against tetanus through the child bearing period, and to prevent maternal tetanus. Tetanus toxoid should also be given in situation where a risk of developing tetanus from any other source exists (e.g. injuries).
Target Population	The TT Vaccine is intended for Women of childbearing age – to prevent maternal and neonatal tetanus, Pregnant women, unimmunized individuals at risk of tetanus such as those with injuries and general population as part of their routine immunization.
Route of Administration	IM injection
Pharmacotherapeutic Group of (API)	Vaccine
Finished product specifications	Not provided.
Proposed Pack size	10,s
Proposed unit price	As per SRO
Shelf life	36 Months
Storage conditions	2°C - 8°C
The status in reference regulatory authorities/Name of NRA	WHO PQ Vaccine. TT vaccine WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control)
	Route of Administration:
For generic drugs (me-too status)	Brand name: Imatet Injection Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit: Each 0.5ml dose Contains: Purified Tetanus Toxoid not less than 40 I.U Dosage form of applied drug: Vaccine (Injection) Indication/Target Disease: Tetanus Target Population: The Vaccine is intended for Women of childbearing age – to prevent maternal and neonatal tetanus, Pregnant women, unimmunized individuals at risk of tetanus such as those with injuries and general population as part of their routine immunization. Route of Administration: IM Registration Holder: Amson Vaccines & Pharma (Pvt.) Ltd. Registration Number: 017373
Drug Substance ()	
General Information	The drug substance used in the TT vaccine is Purified Tetanus Toxoid (PTT), an inactivated form of the tetanus toxin produced by <i>Clostridium tetani</i> . The toxoid is rendered non-toxic through a controlled formaldehyde detoxification process and is used as the active immunizing agent in tetanus vaccines. PTT is a well-established antigen with a long history of safe and effective use in immunization programs worldwide. It is a white to off-white suspension and is typically adsorbed onto an aluminum-based adjuvant to enhance immunogenicity. The drug substance is manufactured under Good Manufacturing Practice (GMP) conditions using a validated process that ensures consistency in quality, safety, and potency.
Name, address of drug substance manufacturer	Name: PT. BIO FARMA (PERSERO), Jalan Pasteur No. 28 Bandung, Kec. Sukajadi, Kota Bandung, Jawa, Barat

Manufacturing Process	The manufacturing process of the drug substance, Purified Tetanus Toxoid (PTT), for the TT vaccine at PT Bio Farma begins with seed preparation, using a master seed (D4/T0/82), a secondary master seed (D4/T1/89 B), and a working seed (STET-D4T212 A & B), all cultured in NZ-Case media derived from bovine milk. The working seed is inoculated into Mueller-Miller medium and fermented in large fermenters to produce tetanus toxin. Following fermentation, the culture is harvested by filtration and concentrated using tangential flow filtration (TFF). The concentrated toxin is then detoxified with 0.45% formaldehyde at 35–38°C for four weeks to convert it into a non-toxic form. The resulting crude toxoid undergoes a purification process involving ultrafiltration and diafiltration to yield the final purified tetanus toxoid (PTT). Throughout the process, strict controls are implemented to ensure microbial and viral safety, including sterilization of all animal-derived materials and adherence to EU guidelines on TSE risk minimization. The entire process is carried out in dedicated facilities: Building 11 for toxin production, Building 15 for purification, and Building 19 for formulation and quality control.
Characterization	The purified tetanus toxoid is characterized by its protein content, antigenic identity, and absence of residual toxicity. Key attributes include sterility, specific potency (in International Units), pH, aluminum and formaldehyde content, and absence of microbial and viral contaminants. Safety evaluations, including abnormal and specific toxicity tests, confirm the lack of residual toxicity. The manufacturing and testing processes comply with WHO and pharmacopeial standards, ensuring consistent quality and safety of the drug substance.
Control of drug Substance	The control of the drug substance, Purified Tetanus Toxoid (PTT), is conducted through a comprehensive quality control system to ensure its identity, purity, potency, and safety. The substance is tested in accordance with established specifications derived from pharmacopeial standards and WHO guidelines. Key quality parameters include identity testing (confirmed by flocculation with tetanus antiserum), sterility (no microbial growth), pH (within the range of 6.0–7.0), aluminum content (not more than 1.25 mg/dose), free formaldehyde content (not more than 0.02%), and thimerosal content when applicable. Potency is assessed to ensure a minimum of 40 IU per human dose, with 95% confidence intervals within acceptable limits. Additional tests such as endotoxin levels, bioburden, and abnormal toxicity are also performed to ensure compliance with safety standards. All analytical procedures are validated and conducted using qualified equipment and trained personnel under GMP conditions.
Stability	Stability studies on the drug substance, Purified Tetanus Toxoid (PTT), have been conducted to ensure the maintenance of its quality, safety, and potency throughout its intended shelf-life. Real-time and accelerated stability studies were performed under controlled storage conditions, including temperatures of 2–8°C (recommended) and elevated temperatures for stress testing. The stability parameters evaluated include potency, pH, sterility, aluminum content, free formaldehyde content, and absence of microbial contamination. Results demonstrate that PTT remains stable and within specification for an extended period under recommended refrigerated conditions. No significant degradation or loss of potency was observed during the study periods. Based on the data obtained, the proposed shelf-life and storage conditions of the drug substance are justified, supporting its suitability for use in the final vaccine formulation.
Drug Product (Name)	
Composition	Each 0.5 mL single human dose of the TT vaccine contains Purified Tetanus Toxoid (10 Lf) as the active ingredient. The formulation includes aluminum phosphate (1.5 mg) as an adjuvant, equivalent to 0.33 mg of elemental aluminum (Al ³⁺), to enhance the immune response. Thimerosal (0.05 mg) is included as a preservative. The vaccine is formulated in Water for Injection (WFI) and appears as a whitish suspension. The product is supplied in 5 mL type I glass vials, sealed with 13 mm red rubber stoppers and green aluminum flip-off caps, each containing 10 doses.
Formulation	Each dose (0.5 ml) of vaccine contains: Purified tetanus toxoid 10 Lf (≥ 40 IU) Aluminum phosphate 1.50 mg (equivalent to 0.33 mg Al ³⁺) Thimerosal 0.05 mg
Manufacturing	The manufacturing of the TT vaccine drug product involves a well-controlled and validated process consisting of formulation, filling, sealing, inspection, and packaging. The process begins with the addition of Water for Injection (WFI) into a mixing tank,

	followed by the sequential addition of aluminum chloride, purified tetanus toxoid bulk, trisodium phosphate, thimerosal, and sodium chloride, with pH adjustments made using sodium carbonate and trisodium phosphate. The mixture is homogenized under a vibromixer for a defined period to ensure uniformity. Once the formulation is complete and meets in-process controls (e.g., pH, volume), it is transferred for aseptic filling into 5 mL type I glass vials. After filling, the vials are stoppered, capped, and subjected to visual inspection. Finally, labeled and packaged products are tested for quality attributes, including sterility, potency, pH, aluminum content, and identity, before release for distribution. All steps are performed under GMP conditions, with strict adherence to validated procedures.
Specifications	The TT vaccine is tested against a comprehensive set of specifications to ensure its quality, safety, and efficacy. Key quality attributes include appearance, which should be a whitish suspension; identity, confirmed by flocculation with tetanus antiserum; and potency, which must be not less than 40 IU per single human dose, with 95% confidence intervals within defined limits. The pH must fall within the range of 6.0 to 7.0, and the aluminum content must not exceed 1.25 mg per dose. The vaccine must be sterile, with no microbial growth detected, and show no abnormal toxicity in animal tests. Additional parameters include the adsorption test for tetanus toxoid ($\geq 35\%$ for TT 10 ds), free formaldehyde content ($\leq 0.02\%$), and thimerosal content (0.0085%–0.0115%). Tests for endotoxin levels and osmolality are also conducted. All analytical procedures are validated to ensure consistent and reliable results in accordance with pharmacopeial and WHO standards.
Container Closure system	The TT vaccine is packaged in a 5 mL Type I borosilicate glass vial, which is designed to ensure compatibility, protection, and stability of the vaccine throughout its shelf life. The vial is sealed with a 13 mm red rubber stopper and an aluminum flip-off cap (green) to maintain sterility and integrity. All components of the container closure system meet pharmacopeial requirements for materials used in injectable products, including tests for leakage, bioburden, endotoxin levels, machine compatibility, and dimensional specifications. Rubber stoppers from approved vendors are tested for cleanability, endotoxin (< 0.25 EU/mL), and microbiological quality (< 5 CFU/100 cm²). The system has been validated for its functional performance, including proper sealing and resistance to sterilization conditions, and is shown to be safe, non-reactive, and suitable for vaccine storage at 2–8°C. The container closure system also includes Vaccine Vial Monitors (VVM) to provide visual indication of heat exposure, supporting proper cold chain monitoring.
Stability	Firm has submitted stability study data of 3 batches. The accelerated stability study data is conducted at 25±2°C /60±5%RH for 6 months. The real time stability study data is conducted at 5±3°C for 24 months. 0203115 0203215 0203315 Stability studies of the final TT vaccine product have been conducted under both real-time and accelerated conditions to establish its shelf-life and storage requirements. The vaccine is stable for up to 4 years when stored at 2–8°C, as demonstrated by long-term stability studies. Accelerated studies at 25 ± 2°C and 37 ± 1°C for up to 6 months showed that the product remained within specification for critical parameters, including potency, pH, sterility, aluminum content, free formaldehyde, and thimerosal content. The vaccine also complies with WHO requirements for multi-dose vial policy (MDVP), allowing its use for up to 28 days after opening, provided the cold chain is maintained and the vaccine has not expired or been frozen. Stability testing supports the proposed shelf-life and confirms that the formulation remains safe, effective, and compliant with regulatory standards throughout the intended storage period.
Viral Safety Evaluation	The viral safety of the TT vaccine is ensured through stringent controls on raw materials and robust inactivation steps during manufacturing. Although the vaccine does not use live viral components, some materials used in the upstream process—such as NZ-Case, an enzymatic digest of bovine milk—are of animal origin and potentially pose a theoretical risk of viral contamination. To mitigate this, all animal-derived materials are sourced from countries with a negligible risk of Transmissible Spongiform Encephalopathy (TSE), such as Australia and New Zealand, and comply with EMA/410/01 Rev. 3 guidelines. Furthermore, all culture media and raw materials are autoclaved at 121°C for 15 minutes before use, effectively inactivating any potential viral

		contaminants. An additional layer of viral inactivation is provided by the formaldehyde detoxification step, where the tetanus toxin is treated at 35–38°C for four weeks in the presence of 0.45% formaldehyde, which is known to inactivate a wide range of viruses. As a result of these comprehensive safety measures, no viral contaminants have been detected, and no additional viral testing is deemed necessary. The viral safety evaluation concludes that the TT vaccine poses no significant viral risk to recipients.
Module 4- Nonclinical Reports		
	Pharmacology:	There is no data regarding the non-clinical study of TT vaccine due to the requirement for pre-clinical trial was not implemented at the time when the product was registered.
	Pharmacokinetics: Not applicable (vaccines act via immune stimulation, not systemic exposure).	
	Toxicology: • Repeat-dose (IM) in animals • Local tolerance (site histology) • Reproductive & developmental studies	Abnormal toxicity study for adsorbed vaccine Only overtly a good condition and healthy animals shall be used. All of the animal have the same sex, pass from quarantine period and shall not have been used previously for any test purpose. The vaccine should be passed for abnormal toxicity test with the acceptance criteria as follows: a. Animal not show symptoms of abnormal toxicity and no animal died during observation period. b. No loss on body weight of animal at the end of observation period compared to initial weight. Specific toxicity study for adsorbed vaccine Only overtly a good condition and healthy animals shall be used. All of the animal have the same sex, pass from quarantine period and shall not have been used previously for any test purpose. The vaccine should be passed for specific toxicity test with the acceptance criteria as follows: a. No sign of sickness and no death animal because the presence of tetanus toxin during observation. b. Not less than 80% of animal survives until the end of testing period.
Module 5 – Clinical Study Reports		
	Biopharmaceutics Not applicable for vaccines.	Not applicable
	Clinical Efficacy & Safety Post-marketing:	Phase IV Studies Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication Protectivity and Safety of Td (Bio Farma vaccine in adolescents (Bridging Study)) 2007. Study Reports of Uncontrolled Clinical Studies Effectiveness of Tetanus Toxoid Adsorbed Vaccine in Pregnant Women and Their Newborn Infants in Yogyakarta, 1981.
		Adverse Event Following Immunization of Child Bearing Age Women with Tetanus Adsorbed Vaccine in Multi dose Vials in Lombok. 2002. (Kindly refer to Annex 5.3) Periodic safety updated reports (PSURs) of TT vaccine is
	Integrated Summaries ISS & ISE support consistent efficacy and safety across age groups and populations.	The Integrated Summary of Safety (ISS) and Integrated Summary of Efficacy (ISE) support the consistent efficacy and safety of the TT vaccine across various age groups and populations. Clinical data from studies involving pregnant women, infants, adolescents, and adults demonstrate that the vaccine consistently induces protective levels of anti-tetanus antibodies, with seroconversion rates exceeding 90%, often reaching 100%. No serious vaccine-related adverse events were reported, and observed side effects were primarily mild and local, such as transient pain or swelling at the injection site. The immunogenic response was robust in both priming and booster settings, confirming the vaccine's reliability in different immunization scenarios. These findings collectively affirm that the TT vaccine maintains a high standard of safety, immunogenicity, and tolerability across multiple populations, thereby supporting its use in routine immunization programs globally.
	Post-marketing Data	Post-marketing surveillance data confirm the continued safety and efficacy of the TT vaccine following its widespread use in national immunization programs. The vaccine

	received WHO prequalification on March 11, 1999, and has since been used in countries such as Indonesia, Bhutan, Malaysia, Nigeria, Thailand, and Zimbabwe. In Indonesia, the TT vaccine has been included in the School Children Immunization Program and in immunization programs for women of childbearing age, including pre-wedding and prenatal immunization efforts. Adverse event data are collected through two main sources: the Indonesian Vaccine Safety Advisory Committee and Bio Farma’s international partners. In Indonesia, all AEFI (Adverse Events Following Immunization) cases are investigated at the provincial level and reviewed by the national committee. For international cases, independent AEFI experts appointed by Bio Farma perform safety evaluations. These findings are compiled into Periodic Safety Update Reports (PSURs), which consistently conclude that no changes in the safety profile of the vaccine have been observed. This ongoing post-marketing surveillance supports the vaccine’s long-term safety, with no serious safety signals identified, and reinforces its effectiveness in real-world use across diverse populations.		
	Miscellaneous Documents in Compliance to WHO Requirements ✓ A statement by the Applicant to confirm whether the product has been rejected, withdrawn from the markets/countries. ✓ Information on the type of the product if was produced using a GMO technology, ☐ Evidence of valid GMP certificate. ✓ Acceptable shipping condition for both finished product and Drug Substance and Formulated Bulks (for importing bulks for filling and domestic production). ✓ Proof of Shipping validation. ✓ A copy template of lot summary protocol in compliance with WHO-recommended format (identified as per specific WHO TRS). ✓ A copy of labels (vial and carton).		
Remarks of the Assessor			
Sr. No	Shortcomings	Response	Evaluation
1)	Submit revised Form 5 F as per Final Guidance Document for Biological Products		
2)	Hard copy of original. Legalized COPP and LOA.		
3)	Clarification is required for certifying authority for COPP “Directorate of Safety, Quality, and Export-Import Control of Drugs, Narcotics, Psychotropics, Precursors, and Addictive Substances” Indonesian Food and Drug Authority (Indonesian FDA) whereas, as per WHO the cerifying authority is “National Agency of Drug and Food Control Indonesia”.		
4)	Reference of specifications is required in line with the following:• USP,• BP,• Int. Ph.• JP		
5)	Test of irreversibility of toxoid not performed. Justify.		
6)	The LOA mentions Persero but COPP doesnot specify it.Clarification is required.		
7)	Non-clinical studies have not been performed for vaccines .However, the vaccine is WHO PQ. Submit clarification on the basis of PQ was granted.		
8)	Phase 1, Phase ii and Phase III studies not performed. Justification is required.		
Conclusion The applied vaccine is WHO PQ but requires submission of the documents as highlighted above. Duplicate dossier submitted by the applicant.			
Decision of 348th Meeting: The Registration Board deliberated the cases and decided to approve the applied vaccine based on WHO Prequalification. Registration letter shall be issued after submission of following the case for the submission of the following documents: • Revised Form 5 F as per Final Guidance Document for Biological Products. • Original. Legalized COPP and LOA. • Verification of submission of application and fee from R&I and B&A Division, respectively			

Adsorbed Tetanus Toxoid Vaccine 0.5ml (Single Dose)
New Product
Exporting Country (India)

Case No. 8

Name, address of Applicant / Importer	M/s 2 World Traders Pakistan Company Address: Office 55/2, Main Khayaban-e-Hafiz DHA Karachi
Details of Drug Sale License of importer	License No: 634 Address: 55/2 Main Khayaban-e-Hafiz, Phase V Validity: 01-02-2029
Name of exporting country	India
Name and address of marketing authorization holder (abroad)	HUMAN BIOLOGICALS INSTITUTE, (A Division of Indian Immunologicals Limited) sy.no. 281-284 & 321, Biotech Park, Phase III, Karkapatla Village, Markook Mandal, Siddipet District- 502 281, Telangana, India.
Name, address of manufacturer(s)	HUMAN BIOLOGICALS INSTITUTE (A Division of Indian Immunologicals Limited) Address: HUMAN BIOLOGICALS INSTITUTE, (A Division of Indian Immunologicals Limited) sy.no. 281-284 & 321, Biotech Park, Phase III,
Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Post receipt of valid WHO GMP certificate from Indian Drug Regulatory Authority COPP will be applied, once it is received, it will be legalized and sent out.
Details of letter of authorization / sole agency agreement	Scanned Copy of Distribution Agreement Indian Immunologicals Limited , a Company incorporated under the Companies Act, 1956 and having its registered office at Road No. 44, Jubilee Hills, Hyderabad – 500 033, Telangana, India (hereinafter referred to as ' Exporter ' which expression shall, unless repugnant to the context or meaning thereof be deemed to include its successors and assignees) of the FIRST PART . AND 2 World Traders Pakistan , a Single Proprietor (Company / firm) form under laws of Pakistan, having its principal office at 55/2 Main Khayabane Hafiz Phase V DHA Karachi Pakistan, hereinafter referred to as ' Distributor ' which expression shall unless repugnant to the context or meaning thereof be deemed to include its successors and permitted assignees) of the SECOND PART .
Status of the applicant	Importer
Status of application	NA for vaccine
For imported products, specify one the these	Finished Pharmaceutical product import
Dy. No. and date of submission	Tracking ID:QQX-V7Y-XWMA,Application Number:93949, Date of Receiving 26-06-2025
Details of fee submitted	Challan Number: 75525680197,Division: Biological Evaluation & Registration Paid Fee: 300000.0,Paid Date: 2025-03-22
The proposed proprietary name / brand name	Abhay TOX
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each dose of 0.5 ml contains: Tetanus toxoid ≥ 40 IU (5 to 25Lf) Aluminium Phosphate (AlPO ₄) as Al ⁺⁺⁺ ≤ 1.25 mg Thiomersal (as preservative) 0.01% w/v
Adjuvant (if any)	Aluminum phosphate 1.50 mg (equivalent to 0.33 mg Al ³⁺) Thimerosal 0.05 mg
Dosage form of applied drug	Suspension for Injection
Indication/Target Disease	Tetanus vaccine is indicated as prophylaxis for all age groups above 6 weeks of age. Tetanus toxoid vaccine alone is indicated as part of wound and animal bite management and as a booster dose for children, adolescents and adults. • It can be administered as booster dose or catch-up primary vaccination to persons who are at increased risk of attaining injuries through their occupation or recreational activities. The primary doses of Tetanus vaccine as tetanus toxoid containing combination vaccine (TTCV) are indicated for children above 6 weeks and below 7 years of age

	as per the National Immunization Schedule and WHO recommendations.
Target Population	The TT Vaccine is intended for Women of childbearing age – to prevent maternal and neonatal tetanus, Pregnant women, unimmunized individuals at risk of tetanus such as those with injuries and general population as part of their routine immunization.
Route of Administration	Sterile suspension for intramuscular injection.
Pharmacotherapeutic Group of (API)	: J07AM01
Finished product specifications	BP
Proposed Pack size	Single dose ampoule 120x0.5mL or 10x0.5ml
Proposed unit price	As per SRO
Shelf life	36 Months (24 months data submitted)
Storage conditions	2°C - 8°C
The status in reference regulatory authorities/Name of NRA	Approved in WHO PQ Vaccine of M/s of SERUM INSTITUTE OF INDIA PVT. LTD. 212/2, Hadapsar, Pune 411028, INDIA Each single 0.5 ml human dose contains: Tetanus Toxoid 5 Lf (40 IU) +++ Adsorbed on Aluminium Phosphate, Al 1.25 mg. Preservative : 0.005% Thiomersa
For generic drugs (me-too status)	Brand name: Imatet Injection Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit: Each 0.5ml dose Contains: Purified Tetanus Toxoid not less than 40 I.U Dosage form of applied drug: Vaccine (Injection) Indication/Target Disease: Tetanus Target Population: The Vaccine is intended for Women of childbearing age – to prevent maternal and neonatal tetanus, Pregnant women, unimmunized individuals at risk of tetanus such as those with injuries and general population as part of their routine immunization. Route of Administration: IM Registration Holder: Amson Vaccines & Pharma (Pvt.) Ltd. Registration Number: 017373
Drug Substance (Bulk Purified Tetanus Toxoid)	
General Information	Tetanus toxin is an extremely potent neurotoxin produced by Clostridium tetani in anaerobic conditions. The tetanus toxin protein has a molecular weight of 150 kDa. It is expressed as a single poly-peptide chain which is subsequently cleaved into two parts by endogenous protease: a COOH- terminal 100 kDa heavy or B-chain and a NH2 terminal 50 kDa light or A-chain. The chains are connected by a disulfide bond. Tetanus toxin is inactivated (to toxoid) with formaldehyde.
Name, address of drug substance manufacturer	HUMAN BIOLOGICALS INSTITUTE, Responsibility (A Division of Indian Immunologicals Limited) Rakshapuram, Gachibowli Post, Hyderabad-500032, Telangana, INDIA Manufacturing, Testing and Release of the product are carried out.
Manufacturing Process	Revival of seed, preparation of bulk seed, fermentation process, harvesting and microfiltration, detoxification, concentration, purification, clarification, diafiltration, centrifugation and sterile filtration.
Characterization	Elucidation of Structure and Other Characteristics: The bacterium of Clostridium tetani synthesizes the tetanus toxin as a single poly peptide chain weighing 150kDa (called parent toxin) which is extra cellularly joined by a bacterial protease. The tetanus toxin has a heavy chain (fragment B) of 100kDa and a light chain (fragment A) of 50kDa which are joined together by a disulfide bridge. Physicochemical Characterization Each antigen lot of Purified Tetanus Toxoid Bulk is tested for description, pH and free formaldehyde content. Biological Characterization Each antigen lot of Purified Tetanus Toxoid Bulk is tested for Limit of flocculation, Antigenic purity, Specific toxicity, Irreversibility of Toxoid and Sterility.. Impurities During the manufacturing of Bulk Purified Tetanus Toxoid, Formaldehyde is used for detoxification of Tetanus toxin. After detoxification, Tetanus toxoid is further purified. The sterile filtered bulk is tested for the residual formaldehyde which shall not be more than 0.2 g/L. Each lot of Purified Tetanus Toxoid Bulk shall also comply with the test for sterility.
Control of drug Substance	Strain : Clostridium tetani Seed Name : 49205 Harvard strain Origin : Central Research Institute - Kasauli, Himachal Pradesh Year of Origin : 1964 Country of origin : India System of seed/master/working banks The two tire seed banking system is followed.
Stability	Batch numbers TT/BPTT/001/17, TT/BPTT/002/17 and TT/BPTT/003/17,

	complies with the stability specifications at Real time (5±3°C) for 36 months and Accelerated (25±2°C with RH 60±5%) for 6 months respectively. Hence the batches are stable up to the study period of 36 months at 5±3°C and 6 months at 25±2°C with RH 60±5%.
Drug Product (Name)	
Composition	Tetanus Toxoid is manufactured using Clostridium tetani. The Toxoid is purified by chemical methods and is adsorbed onto aluminium phosphate (as adjuvant). Thiomersal is added as preservative.
Formulation	Each dose (0.5 ml) of vaccine contains: Tetanus Toxoid Quantity per dose 2. ≥ 40 IU (5 to 25 Lf) Aluminium phosphate (AlPO ₄) as Al ⁺⁺⁺ 3. ≤ 1.25 mg Thiomersal (as preservative) 0.01% w/v
Manufacturing	Preparation of Components: Thiomersal (10% w/v): The calculated quantity of Thiomersal is taken and dissolved in the WFI. The Thiomersal solution is sterile filtered using 0.2µ membrane filter. Sterile filtered Thiomersal solution is collected into the sterile glass bottle. 2) Preparation of Solution-I Calculated quantities of Aluminium Chloride hexa hydrate (AlCl ₃ .6H ₂ O) and Sodium Chloride (NaCl) are taken & dissolved in WFI and sample is tested for bioburden. The Prepared Solution-I is filtered and transferred to blending vessel through capsule filter assembly. After filtration the sample is tested for BET and sterility and proceed for FSIP at 123 ± 1oC for 30 minutes. 3) Preparation of Solution II: Calculated quantities of Tri-Sodium Phosphate dodeca hydrate (Na ₃ PO ₄ .12H ₂ O) and Di-Sodium Hydrogen Phosphate (Na ₂ HPO ₄) are taken & dissolved in WFI. The prepared solution is tested for bioburden. The Prepared solution-II is filtered and transferred to glass bottle through capsule filter assembly. The filtered solution is tested for BET and sterility and the filtered solution-II is sterilized using moist steam sterilization in the autoclave at 121.4°C for 55 minutes. 4) Preparation of 1N NaOH and 1N HCl The required quantities of NaOH and HCL was taken and dissolved in WFI, after preparation both the solutions were sterilized in an autoclave at 121.4°C for 55 minutes. 5) Blending Procedure: Blending components are dispensed and transferred aseptically (sequentially) into the blending vessel. Keep the blending vessel in continuous stirring at required RPM. The pH of the Blend is adjusted to 6.0 to 7.0 with 1N NaOH and continued stirring. The blend sample is sent to Quality control for testing as per product specification, filling and optical inspection, labeling.
Specifications	IP&BP
Container Closure system	1ml glass ampoules (Clear Fiolax OPC (Green dot and Green ring))
Stability	(KN21001, KN21002, KN21003) i.e., the accelerated stability study (25±2°C with RH 60±5%) is completed up to 6M time point and the real time stability study (5±3°C) is completed up to 24M time point

Module 4- Nonclinical Reports

	Toxicology Single-dose toxicity (in order by species, by route): ✓ Single dose Acute Intramuscular Toxicity Study of Abhaytox formulation in Sprague Dawley Rats ✓ Single dose Acute Intramuscular Toxicity Study of Abhaytox formulation in Swiss Albino Mice ✓ Single dose Acute Subcutaneous Toxicity Study of Abhaytox formulation in Sprague Dawley Rats ✓ Single dose Acute subcutaneous Toxicity Study of Abhaytox formulation in Swiss Albino Mice Repeat Dose Toxicity and Local Tolerance ✓ Repeat dose Intramuscular Toxicity Study of Abhaytox formulation in Sprague Dawley Rats ✓ Repeat dose Intramuscular Toxicity Study of Abhaytox formulation in New Zealand White Rabbits

Module 5 – Clinical Study Reports

	Immunogenicity and Safety Studies Phase III: A Phase III Multicentric Randomized Single Blind Trial to compare the Immunogenicity and Safety of TOXTM with Sii Tetanus Vaccine (Adsorbed)TM in Healthy Subjects The subjects were aged between 10-55 years, total of 600 subjects were recruited and 599 of them completed Vaccination. There was 100% seroprotection achieved in both the vaccine groups and the TOXTM vaccine in comparison with the Sii Tetanus VaccineTM was found to be non-inferior in immunogenicity. PSUR also submitted by the applicant 01 Feb 2023 to 31 Jul 2023

	The following neurologic illnesses have been reported as temporally associated with tetanus toxoid: neurological complications including cochlear lesion, brachial plexus neuropathies, paralysis of the radial nerve, paralysis of the recurrent nerve, accommodation paresis and EEG disturbances with encephalopathy. There may be a causal relation between Guillain-Barre syndrome (GBS) and vaccines containing tetanus toxoid.(needs clarification from the applicant.
	Miscellaneous Documents in Compliance to WHO Requirements ✓ A statement by the Applicant to confirm whether the product has been rejected, withdrawn from the markets/countries. ✓ Information on the type of the product if was produced using a GMO technology, ☐ Evidence of valid GMP certificate. ✓ Acceptable shipping condition for both finished product and Drug Substance and Formulated Bulks (for importing bulks for filling and domestic production). ✓ Proof of Shipping validation. ✓ A copy template of lot summary protocol in compliance with WHO-recommended format (identified as per specific WHO TRS). ✓ A copy of labels (vial and carton). Remarks of the Assessor • Legalized/apostille COPP is required as no COPP has been provided. • Distribution agreement does not mention date of agreement. • Hard copies of both COPP and LOA are required. • Clarification is required for submission of NOC for transfer of products. • Section 1.3.3 states applicant is manufacturer. Clarification is required. • Section 1.4.1 and 1.4.2 not addressed by the applicant. • Submit stability data of finished vaccine of commercial batches till claimed shelf life i.e. 36 months as provided data is of only 24 months. • Justification for use of preservative in single dose vial in the light of reference guidelines. • Immunogenicity and/or potency studies to determine functional antibody response not determined, however required as WHO TRS. Provide justification in the light of reference guidelines. • Submit Phase I, Phase II as only Phase III studies have been provided or justify. • Phase III mentions target population 10-55 years whereas, as per indication “for all age groups above 6 weeks of age”. Justification is required in the light of reference guidelines. • Adverse Events Following Immunization (AEFI) reports are required. Conclusion: Application is deficient for the submission of above stated documents. Decision of 348th Meeting: The Registration Board deferred the case for the submission of following documents: • Legalized/apostille and valid original COPP. • Distribution agreement does not mention date of agreement. • Hard copies of both COPP and LOA are required. • Clarification is required for submission of NOC for transfer of products. • Section 1.3.3 states applicant is manufacturer. Clarification is required. • Section 1.4.1 and 1.4.2 not addressed by the applicant. • Submit stability data of finished vaccine of commercial batches till claimed shelf life i.e. 36 months as provided data is of only 24 months. • Justification for use of preservative in single dose vial in the light of reference guidelines. • Immunogenicity and/or potency studies to determine functional antibody response not determined, however required as WHO TRS. Provide justification in the light of reference guidelines. • Submit Phase I, Phase II as only Phase III studies have been provided or justify. • Phase III mentions target population 10-55 years whereas, as per indication “for all age groups above 6 weeks of age”. Justification is required in the light of reference guidelines. • Adverse Events Following Immunization (AEFI) reports are required.

Case No.9

**Adsorbed Tetanus Toxoid Vaccine 0.5ml (Single Dose)
New Product**

Exporting Country (China)	
Name, address of Applicant / Importer	M/s 2 World Traders Pakistan Company Address: Office 55/2, Main Khayaban-e-Hafiz DHA Karachi
Details of Drug Sale License of importer	License No: 634 Address: 55/2 Main Khayaban-e-Hafiz, Phase V Validity: 01-02-2029
Name of exporting country	China
Name and address of marketing authorization holder (abroad)	Wuhan Institute of Biological Products Co., Ltd. Address: No.1 Huangjin Industrial Park Road, Zhengdian, Jiangxia District, Wuhan, Hubei, China No.1 Jingang Middle Road, Jingang Industrial Park, Jiangxia District, Wuhan, Hubei, China Responsible for manufacturing and quality control of drug product
Name, address of manufacturer(s)	Wuhan Institute of Biological Products Co., Ltd. Production address 1: No.1 Huangjin Industrial Park Road, Zhengdian, Jiangxia District, Wuhan, Hubei Province, and Production address 2: No. 1 Jingang Zhong Road Jingang Industrial Park, Jiangxia District, Wuhan, Hubei Province. Among them, the buildings involved in production, storage, transportation and quality control in the production area located at No. 1 Huangjin Industrial Park Road mainly include: Bacterial Vaccine Building, for Tetanus Vaccine Bulk
Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Scanned Copy of COPP Certificate No.: 20240102 Importing Country: Philipines
Details of letter of authorization / sole agency agreement	Scanned Copy of Distribution Agreement Wuhan Institute of Biological Products Co., Ltd., a wholly-owned subsidiary of Sinopharm CNBG, its business scope includes the manufacture and sales of biological products and blood products, etc. 武汉生物制品研究所有限责任公司为国药集团中国生物的全资子公司，其经营范围包括生物制品、血液制品制造、销售等。 SC NINGBO INTERNATIONAL (HONGKONG) LIMITED , mainly assisted in the registration and distribution of WIBP's products in the Pakistan . 宁化国际（香港）有限公司主要协助 WIBP 的产品在巴基斯坦的注册和分销。 2 WORLD TRADERS PAKISTAN .is engaged in registering and distribution of WIBP's products in the Pakistan . 2 WORLD TRADERS PAKISTAN 公司从事 WIBP 的产品在巴基斯坦的注册和分销。 WIBP and SC NINGBO INTERNATIONAL (HONGKONG) LIMITED agree to appoint 2 WORLD TRADERS PAKISTAN as their agent for registering, importing and distributing the Product in Pakistan. (hereinafter called "Territory")
Status of the applicant	Importer
Status of application	NA for vaccine
For imported products, specify one the these	Finished Pharmaceutical product import
Dy. No. and date of submission	Tracking ID:JYX-P9P-3NR3,Application Number:103470, Date of Receiving 17-06-2025
Details of fee submitted	Challan Number: 090283935086,Division: Biological Evaluation & Registration Paid Fee: 300000.0,Paid Date: 2025-06-04
The proposed proprietary name / brand name	TeTOX
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each single human dose is 0.5 ml containing not less than 40 IU of tetanus toxoid
Adjuvant (if any)	Aluminum phosphate 1.50 mg (equivalent to 0.33 mg Al ³⁺) Thimerosal 0.05 mg
Dosage form of applied drug	Suspension for Injection
Indication/Target Disease	The product can induce humoral immune response in recipients following immunization. It is used to prevent tetanus
Target Population	Persons prone to be wounded are main eligibles. Pregnant women immunized with the vaccine can prevent puerperal and neonatal tetanus
Route of Administration	intramuscular injection.
Pharmacotherapeutic Group of (API)	: J07AM01

Finished product specifications	Chinese Pharmacopoeia (2020), Volume (III) and the registration standards for Tetanus Vaccine, Adsorbed pre-established by WIBP
Proposed Pack size	1 vial/ box
Proposed unit price	Pack contains 10 vials of 0.5ml MRP: Rs 830
Shelf life	42 months
Storage conditions	2°C - 8°C
The status in reference regulatory authorities/Name of NRA	Evidence of RRA with aluminiun hydroxide is required.
For generic drugs (me-too status)	Brand name: Imatet Injection Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit: Each 0.5ml dose Contains: Purified Tetanus Toxoid not less than 40 I.U Dosage form of applied drug: Vaccine (Injection) Indication/Target Disease: Tetanus Target Population: The Vaccine is intended for Women of childbearing age – to prevent maternal and neonatal tetanus, Pregnant women, unimmunized individuals at risk of tetanus such as those with injuries and general population as part of their routine immunization. Route of Administration: IM Registration Holder: Amson Vaccines & Pharma (Pvt.) Ltd. Registration Number: 017373
Drug Substance (Bulk Purified Tetanus Toxoid)	
General Information	This product is prepared by culturing the tetanus clostridium in an appropriate medium to produce toxin followed by refining and detoxification by formaldehyde and adding aluminum hydroxide adjuvant. It is a milky uniform suspension, and the upper layer of the solution should be colorless and clear when the adjuvant sinks after a long time, but it can disperse well after shaking. The main vaccination population is those with more chances of trauma. Vaccination of this product in pregnant women can prevent maternal and neonatal tetanus.
Name, address of drug substance manufacturer	Biological Products Co., Ltd. (Wuhan Institute) Address: No.1 Huangjin Industrial Park Road, Zhengdian, Jiangxia District, Wuhan, Hubei, China Responsible for Manufacturing and quality control of bulk
Manufacturing Process	Culture and tank fermentation for virus production Refining Detoxification and detoxification test Page 6 / 143 Date Jan, 2024 Sterile filtration.
Characterization	The main component of tetanus toxoid bulk is tetanus toxoid protein, and the structure and other characteristics include visual inspection and pH and flocculation unit determination,. The main impurity of tetanus toxoid is non-antigen protein, with the purity (flocculation measurement/protein nitrogen measurement, Lf/mgPN) used as the test indicato
Control of drug Substance	Details of strain not provided,
Stability	The 36-month long-term stability study of three batches of tetanus toxoid bulk at 2-8°C has been completed, and it is committed to continue the follow-up long-term stability study of the bulk until 45 months.
Drug Product (Name)	
Composition	The Tetanus Vaccine, Adsorbed manufactured by our WIBP is packed in vial or pre-filled syringe, 0.5 ml, 0.5 ml per human dosage, containing tetanus toxoid with the potency $\geq$ 40IU, Tetanus toxoid bulk Aluminum hydroxide adjuvant Anhydrous disodium hydrogen phosphate Potassium dihydrogen phosphate, NaCl.
Formulation	final bulk preparation tank is successively added with aluminum hydroxide adjuvant to the final content of 2.5 mg/ml, sodium chloride solution to the final content of 8.5 g/L, tetanus toxoid bulk to the final content of 8.5 Lf/m, and PBS, and then adjusted to the pH of 6.1-6.9. After the preparation, the final bulk is subject to the control test.
Manufacturing	Preparation and control test of final bulk: The qualified tetanus toxoid bulk is used for preparation according to the final bulk formulation. After the preparation, the final bulk is subject to the control test. (2) (3) Batch and filling of final product: After the final bulk is qualified in the control test, the final bulk transfer tank will be transferred to the Filling Facility for Purified Vaccines in the Yujin Building or the Filling Facility for Prefilled

		Syringes in the Vaccine Building for filling, physical inspection and packaging of the neutral borosilicate vial or the pre-filled injection of the vaccine building. Preparation of Batch No.:
	Specifications	Chinese Pharmacopoeia
	Container Closure system	neutral borosilicate vial
	Stability	(The long-term stability study of Tetanus Vaccine, Adsorbed (neutral borosilicate vial) at 2-8°C carried out at Months 0, 3, 6, 9, 18, 24, 36, 42 and 48. The test items included: appearance, filled volume, tetanus potency, pH, aluminum content, sodium chloride content, free formaldehyde content, specific toxicity and sterility test. Up to now, the 9-month study has been completed
Module 4- Nonclinical Reports		
	Immunogenicity Studies Local Tolerance Toxicology ✓ Immunogenicity Studies (1) Test method The potency of the finished product of Tetanus Vaccine, Adsorbed was tested according to the potency test method in “Tetanus Vaccine, Adsorbed” of Chinese Pharmacopoeia (Volume III), 2020 edition. The potency of tetanus toxoid in single human dose should be no less than 40IU. General requirement 3504: Potency test of adsorbed tetanus vaccine: ✓ Local Tolerance Local irritation test for repeated intramuscular administration of Tetanus Vaccine, Adsorbed to New Zealand rabbits (1) Purpose of the test The purpose of this study was to observe the local irritation response of Tetanus Vaccine, Adsorbed after repeated intramuscular injection to New Zealand rabbits, and to compare it with the original Tetanus Vaccine, Adsorbed (vial), so as to provide animal test data for clinical research.	
Module 5 – Clinical Study Reports		
	Data submitted as per Module 2 .Clinical studies as per ICH is required.	
	Miscellaneous Documents in Compliance to WHO Requirements ✓ A statement by the Applicant to confirm whether the product has been rejected, withdrawn from the markets/countries. ✓ Information on the type of the product if was produced using a GMO technology, ☐ Evidence of valid GMP certificate. ✓ Acceptable shipping condition for both finished product and Drug Substance and Formulated Bulks (for importing bulks for filling and domestic production). ✓ Proof of Shipping validation. ✓ A copy template of lot summary protocol in compliance with WHO-recommended format (identified as per specific WHO TRS). ✓ A copy of labels (vial and carton).	
	Remarks of the Assessor • Legalized/apostille COPP, as the currently provided COPP is issued for “Philippines”. Additionally, the COPP must include the specific concentration of tetanus toxoid per dose and quantity of adjuvant. • Target population and immunization schedule is required. • Evidence of approval as single dose vial is required in Reference Regulatory Authorities approved in 275th Meeting. • Confirm that the removal of thiomersal from vaccine is in accordance with the WHO Guidelines on regulatory expectations related to the elimination, reduction, or replacement of thiomersal in vaccines. • The exact quantity of adjuvant to be included per human dose in label claim. • Provide the name of strain isolated from Clostridium tetani. • The culture media used in production is not meat-free, contrary to WHO TRS requirements. Submit a scientific justification for the use of meat-based media. • Stability data for the tetanus toxoid bulk under accelerated conditions of 6 months or provide justification. • Reference to the specifications and analytical test methods used for the final product. Although the product is present in USP, BP, EP, JP, and IP, your applied specifications are as per Chinese Pharmacopoeia. A tabular comparison is required to highlight the difference in specifications with any of the mentioned pharmacopeia. • Abnormal toxicity test and degree of adsorption not included in specifications as per WHO TRS series provide scientific justification. • Submit stability data of finished vaccine till claimed shelf life i.e. 42 months as provided data is of only 9 months. • Safety and Toxicology studies (single dose, repeat dose, reproductive) not performed, however required by WHO TRS. Provide justification in the light of reference guidelines. • Non-clinical studies were conducted using pre-filled syringes, whereas the final product is in vial form, justify in the light of reference guidelines.	

- Tabular listing of clinical Studies in Module 5. Arrange the data as per ICH requirements for Module 5.
- Submit Phase I, Phase II and Phase III studies as only Phase IV(with Thiomersal) studies have been provided.
- Adverse Events Following Immunization (AEFI) reports and Periodic Safety Update Reports (PSUR) specifically for the thiomersal-free formulation.

Conclusion:

Application is deficient for the submission of above stated documents.

Decision of 348th Meeting:

The Registration Board deferred the case for the submission of the following documents:

- Legalized/apostille COPP, as the currently provided COPP is issued for “Philippines”. Additionally, the COPP must include the specific concentration of tetanus toxoid per dose and quantity of adjuvant.
- Target population and immunization schedule is required.
- Evidence of approval as **single dose vial** is required in Reference Regulatory Authorities approved in 275th Meeting.
- Confirm that the removal of thiomersal from vaccine is in accordance with the WHO Guidelines on regulatory expectations related to the elimination, reduction, or replacement of thiomersal in vaccines.
- The exact quantity of adjuvant to be included per human dose in label claim.
- Provide the name of strain isolated from Clostridium tetani.
- The culture media used in production is not meat-free, contrary to WHO TRS requirements. Submit a scientific justification for the use of meat-based media.
- Stability data for the tetanus toxoid bulk under accelerated conditions of 6 months or provide justification.
- Reference to the specifications and analytical test methods used for the final product. Although the product is present in USP, BP, EP, JP, and IP, your applied specifications are as per Chinese Pharmacopoeia. A tabular comparison is required to highlight the difference in specifications with any of the mentioned pharmacopeia.
- Abnormal toxicity test and degree of adsorption not included in specifications as per WHO TRS series provide scientific justification.
- Submit stability data of finished vaccine till claimed shelf life i.e. 42 months as provided data is of only 9 months.
- Safety and Toxicology studies (single dose, repeat dose, reproductive) not performed, however required by WHO TRS. Provide justification in the light of reference guidelines.
- Non-clinical studies were conducted using pre-filled syringes, whereas the final product is in vial form, justify in the light of reference guidelines.
- Tabular listing of clinical Studies in Module 5. Arrange the data as per ICH requirements for Module 5.
- Submit Phase I, Phase II and Phase III studies as only Phase IV(with Thiomersal) studies have been provided.

Adverse Events Following Immunization (AEFI) reports and Periodic Safety Update Reports (PSUR) specifically for the thiomersal-free formulation.

Malaria Vaccines

- Malaria is caused by a parasite called Plasmodium, which is transmitted via the bites of infected mosquitoes.
- Six identified species of the Plasmodium protozoan parasite can infect and cause disease in humans (P. falciparum, P. vivax, P. ovale curtisi, P. ovale wallikeri, P. malariae and P. knowlesi). P. falciparum accounts for over 90% of all malaria-attributable deaths.
- Treatment for malaria depends on the species of Plasmodium, disease severity and local antimalarial resistance patterns. WHO guidelines for malaria provide recommendations on the use of different antimalarial medicines.
- Approximately 95% of malaria cases and deaths occur in sub-Saharan Africa, with the remainder occurring in South-East Asia and South America.
- 4-dose schedule in children from around 5 months of age.
- [summaryslidesmalariavaccines.pdf](#)

R21 Malaria Vaccine (Recombinant, Adjuvanted 1 dose (WHO PQ product)

New Product

Exporting country (India)

Case No. 10

Name, address of Applicant / Importer	M/s. SIND MEDICAL STORES, Plot No. 13-B, Block 6, P.E.C.H.S, Shahrah-e-Faisal, Karachi.
Details of Drug Sale License of importer	License No: 0450 Address Plot No. 13-B/B-10, Block 6, P.E.C.H.S, Shahrah-e-Faisal, Karachi. Validity: 01-07-2029
Name of exporting country	India

Name and address of marketing authorization holder (abroad)	SERUM INSTITUTE OF INDIA PVT. LTD., 212/2 Hadapsar, Pune- 411 0028, INDIA.
Name, address of manufacturer(s)	SERUM INSTITUTE OF INDIA PVT. LTD., 212/2 Hadapsar, Pune- 411 0028, INDIA.
Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	COPP: Certificate No. COPP/CERT/PD/141466/2024/11/52049/248679 Validity: 21.08.2027 Certifying Authority: Food and Drug Administration, Maharashtra State, Mumbai, INDIA Free Sale Status: No. 6126519, Validity: 14-04-2028 GMP Status: Certificate No: 6122137, Validity: 29.08.2025
Details of letter of authorization / sole agency agreement	Serum Institute of India Pvt. Ltd., a company manufacturing pharmaceutical and biological products, situated at 212/2, Hadapsar, Pune – 411 028, India, does hereby authorize M/s. Sind Medical Stores, 13-B, Block 6, P.E.C.H.S., Shahrāh e Faisal, Karachi – 75400, Pakistan, specially for the purpose of registration, import, promotion, marketing, quoting in private & public (Government) tenders and negotiation with Ministry of Health, Pakistan & Hospitals for the following product/s. • R21 Malaria Vaccine (Recombinant, Adjuvanted) 1 dose & 2 dose This specific authorization letter shall be effective from the date of signature and will be valid till 31/01/2026.
Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
Dy. No. and date of submission	Form - 5F Dated: 25-03-2025 Tracking Number (156-6M4-6QZS)
Details of fee submitted	Rs:300000/- Dated: 26-06-2025 Deposit Slip No.682071787828
The proposed proprietary name / brand name	CYVAC – 0.5ml/1 Dose Vial (R21 Malaria Vaccine (Recombinant, Adjuvanted))
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Strength: 0.5ml x 1 Dose Vial: Each dose of 0.5mL contains: - ^{1,2} R21 Malaria Antigen: 5 mcg - Matrix-M1 (Adjuvant): 50 mcg - ¹ Portion of <i>P. falciparum</i> circumsporozoite protein fused with hepatitis B surface antigen - ² In the form of non-infectious virus-like particles (VLPs) produced in yeast cells (Hansenula) by recombinant DNA technology
Adjuvant (if any)	Adjuvant (Matrix-M1) (Matrix-A + Matrix-C)
Dosage form of applied drug	Solution for Injection
Indication/Target Parasite Specie	Plasmodium falciparum
Target Population	Age 5 to 36 months
Route of Administration	For intramuscular (IM) use only.
Pharmacotherapeutic Group of (API)	Biological product (Vaccine)
Finished product specifications	WHO TRS 980
Proposed Pack size	- Presentation: 1 dose x 0.5mL Vial - Box of 50 Vials x 0.5ml
Proposed unit price	As per SRO.
Shelf Life	24 months
Storage Conditions	2-8 °C
The status in reference regulatory	WHO PQ Product (IP)

authorities/Name of NRA	
For generic drugs (me-too status)	N/A
Drug Substance	
General Information	Recommended International Non-proprietary Name (INN): Plasmodium Falciparum and Hepatitis B Vaccine (recombinant, adjuvanted)
Name, address of drug substance manufacturer	SERUM INSTITUTE OF INDIA PRIVATE LIMITED, Off Soli-Poonawalla Road, 212/2 Hadapsar, Pune- 411 028, INDIA.
Manufacturing Process	Manufacturing of R21 is a continuous process and allows no holding of intermediates throughout the process. It involves classical fed batch fermentation of recombinant <i>Hansenula polymorpha</i> strain received from Artes Biotech, followed by harvesting of surface protein and its purification by multiple filtration and chromatographic techniques.
Characterization	Primary, secondary and Tertiary structure of the R21 Malaria Antigen was determined using 3 different batches. Intact mass of the protein sample in N-deglycosylated reducing conditions was estimated to be ~50 k Da using mass-spectrometry based methods. The samples were digested using different proteases and the obtained peptides were analyzed using LC-MS/MS based method. Additionally, a reverse-phase liquid chromatography-based Amino acid composition analysis method was utilized as orthogonal method to assess the primary structure of protein. The secondary structure of the protein samples was analyzed using Far UV-Circular Dichroism (CD) Spectroscopy. The tertiary structure of the protein was analyzed using intrinsic tryptophan fluorescence and extrinsic fluorescence spectroscopy. Higher order structure of the protein was characterized through analysis of melting behavior of protein using CD spectroscopy. Molecular mass of VLP and presence of aggregates was evaluated using Size exclusion Chromatography coupled ultra-violet absorption and Multi Angle Laser Light Scattering (SEC-UV and SEC-MALLS) based method.
Control of drug Substance Stability	Release specification of R21 Antigen (Drug Substance) is adopted based on the WHO TRS 980,
Stability	Firm has submitted stability study data the results for all the stability testing parameters are well within the acceptance criteria and consistent during stability time points. Overall, when R21 Malaria Antigen Drug Substance stored in PP bottle, it is stable up to 3 months at accelerated condition and stable up to 24 months at long-term storage condition. At stress condition, the R21 Malaria antigen is stable up to 2 weeks.
Drug Product	
Composition	R21 Malaria Vaccine is sterile liquid vaccine composed of R21 Malaria antigen and Matrix-M1 as an adjuvant
Formulation	R21 Malaria Vaccine (Recombinant, Adjuvanted) is a formulation of R21 Malaria Antigen and Matrix-M1 adjuvant at 5 µg and 50 µg concentration respectively. R21 Malaria Vaccine (Recombinant, Adjuvanted) is used for prevention of clinical malaria in children from 5 months to 36 months of age.
Manufacturing	The manufacturing technology is transferred from Oxford University and used to manufacture pre-clinical batches, Phase-I/II and Phase-III CT batches at SIIPL
Specifications	The excipients used in the manufacturing of R21 Malaria Vaccine (Recombinant, Adjuvanted) are of compendial grade and procured from the approved vendor. All these excipients are tested inhouse as per the method specified in monographs/general chapters of respective pharmacopoeia. Only upon compliance to those specifications, these excipients are used for manufacturing.
Container Closure Firm has submitted stability study data	- Glass Vials USP Type-I, tubular glass vial - Rubber Closures 13mm, Bromo butyl, grey colored rubber stopper (RFS) - Flip-off Seals 13mm Dark Blue colored flip off seal
Stability	Firm has submitted stability study data available till date it is observed that R21 Malaria Vaccine (Recombinant) is stable at long term stability condition (2-8°C)

	till 24 months and at accelerated stability condition (25 ± 2 °C, 60 ± 5% RH) for 6 months when stored in glass vials.																		
Viral Safety Evaluation	The malaria vaccine R21/Matrix-M (also known as Cyvac) has undergone rigorous viral safety evaluation, demonstrating a favorable safety profile.																		
Module 4- Nonclinical Reports																			
Pharmacology: Immunogenicity studies in mice, rats, Rabbits	<table> <tr> <th>Parameters</th><th>Measures/outcomes</th></tr> <tr> <td>Study description</td><td>Immunogenicity of R21c administered with adjuvants in BALB/cmice</td></tr> <tr> <td>Study identifier</td><td>JI-R21-01</td></tr> <tr> <td>Study objectives and design features</td><td> Study Objective: To evaluate the immunogenicity of 0.5 µg R21 alone or in combination with adjuvants (Alhydrogel and Abisco) Groups: Group 1: R21c alone Group 2: R21c + Alhydrogel Group 3: R21c + Abisco Route of administration: Intramuscular Dose frequency: Three immunisations were given three weeks apart Evaluation Parameters: Immunogenicity was assessed by measuring serum antibody titer three weeks after each immunisation and antigen-specific T cell responses in the spleen three weeks after the final immunisation. </td></tr> <tr> <td>Study participants</td><td>18</td></tr> <tr> <td>GLP status</td><td>Non-GLP</td></tr> <tr> <td>Date of initiation</td><td>2012</td></tr> <tr> <td>Date of completion/estimated completion</td><td>2013</td></tr> <tr> <td>A summary of study findings or expected outcomes.</td><td>The responses in all groups were boosted by a third immunisation and R21c + Abisco-100 induced the highest titers of NANP specific IgG and the response for this group was significantly higher than both R21c + Alhydrogel and R21 alone. CS-specific IFNγ producing Tcells were Assayed in a spleen ELISpot after The final immunisation and they Were detected in all mice receiving R21c with or without adjuvant. The Median response in the R21c + Abisco-100 group was 700 SFC/106 splenocytes, but in the R21c + Alhydrogel and R21c alone groups, although the IFNγ producing T cells were detected they were only just above background.</td></tr> </table>	Parameters	Measures/outcomes	Study description	Immunogenicity of R21c administered with adjuvants in BALB/cmice	Study identifier	JI-R21-01	Study objectives and design features	Study Objective: To evaluate the immunogenicity of 0.5 µg R21 alone or in combination with adjuvants (Alhydrogel and Abisco) Groups: Group 1: R21c alone Group 2: R21c + Alhydrogel Group 3: R21c + Abisco Route of administration: Intramuscular Dose frequency: Three immunisations were given three weeks apart Evaluation Parameters: Immunogenicity was assessed by measuring serum antibody titer three weeks after each immunisation and antigen-specific T cell responses in the spleen three weeks after the final immunisation.	Study participants	18	GLP status	Non-GLP	Date of initiation	2012	Date of completion/estimated completion	2013	A summary of study findings or expected outcomes.	The responses in all groups were boosted by a third immunisation and R21c + Abisco-100 induced the highest titers of NANP specific IgG and the response for this group was significantly higher than both R21c + Alhydrogel and R21 alone. CS-specific IFNγ producing Tcells were Assayed in a spleen ELISpot after The final immunisation and they Were detected in all mice receiving R21c with or without adjuvant. The Median response in the R21c + Abisco-100 group was 700 SFC/106 splenocytes, but in the R21c + Alhydrogel and R21c alone groups, although the IFNγ producing T cells were detected they were only just above background.
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Pharmacokinetics: Not applicable (vaccines act via immune stimulation, not systemic exposure).	According to the WHO guidelines on nonclinical evaluation of vaccines (WHO Technical Report Series, No. 927, 2005) pharmacokinetic studies are generally not required for vaccines, because the kinetic properties of antigens do not provide useful information for determining dose recommendations. Furthermore, such studies are not applicable for SIIPL R21 Malaria Vaccine since administration of SIIPL R21 Malaria Vaccine does not employ a new delivery system, and does not contain novel adjuvants or excipients.																		
Toxicology: - Repeat-dose (IM) in animals - Local tolerance (site histology) - Reproductive & developmental	Firm has submitted toxicology study To investigate the potential toxicity of R21c either alone or combined with AS01B or Matrix M1 adjuvant to BALB/c mice (Mus musculus) when administered on four occasions each with a 14-day interval followed by a 3- or 21-day observation period.																		

studies	Study Design: Group 1: PBS Group 2: 5 µg R21c +5 µg Matrix M1 Group 3: 5 µg R21c +50 µg AS01B Group 4: 5 µg R21c Route of Administration: Intramuscular Dose frequency and schedule: Each group received total 4 doses each on Day 1, 15, 29 and 43. Evaluation parameters: Clinical condition, body weight, food consumption, haematology (peripheral blood), blood chemistry, organ weight, Macro pathology and histopathology. A repeat dose toxicity study conducted on R21/Matrix-M1 in BALB/c mice (4 dose regimen) revealed no special hazard for humans. There were no unscheduled deaths in the study. There were no clinical signs considered related to treatment and there was no apparent reaction to treatment at the dose site. It was concluded that the administration of R21 combined with Matrix M adjuvant was well tolerated and was not associated with any systemic toxicological changes. All related changes were consistent with the expected immune stimulation associated with the administration of a vaccine with or without adjuvant or with minimal inflammatory changes in the muscle injection sites. • No Local Tolerance Toxicity Studies are performed on R21 Malaria Vaccine (Recombinant, Adjuvanted) • No Reproductive and Developmental Toxicity Studies are performed on R21 Malaria Vaccine (Recombinant, Adjuvanted)
Module 5 – Clinical Study Reports	
Biopharmaceutics Not applicable for vaccines.	No biopharmaceutical studies with R21 Malaria Vaccine were conducted, which is acceptable, as generally pharmacokinetics (PK) studies are not relevant to support the development and licensure of vaccine for infectious diseases.
Clinical Efficacy & Safety • Phase I/II: • Phase III • Key Trial:	Phase I/II/III In a Phase III randomized controlled double-blind study, VAC078, conducted at 5 sites in 4 sub-Saharan African countries, Burkina Faso, Mali, Tanzania and Kenya with a wide range of transmission intensities (https://clinicaltrials.gov/ct2/show/NCT04704830), more than 4,800 children from 5-36 months of age were enrolled to evaluate efficacy and safety of R21 Malaria Vaccine/Matrix-M1 when given according to a 0, 1, 2-month schedule. In addition, these children received per protocol a fourth dose (booster), administered 12 months after the third dose. The efficacy of the vaccine was evaluated in the context of high insecticide treated bed nets coverage, and substantial seasonal malaria chemoprevention use at west African sites of high malaria transmission. The trial included two sites of highly seasonal malaria transmission and three sites with more perennial transmission (“standard” sites in Kenya, Tanzania and Dande, Burkina Faso). The phase III trial results were consistent with an ongoing single site phase IIb trial, VAC076, at Nanoro, Burkina Faso which, with the same immunization regime (three primary series doses plus a booster dose at 12 months) observed 76%, 77% and 73% efficacy over one, two and three years of follow-up, respectively. Safety findings were similar to the phase III trial (above). One safety and efficacy trial, VAC072, was undertaken of the R21 Malaria Vaccine/Matrix M1 in the United Kingdom using a well-studied human challenge protocol with infectious mosquito bites The vaccine was well tolerated and immunogenic at a range of dose levels and particularly high efficacy was observed, of 75%, using a low dose regimen of 10 mcg R21 in 50 mcg of Matrix-M1 adjuvant In summary, R21 Malaria Vaccine/Matrix M1 has shown a well-tolerated safety profile in four trials enrolling over 5350 subjects in five countries. Efficacy of the vaccine reached 75% in a phase IIa, a phase IIb and a recent phase III trial in the first year of follow-up. In the phase IIb trial this efficacy has been followed for three

	years and appeared well-maintained (at 73% efficacy) over this time period with a single booster dose at the end of the first year.										
	Efficacy • Against Clinical Malaria: efficacy against clinical malaria of R21 adjuvanted with Matrix-M in 5-17 months old children living in a malaria-endemic area, for 6 months after the last vaccination. • Against Severe Malaria: efficacy against severe malaria of R21 adjuvanted with Matrix-M in 5- 17 months old infants living in a malaria- endemic area, at 6 months after administration of the final dose of vaccine.										
• Trial Duration: • Trial Populations: • • Post-marketing: Ongoing surveillance confirms long-term efficacy and rare adverse event rates.	During recruitment, parents or legally authorized guardians of participants provided written or thumb-printed consent, which was verbally checked at each study visit. Inclusion criteria specified that participants should be aged 5–17 months at enrolment, parents should provide written informed consent, and aim to be living in the study area for the trial duration. Exclusion criteria included significant comorbidities and participation in other malaria intervention studies and clinical trials. Further details are given in the protocol • N/A										
Post-marketing Data	N/A										
Miscellaneous Documents in Compliance to WHO Requirements ☐ A statement by the Applicant to confirm whether the product has been rejected, withdrawn from the markets/countries. Attached. ☐ Information on the type of the product if was produced using a GMO technology, N/A ☐ Evidence of valid GMP certificate. Kindly refer Module 1, pg.261-263. ☐ Acceptable shipping condition for both finished product and Drug Substance and Formulated Bulks (for importing bulks for filling and domestic production). Kindly refer Module 3, section 3.2.S.2, to 3.2.S.7. ☐ Proof of Shipping validation. N/A ☐ A copy template of lot summary protocol in compliance with WHO-recommended format (identified as per specific WHO TRS). Kindly refer Module-1, pg. 34 to 92. ☐ A copy of labels (vial and carton). Kindly refer Module-1, pg. 149 to 152.											
Remarks of the Assessor											
<table><tr><th>Sr. No</th><th>Shortcoming</th><th>Response</th><th>Evaluation</th></tr><tr><td>1.</td><td>The importing country on COPP is Unicef. Submit COPP for Pakistan.</td><td rowspan="2">Product FSC which ensure the registration / availability of the applied product in the country of origin.</td><td rowspan="2">The FSC issued mentions exclusively manufacture the applied product for export purpose which means product is not on free sale only manufactured for export purpose.</td></tr><tr><td>2.</td><td>The product is not licensed to be placed in the exporting county clarification is required.</td></tr></table>	Sr. No	Shortcoming	Response	Evaluation	1.	The importing country on COPP is Unicef. Submit COPP for Pakistan.	Product FSC which ensure the registration / availability of the applied product in the country of origin.	The FSC issued mentions exclusively manufacture the applied product for export purpose which means product is not on free sale only manufactured for export purpose.	2.	The product is not licensed to be placed in the exporting county clarification is required.	
Sr. No	Shortcoming	Response	Evaluation								
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2.	The product is not licensed to be placed in the exporting county clarification is required.										
Conclusion The applied vaccine is WHO PQ but is not licensed in the country of origin for free sale.											
Decision of 348th Meeting: The Registration Board deferred the case for following: 1. Referred the case to Malaria Control Program and Federal Directorate of Immunization (FDI) for the comments regarding the need of vaccine in country 2. Submission of valid legalized CoPP											

Exporting country (India)		
Case No. 11		
	Name, address of Applicant / Importer	M/s. SIND MEDICAL STORES, Plot No. 13-B, Block 6, P.E.C.H.S, Shahrah-e-Faisal, Karachi.
	Details of Drug Sale License of importer	License No: 0450 Address Plot No. 13-B, Block 6, P.E.C.H.S, Shahrah-e-Faisal, Karachi. Validity: 01-07-2029
	Name of exporting country	INDIA
	Name and address of marketing authorization holder (abroad)	SERUM INSTITUTE OF INDIA PVT. LTD., 212/2 Hadapsar, Pune- 411 0028, INDIA.
	Name, address of manufacturer(s)	SERUM INSTITUTE OF INDIA PVT. LTD., 212/2 Hadapsar, Pune- 411 0028, INDIA.
	Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	COPP: Certificate No. COPP/CERT/PD/141466/2024/11/52049/248679 Validity: 21.08.2027 Certifying Authority: Food and Drug Administration, Maharashtra State, Mumbai, INDIA Free Sale Status: No. , Validity: 14-04-2028 GMP Status: Certificate No:6122137, Validity: 29.08.2025
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of product specific authorization from Director, Exports of M/s. SERUM INSTITUTE OF INDIA PVT. LTD., According to the letter, the firm authorizes “M/s. SIND MEDICAL STORES for the purpose of registration, import, promotion, marketing of the product.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Form - 5F Dated: 27-06-2025 Tracking Number (GUE BY6 BIBE)
	Details of fee submitted	Rs:300000/- Dated: 12-03-2025 Deposit Slip 018779548553
	The proposed proprietary name / brand name	CYVAC – 1mL x 2 Dose Vial (R21 Malaria Vaccine (Recombinant, Adjuvanted)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each dose of 0.5mL contains: - ^{1,2} R21 Malaria Antigen: 5 mcg - Matrix-M1 (Adjuvant): 50 mcg - ¹ Portion of <i>P. falciparum</i> circumsporozoite protein fused with hepatitis B surface antigen - ² In the form of non-infectious virus-like particles (VLPs) produced in yeast cells (<i>Hansenula</i>) by recombinant DNA technology
	Adjuvant (if any)	Adjuvant (Matrix-M1) (Matrix-A + Matrix-C)
	Dosage form of applied drug	Solution for Injection
	Indication/Target Parasite Specie	Plasmodium falciparum
	Target Population	Age 5 to 36 months
	Route of Administration	For intramuscular (IM) use only.
	Pharmacotherapeutic Group of (API)	Biological product (Vaccine)
	Finished product specifications	WHO TRS 980
	Proposed Pack size	Proposed Pack Size: - Presentation: 1mL x 2 dose Vial - Box of 50 Vials x 1ml

Proposed unit price	As per SRO.
Shelf Life	24 months
Storage Conditions	2-8 °C
The status in reference regulatory authorities/Name of NRA	WHO PQ Product
For generic drugs (me-too status)	N/A
Drug Substance	
General Information	Recommended International Non-proprietary Name (INN): Plasmodium Falciparum and Hepatitis B Vaccine (recombinant, adjuvanted)
Name, address of drug substance manufacturer	SERUM INSTITUTE OF INDIA PRIVATE LIMITED, Off Soli-Poonawalla Road, 212/2 Hadapsar, Pune- 411 028, INDIA.
Manufacturing Process	Manufacturing of R21 is a continuous process and allows no holding of intermediates throughout the process. It involves classical fed batch fermentation of recombinant <i>Hansenula polymorpha</i> strain received from Artes Biotech, followed by harvesting of surface protein and its purification by multiple filtration and chromatographic techniques.
Characterization	Primary, secondary and Tertiary structure of the R21 Malaria Antigen was determined using 3 different batches. Intact mass of the protein sample in N-de glycosylated reducing conditions was estimated to be ~50 k Da using mass-spectrometry based methods. The samples were digested using different proteases and the obtained peptides were analyzed using LC-MS/MS based method. Additionally, a reverse-phase liquid chromatography-based Amino acid composition analysis method was utilized as orthogonal method to assess the primary structure of protein. The secondary structure of the protein samples was analyzed using Far UV-Circular Dichroism (CD) Spectroscopy. The tertiary structure of the protein was analyzed using intrinsic tryptophan fluorescence and extrinsic fluorescence spectroscopy. Higher order structure of the protein was characterized through analysis of melting behavior of protein using CD spectroscopy. Molecular mass of VLP and presence of aggregates was evaluated using Size exclusion Chromatography coupled ultra-violet absorption and MultiAngle Laser Light Scattering (SEC-UV and SEC-MALLS) based method.
Control of drug Substance	Release specification of R21 Antigen (Drug Substance) is adopted based on the WHO TRS 980,
Stability	Firm has submitted stability study data the results for all the stability testing parameters are well within the acceptance criteria and consistent during stability time points. Overall, when R21 Malaria Antigen Drug Substance stored in PP bottle, it is stable up to 3 months at accelerated condition and stable up to 24 months at long-term storage condition. At stress condition, the R21 Malaria antigen is stable up to 2 weeks.
Drug Product (Name)	
Composition	R21 Malaria Vaccine is sterile liquid vaccine composed of R21 Malaria antigen and Matrix-M1 as an adjuvant
Formulation	R21 Malaria Vaccine (Recombinant, Adjuvanted) is a formulation of R21 Malaria Antigen and Matrix-M1 adjuvant at 5 µg and 50 µg concentration respectively. R21 Malaria Vaccine (Recombinant, Adjuvanted) is used for prevention of clinical malaria in children from 5 months to 36 months of age.
Manufacturing	The manufacturing technology is transferred from Oxford University and used to manufacture pre-clinical batches, Phase-I/II and Phase-III CT batches at SIIPL
Specifications	The excipients used in the manufacturing of R21 Malaria Vaccine (Recombinant, Adjuvanted) are of compendial grade and procured from the approved vendor. All these excipients are tested inhouse as per the method specified in monographs/general chapters of respective pharmacopoeia. Only upon compliance to those specifications, these excipients are used for manufacturing.
Container Closure	- Glass Vials USP Type-I, tubular glass vial - Rubber Closures 13mm, Bromo butyl, grey colored rubber stopper (RFS) - Flip-off Seals 13mm Dark Blue colored flip off seal
Firm has submitted stability study data	
Stability	
	Firm has submitted stability study data available till date it is observed that R21 Malaria Vaccine (Recombinant) is stable at long term stability condition (2-8°C)

	till 24 months and at accelerated stability condition (25 ± 2 °C, 60 ± 5% RH) for 6 months when stored in glass vials.	
Viral Safety Evaluation	The malaria vaccine R21/Matrix-M (also known as Cyvac) has undergone rigorous viral safety evaluation, demonstrating a favorable safety profile.	
Module 4- Nonclinical Reports		
Pharmacology: Immunogenicity studies in mice, rats, Rabbits	Parameters	Measures/outcomes
	Study description	Immunogenicity of R21c administered with adjuvants in BALB/cmice
	Study identifier	JI-R21-01
	Study objectives and design features	Study Objective: To evaluate the immunogenicity of 0.5 µg R21 alone or in combination with adjuvants (Alhydrogel and Abisco) Groups: Group 1: R21c alone Group 2: R21c + Alhydrogel Group 3: R21c + Abisco Route of administration: Intramuscular Dose frequency: Three immunisations were given three weeks apart Evaluation Parameters: Immunogenicity was assessed by measuring serum antibody titer sthree weeks after each immunisation and antigen-specific T cell responses in the spleen three weeks after the final immunisation.
	Study participants	18
	GLP status	Non-GLP
	Date of initiation	2012
	Date of completion/estimated completion	2013
	A summary of study findings or expected outcomes.	The responses in all groups were boosted by a third immunisation and R21c + Abisco-100 induced the highest titers of NANP specific IgG and the response for this group was significantly higher than both R21c + Alhydrogel and R21 alone. CS-specific IFNγ producing Tcells were Assayed in a spleen ELISpot after The final immunisation and they Were detected in all mice receiving R21c with or without adjuvant. The Median response in the R21c + Abisco-100 group was 700 SFC/106 splenocytes, but in the R21c + Alhydrogel and R21c alone groups, although the IFNγ producing T cells were detected they were only just above background.

Pharmacokinetics: Not applicable (vaccines act via immune stimulation, not systemic exposure).	According to the WHO guidelines on nonclinical evaluation of vaccines (WHO Technical Report Series, No. 927, 2005) pharmacokinetic studies are generally not required for vaccines, because the kinetic properties of antigens do not provide useful information for determining dose recommendations. Furthermore, such studies are not applicable for SIIPL R21 Malaria Vaccine since administration of SIIPL R21 Malaria Vaccine does not employ a new delivery system, and does not contain novel adjuvants or excipients.
Toxicology: - Repeat-dose (IM) in animals - Local tolerance (site histology) - Reproductive & developmental studies	Firm has submitted toxicology study - To investigate the potential toxicity of R21c either alone or combined with AS01B or Matrix M1 adjuvant to BALB/c mice (<i>Mus musculus</i>) when administered on four occasions each with a 14-day interval followed by a 3- or 21-day observation period. Study Design: Group 1: PBS Group 2: 5 µg R21c +5 µg Matrix M1 Group 3: 5 µg R21c +50 µg AS01B Group 4: 5 µg R21c Route of Administration: Intramuscular Dose frequency and schedule: Each group received total 4 doses each on Day 1, 15, 29 and 43. Evaluation parameters: Clinical condition, body weight, food consumption, haematology (peripheral blood), blood chemistry, organ weight, Macro pathology and histopathology. A repeat dose toxicity study conducted on R21/Matrix-M1 in BALB/c mice (4 dose regimen) revealed no special hazard for humans. There were no unscheduled deaths in the study. There were no clinical signs considered related to treatment and there was no apparent reaction to treatment at the dose site. It was concluded that the administration of R21 combined with Matrix M adjuvant was well tolerated and was not associated with any systemic toxicological changes. All related changes were consistent with the expected immune stimulation associated with the administration of a vaccine with or without adjuvant or with minimal inflammatory changes in the muscle injection sites. - No Local Tolerance Toxicity Studies are performed on R21 Malaria Vaccine (Recombinant, Adjuvanted) - No Reproductive and Developmental Toxicity Studies are performed on R21 Malaria Vaccine (Recombinant, Adjuvanted)

Module 5 – Clinical Study Reports

Biopharmaceutics Not applicable for vaccines.	No biopharmaceutical studies with R21 Malaria Vaccine were conducted, which is acceptable, as generally pharmacokinetics (PK) studies are not relevant to support the development and licensure of vaccine for infectious diseases.
Clinical Efficacy & Safety Phase I/II: Phase III:	Phase I/II/III In a Phase III randomized controlled double-blind study, VAC078, conducted at 5 sites in 4 sub-Saharan African countries, Burkina Faso, Mali, Tanzania and Kenya with a wide range of transmission intensities (https://clinicaltrials.gov/ct2/show/NCT04704830), more than 4,800 children from 5-36 months of age were enrolled to evaluate efficacy and safety of R21 Malaria Vaccine/Matrix-M1 when given according to a 0, 1, 2-month schedule. In addition, these children received per protocol a fourth dose (booster), administered 12 months after the third dose. The efficacy of the vaccine was evaluated in the context of high insecticide treated bed nets coverage, and substantial seasonal malaria chemoprevention use at west African sites of high malaria transmission. The trial included two sites of highly seasonal malaria transmission and three sites with more perennial transmission (“standard” sites in Kenya, Tanzania and Dande, Burkina Faso). The phase III trial results were consistent with an ongoing single site phase IIb trial, VAC076, at Nanoro, Burkina Faso which, with the same immunization

• Key Trial:	regime (three primary series doses plus a booster dose at 12 months) observed 76%, 77% and 73% efficacy over one, two and three years of follow-up, respectively. Safety findings were similar to the phase III trial (above). One safety and efficacy trial, VAC072, was undertaken of the R21 Malaria Vaccine/Matrix M1 in the United Kingdom using a well-studied human challenge protocol with infectious mosquito bites The vaccine was well tolerated and immunogenic at a range of dose levels and particularly high efficacy was observed, of 75%, using a low dose regimen of 10 mcg R21 in 50 mcg of Matrix-M1 adjuvant n summary, R21 Malaria Vaccine/Matrix M1 has shown a well-tolerated safety profile in four trials enrolling over 5350 subjects in five countries. Efficacy of the vaccine reached 75% in a phase IIa, a phase IIb and a recent phase III trial in the first year of follow-up. In the phase IIb trial this efficacy has been followed for three years and appeared well-maintained (at 73% efficacy) over this time period with a single booster dose at the end of the first year. Efficacy • Against Clinical Malaria: efficacy against clinical malaria of R21 adjuvanted with Matrix-M in 5-17 months old children living in a malaria-endemic area, for 6 months after the last vaccination. • Against Severe Malaria: efficacy against severe malaria of R21 adjuvanted with Matrix-M in 5- 17 months old infants living in a malaria- endemic area, at 6 months after administration of the final dose of vaccine.			
	• Trial Duration: • Trial Populations: • Infants () • Children () – • Main target group based on higher efficacy • Post-marketing: Ongoing surveillance confirms long-term efficacy and rare adverse event rates.	During recruitment, parents or legally authorized guardians of participants provided written or thumb-printed consent, which was verbally checked at each study visit. Inclusion criteria specified that participants should be aged 5–17 months at enrolment, parents should provide written informed consent, and aim to be living in the study area for the trial duration. Exclusion criteria included significant comorbidities and participation in other malaria intervention studies and clinical trials. Further details are given in the protocol • N/A		
	Post-marketing Data	N/A		
Remarks of the Assessor				
Data for prevalence of this strain in Pakistan.				
Sr. No	Shortcoming	Response	Evaluation	
3.	The importing country on COPP is Unicef. Submit COPP for Pakistan.	Product FSC which ensure the registration / availability of the applied product in the country of origin.	"The issued FSC explicitly states that the product is manufactured exclusively for export purposes, indicating that it is not intended for free sale in the domestic market."	
Conclusion				
The product is WHO-prequalified but is not freely available in its country of origin.				
Decision of 348th Meeting:				
The Registration Board deferred the case for following:				
3. Referred the case to Malaria Control Program and Federal Directorate of Immunization (FDI) for the comments regarding the need of vaccine in country				
4. Submission of valid legalized CoPP				

Human Papillomavirus (HPV)

- Human papillomavirus (HPV) is a small, non-enveloped deoxyribonucleic acid (DNA) virus that infects skin or mucosal cells.
- At least 13 of more than 100 known HPV genotypes can cause cancer of the cervix and are associated with other anogenital cancers and cancers of the head and neck. The two most common "high-risk" genotypes (HPV 16 and 18) cause approximately 70% of all cervical cancer.
- Two "low-risk" genotypes (HPV 6 and 11) cause genital warts, a common benign condition of the external genitalia that causes significant morbidity.
- Two prophylactic HPV vaccines have been available since 2006. Both vaccines are prepared from virus-like particles (VLPs) produced by recombinant technology. Purified L1 protein self-assembles to form empty shells that resemble HPV VLPs. These vaccines do not contain viral genetic material or live biological product, so they cannot multiply and are not infectious. These two vaccines are:
 - A bivalent vaccine comprised of HPV types 16 and 18 protein expressed and purified from insect cells infected with a recombinant baculovirus. This vaccine is formulated with a novel adjuvant, AS04, which contains aluminium hydroxide and monophosphoryl lipid A (MPL); and
 - A tetravalent vaccine comprised of HPV types 6, 11, 16 and 18 expressed and purified from yeast cells containing the specific L1 expression plasmids.
- Two prophylactic HPV vaccines have been available since 2006. Both vaccines are prepared from virus-like particles (VLPs) produced by recombinant technology. Purified L1 protein self-assembles to form empty shells that resemble HPV VLPs. These vaccines do not contain viral genetic material or live biological product, so they cannot multiply and are not infectious. These two vaccines are:
 - A bivalent vaccine comprised of HPV types 16 and 18 protein expressed and purified from insect cells infected with a recombinant baculovirus. This vaccine is formulated with a novel adjuvant, AS04, which contains aluminium hydroxide and monophosphoryl lipid A (MPL); and
 - A tetravalent vaccine comprised of HPV types 6, 11, 16 and 18 expressed and purified from yeast cells containing the specific L1 expression plasmids.

Human Papillomavirus (HPV)

New Product

Exporting country: China

Case No.12

Name, address of Applicant / Importer	Company Name: M & M Pharma Company Address: Javaid Plaza, Gurumangat Road, Gulberg II, Lahore
Details of Drug Sale License of importer	License No: : 05-352-0065-035822D Address JavaidPlaza, Opposite Pepsi Gate. 2, Gurumangat Road, Gulberg-II, District Lahore. Validity: 19-10-2027
Name of exporting country	China
Name and address of marketing authorization holder (abroad)	Yuxi Zerun Biotechnology Co., Ltd. Address: No. 83 South Dongfeng Road, High-tech Zone, Yuxi, Yunnan Province, 653100, P.R. China
Name, address of manufacturer(s)	Yuxi Zerun Biotechnology Co., Ltd. Address: No. 83 South Dongfeng Road, High-tech Zone, Yuxi, Yunnan Province, 653100, P.R. China
Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	Scanned copy of COPP: Certificate No:20240048 Certifying Authority: Not mentioned on COPP. Free Sale Status:, Yes Validity: 14-04-2028 The trade name on COPP is Walrinux.
Details of letter of authorization / sole agency agreement	Valid LOA <i>Nc, Yuxi Zerun Biotechnology Co., Ltd., a company incorporated and existing under the laws of the People's Republic of China, with registered office at No. 83 South Dongfeng Road, High New Technology Industries Development Zone, Yuxi, Yunnan Province, China ("YUXI ZERUN"), hereby authorize M&M Pharma having NTN # 7397399, a company incorporated and existing under the laws of Pakistan, with registered office at Javaid Plaza, Gurumangat Road, Gulberg II, Lahore, Pakistan ("M&M PHARMA"), as our Sole Distributor of the Recombinant Human Papillomavirus Bivalent (Types 16, 18) Vaccine (Pichia pastoris) manufactured by YUXI ZERUN ("HPV2") in Pakistan.</i> <i>M&M PHARMA is authorized to submit applications of HPV2 to DRAP for registration on our behalf as required under Drugs Act (the "Drugs Act") in Pakistan.</i>
Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
Status of application	☒ New Drug Product (NDP)

	☐ Generic Drug Product (GDP)
For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
Dy. No. and date of submission	Tracking ID:8JH-1ZA-NAU9 Application Number:76674 Receiving date:24-04-2025
Details of fee submitted	Challan Number: 8262975166, Division: Biological Evaluation & Registration, Paid Fee: 300000.0
The proposed proprietary name / brand name	Recombinant Human Papillomavirus Bivalent (Types 16, 18) Vaccine
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each dose (0.5 mL) of the vaccine contains: Human Papillomavirus type 16 L1 protein 40 micrograms Human Papillomavirus type 18 L1 protein 20 micrograms
Adjuvant (if any)	Aluminum Phosphate
Dosage form of applied drug	Solution for Injection
Indication/Target Parasite Specie	
Target Population	WALRINVAX® is a vaccine for use in females 9 through 30 years of age for the prevention of the following diseases caused by high-risk HPV Types 16,18 ● Cervical cancer; ● Cervical intraepithelial neoplasia of grade 2 or grade 3 (CIN2/3) and cervical adenocarcinoma (AIS). WALRINVAX® has not been demonstrated to provide protection against disease from vaccine HPV types to which an individual has previously been exposed. The risk of exposure to HPV increases with age, especially after sexual debut. Therefore, it is recommended to vaccinate as early as possible. Walrinvax is licensed for girls aged 9–14 years as a 2-dose schedule (6 months apart, with a minimum interval of 5 months). From age 15, a 3-dose schedule is indicated (at 0, 2–3 and 6–7 months)
Route of Administration	For intramuscular (IM) use only.
Pharmacotherapeutic Group of (API)	Not provided.
Finished product specifications	Not provided.
Proposed Pack size	The vaccine is supplied as 0.5 mL/vial or in a single-dose pre-filled syringe with 0.5 mL suspension for intramuscular injection. Batch Size: 3000 Doses Supply Price (CIP) per unit (PFS) in private market: 10 USD /dose Supply Price (CIP) per unit (VIAL) in public market: 5 USD /dose
Proposed unit price	The vaccine is supplied as 0.5 mL/vial or in a single-dose pre-filled syringe with 0.5 mL suspension for intramuscular injection. Batch Size: 3000 Doses Supply Price (CIP) per unit (PFS) in private market: 10 USD /dose Supply Price (CIP) per unit (VIAL) in public market: 5 USD /dose
Shelf Life	24 months
Storage Conditions	2-8 °C
The status in reference regulatory authorities/Name of NRA	WHO PQ is in vial whereas applied is PFS. Evidence of approval in same container closure system is required.
For generic drugs (me-too status)	-①Human Papillomavirus (Bivalent) - Cecolin®. Manufactured by Xiamen Innovax Biotech Co., Ltd. ②Human Papillomavirus (Bivalent) – Cervarix. Manufactured by GlaxoSmithKline Biologicals SA
Drug Substance	
General Information	Separate DS part for both antigens is required.
Name, address of drug substance manufacturer	Separate DS part for both antigens is required.
Manufacturing Process	Separate DS part for both antigens is required.
Characterization	Separate DS part for both antigens is required.
Control of drug Substance Stability	Separate DS part for both antigens is required.

Stability	Separate DS part for both antigens is required.
Drug Product	
Composition	The drug substance of Recombinant Human Papillomavirus Bivalent (Types 16, 18) Vaccine (Pichia pastoris) (HPV-2 Vaccine) consists of HPV 16L1 PMAB and HPV 18L1 PMAB. The buffer system components of HPV 16L1 PMAB and HPV 18L1 PMAB were the same as those of the drug product
Formulation	The HPV-2 Vaccine final product is prepared by mixing HPV 16L1 AMAB and HPV 18L1 AMAB. The composition of formulations did not change from phase I clinical study to commercial production. The amount of aluminum phosphate adjuvant was chosen mainly based on two factors, one was the safety, and the other was the immune-enhancement effect. In general, the suitable dosage of aluminum adjuvant was 0.5 mg per dose. WHO requires not more than 1.25 mg aluminum adjuvant should be used in a single dose. With reference to the aluminum content of 450 µg/mL (225 µg/dose) in Merck's Gardasil vaccine, the dosage of aluminum phosphate adjuvant in the formulation was finally determined to be 450 µg/mL (225 µg/dose).
Manufacturing	To demonstrate that the quality of HPV-2 Vaccine manufactured in Yuxi Zerun scale-up commercial manufacture was comparable to that of the clinical trial materials produced in Shanghai Zerun used in Phase III/IIIb, a comparability study was carried out. The preparation process of the HPV-2 Vaccine includes: ➤ Preparation of aluminum phosphate adjuvant; ➤ Preparation of HPV 16L1 AMAB, and HPV 18L1 AMAB adsorption with aluminum phosphate adjuvant respectively; ➤ Preparation of final bulk by mixing HPV 16L1 AMAB and HPV 18L1 AMAB in an equal weight; ➤ Preparation of final product by filling, light inspection, labelling and packaging to obtain HPV-2 Vaccine. T
Specifications	According to Pharmacopoeia of the People's Republic of China 2020 (ChP 2020), "Quality Control of Recombinant DNA Products", ICH and WHO related guidelines, and considering the product characteristics and process requirement
Container Closure	2 mL middle borosilicate glass vial
Stability	Shelf life for 36 months stored at 5±3°C (protected from light). At 5±3°C (protected from light), the in vivo potency of the vaccine meets the specifications for at least 36 months. At 25±2°C (protected from light), the in vivo potency of the vaccine was maintained for 6 months. At 37±2°C (protected from light), the in vivo potency of the vaccine could be maintained for at least 60 days.

Module 4- Nonclinical Reports

Pharmacology: Immunogenicity studies in mice, rats, Rabbits	Immunogenicity Study of HPV-2 Vaccine in Vivo Shanghai Institute of Pharmaceutical Industry was commissioned by Shanghai Zerun Biotechnology Co., Ltd. to evaluate the immunogenicity of HPV-2 Vaccine, which was recorded as "WV001" in the original reports
Toxicology: - Repeat-dose (IM) in animals - Local tolerance (site histology) - Reproductive & developmental studies	Single-dose Acute Toxicity Study of HPV-2 Vaccine in Mice Conclusion The maximum tolerated dose (MTD) of HPV-2 Vaccine in mice by intramuscular injection was above 10 mL/kg (600~1200-fold human dose) Long-Term Toxicity Study of HPV-2 Vaccine in Cynomolgus Monkeys Conclusions The cynomolgus monkey was immunized with HPV-2 Vaccine 4 times with 3 weeks interval and 3 weeks of recovery period by intramuscular injection. The vaccine immunization could result in increasing of WBC as well as muscle interstitial inflammation with fibrosis in the injection sites. Three weeks after the last dose, WBC value could recovery to the baseline. High titer of antibody response could be induced even after one dose of immunization in cynomolgus monkeys and the neutralization antibody titer significantly increased at the 6th week post immunization. No significant toxicity was found. Reproductive and Developmental Toxicity Study in Rats Conclusion It can be concluded that after SD female rats were inoculated with HPV-2 Vaccine 3 times before pregnancy and given one booster vaccination on day 6 of pregnancy, there was no significant effect on the parental generation female rats, parental fertility and reproductive parameters, embryo-fetal development, and development of offspring thereafter. The results of antibody detection showed that maternal rat and offspring antibody levels were significantly increased on day 20 of pregnancy and on day 22 after delivery, after inoculating maternal rats with HPV-2

	Vaccine 3 times before pregnancy and given one booster vaccination on day 6 of pregnancy.
Module 5 – Clinical Study Reports	
Biopharmaceutics Not applicable for vaccines.	
Clinical Efficacy & Safety	Randomized blind placebo-controlled phase I clinical trial of Recombinant Human Papillomavirus Bivalent (Types 16, 18) Vaccine (Pichia pastoris) in healthy women → Primary objectives: To evaluate the safety and tolerance of different dosages in the age group of 9 - 45 years old. → Secondary objectives: To explore the HPV 16/18 neutralizing antibody level after different dosages of vaccination. Randomized blind placebo-controlled phase II clinical trial of Recombinant Human Papillomavirus Bivalent (Types 16, 18) Vaccine (Pichia pastoris) in healthy women aged 9 to 45 years Study objectives: 1. To evaluate the immunogenicity of HPV-2 (types 16/18) in different age groups of healthy women. 2. To evaluate the safety of HPV-2 in healthy women aged 9 - 45 years. 3. To explore the pre-vaccination and post-vaccination differences in gene expression, change trends, and relations with neutralizing antibody level in populations vaccinated with HPV-2. Immunogenicity and safety study of a 2-dose regimen of Zerun recombinant human papillomavirus bivalent (types 16, 18) vaccine (Pichia pastoris), administered in girls (9 to 14 years old) with a comparison to young women (18 to 26 years old) Primary objective: (1) To demonstrate that the immunogenicity of recombinant Human Papillomavirus Bivalent (Types 16, 18) Vaccine (Pichia pastoris) (hereinafter refer to as “HPV2”) administered according to the standard 3-dose schedule of 0, 2, 6 months in 9 to 14 year-old girls was noninferior to that administered according to same 3- dose schedule in 18 to 26 year-old young women, 1 month after the last dose of HPV-2 vaccine. (2) To demonstrate that the immunogenicity of HPV-2 vaccine administered according to a 2-dose schedule of 0, 6 months in 9 to 14 year-old girls was noninferior to that administered according to the standard 3-dose schedule of 0, 2, 6 months in 18 to 26 year-old young women, 1 month after the last dose of HPV-2 vaccine. Secondary objectives: (1) To evaluate the immunogenicity of 2-dose and 3-dose of HPV-2 administered in 9-14 year old girls. (2) To evaluate the immune responses to HPV type 16 and 18 at Month 12, Month 24 and Month 36 among different groups. (3) To evaluate the safety of the vaccine among different groups.
Post-marketing Data	N/A
Remarks of the Assessor • Submit hard copy of COPP and LOA. • Submit Form 5 F as per final guidance document for biological products. • Submit evidence of already registered vaccine with same concentration, dose and container closure system with DRAP. • Submit the pharmacotherapeutic group • References to the relevant specifications. • Provide the Summary of Product Characteristics (SmPC). • Submit data on the prevalence of the applied strains in Pakistan. • Provide a separate drug substance part for each antigen included in the product. • The submitted container closure system and stability data are for a vial presentation, whereas the applied product is a pre-filled syringe (PFS); this needs to be addressed. • The applied vaccine is in PFS form, while the WHO-prequalified (PQ) product is in a vial; a justification for this difference is required. • Non-clinical and clinical studies provided are based on the vial presentation instead of the PFS; justification is needed in line with applicable reference guidelines. • Submit the Periodic Safety Update Report (PSUR) and Adverse Events Following Immunization (AEFI) data for the pre-filled syringe presentation.	
Conclusion	

The applied vaccine is in PFS , while the WHO-prequalified (PQ) product of same manufacturer is in a vial. Application is deficient for the above stated deficiencies.

Decision of 348th Meeting:

The Registration Board deferred the case for the submission of the following documents:

- Hard copy of original, legalized and valid COPP and original or notarized copy of LOA.
- Submit Form 5 F as per final guidance document for biological products.
- Submit evidence of already registered s vaccine with same concentration, dose and container closure system with DRAP.
- The pharmacotherapeutic group of applied vaccine.
- References to the relevant specifications.
- Provide the Summary of Product Characteristics (SmPC).
- Data on the prevalence of the applied strains in Pakistan.
- Separate drug substance part for each antigen included in the product.
- The container closure system and stability data are for a vial presentation, whereas the applied product is a pre-filled syringe (PFS).
- The applied vaccine is in PFS form, while the WHO-prequalified (PQ) product is in a vial; a justification for this difference is required.
- Non-clinical and clinical studies provided are based on the vial presentation instead of the PFS; justification is needed in line with applicable reference guidelines.
- Submit the Periodic Safety Update Report (PSUR) and Adverse Events Following Immunization (AEFI) data for the pre-filled syringe presentation.

POLIO VACCINES

Two different kinds of vaccine are available,

- **an inactivated (killed) polio vaccine (IPV)**
✓ Inactivated polio vaccine was first introduced in 1955 and is produced from wild-type poliovirus strains of each serotype that have been inactivated (killed) with formalin.
✓ As an injectable vaccine, it can be administered alone or in combination with other vaccines (e.g., diphtheria, tetanus, pertussis, hepatitis B, and haemophilus influenza).
- **a live attenuated oral polio vaccine (OPV).**

Oral polio vaccine was first introduced in 1961 and consists of a mixture of the three live attenuated poliovirus serotypes (Sabin types 1, 2 and 3), selected for their lower neurovirulence and reduced transmissibility. In addition to trivalent OPV (tOPV), which is used in many countries for routine or supplemental vaccination, monovalent OPVs, against type-1 (mOPV1) and against type-3 (mOPV3), have been licensed since 2005 for use in some countries.

(a) the wild-type strains that have been used in the manufacture of IPV for many years; (b) the attenuated Sabin strains that have been used in the manufacture of oral poliomyelitis vaccine (OPV); and (c) new alternative poliovirus strains currently under development, including those derived by recombinant DNA technology

The presence of neutralizing antibody against polioviruses is considered a reliable correlate of protection against poliomyelitis. However, immunity induced by one serotype does not provide protection against the other two serotypes.

**Inactivated polio vaccine
Deferred Case 347
Exporting Country (China)**

Case # 13

Name, address of Applicant / Importer	M/s Lab Diagnostic Systems (SMC) Pvt. Ltd. Plot 36-A, PSIC SIE, Taxila
Details of Drug Sale License of importer	License No.01-374-0006-118530D To Sell Drugs As A Distributor Validity: 15-08-2029
Name of exporting country	China
Name and address of marketing authorization holder (abroad)	M/s Sinovac Biotech Co., Ltd. Address: No.15 Zhitong Road, Changping District, Beijing, P.R. China
Name, address of manufacturer(s)	M/s Sinovac Biotech Co., Ltd. Address: No.15 Zhitong Road, Changping District, Beijing, P.R. China
Detail of certificates attached	Scanned COPP
(CoPP, Free sale certificate, GMP certificate)	Certificate No: 20250158 Certifying Authority: Beijing Municipal Medical Products Administration Free Sale Status: Yes

	GMP Status: Yes Validity: 14-11-2025
Details of letter of authorization / sole agency agreement	Scanned Letter of Authorization Validity: 28, Feb, 2029 Sinovac Biotech Co., Ltd. (北京科兴生物制品有限公司) ("Sinovac"), having its registered address at No. 39, Shangdi Xi Road, Haidian District, Beijing, P. R. China, is the manufacturer of the Poliomyelitis Vaccine (Vero Cell), Inactivated, Sabin Strains ("Vaccine"). Sinovac hereby authorizes Lab Diagnostic Systems (SMC) Pvt. Ltd. ("Distributor"), a company incorporated and existing under the laws of Pakistan with its head office at 111 Hal Road, Westridge I, Rawalpindi, Pakistan and its warehouse at Plot No. 36-A, PSIC, SIE, Taxila Rawalpindi, Punjab, to make the application for and further become the holder of the product.
Status of the applicant	Importer
For imported products, specify one the these	Finished product
Dy. No. and date of submission	Tracking ID:ATD-19W-6NGP Application Number:75175 Receiving: 18-04-2025
Details of fee submitted	Challan Number: 53619747366 Division: Biological Evaluation & Registration Paid Fee: 300000.0 Paid Date: 2025-01-14
The proposed proprietary name / brand name	Poliomyelitis Vaccine (Vero Cell), Inactivated Sabin Strains
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains 2.5ml, Each dose of 0.5ml Poliomyelitis Vaccine (Vero Cell) Inactivated Sabin Strains contains" inactivated poliovirus type 1 15DU, inactivated poliovirus type II 45DU inactivated poliovirus type III 45DU.
Adjuvant (if any)	None
Dosage form of applied drug	Intramuscular Injection
Indication/Target Parasite Species	Active immunization against poliomyelitis.
Target Population	Primary Target Population: • Infants aged 2 months and older. • Children who are at risk of exposure to poliovirus or those who have not yet received the vaccine. Secondary Target Population: • Adults who may be at increased risk for poliovirus exposure, such as those traveling to areas with ongoing polio transmission or healthcare workers. • Individuals involved in polio eradication campaigns or living in endemic regions.
Route of Administration	Intramuscular
Pharmacotherapeutic Group of (API)	Vaccine, viral vaccines
Finished product specifications	Chinese Pharmacopeia
Proposed Pack size	1 Vial
Proposed unit price	As per SRO
Shelf life	24 months
Storage conditions	Store between +2°C and +8°C and protect from light. Do not freeze. After first opening, the vaccine can be used for up to 28 days provided it is stored between +2°C and +8°C. Keep out of reach of children.
The status in reference regulatory authorities/Name of NRA	WHO Product ID:FVP-P-387 Status Prequalified Date of prequalification:06/06/2022 Vaccine type:Poliomyelitis vaccine (inactivated-Sabin) Number of doses:1 Route of administration:Intramuscular
For generic drugs (me-too status)	--
Drug Substance	

General Information	Poliomyelitis Vaccine (Vero Cell), Inactivated, Sabin Strains.
Name, address of drug substance manufacturer	Sinovac Biotech Co., Ltd. Registration Address No. 39, Shangdi Xi Road, Haidian District, Beijing, P. R. China Site Address No.15, Zhi Tong Road, Changping Science Park, Changping District, Beijing, P. R. China
Manufacturing Process	The vaccine contains inactivated poliovirus of types I, II, and III . The manufacturing process is carefully controlled and involves several critical steps: 1. Cell Inoculation: The three types of poliovirus (Sabin strains) are inoculated individually into Vero cells (a cell line derived from African green monkey kidney cells). 2. Incubation: Each virus strain is incubated separately to allow the virus to grow. 3. Harvesting: Once the virus has propagated in the cells, it is harvested from the cell culture. 4. Purification: The harvested virus suspension undergoes purification processes to separate the viral components from cellular material and other impurities. 5. Inactivation: The purified viruses are then inactivated using formaldehyde , rendering them non-infectious while retaining their ability to stimulate an immune response. Final Product: The final vaccine product is a combination of the three inactivated poliovirus types. It is then filled into pre-filled syringes or vials for distribution
Characterization	Virus Structure: Poliovirus is an enterovirus belonging to the Picornaviridae family, with a single-stranded positive RNA genome. The virus particle is icosahedral, meaning it has 20 triangular faces, and it lacks an envelope. - The virus is 20-30 nm in diameter and consists of four capsid proteins (VP1, VP2, VP3, VP4) that form the outer surface of the particle. These proteins are essential for the virus's infectivity and immune recognition. Immunogenicity: - The D-antigen (neutralizing antigen) is the primary immunogenic component in the vaccine. The D-antigen induces the production of neutralizing antibodies against poliovirus types I, II, and III.
Stability	Electron microscopy has confirmed that the virus particles maintain their expected morphology and size throughout the manufacturing and purification process Storage Conditions and Stability Duration: Commercial Scale sIPV Bulk: The sIPV bulk for each of the poliovirus types (Type I, Type II, and Type III) was tested under long-term and accelerated storage conditions to evaluate its stability: Long-Term Stability (2°C - 8°C): Type I: Stable for 42 months Type II: Stable for 36 months Type III: Stable for 42 months Accelerated Stability (37°C): Type I: Stable for 28 days at 37°C. Type II: Stable for 28 days at 37°C. Type III: Stable for 28 days 37°C. Testing Parameters: - All other stability testing items, such as D-antigen content, virus titration, sterility, bacterial endotoxins, and residual formaldehyde content, comply with the specifications for both long-term and accelerated conditions. Based on the stability studies, the sIPV bulk of commercial scale can be stored for 36 months at 2 °C - 8°C, and 28 days at 37 °C.
Drug Product	
Composition	Poliomyelitis Vaccine (Vero Cell), Inactivated, Sabin Strains Active Ingredients: Inactivated poliovirus Type I: 15 DU/dose Inactivated poliovirus Type II: 45 DU/dose Inactivated poliovirus Type III: 45 DU/dose Excipients: Media 199, Sodium chloride, Potassium chloride, Glycine, Magnesium sulfate, Calcium chloride, Formaldehyde solution, Disodium hydrogen phosphate, Sodium bicarbonate, Glucose .

Formulation	• The formulation of the vaccine involves combining the inactivated poliovirus (types I, II, and III) with the excipients listed above. This mixture is processed through filtration and sterile processing to ensure it is free from contaminants. • Final Concentration: • The vaccine is formulated to contain 15 DU of Type I antigen, 45 DU of Type II antigen, and 45 DU of Type III antigen per 0.5 mL dose. • The vaccine is filled into pre-filled syringes or vials for use, with each dose ensuring a balanced concentration of inactivated virus and stabilizing agents for effective immunization.																		
Specifications	• D-antigen Content (for each type): • Type I: 15 DU/dose • Type II: 45 DU/dose • Type III: 45 DU/dose The D-antigen is a neutralizing antigen, and its content is a key parameter for measuring the vaccine's potency. • Residual Impurities:																		
	• Residual Vero Cell DNA: ≤ 50 pg/dose. This ensures that there are minimal traces of DNA from the cell culture used in vaccine production. • Bovine Serum Albumin: ≤ 20 ng/dose. This is a protein used in the cell culture medium, and it must be reduced to minimal levels to ensure vaccine safety. • Residual Vero Cell Protein: ≤ 100 ng/dose. Protein from the cell culture should also be minimized in the final product to avoid allergic reactions or other issues. • Sterility: The vaccine must pass sterility testing, ensuring no microbial contamination.																		
Container Closure	• Type: 2 mL neutral borosilicate glass vials with rubber stopper (halogenated butyl rubber) for added protection and to maintain sterility. • The vials are sealed and tested for integrity to ensure no leaks or contamination.																		
Stability	The final product of five-doses sIPV in commercial scale can be stored at 2°C - 8°C for 3 months, at 25°C ± 2°C for 3 months, and at 37°C ± 2°C for 7 days. The in-use stability study shows that it can be used up to 28 days. The stability study for commercial scale is still ongoing and the stability data will be provided. In addition, new stability study will be conducted for final product from process validation and their stability data will be available when they are finished The stability study for commercial scale is still ongoing and the stability data will be provided. In addition, new stability study will be conducted for final product from process validation and their stability data will be available when they are finished. <table><tr><th>Name</th><th>Batch No.</th><th>Filling container</th><th>Strength</th><th>Direction of the vial</th></tr><tr><td rowspan="3">Commercial scale</td><td>F202112001</td><td>Vial</td><td>2.5 mL/vial</td><td>Upright</td></tr><tr><td>F202112002</td><td>Vial</td><td>2.5 mL/vial</td><td>Upright</td></tr><tr><td>F202112003</td><td>Vial</td><td>2.5 mL/vial</td><td>Upright</td></tr></table>	Name	Batch No.	Filling container	Strength	Direction of the vial	Commercial scale	F202112001	Vial	2.5 mL/vial	Upright	F202112002	Vial	2.5 mL/vial	Upright	F202112003	Vial	2.5 mL/vial	Upright
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Viral Safety Evaluation	• Adventitious Agent Testing: • The vaccine undergoes rigorous testing for the presence of adventitious agents (unintended viruses or bacteria). This ensures that no foreign viruses are present in the vaccine, making it safe for human use. • Mycoplasma Testing: • The vaccine is tested for mycoplasma contamination, a potential source of infection, using cell culture and PCR-based methods. • Inactivation Validation: • The formaldehyde inactivation process is validated to ensure that it effectively neutralizes the poliovirus without compromising the virus's immunogenic properties.																		
Module 4- Nonclinical Reports																			
Pharmacology:	Primary Pharmacodynamics																		

	Immunogenicity studies in mice, rats, rabbits.	• Study Title: Immunogenicity Study of Poliomyelitis Vaccine (Vero Cell), Inactivated, Sabin Strains on Wistar Rats. Objective: To evaluate the immunogenicity of the vaccine by measuring serum neutralizing antibody levels after immunization. • Model: • Key Endpoints: ○ Seroconversion rates The immunogenicity was measured by evaluating serum neutralizing antibody levels. ○ Dose-response curve. Various dilutions of the vaccine were administered, and the immune response was assessed to determine the appropriate dose for future human trials. • Conclusion: The study confirmed that the vaccine induced an adequate immune response in Wistar rats, supporting the vaccine's immunogenic efficacy and helping determine the optimal dosage for further trials . Safety Pharmacology • Study Title: Safety Pharmacology studies evaluated acute toxicity, systemic anaphylaxis, and muscle stimulation reactions to assess safety. • Endpoints: Acute Toxicity: ICR mice were injected intramuscularly with inactivated poliomyelitis vaccine and monitored for signs of toxicity. Systemic Anaphylaxis: Guinea pigs were used to evaluate allergic reactions to the vaccine. Muscle Stimulation: Rabbits were tested for muscle irritation following intramuscular vaccine injection • Conclusion: Acute Toxicity: No significant toxicity was observed in mice. Systemic Anaphylaxis: No major allergic reactions were observed in guinea pigs. Muscle Stimulation: Muscle irritation was temporary and reversible in rabbits, with no long-term damage observed Pharmacodynamic Drug Interactions • Usually not applicable for monovalent vaccines. Monovalent vaccines, like the Poliomyelitis Vaccine (Vero Cell), Inactivated, Sabin Strains, are designed to protect against a single pathogen, and therefore, pharmacodynamic drug interactions are typically not a concern. These vaccines are focused on stimulating the immune system to target only one specific virus (in this case, poliovirus), and there is usually no interaction with other drugs. • If co-administered with other pediatric vaccines (e.g. DTP), studies may be included here. If the Poliomyelitis Vaccine is co-administered with other vaccines (for example, DTP - Diphtheria, Tetanus, and Pertussis vaccine), studies may be conducted to assess if there are any interactions. In such cases, the studies would examine if the immune response to either vaccine is affected by the co-administration. The primary concern in these studies is
		ensuring that both vaccines still elicit an appropriate immune response and that there are no adverse interactions between them.
	Pharmacokinetics: Not applicable (vaccines act via immune stimulation, not systemic exposure).	Not applicable (vaccines act via immune stimulation, not systemic exposure).

	Toxicology: ☐ Repeat-dose (IM) in animals ☐ Local tolerance (site histology) ☐ Reproductive & developmental studies	Single-Dose Toxicity Species: ICR mice (5-6 weeks old, 20 males and 20 females) Route: Intramuscular injection of Inactivated Poliomyelitis Vaccine (Sabin Strain). Observation Period: 14 days after administration. Results: ✓ No visible pathology was observed in the gross anatomy of the main organs or at the injection site. ✓ Body weight and food intake showed no significant difference between the test and control groups. ✓ Histopathological examination revealed no significant abnormality at the injection site or in major organs after 14 days. Repeat-Dose Toxicity Not applicable for this vaccine, as it was not studied with repeated doses in the available documents Local Tolerance • Study Title: Muscle Stimulation Test on Rabbits. • Outcome: Injection dose: 0.5 mL per rabbit (Japanese white rabbits). No visible irritation was observed 48 hours after administration. One rabbit showed histopathological change (inflammatory cell infiltration in the muscle tissue), but this reversed after 21 days, with no long-term damage. Conclusion: The vaccine is well tolerated with no permanent irritation or significant adverse reactions . Toxicity Studies (e.g. immunotoxicity, allergenicity) Active Systemic Anaphylaxis Test: The vaccine was negative for systemic anaphylaxis in guinea pigs, indicating that it does not cause severe allergic reactions • Result:.
Module 5 – Clinical Study Reports		
	Biopharmaceutics Not typically applicable to vaccines unless special delivery methods used	Not typically applicable to vaccines unless special delivery methods used
	Reports of Studies	Not applicable — Polio vaccines are not absorbed systemically in a way that requires
	Pertinent to Pharmacokinetics (PK) Not applicable — Polio vaccines are not absorbed systemically in a way that requires PK profiling.	PK profiling.
	Reports of Human Pharmacodynamics (PD) Studies Study: Findings: Markers:	Immunogenicity Studies: • Study Title: Immunogenicity study of sIPV on Wistar rats. • Objective: To assess the immune response to the Sabin strains of the poliomyelitis vaccine. • Model: Wistar rats. • Key Endpoints: ○ Seroconversion rates ○ Dose-response curve • Conclusion: The immunogenicity results supported the vaccine's efficacy for immune stimulation
	Clinical Efficacy & Safety ☐ Phase I/II:. ☐ Phase III:	Phase I/II Trials: • Study Design: ○ Phase I: A single-arm open-label trial conducted in healthy

□ Key Trial: □ Trial Duration: □ Trial Populations: □ Post-marketing: Ongoing surveillance confirms long-term efficacy and rare adverse event rates.	adults and children to assess the safety and immunogenicity of the vaccine. ○ Phase II: Randomized, double-blind, and placebo- controlled trials in children to evaluate the vaccine's safety and immune response. • Objectives: ○ Safety and tolerability were primary endpoints, with secondary endpoints focused on the immune response (i.e., seroconversion rates and antibody titers). - Phase III Trials: • Study Title: Poliomyelitis Vaccine (Vero Cell), Inactivated, Sabin Strains - Phase III Clinical Trial in Infants. • Study Design: ○ A randomized, double-blind, and positive-controlled study to assess the vaccine's immunogenicity and safety. • Trial Duration: ○ The vaccine was administered at 0, 1, and 2 months, with an 18- month follow-up for booster shots. • Trial Populations: ○ Infants aged 2 months and above, including healthy children with no contraindications to vaccination. • Key Results: ○ Seroconversion rates showed high efficacy with neutralizing antibody titers in over 90% of subjects for all three strains of the poliovirus. ○ Safety: No serious adverse events were reported during the trial period. Post-marketing: • Ongoing Surveillance: ○ Post-marketing surveillance confirms the long-term efficacy of the vaccine, showing sustained antibody protection against poliovirus types I, II, and III. ○ Rare adverse event rates remain low, and there are no significant
Integrated Summaries ISS & ISE support consistent efficacy and safety across age groups and populations.	safety concerns observed in large populations. The Integrated Summary of Safety (ISS) and Integrated Summary of Efficacy (ISE) support the consistent efficacy and safety of the Poliomyelitis Vaccine (Vero Cell), Inactivated, Sabin Strains across different age groups and populations. The immunogenicity data demonstrates high efficacy in both infants and older populations, while the safety profile remains consistent, with no new adverse events reported across clinical trials and post-marketing.
Post-marketing Data	Long-Term Efficacy: ○ The vaccine continues to maintain its effectiveness in preventing poliomyelitis in the long term, with high seroconversion rates still observed in vaccinated individuals. Rare Adverse Events: ○ Ongoing surveillance confirms that the vaccine has a favorable safety profile, with rare adverse events associated with the vaccine and no serious long-term health issues reported.
Miscellaneous Documents in Compliance to WHO Requirements ✓ A statement by the Applicant to confirm whether the product has been rejected, withdrawn from the markets/countries. ✓ Information on the type of the product if was produced using a GMO technology, ✓ Evidence of valid GMP certificate. ✓ Acceptable shipping condition for both finished product and Drug Substance and Formulated Bulks (for importing bulks for filling and domestic production). ✓ Proof of Shipping validation. ✓ A copy template of lot summary protocol in compliance with WHO-recommended format (identified as per specific WHO TRS). ✓ A copy of labels (vial and carton).	

Remarks of the Evaluator Shortcomings - Submit stability data of commercial batches till claimed shelf life. - Justification is required for not performing repeat dose toxicity. - Evidence of availability of same in same strength as multiple dose in reference regulatory authority as approved by Registration Board in 275th Meeting. Note: The WHO PQ product is single dose vial. However, the applicant has applied for Variation for an additional 5- dose presentation. This variation should be included in the summary table of variations submitted in your next Annual Report (PQVAR) as described in section 8 of WHO Prequalification.
Comments by BE&R Division Not recommended as applicant has not submitted stability data for commercial batches and justification of non-performance of repeat dose toxicity.

Decision of 347th Meeting: The Registration Board deferred the case for the submission of following documents: - Stability data of drug product of commercial batches till claimed shelf life. - Justification for not performing repeat dose toxicity in the light of reference guidelines. - Evidence of availability of applied formulation in same strength as multiple dose vial in reference regulatory authority as approved by Registration Board in 275th Meeting.

Remarks of the Evaluator			
Sr No.	Shortcomings	Response	Evaluation
1)	Stability data of drug product of commercial batches till claimed shelf life.	Stability data of 42 months provided. At 2-8C	The shelf life as per WHO PQ status is 24 months.
2)	Justification for not performing repeat dose toxicity in the light of reference guidelines.	5 dose is in addition to 1 dose vial and is similar in composition	WHO PQ for 5 doses. Prequalification Status:Current Effective Date:29/08/2024 Product description:Pharmaceutical Form:Liquid: ready to use Presentation:Vial Number of Doses:5
3)	Evidence of availability of applied formulation in same strength as multiple dose vial in reference regulatory authority as approved by Registration Board in 275 th Meeting.	Prequalification Prequalification Status Current Effective Date 29/08/2024 Product description Pharmaceutical Form Liquid: ready to use Presentation Vial Number of Doses 5	WHO PQ for 5 doses. Prequalification Status:Current Effective Date:29/08/2024 Product description:Pharmaceutical Form:Liquid: ready to use Presentation:Vial Number of Doses:5

Conclusion The applied vaccine is approvable based on its WHO Prequalification (PQ) status.

Decision of 348th Meeting The Registration Board approved the product as per “The International Pharmacopoeia” on the basis of WHO Prequalification (PQ) status.

Inactivated Poliomyelitis Vaccine New Case Exporting Country(China)		
Case No. 14		
	Name, address of Applicant / Importer	M/s Amson Vaccines & Pharma (Pvt.) Ltd. Plot No. 115, Industrial Triangle, Kahuta Road, Islamabad.

Details of Drug Sale License of importer	License No: DHO-ISB-1352 Address: 154 Industrial triangle Kahuta Road Islamabad. Validity: 01-12-2025
Name of exporting country	China
Name and address of marketing authorization holder (abroad)	INSTITUTE OF MEDICAL BIOLOGY CHINESE ACADEMY OF MEDICAL SCIENCES 168 Dengzhanhua Street, Majinpu, High-tech Zone, Kunming, Yunnan Province, 935 Jiaoling Road, Kunming, Yunnan Province, China
Name, address of manufacturer(s)	INSTITUTE OF MEDICAL BIOLOGY CHINESE ACADEMY OF MEDICAL SCIENCES 168 Dengzhanhua Street, Majinpu, High-tech Zone, Kunming, Yunnan Province, 935 Jiaoling Road, Kunming, Yunnan Province, China
Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Not provided.
Details of letter of authorization / sole agency agreement	Not provided.
Status of the applicant	Importer
Status of application	Generic Drug Product (GDP)
For imported products, specify one the these	Finished Pharmaceutical Product Import
Dy. No. and date of submission	R&I Date: 16-Oct-2020 Diary Number: 27456
Details of fee submitted	Challan Number: 1926232 Division: Biological Evaluation & Registration Paid Fee: 1,00,000/- Paid Date: 09-10-2020
The proposed proprietary name / brand name	Inactivated Poliomyelitis Vaccine Aibiwei
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 0.5ml/vial, 0.5ml/dose contains: Poliovirus Type I (inactivated): 30DU (D-antigen unit) Poliovirus Type II (inactivated): 32DU Poliovirus Type III (inactivated): 45DU
Adjuvant (if any)	Preservative: 2-Phenoxyethanol: 5.0 mg/mL (acts as an antimicrobial preservative) Formulation Medium: M199 (Ca ²⁺ , Mg ²⁺ free): A common virus culture medium used to dilute and stabilize the vaccine formulation.
Dosage form of applied drug	Injections
Indication/Target Disease	Polio
Target Population	The target population for the Inactivated Poliomyelitis Vaccine (sIPV) made from Sabin strains is infants and young children, who are the primary recipients of poliovirus immunization under national immunization programs.
Route of Administration	IM
Pharmacotherapeutic Group of (API)	Polio Vaccine
Finished product specifications	WHO prequalified
Proposed Pack size	1,s
Proposed unit price	As per S.R.O, for EPI.
Shelf life	24 Months
Storage conditions	2-8° C
The status in reference regulatory authorities/Name of NRA	Brand Name: IPOL® Manufacturer: Sanofi Pasteur SA US-FDA Approved License No 1724 Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit: Each 0.5 mL dose contains inactivated poliovirus of the following types: Type 1 (Mahoney strain): 40 D-antigen units Type 2 (MEF-1 strain): 8 D-antigen units Type 3 (Saukett strain): 32 D-antigen units

	Should be in same concentration. Dosage form of applied drug: Suspension for injection Indication/Target Disease: Polio Target Population: infants, children and adolescents
	Route of Administration:
For generic drugs (me-too status)	Brand name: IMOVAX POLIO VACCINE Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit: Each 0.5 mL dose contains inactivated poliovirus of the following types: Type 1 (Mahoney strain): 40 D-antigen units Type 2 (MEF-1 strain): 8 D-antigen units Type 3 (Saukett strain): 32 D-antigen units Dosage form of applied drug: Suspension for injection Indication/Target Disease: Polio Target Population: infants, children and adolescents Route of Administration: IM Registration Holder: Sanofi-Aventis Pakistan Limited. Registration Number: 045700
Drug Substance ()	
General Information	The drug substance of the Inactivated Poliomyelitis Vaccine (sIPV) is composed of inactivated monovalent bulks derived from Sabin poliovirus strains Type I, II, and III, produced using Vero cells—a continuous cell line derived from African green monkey kidney. Specifically, Type I and II are Sabin strains, while Type III is a Pfizer strain. The production involves culturing these viruses on Vero cells grown on microcarriers in bioreactors, followed by harvesting, purification, and inactivation with formaldehyde. These inactivated monovalent bulks are later combined to formulate the trivalent sIPV. The vaccine contains 2-phenoxyethanol as a preservative and is administered via intramuscular injection. Each 0.5 mL dose contains 30 DU of Type I, 32 DU of Type II, and 45 DU of Type III poliovirus D-antigen. The vaccine has demonstrated strong thermal stability, retaining antigen content for seven days at 37°C and up to two years at 4°C. It is intended for the prevention of poliomyelitis caused by all three poliovirus serotypes.
Name, address of drug substance manufacturer	INSTITUTE OF MEDICAL BIOLOGY CHINESE ACADEMY OF MEDICAL SCIENCES 168 Dengzhanhua Street, Majinpu, High-tech Zone, Kunming, Yunnan Province, 935 Jiaoling Road, Kunming, Yunnan Province, China
Manufacturing Process	The manufacturing process of the drug substance for the Inactivated Poliomyelitis Vaccine (sIPV) made from Sabin strains involves several carefully controlled steps to ensure safety, consistency, and efficacy. The process begins with the inoculation of working seed viruses—Sabin Type I, Sabin Type II, and Pfizer Type III—onto Vero cells that are cultured on microcarriers in bioreactors. The Vero cells are first prepared from a qualified working cell bank and expanded to the required volume. Following viral inoculation, the cells are cultured under optimized conditions to support virus replication. Once sufficient viral growth is achieved, the virus-containing supernatant is harvested. This is followed by clarification to remove cell debris, and the virus is then subjected to concentration and purification through ultrafiltration and chromatography. The purified virus bulk is then inactivated using formaldehyde at 37°C for a defined period, typically up to 12 days, to ensure complete inactivation while preserving the antigenic properties of the virus. Inactivation kinetics are closely monitored by testing samples at various time points to confirm the absence of live virus. After inactivation, each monovalent bulk is stored separately under controlled conditions until it is combined during the final drug product formulation process. Throughout the manufacturing process, strict biosafety and quality controls are in place, including sterility testing, D-antigen quantification, and inactivation validation. All operations are carried out in a GMP-compliant facility equipped with biocontainment measures to meet WHO GAP III biosafety requirements.
Characterization	The characterization of the drug substance for the Inactivated Poliomyelitis Vaccine (sIPV) made from Sabin strains involves comprehensive evaluation to confirm identity, purity, potency, and consistency of the inactivated monovalent bulks (Types I, II, and III).

	Each monovalent bulk is tested for its D-antigen content using a validated ELISA method specific to each poliovirus serotype, which quantitatively measures the presence of immunologically active viral antigen. Identity testing ensures that each monovalent bulk corresponds to the correct poliovirus type by detecting type-specific antigens. Purity is assessed through tests for residual host cell proteins (Vero cell protein), bovine serum albumin (BSA), DNA, and other process-related impurities such as residual formaldehyde and kanamycin, confirming that levels are within acceptable safety limits. Sterility tests and endotoxin assays are conducted to ensure the absence of microbial contamination. Additionally, inactivation is verified by sensitive infectivity assays, confirming that no live poliovirus remains after formaldehyde treatment. These characterization steps are crucial to ensuring that the drug substance meets predefined quality specifications and is suitable for use in the final vaccine formulation.
Control of drug Substance	The control of the drug substance for the Inactivated Poliomyelitis Vaccine (sIPV) made from Sabin strains involves rigorous testing of each monovalent bulk (Type I, II, and III) to ensure its identity, potency, purity, safety, and compliance with established specifications. Identity testing is performed using ELISA to confirm the presence of the correct poliovirus serotype. Potency is assessed by measuring D-antigen content, which must fall within defined ranges to ensure adequate immunogenicity. Purity is evaluated through tests for residual impurities, including Vero cell proteins, bovine serum albumin (BSA), residual DNA, and residual antibiotics (kanamycin), all of which must be within acceptable limits. Safety is ensured through sterility testing, endotoxin testing, and confirmation of effective viral inactivation. The inactivation process is validated by demonstrating the absence of live virus in samples collected at multiple time points during and after formaldehyde treatment. These tests are performed according to validated in-house methods and national pharmacopeial standards. Only batches that meet all quality specifications are approved for use in the formulation of the final vaccine product.
Stability	The stability of the drug substance for the Inactivated Poliomyelitis Vaccine (sIPV) made from Sabin strains is thoroughly evaluated to ensure it maintains its potency, safety, and quality throughout its shelf life. Stability studies are conducted under recommended storage conditions (2–8°C) and include testing of critical parameters such as D-antigen content, pH, sterility, and residual formaldehyde levels at specified intervals. Results from long-term and accelerated stability studies demonstrate that the inactivated monovalent bulks of poliovirus Types I, II, and III remain stable for up to 24 months when stored under refrigerated conditions. The D-antigen content remains within specification throughout the storage period, indicating preservation of immunogenicity.
Drug Substance ()	
Drug Product (Name)	
Composition	The composition of the drug product for the Inactivated Poliomyelitis Vaccine (sIPV) made from Sabin strains consists of the following components per 0.5 mL dose: Active Ingredients (D-Antigen content): Poliovirus Type I (Sabin): 30 DU Poliovirus Type II (Sabin): 32 DU Poliovirus Type III (Pfizer): 45 DU Preservative: 2-Phenoxyethanol: 5.0 mg/mL (acts as an antimicrobial preservative) Formulation Medium: M199 (Ca²⁺, Mg²⁺ free): A common virus culture medium used to dilute and stabilize the vaccine formulation.
Formulation	Each 0.5ml/vial, 0.5ml/dose contains: Poliovirus Type I (inactivated): 30DU (D-antigen unit) Poliovirus Type II (inactivated): 32DU Poliovirus Type III (inactivated): 45DU
Manufacturing	The manufacturing process of the finished drug product for the Inactivated Poliomyelitis Vaccine (sIPV) made from Sabin strains involves several key stages, all conducted under strict GMP conditions to ensure product quality, safety, and efficacy. The process begins with the formulation of the Final Formulated Bulk (FFB). This involves proportionally mixing the inactivated monovalent bulks of poliovirus Types I, II, and III with M199 medium (Ca²⁺ and Mg²⁺ free) to achieve the target D-antigen

	concentrations: 30 DU for Type I, 32 DU for Type II, and 45 DU for Type III per 0.5 mL dose. A preservative, 2-phenoxyethanol, is added to the formulation at a concentration of 5.0 mg/mL. The formulation is then subjected to sterile filtration using a 0.2 µm filter to ensure sterility, after which the bulk is stored at 2–8°C until filling. The next step is the filling and packaging process. Washed and depyrogenated borosilicate glass vials are filled with the sterile bulk solution under aseptic conditions. For single-dose presentations, 0.5 mL is filled into 2 mL vials, and for multi-dose presentations, 2.5 mL (containing 5 doses) is filled into 4 mL vials. The filled vials are then stoppered and sealed with aluminum/polypropylene caps. Following filling and sealing, the vials undergo visual inspection, either manually or via automated systems, to detect any particulate matter or defects. Vials that pass inspection are labeled, and lot numbers and expiry dates are printed. They are then packaged into cartons along with package inserts. Each carton is serialized with a drug electronic supervision code to ensure traceability. Finally, the finished vaccine is stored at 2–8°C and subjected to a comprehensive set of quality control tests, including identity, sterility, potency, pH, residual formaldehyde, preservative content, and container integrity. Only batches that meet all specifications are released for distribution.
Specifications	The specifications of the finished drug product for the Inactivated Poliomyelitis Vaccine (sIPV) made from Sabin strains are designed to ensure the vaccine's safety, potency, identity, purity, and overall quality. The following tests and acceptance criteria are applied to each batch of the final product:
Container Closure System	Primary Container – Vial Material: Type I borosilicate glass Presentation: Single-dose vials: 2 mL capacity, filled with 0.6 mL (0.5 mL extractable) Multi-dose vials (5 doses): 4 mL capacity, filled with 2.9 mL (2.5 mL extractable) Properties: Chemically inert, transparent, and suitable for parenteral products Stopper Material: Halogenated butyl rubber Function: Provides a secure, resealable seal to maintain sterility and allow needle penetration Seal Material: Aluminum cap with polypropylene (PP) flip-off button Function: Protects the rubber stopper and ensures tamper-evidence
Stability	Firm has submitted stability study data of 3 batches. The accelerated stability study data is conducted at 25±2°C /60±5%RH for 6 months. The real time stability study data is conducted at 2-8°C for 36 months. Lot VCIS201901R Lot VCIS201902R Lot VCIS201903R
Module 4- Nonclinical Reports	
Pharmacology:	The pharmacology of the Inactivated Poliomyelitis Vaccine (sIPV) made from Sabin strains, as demonstrated in non-clinical studies, confirmed its safety and immunogenicity in animal models, primarily using rats. Pharmacodynamic evaluations showed that the vaccine elicited strong, specific immune responses against all three poliovirus serotypes (Types I, II, and III), with neutralizing antibody titers comparable to or exceeding those induced by conventional wild-strain IPV. These responses were consistent and dose-dependent, supporting the selected D-antigen dosages of 30 DU (Type I), 32 DU (Type II), and 45 DU (Type III) for clinical use. Safety pharmacology studies in mice and guinea pigs demonstrated that the vaccine was well tolerated, with no systemic toxicity or abnormal local reactions observed. The abnormal toxicity tests confirmed the absence of unexpected adverse effects. Mechanistically, sIPV induces protective immunity by presenting inactivated poliovirus antigens to the immune system, prompting the production of neutralizing antibodies that prevent viral entry into host cells. Overall, the

		preclinical pharmacology data provided strong justification for the vaccine's progression to clinical trials.
	Pharmacokinetics: Not applicable (vaccines act via immune stimulation, not systemic exposure).	Not applicable
	Toxicology: • Repeat-dose (IM) in animals • Local tolerance (site histology) • Reproductive & developmental studies	The toxicity profile of the Inactivated Poliomyelitis Vaccine (sIPV) made from Sabin strains was evaluated through a series of non-clinical toxicology studies in accordance with regulatory guidelines to ensure its safety prior to human use. A repeat-dose intramuscular (IM) toxicity study was conducted in animal models, wherein the vaccine was administered multiple times to assess potential systemic toxicity. The results indicated that the vaccine was well tolerated, with no significant adverse effects on clinical observations, body weight, food consumption, or organ weights. Hematological and biochemical parameters remained within normal limits, and no treatment-related abnormalities were observed in necropsy or histopathological examinations. Local tolerance was assessed through site-specific histological examinations. Animals showed no evidence of severe inflammation or tissue necrosis at the injection site, and the local reactions were minimal and transient, typical of responses to parenteral vaccines. These findings confirmed the vaccine's acceptable local tolerability profile. While the primary toxicology studies focused on general and local toxicity, reproductive and developmental toxicity studies were not explicitly reported in the available non-clinical documentation. However, based on the nature of the inactivated vaccine and the lack of systemic toxicity in repeat-dose studies, no reproductive or developmental concerns were indicated from the available data. Overall, the non-clinical toxicology findings support the conclusion that the sIPV is safe for use, with no evidence of systemic or local toxicity upon repeated intramuscular administration in animals.
Module 5 – Clinical Study Reports		
	Biopharmaceutics Not applicable for vaccines.	Not applicable
	Clinical Efficacy & Safety ☐ Phase I/II: Dose-ranging, immunogenicity in adults and infants.	The clinical efficacy and safety of the Inactivated Poliomyelitis Vaccine (sIPV) made from Sabin strains were evaluated through Phase I, II, and III studies conducted in infants in China. The Phase I study was a placebo-controlled, dose-ranging trial involving infants, children, and adults, although immunogenicity data were only collected from infants. Three ascending doses (low, middle, and high) were tested. The results showed strong immunogenicity with 100% seroconversion for Type I, and over 90% for Types II and III, particularly at the middle and high doses. The Phase II trial further assessed immunogenicity in infants using the same dosing levels, comparing sIPV with oral polio vaccine (OPV) and conventional inactivated poliovirus vaccine (cIPV). It confirmed a dose-response relationship and showed that sIPV, especially at middle and high doses, produced immunogenicity equal to or superior to cIPV for all three poliovirus types. In Phase III, a slightly lower dose than the middle dose used in earlier studies (30 DU for Type I, 32 DU for Type II, and 45 DU for Type III) was selected. Despite being untested in earlier phases, this dose achieved excellent immunogenicity outcomes, with seroconversion rates of 100% for Type I, 94.91% for Type II, and 98.95% for Type III. These results demonstrated non-inferiority to the control vaccine (Sanofi Pasteur's cIPV), meeting WHO criteria for immunogenicity and showing robust post-booster antibody responses. Regarding safety, the vaccine was well tolerated across all three studies. In Phase I, most adverse events (AEs) in infants were mild and transient, primarily low-grade fever (mostly <37.6°C), occurring more frequently in higher dose groups and after the first injection. In adults and children, AEs were infrequent and non-serious. Phase II and III studies confirmed this safety profile, with only isolated cases of serious adverse events (SAEs) reported—none of which were deemed related to sIPV administration. One SAE possibly related to the vaccine occurred in the cIPV group, not sIPV.

		Overall, the clinical data from all three phases show that sIPV is highly immunogenic and has a favorable safety profile in infants, supporting its use as a safe and effective polio vaccine.
Phase III: Multi-regional, randomized, controlled studies demonstrating safety, immunogenicity, and efficacy across diverse geographic populations. ">90% seroconversion rate. Post-marketing: Ongoing surveillance confirms long-term efficacy and rare adverse event rates.		The Phase III clinical study of the Inactivated Poliomyelitis Vaccine (sIPV) made from Sabin strains was a multi-center, randomized, controlled trial conducted across multiple regions in China, including Guangxi, Henan, and Hebei provinces, to assess the vaccine's safety, immunogenicity, and efficacy in diverse geographic populations. The study compared sIPV to a control vaccine (Sanofi Pasteur's conventional IPV) using a 3-dose primary schedule plus 1 booster. A total of 1,200 infants were enrolled, with 900 receiving sIPV and 300 receiving cIPV. The seroconversion rates after the primary series with sIPV were 100% for poliovirus Type I, 94.91% for Type II, and 98.95% for Type III, all exceeding the >90% seroconversion threshold set by WHO for immunogenicity standards. Additionally, after the booster dose, antibody titers increased significantly, indicating strong immune memory and boosting capacity. In terms of safety, the vaccine was well tolerated. Reported adverse events (AEs) were mostly mild, including low-grade fever and localized reactions, with no vaccine-related serious adverse events (SAEs) reported in the sIPV group. These findings confirmed that sIPV is non-inferior to cIPV in both immunogenicity and safety, supporting its use in broad immunization programs, particularly in regions transitioning from OPV to IPV-based strategies. The post-marketing data for the Inactivated Poliomyelitis Vaccine (sIPV) made from Sabin strains indicates ongoing safety monitoring and supports the vaccine's long-term use. According to the data, post-marketing surveillance has been implemented following the vaccine's introduction, confirming its continued safety and efficacy. The reported data show that no new or unexpected safety concerns have arisen since licensure. Adverse events (AEs) reported during post-marketing use remain rare and consistent with those observed during clinical trials. The most commonly reported events include mild systemic reactions such as low-grade fever and localized injection site reactions, which are transient and self-limiting. Importantly, serious adverse events (SAEs) remain extremely rare, and no direct causal relationship with the vaccine has been established for reported SAEs. The document highlights that routine pharmacovigilance activities continue to track the safety profile of sIPV, including ongoing adverse event reporting and evaluation. These data confirm that the vaccine retains its favorable safety profile in the broader population beyond clinical trial settings and continues to meet regulatory and public health expectations for rare adverse events and long-term efficacy. At the time of reporting, China is the primary country where the post-marketing experience has been documented, given that the vaccine was developed and deployed there. However, as the vaccine has received WHO prequalification, it is expected to be introduced in additional countries, where similar surveillance measures would apply.
Post-marketing Data		The post-marketing data demonstrate ongoing safety and effectiveness in real-world use following its licensure and introduction into immunization programs. Since its approval by the National Medical Products Administration (NMPA) of China in January 2015 and official market launch in June 2015, the vaccine has undergone continuous pharmacovigilance monitoring to ensure long-term safety and efficacy. Data collected through post-marketing surveillance have confirmed the vaccine's favorable safety profile, with reported adverse events (AEs) largely consistent with those observed in clinical trials. Most AEs have been mild and transient, including low-grade fever and localized injection site reactions. Serious adverse events (SAEs) have been rare and have shown no confirmed causal relationship with the vaccine. Importantly, there have been no safety signals indicating new or unexpected risks during widespread use.

	In addition to safety, the effectiveness of sIPV has been sustained in post-marketing use, supporting its role in national immunization programs and the global polio eradication strategy. Post-marketing experience in China, where the vaccine is in broad use, supports its suitability for large-scale deployment. Furthermore, the WHO prequalification of sIPV facilitates its introduction into other countries, where similar pharmacovigilance practices will continue to monitor and confirm its performance in diverse populations. Overall, the post-marketing data affirm that sIPV remains a safe, well-tolerated, and immunogenically effective vaccine, with ongoing surveillance confirming rare adverse event rates and durable protection against poliovirus.
	Miscellaneous Documents in Compliance to WHO Requirements ✓ A statement by the Applicant to confirm whether the product has been rejected, withdrawn from the markets/countries. ✓ Information on the type of the product if was produced using a GMO technology, ☐ Evidence of valid GMP certificate. ✓ Acceptable shipping condition for both finished product and Drug Substance and Formulated Bulks (for importing bulks for filling and domestic production). ✓ Proof of Shipping validation. ✓ A copy template of lot summary protocol in compliance with WHO-recommended format (identified as per specific WHO TRS). ✓ A copy of labels (vial and carton).

Remarks of the Assessor			
Sr No.	Shortcomings	Response	Evaluation
1.	Evidence of RRA is required in same composition.		
2.	Original, legalized and valid COPP and LOA is required.		
3.	Submit Me too in same concentration.		
4.	Submit separate drug substance part for each antigen.		
5.	Clarification is required whether the applied product is single dose or multiple dose.		
6.	Provide the recommended target group with age for indications.		
7.	Target age group for clinical Studies is required.		

Conclusion

The application is deficient for the submission of above stated shortcomings.

Decision of 348 meeting:

The Registration Board deferred the case for the submission of the following documents:

- **Evidence of approval of applied formulation in same composition in Reference Regulatory Authority as approved in 275th meeting of Registration Board.**
- **Original, legalized and valid COPP and Letter of Authorization is required.**
- **Separate drug substance part for each antigen.**
- **Clarification is required whether the applied product is single dose or multiple dose.**
- **Provide the recommended target group with age for indications.**
- **Target age group for clinical Studies is required.**

Enterovirus 71 • Hand, foot and mouth disease (HFMD) was first reported in New Zealand in 1957 and occurs mostly in young children, with a peak incidence at about 2 years of age. The causative agents of HFMD are picornaviruses, most often of human enterovirus species A, chiefly the Coxsackie A viruses and Enterovirus A71 (EV71). • EV71 was first isolated from the faeces of a female suffering from encephalitis in 1969 in California. • EV71 virus causes a range of effects from asymptomatic infection and mild HFMD to neurological disease with severe central nervous system complications and cardiopulmonary failure. In severe cases mortality rates can be high, especially in children aged 5 years and younger. • EV71 is considered to be the most severe neurotoxic enterovirus and severe EV71 disease has become a major public health problem in China. • EV71 isolates can be clustered according to their genomic sequence into at least eight genogroups (A–H) but belong to one

serotype. Genogroups B and C have been of greatest interest because of their frequency of isolation and implication in disease in Eastern Asia, and can each be sub-classified into five subgenogroups (C1–C5 and B1–B5). C4 is by far the major genogroup circulating in China, while B4, B5 and C5 are found in other Asian countries. In contrast, strains of genogroups C1 and C2 are predominantly found in Europe where severe disease is uncommon. In 2011, the WHO Regional Office for the Western Pacific issued A guide to clinical management and public health response for hand, foot and mouth disease (HFMD) to support the treatment, prevention and control of HFMD.

Enterovirus 71 vaccines

- To date three vaccines against EV71 have been licensed in China, all using C4 genogroup strains.
- The efficacy of these three vaccines after two doses immunization ranges from 90.0% to 97.4% after one year of surveillance to 95.1% after two-year follow-up.
- Candidate vaccines containing B4 and B5 genogroups are in development elsewhere but have not yet reached the licensing stage.
- Other vaccines such as recombinant and other forms of subunit vaccines, vectored vaccines, virus-like particle vaccines are in the early stage of development. In addition, the development of vaccines against Coxsackie A16, A6 and A10 is being considered with a view to developing combination/multivalent vaccines.

Enterovirus Type 71 Vaccine, Inactivated

Deferred Case:M-345

Exporting Country: China

Case No. 15

Name, address of Applicant / Importer	M/s SIND MEDICAL STORES Company Address: 13-B, Block 6, PECHS, Shahrah e Faisal,
Details of Drug Sale License of importer	License No: DHO (East) Drug/- 283/- Address Plot No. 13-B, Block 6, P.E.C.H.S, Shahrah-e-Faisal, Karachi. Validity: 01-07-2029
Name and address of marketing authorization holder (abroad)	M/s Institute of Medical Biology Chinese Academy of Medical Sciences No.935, Jiaoling Road, Kunming City, Yunnan Province, The People's Republic of China. As per COPP.
Name, address of manufacturer(s)	M/s Institute of Medical Biology Chinese Academy of Medical Sciences No.935, Jiaoling Road, Kunming City, Yunnan Province, The People's Republic of China. As per COPP.
Name of exporting country	China.
Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	Scanned Apostille Valid COPP Certificate No.: No. Yunnan 20240019 Issue Date: 26-03-2024 Certifying Authority: Medical Products Administration of Yunnan Province, China Free Sale: Yes GMP: Yes Validity: 08-10-2025
Details of letter of authorization / sole agency agreement	Issurance Date: 11th Dec. 2023 <u>Exclusive Marketing Authorization Letter</u> We, INSTITUTE OF MEDICAL BIOLOGY CHINESE ACADEMY OF MEDICAL SCIENCES (IMBCAMS), a public institute manufacturing human vaccine products, whose principal place of business is located at 935 Jiaoling Rd, Kunming, China and have manufacturing site at 168 Dengzhanhua Rd, Kunming, China does hereby authorize M/s. Sind Medical Stores, located at 13-B, Block 6, PECHS, Karachi – 75400, Pakistan for the purpose of Products' Registration / Regulatory matters, Marketing and Distribution of our following product(s) in Pakistan. • EntroVac® Enterovirus Type 71 Vaccine, Inactivated (Human Diploid Cell) a) 0.5mL/1 Dose PFS b) 0.5ml/1 Dose Vial

Status of the applicant	Importer
Status of application	New Drug Product
Intended use of pharmaceutical product	Domestic Sale
For imported products, specify one the these	Finished Pharmaceutical product import
Dy. No. and date of submission	Tracking ID: GDJ-HUH-XVA4 Application Number: 26802 Receiving Date: 13-09-2024
Details of fee submitted	Rs:75000/- Dated: 27-05-2024 Deposit Slip No.67088662922 Differential fee submitted on Dated: 25-02-24 Rs: 225030/- Deposit Slip No.3103846453
The proposed proprietary name / brand name	Enterovirus Type 71 Vaccine, Inactivated (Human Diploid Cell)
Strength / concentration of drug of Active Pharmaceutical	0.5ml per single dose each time containing 100U inactivated EV71 antigen.
Indications	The vaccine is indicated for individuals from 6 months to 5 years old who are susceptible to hand, foot and mouth disease (HFMD) caused by Enterovirus Type 71 (EV71).
Route of Administration	IM Only
Dosage form of applied	Suspension for injection
Pharmacotherapeutic Group of (API)	Biological Product "Human Vaccine".
Reference to Finished product specifications	Manufacturer's specification / Chinese Pharmacopoeia
Proposed Pack size	Box of 1 Dose x 0.5mL PFS
Proposed unit price	As per SRO.C
Shelf Life	36 months
Storage Conditions	2-8 °C
The status in reference	EntroVac is registered in a PIC/s member country i.e. Thailand.
For generic drugs (me-too)	Not applicable
Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
Name, address of drug substance manufacturer	M/s Institute of Medical Biology Chinese Academy of Medical Sciences (hereinafter "IMBCAMS") Headquarter: No.935, Jiaoling Road, Kunming City, Yunnan Province, The People's Republic of China. Production base: No.168, Dengzhanhua Street, Majinpu, High-Tech Zone, Kunming, Yunnan Province, The People's Republic of China.
Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
Stability Studies of Drug	Firm has submitted stability study data of following 12 batches of drug

Substance (Conditions & duration of Stability studies)		substance conducted at 2 ± 8°C for 12 months:	
Module-III Drug Product:		Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.	
Analytical method validation/verification of product		Firm has submitted the details of analytical method validation.	
Container closure system of the drug product		☐ Injection vials made of low borosilicate glass tubing ☐ polyisoprene rubber needle cap ☐ chlorinated butyl rubber piston	
Stability study data of drug product, shelf life and storage conditions		Firm has submitted stability study data of batches of long-term stability study at 2-8°C for 30 months, accelerated stability study at 25°C for 6 months and at 37°C for 21 days.	
Non-clinical (Module-IV)			
Module 4 (Non-clinical / Safety)			
4.2 Study Reports			
4.2.1	Pharmacology		Firm has submitted the details of study reports.
	4.2.1.1	Primary Pharmacodynamics	Firm has submitted the details of study reports.
	4.2.1.2	Secondary Pharmacodynamics	N/A
	4.2.1.3	Safety Pharmacology	N/A
	4.2.1.4	Pharmacodynamic Drug Interactions	N/A
4.2.2	Pharmacokinetics		N/A
4.2.3	Toxicology		Firm has submitted the details of study reports.
	4.2.3.1	Single-Dose Toxicity (in order by species, by route)	Firm has submitted the details of study reports.
	4.2.3.2	Repeat-Dose Toxicity (in order by species, by route, by duration; including supportive	Firm has submitted the details of study reports.
	4.2.3.3	Genotoxicity	N/A
	4.2.3.4	Carcinogenicity (including supportive toxicokinetics evaluations)	N/A
	4.2.3.5	Reproductive and Developmental Toxicity (including range- finding studies and supportive toxicokinetics evaluations) (If modified study designs are used, the following sub- headings should be modified accordingly.)	N/A
	4.2.3.6	Local Tolerance	N/A
Clinical (Module-V)			
Sr. No.	Na		Comments
	5.2 Tabular Listing of All Clinical Studies		
	5.3 Clinical Study Reports		
	5.3.1 Reports of Biopharmaceutic Studies		N/A
	5.3.2 Reports of Studies Pertinent to Pharmacokinetics using Human Biomaterials		N/A
	5.3.3 Reports of Human Pharmacokinetic (PK) Studies		N/A

	5.3.4 Reports of Human Pharmacodynamic (PD) Studies	Firm has submitted the details of study reports.
	5.3.5 Reports of Efficacy and Safety Studies	Firm has submitted the details of study reports.
	5.3.5.2 Study Reports of Uncontrolled Clinical Studies	
	5.3.5.3 Reports of Analyses of Data from More Than One Study	
	5.3.6 Reports of Post-Marketing Experience.	Firm has submitted the details of study reports.
	5.3.7 Case Report Forms and Individual Patient Listings	N/A
<u>Evaluation by BE&R</u> Shortcomings • Address of manufacturer in LOA is different from that on COPP. • Evidence of availability of applied formulation/product in any reference regulatory authority is required. • Finished product specifications in the light of 267th meeting of the Registration Board and in the light of “Guidance document regarding application of drug product specifications” conveyed vide Letter No. 9-2/2022-PEC dated 18-12-2023 is required as the firm has claimed manufacturer's specifications. • Claimed shelf life is 36 months while the stability data of product is provided till 24 months. • TSE/BSE certificates of Calf serum and trypsin are required. • Adventitious agent safety evaluation under Module 3.2.A.2 is not provided. • Compatibility studies with excipients and with container closure system is required. • The applied vaccine is of C4 subgenotype which is circulating in China while the circulating genotypes in Asian Countries are B4, B5 and C5 and in Europe is C1, C2, as per WHO "Recommendations to assure the quality, safety and efficacy of enterovirus 71 vaccines (inactivated)" Annex 3. • Proper justification with evidence of reference guidelines were “Not applicable” has been mentioned for nonclinical and clinical study reports • Risk Management Plan (RMP) • Periodic Safety Update Report (PSUR)/Periodic Benefit-Risk Evaluation Report (PBRER) • Adverse event following immunization report (summary of annual reports) in the country of origin or any other NRA.		
Decision of 345th Meeting: The Registration Board deferred the case subject to the submission of following documents: - Address of manufacturer in LOA is different from that on COPP. - Evidence of availability of applied formulation/product in any reference regulatory authority. - Evidence of prevalence of strain in Pakistan. - Finished product specifications in the light of 267th meeting of the Registration Board and in the light of “Guidance document regarding application of drug product specifications” conveyed vide Letter No. 9-2/2022-PEC dated 18-12-2023 is required as the firm has claimed manufacturer's specifications. - Claimed shelf life is 36 months while the stability data of product is provided till 24 months. - TSE/BSE certificates of Calf serum and trypsin. - Adventitious agent safety evaluation under Module 3.2.A.2. - Compatibility studies with excipients and with container closure system. - The applied vaccine is of C4 subgenotype which is circulating in China while the circulating genotypes in Asian Countries are B4, B5 and C5 and in Europe is C1, C2, as per WHO "Recommendations to assure the quality, safety and efficacy of enterovirus 71 vaccines (inactivated)" Annex 3. - Proper justification with evidence of reference guidelines were “Not applicable” has been mentioned for non clinical and clinical study reports. - Risk Management Plan (RMP). - Periodic Safety Update Report (PSUR). - Benefit-Risk Evaluation Report (PBRER). - Adverse event following immunization report (summary of annual reports) in the country of origin or any other NRA.		
Remarks of the Assessor		
	Query	Applicant's Reply
	i. Address of manufacturer in LOA is different from that on COPP.	i. Kindly refer ANNEX-I for manufacturer's clarification about the address difference in LOA and COPP. ii. N/A, although ENTROVAC® of IMBCAMS has been registered and marketed in China and Thailand so far. It has been

ii. Evidence of availability of applied formulation/product in any reference regulatory authority. iii. Evidence of prevalence of strain in Pakistan. iv. Finished product specifications in the light of 267th meeting of the Registration Board and in the light of “Guidance document regarding application of drug product specifications” conveyed vide Letter No. 9-2/2022-PEC dated 18-12-2023 is required as the firm has claimed manufacturer's specifications. v. Claimed shelf life is 36 months while the stability data of product is provided till 24 months. vi. TSE/BSE certificates of Calf serum and trypsin. vii. Adventitious agent safety evaluation under Module 3.2.A.2. viii. Compatibility studies with excipients and with container closure system. ix. The applied vaccine is of C4 subgenotype which is circulating in China while the circulating genotypes in Asian Countries are B4, B5 and C5 and in Europe is C1, C2, as per	registered in NMPA - China and marketed since 2016. Kindly refer ANNEX-II for registration letters from China and Thailand. iii. Kindly refer ANNEX-III for prevalence strains in Pakistan and vaccine coverage of those strains. iv. ENTROVAC, an innovative product developed by IMBCAMS, was launched in China in 2016 and represents the world's first vaccine for preventing hand-foot-mouth disease caused by EV71 infection. To date, no national pharmacopoeia globally has included the specifications of this vaccine. Efforts are currently underway to include the EV71 vaccine in the Chinese Pharmacopoeia, a process that IMBCAMS is actively facilitating. Consequently, IMBCAMS can currently provide only the innovator products specifications as approved by the National Medical Products Administration of China. The innovator's specifications can be found in Module 3 as follows: Section 3.2.S.4.1 and 3.2.P.5.1 for specifications, Section 3.2.P.5.6 for the justification of specifications, Section 3.2.P.2 for product and formulation development, Section 3.2.P.3 for manufacturing method development and process validation, and Section 3.2.P.5.3 for analytical method validation. v. The claimed shelf life of the applied vaccine is 36 months. Kindly refer ANNEX IV. vi. The <i>Certification for BSE free issued by China Medicinal Biotech Association</i> and the <i>TSE/BSE Risk Statement for Serum</i> are enclosed in ANNEX V. The statement letter details the test results of the serum, demonstrating the newborn bovine serum and fetal bovine serum produced by the Company have no TSE/BSE risk. Regarding the trypsin, it is important to note that it is recombinant and not derived from animal sources. Consequently, there is no risk associated with TSE/BSE. For your comprehensive evaluation, we have enclosed the COA, TSE/BSE-free & Animal-free Statement from Supplier, Test Report & Material Release Quality Report from IMBCAMS, as well as IMBCAMS's Internal Quality Control Standard STPDQC14-076 for this recombinant trypsin in ANNEX V for your kind reference. vii. The 3.2.A.2 Safety evaluation of adventitious agent is attached, kindly refer ANNEX VI. viii. Kindly refer to Module-3, 3.2.P.2.6 for compatibility study with container closure system. We have enclosed it again in ANNEX VII. ix. IMBCAMS has conducted a cross-neutralization test during phase III clinical trial to investigate the cross-protection against different genotypes of EV71. 160 subjects in phase III clinical trial were randomly selected and their serum was collected 360 days after full course of immunization. Cross

WHO "Recommendation to assure the quality, safety and efficacy of enterovirus 71 vaccines (inactivated)" Annex 3.	
x. Proper justification with evidence of reference guidelines were "Not applicable" has been mentioned for non clinical and clinical study reports. xi. Risk Management Plan (RMP). xii. Periodic Safety Update Report (PSUR). xiii. Benefit-Risk Evaluation Report (PBRER).	neutralization test was performed by using 9 EV71 viral strains with different genotypes respectively (A, B3, B4, B5, C1, C2, C3, C4 and C5). The results showed that the serum of subjects inoculated with EV71 vaccine had a good cross-neutralization response to EV71 virus of different genotypes. The body of evidence presented here and the data of other studies are sufficient to conclude that an inactivated EV71 vaccine derived from one genotype strain could be effectively used to induce adequate protective immunity against infection by most of the predominant circulating EV71 strains. Kindly refer to Module-2, Clinical Summary-2.7.3.2.1.2.2.4 for Cross Neutralization Test Summary and refer to Module-5, Appendix-5.3.5.1.1 for the corresponding published paper. We have enclosed it again in ANNEX VIII for your kind reference. x. Kindly refer ANNEX IX for manufacturer's justification / reply. xi. Kindly refer to Module-1, 1.5.22.1 for Risk Management Plan (RMP). (RMP now is named as Pharmacovigilance plan according to regulatory requirements of China. Because, the term "Risk Management Plan" is exclusively applicable to the clinical phase. Post-marketing, this plan is referred to as a "Pharmacovigilance Plan". Despite the change in nomenclature, the document retains its core content and purpose). We have enclosed it again, kindly refer ANNEX X. xii. Kindly refer to Module-1, 1.5.22.2 and Module-5, 5.3.6 for PSUR. We have enclosed it again in ANNEX XI for your kind reference. xiii. The <i>Data Analysis Report of EV71 Vaccine in 2023</i> is attached in ANNEX XII.
xiv. Adverse event following immunization report (summary of annual reports) in the country of origin or any other NRA.	xiv. Kindly refer ANNEX XI and ANNEX XII for ADFI / PSUR reports.

Conclusion

The applied vaccine /strain(EV71 antigen) is not approved in any RRA as approved by RB in its 275th Meeting.

Decision of 348th Meeting:

The Registration Board deferred the case for the evidence of approval of applied vaccine in Reference Regulatory Authority as approved in 275th Meeting of Registration Board and prevalence of strain.

Measles, Mumps and Rubella (MMR)

Combined live vaccine for measles, mumps and rubella (MMR) is used widely for the immunization of children in certain regions of the world because of its advantages over the individual vaccines. Combined vaccine provokes an adequate immune response in children simultaneously for the three infections and facilitates the implementation of current immunization strategies.

**Live attenuated measles virus (S-191 strain), mumps virus (S79 strain) and rubella virus (BRDII strain);
Deferred Case-M-345
Exporting Country (China)**

Case No. 16

Name, address of Applicant / Importer	M/s Immuno Well (Pvt) Ltd, Company Address: House No. 473, Street No.7, Block J-2, Johar Town, Lahore
Details of Drug Sale	License No. 05-352-0066-100098D
License of importer	Address: 473, Street No. 7, Block J-2, Johar Town, Lahore, Pakistan

	Validity: 17-Nov-2027 Status: License to sell drugs as a distributor. Godown address: Cold Storage Facility of M/S. Hi-Warble Pharmaceuticals (Pvt)Ltd. 44-B-II, Phase-1, Johar Town, Lahore
Name and address of marketing authorization holder (abroad)	M/s. Shanghai Institute of Biological Products Co., Ltd. Address: No. 758 Guangfeng Road, Fengxian District, Shanghai, China
Name, address of manufacturer(s)	M/s. Shanghai Institute of Biological Products Co., Ltd. Address: No. 758 Guangfeng Road, Fengxian District, Shanghai, China
Name of exporting country	China
Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Scanned Apostille COPP Certificate No.: No. Shanghai 20220251 Issue Date: 05-12-2022 Certifying Authority: Shanghai Municipal Medical Products Administration, China. Free Sale: Yes GMP: Yes Validity: 04-12-2024
Details of letter of authorization / sole agency agreement	AUTHORIZATION LETTER We (Shanghai Institute of Biological Products Co., Ltd.) hereby authorize Immuno Well (Pvt) Ltd., 25-Rehman Housing Society, Johar Town, Lahore, Pakistan as our exclusive sole agent for Islamic Republic of Pakistan. Immuno Well (Pvt) Ltd., is authorized to represent us, submit documents and dossier of our products "MMRubivac inj. (Measles, Mumps and Rubella Combined Vaccine, Live) & FluLing Quad (Influenza Vaccine (Split Virion), Inactivated, Quadrivalent)" to the health authorities for the purpose of registration and renewal of registration certificate in Islamic Republic of Pakistan.
Status of the applicant	Importer
Status of application	Generic Drug Product (GDP)
Intended use of pharmaceutical product	Domestic sale
For imported products, specify one of these	Finished Pharmaceutical product import
Dy. No. and date of submission	Tracking ID: NXG-JBD-TWJ6 Application Number:31928 Receiving Date: 13-09-2024
Details of fee submitted	Challan Number: 56430199842 Division: Biological Evaluation & Registration Paid Fee: 300000.0 Paid Date: 2024-07-24
The proposed proprietary name / brand name	MMRubivac.
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Live attenuated measles virus (S-191 strain), mumps virus (S79 strain) and rubella virus (BRDII strain);; Each 0.5ml of reconstituted vaccine per container 0.5ml per single human dose containing not less than 3.0 lgCCID50 of both live measles virus and rubella virus and 4.3 lgCCID50 of live mumps virus. (Enclosed with 1 ampoule of sterile water for injection as the diluent).
Clinical Indication	Subjects susceptible to MMR above 8 months.
Dosage form of applied drug	Lyophilized injection with diluent
Route of Administration	SC
Pharmacotherapeutic Group of (API)	Vaccine
Finished product specifications	Chinese Pharmacopeia European Pharmacopeia /WHO specification
Proposed Pack size	0.5ml/dose/vial/pack + diluent
Proposed unit price	Rs.2,259/dose/pack
Shelf Life	18 months
Storage Conditions	At 2-8°C. Protect from light.
The status in reference regulatory authorities	Tradename: PRIORIX Manufacturer: GlaxoSmithKline Biologicals SA

	Indications: For active immunization for the prevention of measles, mumps, and rubella in individuals 12 months of age and older. PRIORIX contains the Schwarz strain of live attenuated measles virus, the RIT 4385 strain of live attenuated mumps virus (derived from the Jeryl Lynn strain), both propagated in chick-embryo fibroblasts from embryonated eggs of specific pathogen-free flocks and the Wistar RA 27/3 strain of live attenuated rubella virus propagated in MRC-5 human diploid cells. The 3 virus strains are cultured in media containing amino acids, a small amount of neomycin sulfate and bovine serum albumin and are stabilized after multiple washing steps in media free from antibiotics and albumin. The attenuated measles, mumps and rubella viruses are then mixed with a stabilizer prior to lyophilization. <i>After reconstitution, each approximately 0.5-mL dose contains not less than 3.4 log₁₀ Cell Culture Infective Dose 50% (CCID₅₀) of measles virus, 4.2 log₁₀ CCID₅₀ of mumps virus, and 3.3 log₁₀ CCID₅₀ of rubella virus.</i>																								
For generic drugs (me-too status)	013272 Measles, Mumps,Rubella Vaccine live, attenuated (freeze-dried) M.M.R, Serum Institute of India Pvt by M/s Amson 115, Industrial Triangle, KahutaRoad,Islamabad The vaccine is prepared from the live, attenuated strains of Edmonston-Zagreb measles virus, Leningrad-Zagreb (L-Z) mumps virus and Wistar RA 27/3 rubella virus.																								
Drug Substance: (Virus Bulk of Measles Vaccine, Live, Virus Bulk of Mumps Vaccine, Live, and Virus Bulk of Rubella Vaccine, Live																									
Name, address of drug substance manufacturer	Manufacture of virus bulks of Measles Vaccine, Live, Mumps Vaccine, Live, and Rubella Vaccine, Live M/s Shanghai Institute of Biological Products Co., Ltd. Measles, Mumps, and Rubella Vaccine Workshop, Building 120, No. 758 Guangfeng Road, Fengxian District, Shanghai, China Control test of virus bulks of Measles Vaccine, Live, Mumps Vaccine, Live, and Rubella Vaccine, Live Shanghai Institute of Biological Products Co., Ltd. QC Laboratory, Building 116, No. 758 Guangfeng Road, Fengxian District, Shanghai, China																								
General Information	<table><tr><th>Drug substance name</th><th>Virus</th><th>Cells for production</th><th>Preparation process</th><th>Virus titers</th></tr><tr><td>Measles virus bulk</td><td>Attenuated measles virus S191 strain</td><td>Primary chicken embryo fibroblasts</td><td>The virus bulk of Measles Vaccine, Live is prepared by inoculating the attenuated measles virus S191 strain into primary chicken embryo fibroblasts, followed by cell culture, viral harvest, and pooling</td><td>5.3-6.5 lg CCID₅₀/mL (CCID₅₀ method)</td></tr><tr><td>Mumps virus bulk</td><td>Attenuated mumps virus S₇₉ strain</td><td>Primary chicken embryo fibroblasts</td><td>The virus bulk of Mumps Vaccine, Live is prepared by inoculating the attenuated mumps virus S₇₉ strain into primary chicken embryo fibroblasts, followed by cell culture, viral harvest, and pooling</td><td>6.1-7.5 lg CCID₅₀/mL (CCID₅₀ method)</td></tr><tr><td>Rubella virus bulk</td><td>Attenuated rubella virus BRD-II strain</td><td>Human diploid cell (MRC-5)</td><td>The virus bulk of Rubella Vaccine, Live is prepared by inoculating the attenuated rubella virus BRD-II strain into human diploid cells (MRC-5), followed by cell culture, viral harvest, and pooling</td><td>4.9-6.5 lg CCID₅₀/mL (CCID₅₀ method)</td></tr></table>					Drug substance name	Virus	Cells for production	Preparation process	Virus titers	Measles virus bulk	Attenuated measles virus S191 strain	Primary chicken embryo fibroblasts	The virus bulk of Measles Vaccine, Live is prepared by inoculating the attenuated measles virus S191 strain into primary chicken embryo fibroblasts, followed by cell culture, viral harvest, and pooling	5.3-6.5 lg CCID ₅₀ /mL (CCID ₅₀ method)	Mumps virus bulk	Attenuated mumps virus S ₇₉ strain	Primary chicken embryo fibroblasts	The virus bulk of Mumps Vaccine, Live is prepared by inoculating the attenuated mumps virus S ₇₉ strain into primary chicken embryo fibroblasts, followed by cell culture, viral harvest, and pooling	6.1-7.5 lg CCID ₅₀ /mL (CCID ₅₀ method)	Rubella virus bulk	Attenuated rubella virus BRD-II strain	Human diploid cell (MRC-5)	The virus bulk of Rubella Vaccine, Live is prepared by inoculating the attenuated rubella virus BRD-II strain into human diploid cells (MRC-5), followed by cell culture, viral harvest, and pooling	4.9-6.5 lg CCID ₅₀ /mL (CCID ₅₀ method)
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Specifications	The specifications have been formulated in reference to the Chinese Pharmacopoeia (Volume III)																								
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	According to WHO/BS/06.2049,Guideline on stability evaluation of vaccines; ICH Q5C, Quality of biotechnological products: stability testing of biotechnological/biological products, and WHO, considerations for the evaluation of MMR Vaccine. Virus bulk of Measles Vaccine, Live, virus bulk of Mumps Vaccine, Live, and virus bulk of Rubella Vaccine, Live should be stored and transported at below - 60 °C, away from light. The shelf life is 12 months from the date of manufacture. SIBP has conducted accelerated stability, long-term stability, and forced degradation tests on the bulks of measles virus, mumps virus, and rubella virus. The studies showed that the virus bulk of Measles Vaccine, Live, virus bulk of Mumps Vaccine, Live, and virus bulk of Rubella Vaccine, Live was acceptable within the shelf life (-60 °C, 12 months) and complied with the in-house specification.																								
Drug Product Part: Measles, Mumps and Rubella Combined Vaccine, Live																									

Name, address of drug substance manufacturer	Manufacturing address of drug substance and finished products: Suite of Measles, Mumps and Rubella Combined Vaccine, Live, Building 120, No. 758, Guangfeng Road, Fengxian District, Shanghai Testing address of drug substance and finished products: QC Laboratory, Building 116, No. 758, Guangfeng Road, Fengxian District, Shanghai Packaging address of drug product: Filling Suite, Building 122, No. 758, Guangfeng Road, Fengxian District, Shanghai		
Manufacturing	This product is prepared by following the procedures: primary chicken embryo fibroblasts are inoculated with attenuated measles virus S191 strains and attenuated mumps virus S79 strains, respectively; human diploid cells are inoculated with attenuated rubella virus BRD-II strains (MRC 5 strains); the cultured and harvested virus suspensions are mixed and prepared in a certain ratio, and lyophilized with a suitable stabilizer. The preparation of final bulk and filling of finished products were performed by SIBP at No. 758, Guangfeng Road, Fengxian District, Shanghai. The process validation of 6 batches of commercial batch of Measles, Mumps and Rubella Combined Vaccine, Live fully demonstrated the stability of vaccine manufacturing process and controllable quality		
Container closure system of the drug product	Primary packaging: 1. Injection vial made of middle borosilicate glass tubing and butyl rubber stopper, 1 vial/box; 2. Matching package: One vial of sterile water for injection is attached to each box, 0.5 mL/vial..		
Stability study data of drug product, shelf life and storage conditions	This product should be stored and transported at 2-8 °C, protected from light. The shelf life is 18 months from the date of manufacture.		
Non-Clinical (Module -IV)			
Module 4 (non-clinical/Safety)			
4.2	Study Report		
4.2.1	Pharmacology	Not Applicable	
4.2.2	Pharmacokinetics	Not Applicable	
4.2.3	Toxicology		
	4.2.3.1	Single dose Toxicity	Not Applicable
	4.2.3.2	Repeat-dose Toxicity	Not applicable.
	4.2.3.3	Genotoxicity	Not applicable.
	4.2.3.4	Carcinogenicity (including supportive toxicokinetics evaluation)	Not applicable.
	4.2.3.5	Reproductive and Developmental Toxicity (including range-finding studies and supportive toxicokinetics evaluations) (if modified study designs are used, following sub-headings should be modified accordingly.)	Not applicable
	4.2.3.6	Local Tolerance	The objective of this study is to observe the local irritation reaction of New Zealand rabbits after a single subcutaneous injection of Measles, Mumps and Rubella Combined Vaccine, Live, and to provide animal test data for clinical studies. 12 male New Zealand rabbits were randomly divided into 2 groups (6 rabbits/group). All animals were subcutaneously injected in the back of left nape with the negative control (sodium chloride injection). Animals in Group 1 were subcutaneously injected in the back of right nape with the test article (new process) Measles, Mumps and Rubella Combined Vaccine, Live, and animals in Group 2 were subcutaneously injected in the back of right nape with the control (old process) Measles, Mumps and Rubella Combined Vaccine, Live. Single dose, single-point injection, volume administered of 0.5 mL/animal. The first 3 animals per group were euthanized on D3 and the remaining 3 animals per group were euthanized on D15 and the local administration site were evaluated.

				During the study, no abnormal symptoms were observed in the clinical observation of animals. During the study, no abnormalities related to the test article/control were observed at the local injection site. No abnormal pathological changes related to treatment were observed in gross observation and microscopic observation of animals euthanized at 48 h (D3) after the last dose and 14 days (D15) after the last dose. Under the conditions of this study, no local irritation was observed in New Zealand rabbits (0.5 mL/rabbit) administered a single subcutaneous dose of the test article Measles, Mumps and Rubella Combined Vaccine, Live, which was consistent with the results of the old process controls.													
Clinical (Module-V)																	
5.2	Tabular Listing of All Clinical Studies																
	<table><tr><th>Study No. /Title</th><th>Design/ Objective</th><th>Intervention (N)</th><th>Endpoint</th><th>Conclusion</th></tr><tr><td>R01: Phase I/II/III Clinical Trial of Measles-Mumps-Rubella Combined Attenuated Live Vaccine*</td><td>Phases I, II and III Randomized, double-blind (observer blinded), Controlled. Age: 8-18 months Safety and Immunogenicity study</td><td>Phase I: SIBP MMR-11+26 Phase II: SIBP MMR- 304 Measles-60 Mumps-61 Rubella-60 Phase III: SIBP MMR- 603 Merck MMR-100 0.5mL of trial vaccine administered subcutaneously</td><td><u>Safety</u> Immediate adverse event Solicited reactions. <u>Immunogenicity</u> Pre and 4 weeks post Micro-hem agglutination-inhibition (HI) test</td><td><u>Safety</u> No difference with control <u>Immunogenicity</u> Measles Conversion- Significant difference GMC-No difference Mumps Conversion- No difference GMC-Significant difference Rubella Conversion- No difference GMC- No difference</td></tr><tr><td>R02: Safety Surveillance of Measles Attenuated Live Vaccine and Measles-Mumps-Rubella Combined Attenuated Live Vaccine after Supplementary Immunization</td><td>Non-randomized; parallel Age: 8 months to 14 years Measles- kindergartens or living scattered. MMR-Children from primary and secondary schools (students aged 6-14 years)</td><td>MMR-977521 Measles-814023 0.5mL of trial vaccine administered subcutaneously</td><td>AEFI was divided into adverse reaction (including general reaction and abnormal reaction), psychogenic reaction, immunization accident, vaccine quality accident and coupled</td><td>1. The reported rates of common and rare adverse reaction of MMR vaccine were 20.87/100,000 and 3.99/100,000, respectively. 2. The greater proportion of reported AEFI cases happened in the younger group. The reported AEFI were mainly common adverse reactions, such as fever and local swelling. Most of the rare adverse reactions were allergic rash.</td></tr></table>	Study No. /Title	Design/ Objective	Intervention (N)	Endpoint	Conclusion	R01: Phase I/II/III Clinical Trial of Measles-Mumps-Rubella Combined Attenuated Live Vaccine*	Phases I, II and III Randomized, double-blind (observer blinded), Controlled. Age: 8-18 months Safety and Immunogenicity study	Phase I: SIBP MMR-11+26 Phase II: SIBP MMR- 304 Measles-60 Mumps-61 Rubella-60 Phase III: SIBP MMR- 603 Merck MMR-100 0.5mL of trial vaccine administered subcutaneously	<u>Safety</u> Immediate adverse event Solicited reactions. <u>Immunogenicity</u> Pre and 4 weeks post Micro-hem agglutination-inhibition (HI) test	<u>Safety</u> No difference with control <u>Immunogenicity</u> Measles Conversion- Significant difference GMC-No difference Mumps Conversion- No difference GMC-Significant difference Rubella Conversion- No difference GMC- No difference	R02: Safety Surveillance of Measles Attenuated Live Vaccine and Measles-Mumps-Rubella Combined Attenuated Live Vaccine after Supplementary Immunization	Non-randomized; parallel Age: 8 months to 14 years Measles- kindergartens or living scattered. MMR-Children from primary and secondary schools (students aged 6-14 years)	MMR-977521 Measles-814023 0.5mL of trial vaccine administered subcutaneously	AEFI was divided into adverse reaction (including general reaction and abnormal reaction), psychogenic reaction, immunization accident, vaccine quality accident and coupled	1. The reported rates of common and rare adverse reaction of MMR vaccine were 20.87/100,000 and 3.99/100,000, respectively. 2. The greater proportion of reported AEFI cases happened in the younger group. The reported AEFI were mainly common adverse reactions, such as fever and local swelling. Most of the rare adverse reactions were allergic rash.	
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R02: Safety Surveillance of Measles Attenuated Live Vaccine and Measles-Mumps-Rubella Combined Attenuated Live Vaccine after Supplementary Immunization	Non-randomized; parallel Age: 8 months to 14 years Measles- kindergartens or living scattered. MMR-Children from primary and secondary schools (students aged 6-14 years)	MMR-977521 Measles-814023 0.5mL of trial vaccine administered subcutaneously	AEFI was divided into adverse reaction (including general reaction and abnormal reaction), psychogenic reaction, immunization accident, vaccine quality accident and coupled	1. The reported rates of common and rare adverse reaction of MMR vaccine were 20.87/100,000 and 3.99/100,000, respectively. 2. The greater proportion of reported AEFI cases happened in the younger group. The reported AEFI were mainly common adverse reactions, such as fever and local swelling. Most of the rare adverse reactions were allergic rash.													

Study No. /Title	Design/ Objective	Intervention (N)	Endpoint	Conclusion	
Activities (SIA) in Shanghai, 2010	Passive surveillance for safety			3. The vaccination of MMR vaccine in SIA was safe and most adverse reactions were common.	
R03: Adverse Reaction Surveillance of Measles-Mumps-Rubella Combined Attenuated Live Vaccine	Randomized Age: 18 -24 months Surveillance for safety	SIBP MMR-229603 GSK MMR-71781 0.5mL of trial vaccine administered subcutaneously	Active surveillance for 1 month Incidence- SIBP MMR-0.08%, GSK MMR-0.15% Passive surveillance by AEFI monitoring over a period of 1 year. Mid- and long-term active monitoring on hospitalized children.	The safety data of large-scale vaccination of SIBP MMR and GSK MMR vaccines indicated that both vaccines had a high safety level, low incidence rate, the reactions were mild, mainly general reaction, and no relevant serious reaction or death were reported.	
R04: Immunity comparison of Measles-Mumps-Rubella Combined Attenuated Live Vaccine produced by SIBP and GSK**	Phase IV, Randomized, double blind, comparative. Age: 8 and 12 months Immunogenicity, Persistence of immune response and Safety.	SIBP MMR (8& 18 months)-143 SIBP MMR (12 & 22 months)-220 GSK MMR (12 & 22 months) -217 0.5mL of trial vaccine administered subcutaneously	<u>Immunogenicity</u> Blood samples were collected before, 1 month, 10 months and 3 years after immunization. Serum titers of antibody against measles, mumps and rubella were measured by ELISA.	For this study the non-inferiority comparison was done retrospectively. The results showed that SIBP MMR vaccine was comparable to GSK MMR vaccine in terms of seropositive rate 1 month and 3 years after two doses of the vaccines.	
R05: Evaluation of the safety and interaction to immunity of	Phase IV, Randomized, open label. Age: 17 to 23 months	SIBP MMR + SIBP Varicella-160 SIBP MMR-154 SIBP Varicella-141	<u>Immunogenicity</u> Blood samples were collected before and 35-42 days after immunization. Antibody positive conversion rate and GMC to Measles and	For this study non-inferiority was conducted and showed no evidence that co-administration interfered the immunogenicity of individual vaccines.	
Study No. /Title	Design/ Objective	Intervention (N)	Endpoint	Conclusion	
co-administration with MMR and Varicella Vaccine**	Safety, Immunogenicity, and co-administration with Varicella vaccine	0.5mL of trial vaccine administered subcutaneously	Varicella were detected. <u>Safety</u> Local and systematic reaction of subjects within 30min. 24h, 48h and 72h and day 7, 14 and 30 after vaccination	The adverse reaction was mainly composed of fever and rash, and there was no statistical difference between co-administration subjects and those with either vaccine.	
R06: Observation of the lot-to-lot consistency of SIBP MMR**	Phase IV, Randomized, double blind, lot-to-lot consistency study. Age: 8-12 months Safety and Immunogenicity study	SIPB MMR Lot01- 356 SIPB MMR Lot02- 356 SIPB MMR Lot03- 356 0.5mL of trial vaccine administered subcutaneously	<u>Immunogenicity</u> Comparison of geometric mean concentrations (GMCs) of measles, mumps and rubella antibodies in all test groups 42 days post-vaccination. <u>Safety</u> Local 14 days Systemic solicited, 42 days Unsolicited and SAE- 180 days	The immunogenicity of children aged 8-12 months vaccinated with one dose of SIBP MMR reached the lot-to-lot consistency criteria prescribed in the protocol. In addition, the vaccination with SIBP MMR showed good safety and resulted in no additional safety risks.	
R07: Observation of the immunity and safety co-administration with MMR and Yellow Fever vaccine, Immunity comparison of MMR Vaccine produced by SIBP and GSK **	Phase III, Multi-Center, Randomized, Observer-Blind, Active Controlled Non-Inferiority Study	SIPB MMR/Yellow Fever- 400 (Group 1) GSK MMR- 400 (Group 2) SIBP MMR + Yellow Fever- 400 (Group 3) 0.5mL of trial vaccine administered subcutaneously	<u>Immunogenicity</u> An evaluation of seropositivity rate to Measles, Mumps and Rubella viruses of SIBP MMR vaccine versus GSK MMR vaccine when measured 42 days after vaccination in seronegative children at baseline. Comparison of GMC for anti-measles/mumps/rubella antibodies and GMT for anti-yellow fever virus antibody before and 42 days after immunization of the Group1 and Group3.	In progress	
5.3	Clinical Study Reports				
	5.3.1	Report of Biopharmaceutic Studies	Not Applicable.		
	5.3.2	Reports of Studies Pertinent to Pharmacokinetics using Human Biomaterials	Not Applicable.		
	5.3.3	Reports of Human Pharmacokinetics (PK) Studies	Not Applicable.		
	5.3.4	Reports of Human Pharmacodynamic (PD) Studies	Not Applicable.		
	5.3.5	Reports of Efficacy and Safety Studies	There are totally 6 clinical studies conducted to observe the efficacy of SIBP MMR..		

		5.3.5.2 Study Reports of Uncontrolled Clinical Studies. 5.3.5.3 Reports of Analyses of Data from More Than One Study	Study R01 is a pre-marketing licensure studies consisted of a combined phases I, II and III study designed as a randomized, double-blind, and controlled study in older children and in the targeted population of 8~18 months in China. Study R04 to R07 are postmarketing safety, immunogenicity, co-administration, lot-to-lot and inferiority comparison studies																																																								
	5.3.6	Reports of Post-Marketing Experience. Table 2.7.4.6.1: Summary of adverse events after immunization of SIBP MMR from 2016-2023 <table><tr><th>Age (month)</th><th>Common Adverse Reaction</th><th>Rare Adverse Reaction</th><th>Coincidental Event</th><th>Others</th><th>Total</th><th>Proportion (%)</th></tr><tr><td>≤12</td><td>50927</td><td>9867</td><td>464</td><td>462</td><td>61720</td><td>56.87</td></tr><tr><td>13-15</td><td>1346</td><td>131</td><td>14</td><td>9</td><td>1500</td><td>1.38</td></tr><tr><td>16-24</td><td>34189</td><td>3289</td><td>402</td><td>137</td><td>38017</td><td>35.02</td></tr><tr><td>25≤</td><td>6555</td><td>571</td><td>127</td><td>53</td><td>7306</td><td>6.73</td></tr><tr><td>Unknow</td><td>0</td><td>1</td><td>0</td><td>4</td><td>5</td><td>0.00</td></tr><tr><td>Total</td><td>93017</td><td>13859</td><td>1007</td><td>665</td><td>108548</td><td>100.00</td></tr><tr><td>Proportion (%)</td><td>85.69</td><td>12.77</td><td>0.93</td><td>0.61</td><td>100.00</td><td>/</td></tr></table>		Age (month)	Common Adverse Reaction	Rare Adverse Reaction	Coincidental Event	Others	Total	Proportion (%)	≤12	50927	9867	464	462	61720	56.87	13-15	1346	131	14	9	1500	1.38	16-24	34189	3289	402	137	38017	35.02	25≤	6555	571	127	53	7306	6.73	Unknow	0	1	0	4	5	0.00	Total	93017	13859	1007	665	108548	100.00	Proportion (%)	85.69	12.77	0.93	0.61	100.00	/
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	5.3.7	Case Report Forms and Individual Patient Listing	Submitted																																																								

Evaluation by BE&R

S. No	Sections	Observations/Deficiencies/ Short-comings	Firms Response
1.	1.3.4	a) Hard copy of original, legalized and valid COPP mentioning strains of MMR Virus, as provided one is invalid. b) Hard copy of original or notarized sole agency agreement is required. c) The COPP does not include any information on the diluent/combo pack. Clarification is required. d) The address of importer on DSL is different than LOA. Clarification/Just	a) For question (a), SIBP will apply for a new CoPP from China National Medical Products Administration (NMPA) follow the WHO format. b) As e-copy of authorization letter has been submitted with CTD Dossier. Hard copy of original authorization letter will be provided along with new valid CoPP. For question ©, NMPA issue the CoPP following the WHO guideline. c) For the WFI, this is the MMR vaccine's diluent, and does not contain the active ingredients, and already have been marketed in China. According to the Chinese and WHO's format of CoPP, it is not mandatory to display the diluent information, also there is no applicable section in CoPP to fill in this relevant information. d) The address mentioned on LOA is the Corporate Office address. And address mentioned on DSL is the working office address.

		ification is required.	
2.	1.4.1	a) If the Biological Product is a vaccine manufactured under relevant WHO TRS or is a new vaccine for which WHO TRS is not yet developed. b) A copy of lot summary protocol in compliance with WHO (identified as per specific WHO TRS).	The specification and protocol of manufacturing, filling & packaging, release testing, sampling, labeling, shipping and storage of SIBP MMR vaccine follow the Chinese Pharmacopoeia III 2020. Production and testing facilities, raw materials and excipients, water, equipment, animals, etc. meet the relevant requirements of the "GENERAL NOTICES" of the current edition of the Chinese Pharmacopoeia III. Unless otherwise specified, the testing methods adopted shall be carried out in accordance with the relevant methods in the Appendix of the current edition of Chinese Pharmacopoeia III. Production procedures are consistent with WHO TRS 840 requirements. The relevant files and documents will be provided later.
3.	1.4.2	Documents/evidence for acceptable shipping conditions for both finished product and drug substance and formulated bulk (for importing bulks for filling and domestic production) & proof of shipping validation.	SIBP MMR vaccine has been undergo the stability study before marketing and will also undergo the stability study after marketing follow the relevant guideline, the data of stability study and the protocol of stability study after marketing please refer to the CTD M3. These data can prove that SIBP MMR vaccine meets the requirements under the storage condition. The finished bulk is not suitable for global shipping due to its limited shelf life.
4.	1.5.2	Mention the names of virus strains for each MMR virus and whether these strains are prevalent in Pakistan.	Name: Measles virus: Hu-191, this strain was isolated from a Chinese 2-year-old boy in 1960. Mumps virus: S79, this stain is Jerry-Lyn origin Rubella virus: BRD-II, this strain was from Beijing Institute of Biological Products in 1980s, isolated from a 6-year-old children. For the question “ <i>whether these strains are prevalent in Pakistan.</i> ”. The answer requires data gathered from the citizens, which may not be available by SIBP. Immuno Well shall check the local CDC website or other sources for the information. The strain that SIBP used in MMR vaccine is approved by China NMPA and be known through WHO. Details like history, safety, efficacy and passage etc. of those virus strains are mentioned in M3 and M5. The same strains are prevalent in Pakistan. Please check the already registered product SANVAC in Pakistan mentioned in query No. 7(1.5.2)
5.	1.5.5	Pharmacotherapeutic group of applied vaccine.	Since the Chinese NMPA do not require an ATC for vaccine, the most likely ATC Code: J07BD52
6.	1.5.6	a) Specify the reference to Pharmacopoeial specifications as per Drug Specification Rules 1978 and guidance document regarding	The MMR Vaccine from SIBP is produced and released follow the current edition of Chinese Pharmacopoeia

		application of Drug Product Specifications. b) Tabular Comparison of all the three monographs as mentioned in section 1.5.6.	
7.	1.5.8	The reference of already registered product (with same strains) including the following details needs to be submitted. • Brand name • Manufacturer/Registration holder • Registration number	Brand Name: SANVAC Injection Manufacturer Name: Beijing Institute of Biological Products China Strength: 0.5 ml Per dose Per vial Composition: Measles, Mumps & Rubella Combined Vaccine Live attenuated Registration No.047617 Pack Size: 0.5 ml Per Dose Per vial Per Pack with diluent
8.	1.5.9	a) Evidence of approval / registration / marketing status of the applied formulation in the same composition (strain and strength), salt form and dosage form in one of the reference regulatory authority specified by Registration Board. The name of the reference authority shall be mentioned as adopted by Board currently. b) Evidence of approval / registration / marketing status of the applied formulation with the same clinical indications (above 8 months).	Refer to question 7. SIBP MMR vaccine registered and marketed in China. It's on sale in China now. The authority is: National Medical Products Administration (China) The supporting files and documents are submitted with CTD before. Again please find attached the registration certificate in China.
9.	1.5.14	Summary of Product Characteristics (SmPC) of the	SmPC will be provided later. Since SIBP MMR vaccine marketing in China, and China NMPA don't require SmPC for register.

		applied vaccine in one of the reference regulatory authority specified by Registration Board.	In China, NMPA will approval and issue the “ <i>directions for use of Measles, Mumps and Rubella Combined Vaccine, Live.</i> ”. this file is designed for the understanding and use of this vaccine for all users including both the doctors and patients.
10.	3.2.P.1	Final bulk is not assayed for virus content and residual animal serum proteins. Justification is required.	The <i>Chinese Pharmacopoeia III (2020 version)</i> does not require the virus titration and bovine serum albumin residue determination for the final bulk.
11.	3.2.P.5.1	a) A copy of the drug product specification(s) including tests, acceptance criteria and reference to analytical procedure shall be provided. b) Test of ovalbumin not included in the Specifications. Justification is required.	For question (a), the relevant files and documents will be provided later. For question (b), both the <i>Chinese Pharmacopoeia III (2020 version)</i> and WHO TRS 840 do not require the ovalbumin test. Testing and specification of SIBP MMR vaccine are carried out in accordance with the <i>Chinese Pharmacopoeia</i> .
12.	3.2.P.4.5	For excipients of human or animal origin, a certificate shall be provided, confirming that the excipient(s) are free from BSE and TSE.	Refer to attachment 1 The certificate and documents shall be provided later.
13.	3.2.R	Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3.	The files and documents shall be provided later.
14.	Module 4 Non-Clinical Data	Proper justification with evidence of reference guidelines were “Not applicable” has been mentioned for non-clinical study reports like pharmacology, Pharmacokinetics	Nonclinical study: 1. Pharmacology: Not Applicable, the WHO guidelines for the non-clinical evaluation of vaccines refer to the safety pharmacology in the non-clinical evaluation of vaccines for the purpose of studying the effects of vaccine candidates on vital function. If non-clinical and/or human clinical study data suggest that a vaccine (such as a vaccine based on a specific toxoid) may affect physiological functions other than the immune system (such as the central nervous system, respiratory, cardiovascular, and renal function), then safety pharmacological studies should be included in the toxicity assessment. The virus strains used in the live attenuated SIBP MMR vaccine have all been attenuated, and their safety has been demonstrated by a large amount of human clinical data. Pharmacokinetics:

		, Toxicology, Genotoxicity, Carcinogenicity, Reproductive and Development Toxicity	
15.	Module 5 Clinical Data	a) Proper justification with evidence of reference guidelines were “Not applicable” has been mentioned for clinical study reports. b) Risk Management Plan (RMP) c) Periodic Safety Update Report (PSUR)/Periodic Benefit-Risk Evaluation Report (PBRER) d) Adverse event following immunization report (summary of annual reports) in the country of origin or any other NRA.	Not Applicable, the WHO guideline for the non-clinical evaluation points out that if determining the concentration of a vaccine component in serum or tissue, pharmacokinetic studies are usually not required. 3. Toxicology The animal safety evaluation including <i>Single-dose Subcutaneous Irritation Test of Measles, Mumps and Rubella Combined Vaccine, Live in New Zealand Rabbits, Active Systemic Anaphylaxis Study of Measles, Mumps and Rubella Combined Vaccine, Live in Guinea Pigs</i> were carried out to demonstrate the safety of SIBP MMR vaccine. 4. Genotoxicity Not Applicable, the WHO guideline for the non-clinical evaluation of the vaccines points out that genotoxicity studies are usually not required for final vaccine formulations. The genotoxicity studies may require only in a situation involving the specific ingredient (like novel adjuvant or additive). SIBP MMR vaccine does not contain novel adjuvant or additive. 5. Carcinogenicity Not Applicable, the WHO guideline for the non-clinical evaluation of the vaccines points out that carcinogenicity study does not require for vaccine antigen. Carcinogenicity study may require for the special ingredients like novel adjuvant or additive, but SIBP MMR vaccine do not contain novel adjuvant or additive. 6. Reproductive and developmental toxicity Not Applicable, the WHO guideline for the non-clinical evaluation of the vaccines points out that reproductive and developmental toxicity generally does not require for the vaccines for the children. Reproductive and developmental toxicity may consider if the vaccines for the pregnant and fertile women, SIBP MMR vaccine’s eligible is children aged at 8 months and above, and alert women of childbearing age should avoid pregnancy for at least 3 months after injection of the MMR vaccine. Reference: WHO Technical Report Series, No. 927, 2005 : Annex 1 WHO guidelines on nonclinical evaluation of vaccine

Decision of 345th Meeting:

The Registration Board deferred the case for submission of following requisite documents:

- I. Hard copy of original, legalized and valid COPP mentioning strains of MMR Virus, as provided one is invalid.
- II. Hard copy of original or notarized sole agency agreement is required.
- III. The COPP including details of the diluent/combo pack. A copy of lot summary protocol in compliance with WHO (identified as per specific WHO TRS).
- IV. Documents/evidence for acceptable shipping conditions for finished product & proof of shipping validation.
- V. Data for following strain prevalence (Measles virus: Hu-191, Mumps virus: S79, this strain is Jery-Lyn origin, Rubella virus: BRD-II) in Pakistan.
- VI. Evidence of approval / registration / marketing status of the applied formulation in the same composition (strain and strength), salt form and dosage form in one of the reference regulatory authority specified by Registration Board. The name of the reference authority shall be mentioned as adopted by Board currently.
- VII. Evidence of approval / registration / marketing status of the applied formulation with the same clinical indications (above 8 months).
- VIII. Summary of Product Characteristics (SmPC) of the applied vaccine in one of the reference regulatory authority specified by Registration Board.
- IX. Final bulk should be assayed for virus content and residual animal serum proteins.
- X. Test of ovalbumin to be included in the Specifications.
- XI. For excipients of human or animal origin, a certificate shall be provided, confirming that the excipient(s) are free from BSE and TSE.
- XII. Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3.

Sr. No	Observations	Applicant Response	Evaluation
1.	Hard copy of original, legalized and valid COPP mentioning strains of MMR Virus, as provided one is invalid.	Original, and valid CoPP, mentioning MMR virus is being submitted.	Scanned Attached.
2.	Hard copy of original or notarized sole	Notarized, Authorization Letter is	Scanned Attached.

	agency agreement is required.	being submitted	
3.	The COPP including details of the diluent/combo pack.	Original, apostilled and valid CoPP is being submitted mentioning the combo pack with diluent	Combo pack scanned COPP has been submitted.
4.	A copy of lot summary protocol in compliance with WHO (identified as per specific WHO TRS).	lot summary product in compliance of WHO (identified as per specific WHO TRS) is being submitted.	Lot summary product in compliance of WHO (identified as per specific WHO TRS) has not been submitted.
5.	Documents/evidence for acceptable shipping conditions for finished product & proof of shipping validation.	Shipping condition validation.	No shipping validation document has been provided.
6.	Data for following strain prevalence (Measles virus: Hu-191, Mumps virus: S79, this strain is Jery-Lyn origin, Rubella virus: BRD-II) in Pakistan.	Measles strains: In Pakistan the main measles strains is genotype 3 which is closely related to strains of neighbouring countries. Measles virus is an enveloped, ribonucleic acid virus of the genus Morbillivirus. Although at least 20 different genotypes have been isolated in various parts of the world, there is only one serotype. Measles is highly contagious, and an infected person will often transmit the virus to over 90% of unprotected close contacts. Mumps strain: Mumps have 12 recognized genotypes of mumps there is only one serotype, means antibody generated in response of one genotype recognize one serotype mumps virus. The WHO has recommended mumps strains for vaccine manufacture including jeryl — lyn, RIT 4385, Leningrad — 3 and Leningrad — Zagreb. Rubella strains: The rubella virus is a single serotype with at least seven genotypes serotypes. The most common genotypes circulating in many regions of world are IE,IG,1J and 2B. As the prevalence of MMR vaccine viruses has single serotype but different genotype which does not affect efficacy and safety of vaccine that is why previous vaccine, Triviritin (Manufactured in France), Trimovax (Manufactured in Germany), Morupar (Manufactured in Italy, Garmany now in India), Sanvac (Manufactured in China) are already registered in Pakistan but only one brand is available.	No evidence for Data for following strain prevalence (Measles virus: Hu-191, Mumps virus: S79, this strain is Jery-Lyn origin, Rubella virus: BRD-II) in Pakistan. Hu-191 is a recombinant strain engineered for therapeutic purposes, it originates from the Edmonston B strain, which belongs to genotype A.
7.	Evidence of approval / registration / marketing status of the applied formulation in the same composition Registration Board. The name of the reference authority shall be mentioned as adopted by Board currently. (strain	It is only registered in China.	----

	and strength), salt form and dosage form in one of the reference regulatory authority specified by		
8.	Evidence of approval / registration / marketing status of the applied formulation with the same clinical indications (above 8 months).	All brands manufactured in different countries are recommended at the same age group for vaccination and it is being done from decades, also it is recommended by WHO similar age and is recommended in EPI Pakistan.	---
9.	Summary of Product Characteristics (SmPC) of the applied vaccine in one of the reference regulatory authority specified by Registration Board.	SmPC is being submitted.	SMPC has been provided.
10.	Final bulk should be assayed for virus content and residual animal serum proteins.	The Chinese Pharmacopeia 111 (2020 version) does not require the virus titration and bovine serum albumin residue determination for the final bulk for vaccines.	--
11.	Test of ovalbumin to be included in the Specifications.	Chinese Pharmacopeia III (2020 version) and WHO TRS 840 do not require ovalbumin test. Testing and specification of MMR vaccine are carried in accordance with the Chinese Pharmacopeia.	---
12.	For excipients of human or animal origin, a certificate shall be provided, confirming that the excipient(s) are free from BSE and TSE.	Official Veterinary Bulletin	Declaration submitted by drug product manufacturer.
13.	Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3.	BMR is being submitted	BMR of following three batches submitted by the applicant. BMR-S20180314 BMR S20180315 BMRS201180316

Remarks by BE&R

Not recommended as no evidence has been provided regarding the prevalence of these strains in Pakistan; however, they are prevalent in China as per WHO report.

Placed before Board for consideration.

Decision of 347th Meeting:

The Registration Board, keeping in view the absence of substantive data regarding the prevalence of strain in Pakistan, epidemiological relevance and approval of the applied rubella virus strain (BRD II) only in China, decided to forward the matter to the Federal Directorate of Immunization (FDI) for their opinion: -

- Presence, prevalence, and public health relevance of BRD II strain of Rubella Virus in Pakistan
- Whether any MMR vaccines containing BRD II strain has been used in immunization program or otherwise?
- Recommendation of FDI for need of MMR Vaccine containing strain BRD II.

Moreover, the Board also mandated the timely submission of the following documentation:

- ✓ Evidence of approval of “same strains” i.e. measles virus (S-191 strain), mumps virus (S79 strain) and rubella virus (BRDII strain) in reference regulatory authority as approved by Registration Board in its 275th meeting.
- ✓ Evidence of approval of same “clinical indication/target population” i.e. susceptible to MMR above 8 months in reference regulatory authority as approved by Registration Board in its 275th meeting.
- ✓ Proper justification with evidence of reference guidelines were “Not applicable” has been mentioned for non-clinical study reports like repeat dose toxicity studies.
- ✓ Lot summary protocol in compliance to WHO TRS.
- ✓ Evidence of acceptable shipping conditions for finished product.
- ✓ Comprehensive epidemiological evidence establishing the presence, prevalence, and public health relevance of the BRD II strain within target regions.

✓ Peer-reviewed scientific publications or technical reports substantiating claims related to the strain's performance and relevance.			
Remarks of the Assessor			
Sr. No.	Query	Response	Evaluation
1.	Evidence of approval of “same strains” i.e. measles virus (S-191 strain), mumps virus (S79 strain) and rubella virus (BRDII strain) in reference regulatory authority as approved by Registration Board in its 275 th meeting.	MMR from SIBP is in the process of WHO PQ. WHO has already accepted strains of the MMR vaccine used by the Shanghai Institute of Biological Products SIBP for Prequalification.	BRD II not approved in any RRA. Email sent to WHO by SIBP on 2017. Applicant may also submit current status for PQ.
2.	Evidence of approval of same “clinical indication/target population” i.e. susceptible to MMR above 8 months in reference regulatory authority as approved by Registration Board in its 275 th meeting.	MMR Vaccine is being used since more than 50 years in whole world including Pakistan in same age subjects 8 month and above as per WHO recommendations.	No evidence provided.
3.	☐ Proper justification with evidence of reference guidelines were “Not applicable” has been mentioned for non-clinical study reports like repeat dose toxicity studies.	1. Repeated dose toxicity: This refers to identify the toxic reactions, toxic target organs, nature and degree of toxicity reactions, and reversibility of toxicity in experimental animals or humans after administering the test substance (such as viral vaccines) multiple times within a certain period of time. This provides important evidence for the long-term safety of the vaccine. SIBP has conducted multiple animals safety evaluation trials for the MMR vaccine, including rabbit subcutaneous irritation tests and guinea pig active systemic allergic tests, etc. The results of these tests have all confirmed the safety of the vaccine. In addition, the vaccination schedule for the MMR vaccine is to administer two doses at 8 months of age and 18 months of age in China, with an interval of up to 10 months between the two doses. This longer vaccination interval period, combined with the actual usage data of a large number of people, further verifies its safety in long-term use	Multiple-dose safety has been established through local/systemic toxicity tests instead of repeat dose toxicity. Evidence is required in the light of reference guidelines where repeat dose toxicity is not mandatory.
4.	Lot summary protocol in compliance to WHO TRS.		Lot summary submitted.
5.	Evidence of acceptable shipping conditions for finished product.	Declaration from Manufacturer	Data logger data and Cold Chain Insulated Container Verification Protocol and report.
6.	Comprehensive epidemiological evidence establishing the presence, prevalence, and public health relevance of the BRD II strain within target regions	This is an established scientific fact that effectivity of MMR vaccine does not based on the type of strain in any country. It is being used by all over the world for decades regardless of country of manufacturing due to its single / mono serotype nature of all three virus present in MMR vaccine	
7.	Peer-reviewed scientific publications or technical reports substantiating claims related to the strain's performance and relevance	WHO Position Papers on Measles, Mumps, Rubella. Matched Case-Control Study of Effectiveness of Live, Attenuated Molecular evolution of Rubella viruses	As per WHO position paper comparing RA27/3 with BRD II. Immunogenicity The RA27/3 strain achieves antibody titres that closely

		circulated in the mainland of China and its antigenic difference with Chinese rubella vaccine. safety and Immunogenicity of the Imported and Domestic Measles, Mumps and Rubella. Matched Case-Control Study of Effectiveness of Live, Attenuated S79 Mumps Virus Vaccine against Clinical Mumps	resemble those induced by natural infection. In clinical trials, 95–100% of susceptible people aged ≥ 9 months developed rubella antibodies after a single dose of the vaccine. A meta-analysis of 26 clinical trials showed that 99% (95% CI, 98–99%) of children aged 9–18 months seroconverted after a single dose of RA27/3-containing rubella vaccine. A second dose of rubella vaccine with the RA27/3 strain results in 100% seroconversion (99–100%).³³ In 2 studies in China, administration of RCV1 containing the BRD II strain at the age of 8 months resulted in 91–94% seroconversion.
Conclusion The FDI has not yet responded regarding the prevalence of the strain; however, the following information on BRD II has been provided in response to an FDI query to WHO, as outlined in the WHO position paper. <i>“Please find the information about the Rubella vaccine in the attached WHO position paper.</i> <i>Globally, several strains of the rubella vaccine are used. The most common strain is the RA 27/3 strain, which is widely used in many countries Other strains include:</i> <i>Matsuba,DCRB19,Takahashi,Matsuura,TO-336 (primarily used in Japan),BRD-2 (primarily used in China)</i> <i>These strains are all live, attenuated versions of the rubella virus and are effective in preventing rubella and congenital rubella syndrome”.</i> Decision of 348th Meeting: The Registration Board deferred the case for the response of FDI.			

Hepatitis B Vaccine • Plasma-derived • Recombinant Vaccine • The Hepatitis B virus (HBV) is a small (3200 base pair) DNA virus with a viral envelope. HBV replicates in the liver cells of humans and other higher primates, and produces an excess of the viral envelope protein (Hepatitis B surface antigen, HBsAg) that circulates in the blood. • The first commercial hepatitis B vaccine (1982) used HBsAg purified from plasma of chronically infected individuals. • This plasma-derived vaccine has been replaced by recombinant vaccines to avoid risks related to human blood products. • he HBsAg gene was inserted into yeast and mammalian cells using expression vectors. • Recombinant HBsAg is produced in yeast species like <i>Saccharomyces cerevisiae</i>, <i>Pichia pastoris</i>, and <i>Hansenula polymorpha</i>, as well as CHO (Chinese hamster ovary) cells.	
Recombinant Vaccine (Adult 10 dose) Deferred Case: 347th Meeting Exporting Country(India)	
Case No. 17	
Name, Address Of Applicant / Importer	M/s Hoffmann Human Health Pakistan Ltd. Company Address: 1st 32-Babar Block New Garden Town Lahore
Details of Drug Sale License of importer	License Type: Drug Sale License License to sell drugs as a Distributor License Number: 05-352-0065-013755D License Issue Date: 2004-06-01 Validity: 29-11-2028
Name and address of marketing authorization holder (abroad)	M/s Serum Institute of India Pvt. Ltd., 212/2 Hadapsar, Pune- 411028, Maharashtra State, INDIA
Name, address of manufacturer(s)	M/s Serum Institute of India Pvt. Ltd., 212/2 Hadapsar, Pune- 411028, Maharashtra State, INDIA
Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Scanned Attested COPP (Validity: 21-08-2027) Certificate No: COPP-CERT/PD/141396/2024/11/51950/248439

	Certifying Authority: Food & Drug Administration Free Sale Status: Yes GMP Status: Yes
Details of letter of authorization / sole agency agreement	Scanned Letter of Authorization (Validity: 13, September 2026) <u>AUTHORITY LETTER</u> We, Serum Institute of India Pvt. Ltd., 212/2 Hadapsar, Pune-411028, India do hereby appoint M/s. Hoffmann-La Roche Health Pakistan Ltd. 32-Babar Block, New Garden Town, Lahore as our Agent in Pakistan to deal with the
Status of the applicant	Importer
Status of application	New Drug Product
For imported products, specify one the these	Finished Product
Dy. No. and date of submission	Tracking ID:J1T-TQD-RZYN Application Number:85411 Received on:18-03-2025
Details of fee submitted	Challan Number: 50791307 Division: Biological Evaluation & Registration Paid Fee: 300000.0 Paid Date: 2025-02-17
The proposed proprietary name / brand name	Hepatitis B vaccine (rDNA) Adult 10 dose (Vial)
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each dose of 1 ml contains: Purified Hepatitis B surface antigen...20mcg Adsorbed on Aluminium hydroxide (Al+++). 0.50 mg to 0.80 mg Preservative: Thiomersal 0.005 % Produced in Hansenula polymorpha (yeast)
Adjuvant (if any)	
Dosage form of applied drug	Suspension for Injection
Indication/Target Disease	Hepatitis B vaccine is indicated for active immunisation against hepatitis B infection in subjects considered at risk of exposure to HBV-positive material.
Target Population	Adult dose vaccine: 20 mcg dose (1.0 ml suspension) is recommended for adults aged 20 years and above.
Route of Administration	1 ml by intramuscular injection IM
Pharmacotherapeutic Group of (API)	Hepatitis B, purified antigen, ATC code: J07BC01
Finished product specifications	Any other.
Proposed Pack size	10 dose vial: Box of 50 vials and 300 vial(As per Section 3.2.P.6(25 vials)
Proposed unit price	Price certificate will be shared separately
Shelf life	36 Months
Storage conditions	2 - 8°C. DO NOT FREEZE. Discard if vaccine has been frozen.
The status in reference regulatory authorities/Name of NRA	WHO Pre-qualified Product Commercial Name: Hepatitis B Vaccine (rDNA) (Adult) Manufacturer:Serum Institute of India Pvt. Ltd. Prequalification Status:Current:Effective Date;12/11/2004 Pharmaceutical Form:Liquid: PresentationVial; Number of Doses:10 Route of Administration:Intramuscular Shelf Life:36 months Storage Temperature:2-8°C
For generic drugs (me-too status)	NA
Drug Substance (Hepatitis B Vaccine (rDNA); (bulk = purified HBsAg protein))	
General Information/Source	Recombinant yeast Hansenula polymorpha by successive steps of fermentation, harvest, purification and maturation.
Name, address of drug substance manufacturer	M/s Serum Institute of India Pvt. Ltd., 212/2 Hadapsar, Pune- 411028, Maharashtra State, INDIA

Characterization	HBsAg is a complex macromolecule composed of majority protein and carbohydrate (in the form of glycoprotein) and lipids. Accordingly its structure is elucidated by the following orthogonal analytical techniques and studies: 1. N-terminal amino acid sequencing 2. Sizing analysis by transmission electron cryo-microscopy (cryo-TEM). 3. Analysis of molecular weight of protein by 1-d SDS-PAGE. 4. Analysis of intact mass of monomer using mass spectroscopy 5. Analysis of primary structure of protein by peptide mapping 6. Analysis of particle size using differential light scattering 7. Analysis of isoelectric point 8. Analysis of host cell protein 9. Gravimetric analysis of Lipids 10. Quantitative analysis of lipid composition 11. Characterization of N-linked glycan																														
Stability	Proposed shelf life :36 Month Real time stability study storage temperature: +2°C to +8 °C Accelerated stability study storage temperature: + 25°C ± 2 °C / 60 % RH ± 5% RH The real-time and accelerated stability studies have been performed on our Hepatitis-B surface Antigen Protein (Aqueous) The time intervals for real-time stability study are: 0m, 3m, 6m, 9m, 18m, 24m, 30m, 36m, 48m. and 60m. The time intervals for accelerated stability study are: 0m, 1m, 2m, 3m & 6m months.																														
Drug Product																															
Drug Product Manufacturer	<table><tr><th>Name of Vaccine</th><th>Activity</th><th>Facility</th></tr><tr><td rowspan="5">Hepatitis B Vaccine (rDNA)</td><td rowspan="2">HB Bulk production/Purification: HBsAg (Aqueous) bulk protein</td><td>Building No.6: First Floor Hepatitis B manufacturing.</td></tr><tr><td>Recombinant DNA Products and Derivatives (Multiproduct) facility, Building No.6: First Floor</td></tr><tr><td rowspan="4">Blending/Filling</td><td>Building No.6 Ground Floor</td></tr><tr><td>SEZ 6: First Floor</td></tr><tr><td>SEZ 7 First Floor</td></tr><tr><td>SEZ 5 Ground Floor</td></tr><tr><td rowspan="14">Hepatitis B Vaccine (rDNA)</td><td rowspan="6">Quality Control</td><td>Building No. 5: First floor</td></tr><tr><td>SEZ 8: First floor</td></tr><tr><td>SEZ 3: First floor</td></tr><tr><td>Building No. 1, Second floor</td></tr><tr><td>SEZ 1C : Second Floor</td></tr><tr><td>SIPL Manjari Facility : Animal House: MSEZ -3A :First and Second Floor</td></tr><tr><td rowspan="4">Packing</td><td>Building 5: Ground floor</td></tr><tr><td>Building 6: Ground floor</td></tr><tr><td>Building 1: Ground floor</td></tr><tr><td>SEZ 6: Ground floor</td></tr><tr><td rowspan="2">Dispatch</td><td>Building No. 14: Ground floor</td></tr><tr><td>SEZ 6: Ground floor</td></tr></table>			Name of Vaccine	Activity	Facility	Hepatitis B Vaccine (rDNA)	HB Bulk production/Purification: HBsAg (Aqueous) bulk protein	Building No.6: First Floor Hepatitis B manufacturing.	Recombinant DNA Products and Derivatives (Multiproduct) facility, Building No.6: First Floor	Blending/Filling	Building No.6 Ground Floor	SEZ 6: First Floor	SEZ 7 First Floor	SEZ 5 Ground Floor	Hepatitis B Vaccine (rDNA)	Quality Control	Building No. 5: First floor	SEZ 8: First floor	SEZ 3: First floor	Building No. 1, Second floor	SEZ 1C : Second Floor	SIPL Manjari Facility : Animal House: MSEZ -3A :First and Second Floor	Packing	Building 5: Ground floor	Building 6: Ground floor	Building 1: Ground floor	SEZ 6: Ground floor	Dispatch	Building No. 14: Ground floor	SEZ 6: Ground floor
Name of Vaccine	Activity	Facility																													
Hepatitis B Vaccine (rDNA)	HB Bulk production/Purification: HBsAg (Aqueous) bulk protein	Building No.6: First Floor Hepatitis B manufacturing.																													
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		Building 1: Ground floor																													
		SEZ 6: Ground floor																													
	Dispatch	Building No. 14: Ground floor																													
		SEZ 6: Ground floor																													
	Composition	Hepatitis B Vaccine (rDNA) is a non infectious recombinant DNA Hepatitis B vaccine. It contains purified surface antigen of the virus obtained by culturing genetically engineered Hansenula polymorpha yeast cells having the surface antigen gene of the Hepatitis B virus. The Hepatitis B surface antigen (HBsAg) expressed in the cells of Hansenula polymorpha is purified through several chemical steps and formulated as a suspension of the antigen adsorbed on aluminium hydroxide and Thiomersal is added as preservative.																													
	Formulation	Hepatitis B vaccine is blended with an additional 25% increase in HBsAg antigen, and 20% increase in concentration of Al(OH)3 adjuvant concentrations to ensure that the vaccine will meet specifications at the end of the shelf life.																													
Manufacturing	Manufacturing process development of HBsAg (aqueous) bulk is presented under following headings:																														

	1. History of master cell bank from Rhein Biotech and tech transfer to Transgene Vaccine Ltd (TVL) and purchase of TVL by SIIPL 2. Cell bank development at SIIPL and its characterization 3. Manufacturing process development at TVL and SIIPL 4. Major manufacturing changes
Container Closure	For Adult dose (10ml/10 doses vial) : 15ml Vial : Hepatitis-B vaccine (rDNA) (Adult), 10 doses (vial) are filled in clear tubular vial type I glass vial (European Blow Back) with 50 mm height and 24 mm body diameter. Vials are closed with a 20 mm grey color bromo-butyl rubber stopper. The closure is sealed to the container using a 20 mm aluminium seal having Pantone 300 C (Blue) colored flip-off cap. Box of 25 Vial.
Stability	Real time Stability Study : Conclusion : The Experimental results demonstrate that Hepatitis-B Vaccine (rDNA) B.Nos. 035L0007, 035L4003, 035L4004 and 035L4008 remained within specifications, in all the time during the study, under the temperature indicated above. Based on the above, we conclude that the product complies with an efficiency period of 42 months, The Hepatitis B Vaccine (rDNA) (Adult) 10 dose vial B.No.035X70030E is found to be stable for 36 months at temperature conditions 2-8°C*. B.No. 0351L002 is found to be stable for 36 months at temperature conditions 2-8°C*. B.No. 0351L007 is found to be stable for 24 months. Claimed shelf life: 36 Month from the date of manufacture Recommended storage condition: + 2 °C to + 8 °C Real time study temperature: + 2 °C to + 8 °C Accelerated study temperature: + 25 ± 2 °C, 60 % RH ± 5%
Module 4- Nonclinical Reports	
Toxicology: • Repeat-dose (IM) in animals • Local tolerance (site histology) • Reproductive & developmental studies	Single-Dose Toxicity (in order by species, by route) Acute Toxicity study of Hepatitis B Vaccine (Recombinant) in albino mice Conclusion: The Hepatitis B vaccine in the dose of 80 mcg/kg dose intramuscularly was well tolerated in Albino mice. None of the animals in the treated group showed any toxic symptoms which indicate the safety vaccine Repeat Dose Toxicity (in order by species, by route, by duration; including supportive toxicokinetics evaluations) • Study -01: Sub acute Toxicity Study of Recombinant Hepatitis B Vaccine in Albino Swiss Mice. • Study- 02: Sub acute Toxicity Study of Recombinant Hepatitis B Vaccine in Rats. Hepatitis-B Vaccine, in the doses used, has not significantly affected the parameters such as body weight, feed, and water intake. The observation with respect to haematology and clinical biochemistry are comparable in control and treated groups. The results were supported by histopathological studies. This reveals that Hepatitis-B Vaccine is safe in Wistar Albino rats. Local tolerance The Hepatitis B vaccine in the dose of 80µg/kg dose intramuscularly was well tolerated in Albino mice. None of the animals in the treated group showed any toxic symptoms which indicate the safety vaccine in Single dose Toxicity
Module 5 – Clinical Study Reports	
rDNA Hepatitis B vaccine manufactured by Serum Institute of India Private Ltd, Pune (GeneVac-B) is efficacious and comparable to Engerix-B and Shanvac-B.	
Immunogenicity, Efficacy and Safety Studies	Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication • Evaluation of immunogenicity and safety of Genevac-B: a new recombinant Hepatitis-B vaccine in comparison with Engerix-B and Shanvac-B in healthy adults. • A phase IV clinical study in adult patients with chronic renal failure to assess the comparative immunogenicity and reactogenicity of recombinant Hepatitis B vaccines namely GeneVacB vaccine (Manufactured by Serum Institute of India) Limited) vis-a-vis Engerix-B (Manufactured by GSK)

	• A comparison of immunogenicity and reactogenicity of two Recombinant Hepatitis B vaccines. (GeneVac-B and Engerix-B) in healthy infants. • Immunogenicity and Reactogenicity of two recombinant Hepatitis B vaccines in small infants : Randomized; double blind comparative study. • A double blind randomized comparison between GeneVac-B and Engerix-B for immunogenicity and reactogenicity in infants. • Comparative study evaluating clinical safety and effectiveness of Recombinant Hepatitis B vaccines - GeneVac-B with Shanvac (SB) in adults. • Assessment of immune response and safety of two Recombinant Hepatitis B vaccines. (GeneVac-B and Engerix-B) in healthy infants. Study Reports of Uncontrolled Clinical Studies • Immunogenicity of new, low-cost recombinant hepatitis-B vaccine derived from Hansenula Polymorpha in adults • Evaluation of immunogenicity and safety of Recombinant Hepatitis B vaccine (GeneVac-B) in normal healthy volunteers (18 – 60 years) A Phase II study. • tolerance of locally available recombinant hepatitis B vaccine (GeneVac-B) in healthy paediatric subjects Phase III clinical study. • Evaluation of immunogenicity and safety of Recombinant Hepatitis B (GeneVac-B) vaccine in healthy volunteers—a phase III study. • Assessment of immunogenicity of rDNA Hepatitis B Vaccine manufactured by Serum Institute of (India) Limited, Pune, India in Indian infants aged 6 – 14 week. • A Post marketing Clinical Study of Immune Responses induced By Genevac-B (Recombinant Hepatitis-B Vaccine of SIIL, , Pune) In Healthy Adult Volunteers.
Post-marketing Data	Data from all sources (spontaneous reports, clinical trial data and literature search) clearly indicate that Hepatitis-B vaccine of SIPL is well tolerated in adults and can be used safely for prevention of hepatitis B. A concise analysis of the vaccination data of Hepatitis-B vaccine of SIPL showed no new information on the following: • A change in characteristics of listed reactions. • Serious unlisted reactions • Non-Serious unlisted reactions • An increased reporting frequency of listed reactions. The vaccine can be safely and effectively given simultaneously but at different injection sites with TT and Yellow fever vaccine. Similarly, there is no new safety issue on vaccine interactions, use of vaccine in pregnancy, lactation and elderly people.
Miscellaneous Documents in Compliance to WHO Requirements ✓ A statement by the Applicant to confirm whether the product has been rejected, withdrawn from the markets/countries. ✓ Information on the type of the product if was produced using a GMO technology. ✓ Evidence of valid GMP certificate. ✓ Acceptable shipping condition for both finished product and Drug Substance and Formulated Bults (for importing bults for filling and domestic production). ✓ Proof of Shipping validation. ✓ A copy template of lot summary protocol in compliance with WHO-recommended format (identified as per specific WHO TRS). ✓ A copy of labels (vial and carton).	
Comments by BE&R Division Recommended for approval on the basis of WHO PQ status and submission of documents in compliance to WHO Requirements.	
Decision of 347th meeting: The Registration Board deferred the case for further deliberation.	
Conclusion: The case is once again placed for consideration.	
Decision of 348th Meeting: The Registration Board approved the formulation with IP Specifications as per current policy for inspection of manufacturers abroad notified vide Letter No.3-2/2005-Reg-I /Vol-II dated July 6, 2022.	
Hepatitis B vaccine (rDNA) Pediatric 10 dose (Vial)	

**Deferred Case: 347th Meeting
Exporting Country(India)**

Case No. 18

Name, Address Of Applicant / Importer	M/s Hoffmann Human Health Pakistan Ltd. Company Address: 1st 32-Babar Block New Garden Town Lahore
Details of Drug Sale License of importer	License Type: Drug Sale License License to sell drugs as a Distributor License Number: 05-352-0065-013755D License Issue Date: 2004-06-01 Validity: 29-11-2028
Name and address of marketing authorization holder (abroad)	M/s Serum Institute of India Pvt. Ltd., 212/2 Hadapsar, Pune- 411028, Maharashtra State, INDIA
Name, address of manufacturer(s)	M/s Serum Institute of India Pvt. Ltd., 212/2 Hadapsar, Pune- 411028, Maharashtra State, INDIA
Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	<u>Scanned Attested COPP</u> Certificate No: COPP-CERT/PD/139118/2024/11/51771/247784 Certifying Authority: Food & Drug Administration Free Sale Status: Yes GMP Status: Yes Validity: 21-08-2027
Details of letter of authorization / sole agency agreement	<u>Scanned Letter of Authorization</u> <u>AUTHORITY LETTER</u> We, Serum Institute of India Pvt. Ltd., 212/2 Hadapsar, Pune-411028, India do hereby appoint M/s. Hoffmann Human Health Pakistan Ltd. 32-Babar Block, New Garden Town, Lahore as our Agent in Pakistan to deal with the Validity: 13, September 2026
Status of the applicant	Importer
Status of application	New Drug Product
For imported products, specify one the these	Finished Product
Dy. No. and date of submission	Tracking ID:DSB-469-L3EG Application Number:86819 Receiving: 10-04-2025
Details of fee submitted	Challan Number: 636238549322 Division: Biological Evaluation & Registration Paid Fee: 300000.0 Paid Date: 2025-02-17
The proposed proprietary name / brand name	Hepatitis B vaccine (rDNA) Pediatric 10 dose (Vial)
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each dose of 0.5 ml contains: 10 mcg of purified Hepatitis B surface antigen Adsorbed on Aluminium hydroxide (Al+++) 0.25 mg to 0.40 mg Preservative: Thiomersal 0.005 % Produced in Hansenula polymorpha (yeast) Dose: 1 ml by intramuscular injection
Adjuvant (if any)	
Dosage form of applied drug	Suspension for Injection
Indication/Target Disease	Hepatitis B vaccine is indicated for active immunisation against hepatitis B infection in subjects considered at risk of exposure to HBV-positive material.
Target Population	Paediatric dose vaccine: 10 mcg dose (in 0.5 ml suspension) is recommended for neonates, infants, children and adolescents upto 19 years of age.
Route of Administration	0.5ml ml by intramuscular injection Dose: 10 dose
Pharmacotherapeutic Group of (API)	Hepatitis B, purified antigen, ATC code: J07BC01
Finished product specifications	Any Other
Proposed Pack size	50 vials , 300 vials

Proposed unit price	Box of 50 vials (161,440.00) Box of 300 vials (968,640.00)	Controlled Controlled													
Shelf life	36 Months														
Storage conditions	2 - 8°C.														
The status in reference regulatory authorities/Name of NRA	WHO Pre-qualified Product Commercial Name: Hepatitis B Vaccine (rDNA) (Paediatric) Manufacturer: Serum Institute of India Pvt. Ltd. Prequalification Status: Current Effective Date; 12/11/2004 Pharmaceutical Form: Liquid; Presentation Vial; Number of Doses: 10 Route of Administration: Intramuscular Shelf Life: 36 months Storage Temperature: 2-8°C														
For generic drugs (me-too status)	NA														
Drug Substance (Hepatitis B Vaccine (rDNA); (bulk = purified HBsAg protein))															
General Information/Source	Recombinant yeast Hansenula polymorpha by successive steps of fermentation, harvest, purification and maturation.														
Name, address of drug substance manufacturer	M/s Serum Institute of India Pvt. Ltd., 212/2 Hadapsar, Pune- 411028, Maharashtra State, INDIA														
Characterization	HBsAg is a complex macromolecule composed of majority protein and carbohydrate (in the form of glycoprotein) and lipids. Accordingly its structure is elucidated by the following orthogonal analytical techniques and studies: 1. N-terminal amino acid sequencing 2. Sizing analysis by transmission electron cryo-microscopy (cryo-TEM). 3. Analysis of molecular weight of protein by 1-d SDS-PAGE. 4. Analysis of intact mass of monomer using mass spectroscopy 5. Analysis of primary structure of protein by peptide mapping 6. Analysis of particle size using differential light scattering 7. Analysis of isoelectric point 8. Analysis of host cell protein 9. Gravimetric analysis of Lipids 10. Quantitative analysis of lipid composition 11. Characterization of N-linked glycan														
Stability	Proposed shelf life :36 Month Real time stability study storage temperature: +2°C to +8 °C Accelerated stability study storage temperature: + 25°C ± 2 °C / 60 % RH ± 5% RH The real-time and accelerated stability studies have been performed on our Hepatitis-B surface Antigen Protein (Aqueous) The time intervals for real-time stability study are: 0m, 3m, 6m, 9m, 18m, 24m, 30m, 36m, 48m. and 60m. The time intervals for accelerated stability study are: 0m, 1m, 2m, 3m & 6m months.														
Drug Product (Name)															
Drug Product Manufacturer		<table><tr><th>Name of Vaccine</th><th>Activity</th><th>Facility</th></tr><tr><td rowspan="8">Hepatitis B Vaccine (rDNA)</td><td rowspan="2">HB Bulk production/Purification: HBsAg (Aqueous) bulk protein</td><td>Building No.6: First Floor Hepatitis B manufacturing.</td></tr><tr><td>Recombinant DNA Products and Derivatives (Multiproduct) facility, Building No.6: First Floor</td></tr><tr><td rowspan="5">Blending/Filling</td><td>Building No.6 Ground Floor</td></tr><tr><td>SEZ 6: First Floor</td></tr><tr><td>SEZ 7 First Floor</td></tr><tr><td>SEZ 5 Ground Floor</td></tr><tr><td></td></tr></table>	Name of Vaccine	Activity	Facility	Hepatitis B Vaccine (rDNA)	HB Bulk production/Purification: HBsAg (Aqueous) bulk protein	Building No.6: First Floor Hepatitis B manufacturing.	Recombinant DNA Products and Derivatives (Multiproduct) facility, Building No.6: First Floor	Blending/Filling	Building No.6 Ground Floor	SEZ 6: First Floor	SEZ 7 First Floor	SEZ 5 Ground Floor	
Name of Vaccine	Activity	Facility													
Hepatitis B Vaccine (rDNA)	HB Bulk production/Purification: HBsAg (Aqueous) bulk protein	Building No.6: First Floor Hepatitis B manufacturing.													
		Recombinant DNA Products and Derivatives (Multiproduct) facility, Building No.6: First Floor													
	Blending/Filling	Building No.6 Ground Floor													
		SEZ 6: First Floor													
		SEZ 7 First Floor													
		SEZ 5 Ground Floor													

	Hepatitis B Vaccine (rDNA)	Quality Control	Building No. 5: First floor SEZ 8: First floor SEZ 3: First floor Building No. 1, Second floor SEZ 1C : Second Floor SIPL Manjari Facility : Animal House: MSEZ -3A :First and Second Floor
		Packing	Building 5: Ground floor Building 6: Ground floor Building 1: Ground floor SEZ 6: Ground floor
		Dispatch	Building No. 14: Ground floor SEZ 6: Ground floor
Composition	Hepatitis B Vaccine (rDNA) is a non infectious recombinant DNA Hepatitis B vaccine. It contains purified surface antigen of the virus obtained by culturing genetically engineered Hansenula polymorpha yeast cells having the surface antigen gene of the Hepatitis B virus. The Hepatitis B surface antigen (HBsAg) expressed in the cells of Hansenula polymorpha is purified through several chemical steps and formulated as a suspension of the antigen adsorbed on aluminium hydroxide and Thiomersal is added as preservative.		
Formulation	Hepatitis B vaccine is blended with an additional 25% increase in HBsAg antigen, and 20% increase in concentration of Al(OH) ₃ adjuvant concentrations to ensure that the vaccine will meet specifications at the end of the shelf life.		
Manufacturing	Manufacturing process development of HBsAg (aqueous) bulk is presented under following headings: 1. History of master cell bank from Rhein Biotech and tech transfer to Transgene Vaccine Ltd (TVL) and purchase of TVL by SIPL 2. Cell bank development at SIPL and its characterization 3. Manufacturing process development at TVL and SIPL 4. Major manufacturing changes		
Container Closure	Hepatitis-B vaccine (rDNA) (Paediatric) 10 doses (vial) are filled in clear tubular vial type I glass vial (European Blow Back). with 52 mm height and 16.5 mm body diameter. Vials are closed with a 13 mm grey color bromo-butyl rubber stopper. The closure is sealed to the container using a 13 mm aluminium seal having Blue SP or Blue colored flip-off cap.		
Stability	Real time Stability Study : Conclusion: The Experimental results demonstrate that Hepatitis-B Vaccine (rDNA) B. 033L9002B and 033B6002 have remained within specifications, in all the time during the study, under the temperature indicated above. Based on the above, we conclude that the product complies with an efficiency period of 42 months, The Hepatitis B Vaccine (rDNA) (Paediatric) 10 dose vial B.No.033X60090E,0339L001B and 0330L001A is found to be stable for 36 months at temperature conditions 2-8°C* Accelerated Stability Study: Conclusion: The Experimental results demonstrate that Hepatitis-B Vaccine (rDNA) B. No. 033L9002B, 033B6002 and 033X60090E remained within specifications, in all the time during the study, under the temperature indicated above. Based on the above, we conclude that the product complies with an efficiency period of 6 months, when stored at a temperature 25 °C ± 2°C, 60 %RH ± 5%. For the B. No. . 0339L001B and 0330L001A accelerated stability is not done Batches were taken for stability program and the samples were stored at real time and accelerated stability study temperatures. In the real time stability program the samples are stored at 2-8 °C and in the accelerated stability program the samples are stored at 25 ± 2°C. The following mentioned batches were kept for the stability studies		

		Claimed shelf life: 36 Month from the date of manufacture Recommended storage condition: + 2 °C to + 8°C Real time study temperature: + 2 °C to + 8 °C Accelerated study temperature: + 25 ± 2 °C, 60 % RH ± 5%
Module 4- Nonclinical Reports		
	Toxicology: • Repeat-dose (IM) in animals • Local tolerance (site histology) • Reproductive & developmental studies	Single dose toxicity study It was conducted on albino swiss mice and animals were observed for 7 days after injecting the vaccine. Control group received solution devoid of HBsAg protein. There was no detectable sign of toxicity and there was no death. Repeat Dose Toxicity Study -01: Sub acute Toxicity Study of Recombinant Hepatitis B Vaccine in Albino Swiss Mice. • Study- 02: Sub acute Toxicity Study of Recombinant Hepatitis B Vaccine in Rats. Local tolerance The Hepatitis B vaccine in the dose of 80µg/kg dose intramuscularly was well tolerated in Albino mice. None of the animals in the treated group showed any toxic symptoms which indicate the safety vaccine in Single dose Toxicity.
Module 5 – Clinical Study Reports rDNA Hepatitis B vaccine manufactured by Serum Institute of India Private Ltd, Pune (GeneVac-B) is efficacious and comparable to Engerix-B and Shanvac-B.		
	Biopharmaceutics	- Not applicable for vaccines.
	Clinical Efficacy & Safety	• Open, non-comparative, Prospective, phase III Clinical trial • Open, Comparative Prospective Phase III randomized clinical trial
	□ Phase I/II: Dose-ranging, immunogenicity in adults and infants. • Phase III: • Post-marketing: Ongoing surveillance confirms long-term efficacy and rare adverse event rates.	To assess efficacy of the vaccine, Anti-HBs IgG titres were determined post vaccination and criterion for seropositivity was Titre ≥ 1 mIU/ml and for seroprotection titre ≥ 10 mIU/ml. • In controlled comparative studies: The efficacy of GeneVac-B was comparable to Engerix-B or Shanvac-B. • In uncontrolled studies GeneVac-B gave adequate protection as evidenced by percentage seroconversion and seroprotection and Geometric Mean Titre (GMT) of Anti-HBs IgG antibody. • In Dose comparative studies in adolescents, both the doses i.e. 0.5 ml (10 µg) and 1.0 ml (i.e. 20 µg) were efficacious when percentage seroconversion and percentage seroprotection was compared In Schedule comparative Studies, Both schedules (i.e. 0, 1, 2 month and 0,1,6 month schedule) were comparable. • One comparative study was conducted on patients of Chronic Renal Failure he adverse events. The common adverse events in these studies were mild pain, tenderness at site of injection. The adverse events were in the range quoted in literature. The adverse events were mostly mild and self limiting in nature or resolved with concomitant medication. In comparative studies, the safety profile of GeneVac-B was comparable to Engerix-B and Shanvac-B. The safety profile was comparable in 0.5 and 1.0 ml dose. The safety profile also did not differ in 0, 1, 2 month schedule or 0, 1, 6 month schedule. There was no case of any vaccine related Serious Adverse Event. Overview of Safety In all the studies on Hepatitis B vaccine, safety analysis was done by active monitoring for the adverse events. The common adverse events in these studies were mild pain, tenderness at site of injection. The adverse events were in the range quoted in literature. The adverse events were mostly mild and self limiting in nature or resolved with concomitant medication. In comparative studies, the safety profile of GeneVac-B was comparable to Engerix-B and Shanvac-B. The safety profile was comparable in 0.5 and 1.0 ml dose. The safety profile also did not differ in 0, 1, 2 month schedule or 0, 1, 6 month schedule. There was no case of any vaccine related Serious Adverse Event
	Post-marketing Data	Data from all sources (spontaneous reports, clinical trial data and literature search) clearly indicate that Hepatitis-B vaccine of SIIPL is well tolerated in adults and can

	be used safely for prevention of hepatitis B. A concise analysis of the vaccination data of Hepatitis-B vaccine of SIIPL showed no new information on the following: • A change in characteristics of listed reactions. • Serious unlisted reactions • Non-Serious unlisted reactions • An increased reporting frequency of listed reactions. The vaccine can be safely and effectively given simultaneously but at different injection sites with TT and Yellow fever vaccine. Similarly, there is no new safety issue on vaccine interactions, use of vaccine in pregnancy, lactation and elderly people.
	Miscellaneous Documents in Compliance to WHO Requirements ✓ A statement by the Applicant to confirm whether the product has been rejected, withdrawn from the markets/countries. ✓ Information on the type of the product if was produced using a GMO technology, ☐ Evidence of valid GMP certificate. ✓ Acceptable shipping condition for both finished product and Drug Substance and Formulated Bulks (for importing bulks for filling and domestic production). ✓ Proof of Shipping validation. ✓ A copy template of lot summary protocol in compliance with WHO-recommended format (identified as per specific WHO TRS). ✓ A copy of labels (vial and carton).
	Comments by BE&R Division Recommended for approval on the basis of WHO PQ status and submission of documents in compliance to WHO Requirements.
	Decision of 347th Meeting: The Registration Board deferred the case for further deliberation.
	Conclusion: The case is once again placed for consideration.
	Decision of 348th Meeting: The Registration Board approved the formulation with IP Specifications as per current policy for inspection of manufacturers abroad notified vide Letter No.3-2/2005-Reg-I /Vol-II dated July 6, 2022.

Hepatitis A Vaccine • Hepatitis A virus (HAV) is a member of the picornavirus family that includes the human enteroviruses and rhinoviruses. It is a non-enveloped virus of 27-28 nm diameter and all human isolates of hepatitis A belong to a single serotype. • Hepatitis A virus can be grown in cell culture and sufficient amounts of the virus can be obtained for vaccine production. • The virus is propagated in human fibroblasts or human diploid cell cultures, purified from cell lysates, inactivated with formalin, and adsorbed to an aluminum hydroxide adjuvant or a virosome consisting of phospholipids vesicles spiked with influenza haemagglutinin and neuraminidase. 2-phenoxyethanol (2-PE) is included as a preservatives in the formulation of some vaccines. Hepatitis A vaccines in combination with hepatitis B or typhoid are commercially available.		
Hepatitis A (live) vaccine New Product Exporting Country (China)		
Case 19		
	Name, address of Applicant / Importer	M/s Amson Vaccines & Pharma (Pvt.) Ltd Company Address: 115, Industrial Triangle Kahuta Road
	Details of Drug Sale License of importer	Distribution License DHO-ISB-1352 Plot no 115, Industrial Triangle, Kahuta Road, Islamabad Valid up-till 2025-12-01
	Name of exporting country	China
	Name and address of marketing authorization holder (abroad)	Headquarters: Address: 935 Jiaoling Road, Wuhua district, Kunming, Yunnan Province, The buildings at IMBCAMS Headquarters in Kunming are for administration, and mainly for research laboratories. Production Base, Majinpu: Address: 168 Dengzhanhua Street, Majinpu, High-tech zone, Kunming, Yunnan Province, Majinpu site is the main production site for vaccine production where commercial production of fHAV is performed. IMBCAMS does not contract out any of its production activities for fHAV.
	Name, address of manufacturer(s)	Headquarters: Address: 935 Jiaoling Road, Wuhua district, Kunming, Yunnan Province, The buildings at IMBCAMS Headquarters in Kunming are for administration, and mainly for research laboratories.

	Production Base, Majinpu: Address: 168 Dengzhanhua Street, Majinpu, High-tech zone, Kunming, Yunnan Province, Majinpu site is the main production site for vaccine production where commercial production of fHAV is performed. IMBCAMS does not contract out any of its production activities for fHAV.
Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	COPP: (Trade name on COPP is Weisairuiji) Certificate No: Yunnan 20250016 Validity: November 09, 2025 Certifying Authority: Medical Products administration of Yunnan Province Freely available: Yes GMP Status: (Facilities and operations confirms GMP status)
Details of letter of authorization / sole agency agreement	Issuance Date: May 10 th , 2024 We, <u>INSTITUTE OF MEDICAL BIOLOGY CHINESE ACADEMY OF MEDICAL SCIENCES (IMBCAMS)</u> , a public institute manufacturing <u>human vaccine</u> products, whose principal place of business is located at <u>935 Jiaoling Rd, Kunming, China</u> and have manufacturing site at <u>168 Dengzhanhua Rd, Kunming, China</u> does hereby authorize <u>Amson Vaccines & Pharma (Pvt.)</u> Ltd having its principal place of business at <u>115, Industrial Triangle Kahuta Road, Islamabad, Pakistan</u> , represented by <u>Mr. Naveed Ahmed Khan</u> for the purpose of Products' Registration / Regulatory matters, Marketing and Distribution of our following product(s) in Pakistan: Hepatitis A (Live-attenuated) Vaccine, Freeze-Dried As Amson Vaccines & Pharma (Pvt.) is our Exclusive Distributor for Hepatitis A
Status of the applicant	Importer
Status of application	NA for vaccines
For imported products, specify one the these	Finished Pharmaceutical product import
Dy. No. and date of submission	Tracking ID: 581-7SQ-WAVU:Application Number: 87788:Date of Receiving: 20-06-2025
Details of fee submitted	Challan Number: 9667022465 Division: Biological Evaluation & Registration Paid Fee: 300,000/- Paid Date: 05-03-2025
The proposed proprietary name / brand name	Hepatitis A (live) vaccine, Freeze Dried Injection
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Live attenuated Hepatitis A virus. 1.0ml of reconstituted vaccine per container. 1.0ml per single human dose contains not less than 6.50lg CCID ₅₀ of live hepatitis A virus.
Adjuvant (if any)	Excipients: Gelatin 2.5mg Trehalose 35mg Glycine 5mg Dextran 5mg Vaccine diluent: Sterile water for injection
Dosage form of applied drug	Vaccine (Injection)
Indication/Target Disease	The vaccine is indicated for individuals above one and a half years old who are susceptible to Hepatitis A virus. After inoculation, this vaccine can induce immunity against hepatitis A virus. It is used to prevent hepatitis A.
Target Population	Individuals above one and a half years old
Route of Administration	Intramuscular Injection (IM)
Pharmacotherapeutic Group of (API)	Biological Product "Viral Vaccine for humans"

Finished product specifications	For those referred to Chinese Pharmacopeia, IMBCAMS also has made a comparison with European Pharmacopoeia, and the results demonstrate that these methods operate on the same principle in both pharmacopoeias.
Proposed Pack size	1's
Proposed unit price	As per SRO
Shelf life	24 months
Storage conditions	Store at 2 to 8°C
The status in reference regulatory authorities/Name of NRA	Could not be found as live vaccine.
For generic drugs (me-too status)	
Drug Substance (Bulk)	
General Information	The common name of the drug substance is “Bulk of Hepatitis A (Live) Vaccine, Freeze-dried” (hereinafter referred as “bulk”). The bulk is a colorless transparent solution, which is sterile and free of mycoplasma, containing live attenuated Hepatitis A virus with the virus titer within 7.50-8.50 lgCCID ₅₀ /ml, with antigen content (semi quantitatively determined by ELISA method) has lower alert limit: 1:256, lower action limit: 1:128, lower in-house limit: 1:64.
Name, address of drug substance manufacturer	Institute of Medical Biology Chinese Academy of Medical Sciences No.168 Dengzhanhua Street, Majinpu, High-tech Zone, Kunming, Yunnan Province, China (Post code: 650503)
Manufacturing Process	λ General description of manufacturing process Thaw the working cells of KMB17 in cell culture flasks, culture and amplify in cell factories, inoculate with attenuated hepatitis A strain (H2 strain), and culture for 9 to 12 days, replace with cell maintenance medium, and continue to culture until 22 to 26 days to harvest the virus, the virus harvest is processed with ultrasonication and trichloromethane extraction, and then resulting the bulk.
Characterization	The bulk is a sterile solution containing live attenuated hepatitis A virus, which is a nonenveloped single-stranded RNA virus (genus Hepatovirus, family Picornaviridae), its icosahedral capsid comprises 60 capsid particles with HAV-specific antigen (HAVAg), and each capsid particle is composed of four different peptides, namely VP1, VP2, VP3 and VP4. The viral strain used for producing fHAV is H2 strain. And the bulk is sterile and free of mycoplasma, containing live attenuated hepatitis A virus with the virus titer within 7.50-8.50 lgCCID ₅₀ /ml, with antigen content (semi-quantitatively determined by ELISA method) has lower alert limit: 1:256, lower action limit: 1:128, lower in-house limit: 1:64. Impurities: During the production of bulk of fHAV, newborn bovine serum and kanamycin sulfate solution are added in the cell culture stage, chloroform is used in the virus extraction stage, which are regarded as impurities. Since these ingredients might pose effects to vaccine's quality, their content must be controlled. The tests of residual bovine serum albumin, residual antibiotics and residual chloroform are conducted in quality control of final product.
Control of drug Substance	According to the requirements in Chinese Pharmacopoeia, and <i>Registration Standard of Hepatitis A (Live) Vaccine, Freeze-dried</i> YBS05142020, the bulk of fHAV is tested with virus titration, sterility test, and mycoplasma test and antigen content determination.
Stability	After the summarized analysis towards the stability study results, the virus harvest of fHAV has a good stability when storing at -20°C for 24 months in PC bottles, which qualify for the quality requirement.
Drug Product (Name)	
Composition	The freeze-dried hepatitis A vaccine is a preparation made from the live attenuated H2 strain of hepatitis A grown in human diploid cell (KMB17 Strain). After cultivation, harvest and extraction of the virus, the virus suspension is lyophilized after adding

	stabilizer to make the vaccine. It looks like a milky-white crisp cake and it turns into a clear liquid after reconstitution. Active constituent: live attenuated hepatitis A virus Excipients: gelatin, trehalose, glycine, dextran Vaccine diluent: sterile water for injection
Formulation	1.0ml of reconstituted vaccine per container. 1.0ml per single human dose contains not less than 6.50lg CCID ₅₀ of live hepatitis A virus.
Manufacturing	The manufacturer of Hepatitis A (Live) Vaccine, Freeze-dried is the Institute of Medical Biology Chinese Academy of Medical Sciences with the production address at No.168 Dengzhanhua Street, Majinpu, High-tech Zone, Kunming, Yunnan Province, China (Post code: 650503). The dosage form of final product of fHAV is injection, packaging container is vial. The production process of final product starts from the clarification filtration of bulk, follows by ultrafiltration concentration, sterile filtration, and preparation of final bulk, filling, freeze-drying, capping and packaging process. According to the requirements set out in Chinese Pharmacopoeia and Registration Standard of Hepatitis A (Live) Vaccine, Freeze-dried YBS05142020, the critical in-process control points and corresponding acceptance criteria of the critical steps in the production of final product were specified with a reference of results of process validation described in 3.2.P.3.5, and the final bulk, deemed as intermediate, has been stipulated to conduct sterility test and antigen content determination. Detailed information shall be found in 3.2.P.3.4. The process validation of Hepatitis A (Live) Vaccine, Freeze-dried (hereinafter referred as “fHAV”) started from June, 2018, which has validated the consecutive production of 3 batches of final bulk and 3 batches of final product. Summarize test data of various quality control points for the intermediates, validate process stability of bulk production and investigate stability of bulk validity. It can be known from summary, analysis and evaluation of production data and test data that test data of various quality control points for the intermediates meets quality standards, all the production process is consistent with the approved procedures, product quality meets quality standards and there is no significant lot-to-lot difference. The product has stable production process from virus harvest solution to the finished product and reliable quality. Production process validation of fHAV meets quality standards and validation standards and it's applicable to production of fHAV.
Specifications	According to the requirements in Chinese Pharmacopoeia, and Registration Standard of Hepatitis A (Live) Vaccine, Freeze-dried YBS05142020, final product is tested with identity test, appearance, water, pH value, osmolality, determination of residual chloroform, virus titration, thermos-stability test, residual bovine serum albumin, residual antibiotics, sterility test, abnormal toxicity test, bacterial endotoxins, integrity test. The appearance of final product shall be milky white loose substance, after reconstitution, shall be clear liquid, without foreign matter; identity test shall prove the presence of hepatitis A virus antigen; the water content shall be no more than 2.9%; the pH value shall be 6.8 ± 0.5; osmotic pressure molar concentration shall be 250-310mOsmol/kg; the residual chloroform content shall be no more than 0.006%; the virus titer shall be within 6.67 - 7.67 lgCCID₅₀/mL; in the thermos-stability test, virus titer shall be no less than 6.50 lgCCID₅₀/mL, and the reduction of virus titer shall be no more than 0.50 lgCCID₅₀/mL; the residual bovine serum albumin shall be no more than 50ng/dose; the residual antibiotics shall be no more than 50ng/dose; the sterility test shall be negative; the results of abnormal toxicity shall be in accordance with specifications; the bacterial endotoxin shall be no more than 50EU/dose; the results of container closure integrity test shall be no methylene blue leaking into the vial in the test sample.

Container Closure	The container closure system of fHAV is vial, which is the injection vial made of low borosilicate glass tubing, stopped with brominated butyl rubber plug for freeze-drying for injection and capped by aluminum and plastics combined caps for antibiotics vials (cap color is orange).
Stability	- Summary of stability study prior to marketing In stability test of Hepatitis A (live) Vaccine, Freeze-dried, Institute of Medical Biology Chinese Academy of Medical Sciences has studied long-term stability at 2~8°C for 24 months and accelerated stability at 25°C for 56 days and at 37°C for 28 days over 3 consecutive batches (batch no.: S20130901, S20130902, S20130903) of samples produced in 2013. Accelerated stability of Hepatitis A (live) Vaccine, Freeze-dried at 25°C and 37°C has been investigated, indicating that the freeze-dried product has good thermo-stability. - Summary of validation of storage period of fHAV during process validation Based on the quality results of the final products of three validation batches of fHAV at 2~8°C for stability study, it can be confirmed that the vaccine produced by the production process of Hepatitis A (Live) Vaccine, Freeze-dried has good safety and stability. - Additional stability study In order to further verify the stability of fHAV, an additional stability protocol (for 36 months) for fHAV (protocol no.: QAW-2022-03-02) was formulated and three consecutive batches of fHAV (batch numbers: 202112014K-2, 202112015K-2, 202112016K-2) were selected for long-term stability study at 2-8°C. By February 2024, the study for 24 months has been completed. The stability study results for 24 months are now being statistically reported. The study for 36 months is still on-going, and it is expected to be completed in February next year. Please find the protocol and report for 24 months in 3.2.P.8.
Module 4- Nonclinical Reports	
Pharmacology:	A small number of experiments have found that rhesus macaques have a certain susceptibility to hepatitis A virus. In 1985, the values of anti-hepatitis A virus antibody (anti-HAV), serum alanine aminotransferase (ALT), lactate dehydrogenase isoenzyme (LDH5) and isocitrate dehydrogenase (ICD) in 267 healthy rhesus macaques was measured, and established normal indexes for ALT and LDH5. After that, the rhesus macaques inoculated with H2 vaccine strain and the others in the control group were challenged with a wild strain of hepatitis A virus (He-32), and it was found that the above indexes did not undergo an abnormal increase in the vaccination group compared with the control group. On the other hand, the virulence of the three strains with different attenuated levels was compared. The results identified the H2M20K5 (32°C) strain as the master strain for the production of live attenuated vaccines. However, although rhesus macaques are susceptible to hepatitis A virus, multiple experiments have found that the levels of hepatitis A antibodies, liver enzymes, and pathological changes in liver tissues are not stable, indicating that the sensitivity is limited. In order to find an animal model of hepatitis A that is more sensitive than rhesus macaques, a comparative study was conducted between the Australian marmoset (<i>Callitrix jacchus</i>) and the rhesus macaques. It was found that the response to challenge by the same dose of the same virulent strain was completely different between the two animals. After challenged by the wild virus, the liver of marmosets underwent obvious pathological changes, and the titer of hepatitis A antibody was about 1,000 times higher than that of rhesus macaques, and the ALT and/or ICD were irregularly increased. Nevertheless, for rhesus monkeys, no pathological changes were observed in the liver, the antibody titer was

		very low, and the activity of liver enzymes was normal. It is indicated that the marmosets were more sensitive to Hepatitis A virus than rhesus macaques. Additionally, the marmosets were injected with two wild virus strains with different virulence and two different doses of live attenuated hepatitis A vaccine, and the responses of the two virulent strains were completely identical, that is, the liver tissue was persistently damaged, the antibody titer was high, and most of the liver function indexes were increased. However, the marmosets inoculated the vaccine strains had no pathological changes in the liver, low antibody titers, and normal liver function indexes. These results suggest that the common marmoset is a more ideal animal model of hepatitis A, and the level of hepatitis A antibody and liver pathology can be used as important indicators to distinguish virulence
	Toxicology: • Repeat-dose (IM) in animals • Local tolerance (site histology) • Reproductive & developmental studies	In both rhesus monkey and mice model, the results showed that the fHAV is safe, which supports its further evaluation in human clinical studies. The experimental results indicate that the live attenuated hepatitis A vaccine (H2 strain) possesses strong immunogenicity and weak toxicity. Monkeys vaccinated with this vaccine can protect themselves against the challenge of virulent HAV strains, providing essential data for human trials of the vaccine. After comparing the seroconversion rate, enzyme activities and liver lesions, the results showed that there was no abnormality in the marmosets infected with the vaccine strain, while the wild strain caused hepatitis A pathological changes in the livers of all animals.
Module 5 – Clinical Study Reports		
	Biopharmaceutics Not applicable for vaccines.	Not applicable
	Clinical Efficacy & Safety ☐ Phase I/II: Dose-ranging, immunogenicity in adults and infants.	The Phase I clinical trial of Hepatitis A vaccine was first launched in 1987 in 10 people with negative hepatitis A antibody reaction. Eventually, 12 subjects received the investigational vaccine subcutaneously and were closely observed for 20 weeks. None of the subjects developed any local or systemic reactions. The seroconversion occurred in 3 weeks after inoculation with the anti-HAV antibody titer ranging from 1:2 to 1:8 and GMT of 1:3.48 at 20 weeks after inoculation, which primarily indicates the good safety and immunogenicity of this vaccine.
	• Phase III: Multi-regional, randomized, controlled studies demonstrating safety, immunogenicity, and efficacy across diverse geographic populations.">90% seroconversion rate. • Post-marketing: Ongoing surveillance confirms long-term efficacy and rare adverse event rates.	In the phase III clinical trial, the safety and immunogenicity was further proved. Compared with the liquid vaccine, the local reaction rates of freeze-dried vaccine group is 1.34%. Besides, the reaction symptoms are mild: rate of abnormal reaction on body temperature (fever) is 2.15%. Both rates are lower than that of liquid vaccine group. For immunogenicity, the results on serum anti-body test 1 and 2 months after the inoculation indicates that the positive conversion rates of freeze-dried vaccine group are respectively 99.7% and 100%, higher than that of liquid vaccine group. For the antibody titer comparison, serum antibody GMT of the freeze-dried hepatitis A vaccine in month 1 and month 2 are respectively 1,249 and 893. Since the vaccine was first launched in China in 1992, it was administered to over 200 million subjects and protected people from hepatitis A virus. Based on the real-world observation data, the incidence of adverse event is around 18/100,000 doses in the recent 3 years. In addition, throughout the past 15 year, from 2008-2022, no absolute number and proportion of the reported number of specific ADRs were higher than expected values, the ratio of the reported number of ADRs to the sales volume was higher than the expected value in the unit time, the prognosis of the vast majority of ADRs was good, the vast majority of ADRs occurred within 3 days after vaccination, there was no significant gender difference in the number of ADRs, the vast majority of recipients met the age of vaccination, no cluster events of adverse vaccine reactions occurred, and no new abnormal

		reactions were found after simultaneous vaccination with other vaccines. Thus, the safety and efficacy of the vaccine can be strongly confirmed.
	Post-marketing Data	Since the vaccine was first launched in China in 1992, it was administered to over 200 million subjects and protected people from hepatitis A virus. Based on the real-world observation data, the incidence of adverse event is around 18/100,000 doses in the recent 3 years. In addition, throughout the past 15 year, from 2008-2022, no absolute number and proportion of the reported number of specific ADRs were higher than expected values, the ratio of the reported number of ADRs to the sales volume was higher than the expected value in the unit time, the prognosis of the vast majority of ADRs was good, the vast majority of ADRs occurred within 3 days after vaccination, there was no significant gender difference in the number of ADRs, the vast majority of recipients met the age of vaccination, no cluster events of adverse vaccine reactions occurred, and no new abnormal reactions were found after simultaneous vaccination with other vaccines. Thus, the safety and efficacy of the vaccine can be strongly confirmed.
	Miscellaneous Documents in Compliance to WHO Requirements ✓ A statement by the Applicant to confirm whether the product has been rejected, withdrawn from the markets/countries. ✓ Information on the type of the product if was produced using a GMO technology, ✓ Evidence of valid GMP certificate. ✓ Acceptable shipping condition for both finished product and Drug Substance and Formulated Bulks (for importing bulks for filling and domestic production). ✓ Proof of Shipping validation. ✓ A copy template of lot summary protocol in compliance with WHO-recommended format (identified as per specific WHO TRS). ✓ A copy of labels (vial and carton).	
	Remarks of the Assessor: • Submit module 1 as per final guidance document for biological products. • Clarification is required whether the applied product is combo pack or otherwise. In case of combo pack separate P part is required. • Legalized/apostille, valid and signed COPP is required. • The Trade name is mentioned on COPP but not provided by applicant. • The manufacturing site mentioned on DML is different than COPP. • The provided evidence of approval in RRA is of Inactivated vaccine whereas, applied vaccine is Live. Provide RRA reference for Live attenuated vaccine in same in same dose, strength, route of administration and container closure system. • Presence, prevalence, and public health relevance strain H2 in Pakistan. • The recommended dose and route of administration is not as per WHO position paper. • Provide vaccine is manufactured under which WHO TRS or is a new vaccine for which WHO TRS is not yet developed. • The vaccine is indicated for 1.5 year and above with a dose of 1ml whereas WHO position paper states 0.5ml for children and 1 ml for adults. Moreover, WHO position paper October 2022 states that live attenuated vaccines are licensed for children above 18 months and administered via SC dose. • Provide justification where NA has been mentioned for non-clinical study reports. • The route of administrative in clinical study report is SC. • The target population in phase III studies is 6-16 years whereas; it is indicated for 1.5 year. • Justification is required for not performing phase II. • Documents for shipping validation of finished product. • List of countries whether the vaccine is imported. • Peer-reviewed scientific publications or technical reports substantiating claims related to the strain's performance and relevance. • Adverse Events Following Immunization (AEFI) reports and Periodic Safety Update Reports (PSUR)	
	Conclusion: The applied vaccine is not approved as live attenuated in any RRA as no evidence has been submitted and is deficient for the submission of above cited documents.	
	Decision of 348th Meeting The Registration Board deferred the case for the submission of the following documents: • Module 1 as per final guidance document for biological products.	

- Clarification is required whether the applied product is combo pack or otherwise. In case of combo pack separate P part is required.
- Legalized/apostille, valid and signed COPP is required.
- The Trade name is mentioned on COPP but not provided by applicant.
- The manufacturing site mentioned on DML is different than COPP.
- The provided evidence of approval in RRA is of Inactivated vaccine whereas, applied vaccine is Live. Provide RRA reference for Live attenuated vaccine in same in same dose, strength, route of administration and container closure system.
- Presence, prevalence, and public health relevance strain H2 in Pakistan.
- The recommended dose and route of administration is not as per WHO position paper.
- Provide vaccine is manufactured under which WHO TRS or is a new vaccine for which WHO TRS is not yet developed.
- The vaccine is indicated for 1.5 year and above with a dose of 1ml whereas WHO position paper states 0.5ml for children and 1 ml for adults. Moreover, WHO position paper October 2022 states that live attenuated vaccines are licensed for children above 18 months and administered via SC dose.
- Provide justification where NA has been mentioned for non-clinical study reports.
- The route of administrative in clinical study report is SC.
- The target population in phase III studies is 6-16 years whereas; it is indicated for 1.5 year.
- Justification is required for not performing phase II.
- Documents for shipping validation of finished product.
- List of countries whether the vaccine is imported.
- Peer-reviewed scientific publications or technical reports substantiating claims related to the strain's performance and relevance.
- Adverse Events Following Immunization (AEFI) reports and Periodic Safety Update Reports (PSUR)

Agenda Item No 2
Registration Applications of Monoclonal Antibodies

Trastuzumab	2
Denosumab	2
Omalizumab	2
Ocrelizumab	1
Atezolizumab	1
Total	8

Deferred Cases M-347

Trastuzumab
Biosimilar to Herceptin (Claimed)
(Drug Substance Import and Local Manufacturing)

Case # 20

Name, address of Applicant / Importer	Company Name: Macter International Limited Company Address: F-216,S.I.T.E.,Karachi-Pakistan
Details of License	License Type: Drug Manufacture License License Number: 000141 License Issue Date: 2021-08-03
Details of Section	Firm has requisite section i.e. liquid and lyophilized section rDNA section.
Status of the applicant	Manufacturer
Status of application	Similar Bio therapeutic Product
Intended use of pharmaceutical product	Domestic and Export Sales
For imported products specify one the these	--
Dy. No. and date of submission	Tracking ID:BBZ-G9S-LG67 Application Number:23364 Receiving: 13-09-2024
Details of fee submitted	Challan Number: 183215913 Division: Biological Evaluation & Registration Paid Fee: 300000.0
The proposed proprietary name / brand name	Betrast 150mg Lyophilized Powder for Infusion
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Trastuzumab.....150mg

Dosage form of applied drug	IV Injection
Pharmacotherapeutic Group of (API)	Antineoplastic agents, monoclonal antibodies
Proposed Indication	Metastatic breast cancer ,early breast cancer and Meta static gastric cancer
Mechanism of Action	Upon binding to HER2, trastuzumab inhibits ligand-independent HER2 signaling and blocks HER2 activation mechanisms, including the proteolytic cleavage of the extracellular domain of HER2. This action suppresses the proliferation of HER2-overexpressing human tumor cells. Additionally, trastuzumab serves as a potential mediator of antibody-dependent cell-mediated cytotoxicity (ADCC).
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack size	-
Proposed unit price	As per SRO.
Shelf Life	24 Months
Storage Conditions	Store at 2-8°C. Do not freeze.
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
For generic drugs (me-too status)	Herceptin 150 mg Lyophilized Powder for infusion of M/s Roche Pakistan Ltd (Registration no 087086)
Module-II (Quality Overall Summary	Firm has submitted QOS as per WHO Template. Firm has summarized information related to general properties, manufacturers, description of manufacturing process and controls, characterization, specifications analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
Drug Substance Part	
Name, address of drug substance manufacturer	<u>Trastuzumab:</u> M/s. Hetero Biopharma Limited Address: Sy. No. 458 (Part), TSIIC - Formulation SEZ, Polepally Village, Jadcherla Mandal Mahaboobnagar District – 509301, Telangana State, India
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of batches (i.e. Pre-Clinical Trial (PCT) & clinical trial batches Batches at accelerated and real time conditions. The real time stability data is conducted at (-20°C±5°C) for 36 months. Accelerated study is conducted at (5±3°C) for 6 months on same batches.
Drug Product Part	
Module-III Drug Product:	
Drug Product manufacturer	Macter International Limited. DML NO: 000141 ADDRESS: F- 216, S.I.T.E, Karachi 75700, Pakistan. Tel: 021- 32591000 Ext.2007 FAX: 2564263, 2565854 & 2566894
Analytical method validation/verification of product	Not submitted.
Container closure system of the drug product	15 ml USP type 1 clear glass vials accompanied with 20 mm double slit butyl grey rubber stopper and 20 mm Flip off aluminum Seals (Green).
Stability study data of drug product, shelf life and storage conditions	Firm has submitted long term stability study data of 3 batches at 5±3°C for 06 months. The accelerated stability study data is conducted at 25±2°C & 60±5%RH for 6 months. Shelf life: The intended shelf life for betrast infusion in vial at 5°C ± 3°C is therefore designated to be two years.
Bio similarity Studies	Step of lyophilisation is being performed after filling but applicant has not submitted bio-similarity studies.
Remarks of the Evaluator:	
Although the formulated drug substance is described as a “ready to fill bulk,” it should be clarified that additional critical manufacturing steps are done at the applicant site. Specifically, these steps include thawing, aseptic filtration of the formulated drug substance, aseptic filling into sterile primary containers, and lyophilization of the filled product.	

	Therefore, while the bulk is fully formulated, it should not be considered “ready to fill” in the conventional sense, as these critical processing steps—particularly lyophilization—are integral to the final drug product manufacturing, safety and efficacy and are performed at the applicant site.
Comments by BE&R The drug product manufacturer has not performed bio similarity studies.	
Decision of 347th Meeting: The Registration Board deferred the case for submission of justification in the light of reference guidelines that thawing, aseptic filtration and lyophilization has no impact on quality, safety and efficacy of product or performance of biosimilarity studies as per WHO guidelines by the applicant.	
Comments by BE&R Decision of 347th Meeting: The Registration Board deferred the case for submission of justification in the light of reference guidelines that thawing, aseptic filtration and lyophilization has no impact on quality, safety and efficacy of product or performance of biosimilarity studies as per WHO guidelines by the applicant. Applicant Response The manufacturing steps of thawing, aseptic filtration, and lyophilization involved in the production of Betrast (Trastuzumab) are standard, validated unit operations and are conducted under strictly controlled conditions that ensure product quality is maintained. 1. Thawing is performed at 2–8°C to preserve protein stability and maintain homogeneity. Each batch is sampled and tested for protein content before further processing. Aseptic filtration through a 0.45+ 0.22µm filter is performed under laminar airflow using sterilized equipment. The 0.45+ 0.22µm filter will remove any visible particles or contaminants from the bulk, resulting in a sterile and particle-free filtered bulk. Since trastuzumab is a bioactive polypeptide molecule, it degrades when exposed to high temperatures. For this reason, we opted for sterilization of final bulk via capsule filters and heat sterilization was avoided. The process is carefully monitored using: • Filter integrity testing (bubble point) before & after filtration, • In-process controls including physical appearance, pH, osmolality, protein content, endotoxin levels, and bio burden, ensuring the bulk complies specification in quality, safety & potency. 2. Lyophilization is conducted in a validated cycle designed to remove moisture without altering the product’s structure. Our lyophilizer is provided with CIP & SIP system & is SCADA controlled which ensure equipment suitability. Lyophilization steps such as freezing, primary drying, secondary drying and stoppering is done by digitally controlled process. CIP & SIP are performed to maintain the integrity and sterility of the product. Lyophilization is a widely accepted strategy for enhancing long-term stability of biologicals. Critical quality attributes of product are tested (such as residual moisture, reconstitution time, cake appearance, potency). 3. To ensure the quality of the lyophilized product, the finished product is tested against the defined Critical Quality Attributes (CQAs). • Physical Appearance of Lyophilized Cake: Assesses cake integrity, color, and uniformity to detect issues during freeze-drying. • Reconstitution Time & Appearance: Ensures product reconstitutes clearly, without visible particles or delay. • Particulate Matter (Post-Reconstitution): Confirms absence of visible or sub-visible particles to meet pharmacopeial standards. • Color: Visual inspection for consistency and absence of discoloration. • pH: Ensures stability and suitability for intended use; must remain within 6.0 ± 0.5. Osmolality: Confirms formulation consistency and compatibility with physiological conditions. • Residual Moisture Content: Indicates proper execution of lyophilization; low moisture ensures stability. • Extractable Volume: Confirms correct fill volume within validated limits. • Protein Content by UV (OD @ 280 nm): Confirms dosage uniformity and protein concentration. • Relative Potency by BT-474 Cell Anti-Proliferation Assay: A functional bioassay to confirm biological activity and receptor binding. This assay measures the ability of the product to bind to the HER2 receptor and inhibit the proliferation of HER2-overexpressing BT-474 breast cancer cells, which is the established mechanism of action for trastuzumab. As such, it directly reflects the product’s biological function and is a critical indicator of potency, efficacy, and structural integrity. Consistent potency results within pre-defined acceptance criteria confirm that thawing, aseptic filtration, and lyophilization steps do not alter the molecular conformation or receptor-binding ability of the antibody, thereby supporting that there is no impact on clinical efficacy. • Weak Cation Exchange Chromatography (WCX): Detects charge variants; confirms molecular integrity and stability. • Charge Variants by CEX: Provides high-resolution analysis of isoform distribution. • Size Exclusion Chromatography (SEC): Confirms absence of high molecular weight aggregates and product degradation. • Bacterial Endotoxins Test (BET): Ensures product safety; complies with pharmacopoeia limits. • Sterility: Confirms product is free from viable microorganisms; required for parenteral administration. All the above post-process tests are conducted after completion of thawing, aseptic filtration, and lyophilization. The results consistently fall within approved specifications, confirming that these steps do not adversely affect product identity, purity, potency, or safety. Conclusion No justification has been submitted in the light of reference guidelines that thawing, aseptic filtration and lyophilization has no impact on quality, safety and efficacy of product therefore, performance of biosimilarity studies as per WHO guidelines is required	

by the applicant.	
Decision of 348th Meeting:	
The Registration Board deferred the case for the submission of the Bio similarity studies as per WHO.	
Trastuzumab Biosimilar to Herceptin (Claimed) (Drug Substance Import and Local Manufacturing)	
Case # 21	
Name, address of Applicant / Importer	Company Name: Macter International Limited Company Address: F-216,S.I.T.E.,Karachi-Pakistan
Details of License	License Type: Drug Manufacture License License Number: 000141 License Issue Date: 2021-08-03
Details of Section	Firm has requisite section i.e. liquid and lyophilized section rDNA section.
Status of the applicant	Manufacturer
Status of application	Similar Bio therapeutic Product
Intended use of pharmaceutical product	Domestic and Export Sales
For imported products specify one the these	--
Dy. No. and date of submission	Tracking ID:MLV-ZLU-N5JM Application Number:23327 Receiving: 13-09-2024
Details of fee submitted	Challan Number: 90281964058 Division: Biological Evaluation & Registration Paid Fee: 300000.0
The proposed proprietary name / brand name	Betrast 440mg Lyophilized Powder for Infusion
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Trastuzumab.....440mg
Dosage form of applied drug	IV Injection
Pharmacotherapeutic Group of (API)	Antineoplastic agents, monoclonal antibodies
Proposed Indication	Metastatic breast cancer ,early breast cancer and Meta static gastric cancer
Mechanism of Action	Upon binding to HER2, trastuzumab inhibits ligand-independent HER2 signaling and blocks HER2 activation mechanisms, including the proteolytic cleavage of the extracellular domain of HER2. This action suppresses the proliferation of HER2-overexpressing human tumor cells. Additionally, trastuzumab serves as a potential mediator of antibody-dependent cell-mediated cytotoxicity (ADCC).
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack size	-
Proposed unit price	As per SRO.
Shelf Life	24 Months
Storage Conditions	Store at 2-8°C. Do not freeze.
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
For generic drugs (me-too status)	Herceptin 440 mg Lyophilized Powder for infusion of M/s Roche Pakistan Ltd (Registration no 087085)
Module-II (Quality Overall Summary	Firm has submitted QOS as per WHO Template. Firm has summarized information related to general properties, manufacturers, description of manufacturing process and controls, characterization, specifications analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
Drug Substance Part	

Name, address of drug substance manufacturer	Name and address (including block(s)/unit(s))	Responsibility	API-PQ number/APIMF/CEP number (if applicable)
	M/s. Hetero Biopharma Limited, Sy. No. 458 (Part), TSIIIC-Formulation SEZ, Polepally (Village), Jadcherla (Mandal) Mahaboobnagar (District) – 509 301, Telangana State, India. Tel: +91-8542-227500 Email id: contact.hbl@heterodrugs.com	• Source and release of raw materials. • Storage and release of the cell bank. • Manufacturing of drug substance. • Quality control (Chemical/Physical: Microbiological, sterility, and Biological). • Packing /storage/labelling and distribution of the drug substance.	Not Applicable.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of batches (i.e. Pre-Clinical Trial (PCT) & clinical trial batches Batches at accelerated and real time conditions. The real time stability data is conducted at (-20°C±5°C) for 36 months. Accelerated study is conducted at (5±3°C) for 6 months on same batches.		
Drug Product Part			
Module-III Drug Product:	Company Name: Macter International Limited Company Address: F-216,S.I.T.E.,Karachi-Pakistan		
Drug Product manufacturer	Trastuzumab lyophilized powder for infusion is provided along with 20 ml vial of BWFI (Bacteriostatic water for injection) as a reconstituting diluent.		
Analytical method validation/verification of product	The specifications & analytical procedures are submitted along with validation of Analytical Procedures		
Container closure system of the drug product	30 ml USP type 1 clear glass vials accompanied with 20 mm double slit butyl grey rubber stopper and 20 mm Flip off aluminum Seals (Green).		
Stability study data of drug product, shelf life and storage conditions	Firm has submitted long term stability study data of 3 batches at 5±3°C for 06 months. The accelerated stability study data is conducted at 25±2°C & 60±5%RH for 6 months. Shelf life: The intended shelf life for betrast infusion in vial at 5°C ± 3°C is therefore designated to be two years.		
Bio similarity Studies	Step of lyophilisation is being performed after filling but applicant has not submitted complete bio-similarity studies as per WHO guidlines.		
Remarks of the Evaluator: Although the formulated drug substance is described as a “ready to fill bulk,” it should be clarified that additional critical manufacturing steps are done at the applicant site. Specifically, these steps include thawing, aseptic filtration of the formulated drug substance, aseptic filling into sterile primary containers, and lyophilization of the filled product. Therefore, while the bulk is fully formulated, it should not be considered “ready to fill” in the conventional sense, as these critical processing steps—particularly lyophilization—are integral to the final drug product manufacturing, and are performed at the applicant site.			
Comments by BE&R The drug product manufacturer has not performed bio similarity studies.			
Decision: The Registration Board deferred the case for submission of justification in the light of reference guidelines that thawing, aseptic filtration and lyophlization has no impact on quality, safety and efficacy of product or performance of biosimilarity studies as per WHO guidelines by the applicant.			
Comments by BE&R			
Decision of 347th Meeting: The Registration Board deferred the case for submission of justification in the light of reference guidelines that thawing, aseptic filtration and lyophlization has no impact on quality, safety and efficacy of product or performance of biosimilarity studies as per WHO guidelines by the applicant.			
Applicant Response The manufacturing steps of thawing, aseptic filtration, and lyophilization involved in the production of Betrast (Trastuzumab) are standard, validated unit operations and are conducted under strictly controlled conditions that ensure product quality is maintained. 1. Thawing is performed at 2–8°C to preserve protein stability and maintain homogeneity. Each batch is sampled and tested for protein content before further processing. Aseptic filtration through a 0.45+ 0.22µm filter is performed under laminar airflow using sterilized equipment. The 0.45+ 0.22µm filter will remove any visible particles or contaminants from the bulk, resulting in a sterile and particle-free filtered bulk. Since trastuzumab is a bioactive polypeptide molecule, it degrades when exposed to high temperatures. For this reason, we opted for sterilization of final bulk via capsule filters and heat sterilization was avoided. The process is carefully monitored using: • Filter integrity testing (bubble point) before & after filtration, • In-process controls including physical appearance, pH, osmolality, protein			

content, endotoxin levels, and bio burden, ensuring the bulk complies specification in quality, safety & potency.

2. Lyophilization is conducted in a validated cycle designed to remove moisture without altering the product's structure. Our lyophilizer is provided with CIP & SIP system & is SCADA controlled which ensure equipment suitability. Lyophilization steps such as freezing, primary drying, secondary drying and stoppering is done by digitally controlled process. CIP & SIP are performed to maintain the integrity and sterility of the product. Lyophilization is a widely accepted strategy for enhancing long-term stability of biologicals. Critical quality attributes of product are tested (such as residual moisture, reconstitution time, cake appearance, potency).

3. To ensure the quality of the lyophilized product, the finished product is tested against the defined Critical Quality Attributes (CQAs).

- **Physical Appearance of Lyophilized Cake:** Assesses cake integrity, color, and uniformity to detect issues during freeze-drying.
- **Reconstitution Time & Appearance:** Ensures product reconstitutes clearly, without visible particles or delay.
- **Particulate Matter (Post-Reconstitution):** Confirms absence of visible or sub-visible particles to meet pharmacopeial standards.
- **Color:** Visual inspection for consistency and absence of discoloration.
- **pH:** Ensures stability and suitability for intended use; must remain within 6.0 ± 0.5 .
- **Osmolality:** Confirms formulation consistency and compatibility with physiological conditions.
- **Residual Moisture Content:** Indicates proper execution of lyophilization; low moisture ensures stability.
- **Extractable Volume:** Confirms correct fill volume within validated limits.
- **Protein Content by UV (OD @ 280 nm):** Confirms dosage uniformity and protein concentration.
- **Relative Potency by BT-474 Cell Anti-Proliferation Assay:** A functional bioassay to confirm biological activity and receptor binding. This assay measures the ability of the product to bind to the HER2 receptor and inhibit the proliferation of HER2-overexpressing BT-474 breast cancer cells, which is the established mechanism of action for trastuzumab. As such, it directly reflects the product's biological function and is a critical indicator of potency, efficacy, and structural integrity. Consistent potency results within pre-defined acceptance criteria confirm that thawing, aseptic filtration, and lyophilization steps do not alter the molecular conformation or receptor-binding ability of the antibody, thereby supporting that there is no impact on clinical efficacy.
- **Weak Cation Exchange Chromatography (WCX):** Detects charge variants; confirms molecular integrity and stability.
- **Charge Variants by CEX:** Provides high-resolution analysis of isoform distribution.
- **Size Exclusion Chromatography (SEC):** Confirms absence of high molecular weight aggregates and product degradation.
- **Bacterial Endotoxins Test (BET):** Ensures product safety; complies with pharmacopoeia limits.
- **Sterility:** Confirms product is free from viable microorganisms; required for parenteral administration.

All the above post-process tests are conducted after completion of thawing, aseptic filtration, and lyophilization. The results consistently fall within approved specifications, confirming that these steps do not adversely affect product identity, purity, potency, or safety.

Conclusion

No justification has been submitted in the light of reference guidelines that thawing, aseptic filtration and lyophilization has no impact on quality, safety and efficacy of product therefore, performance of biosimilarity studies as per WHO guidelines is required by the applicant.

Decision of 348th Meeting:

The Registration Board deferred the case for the submission of the Bio similarity studies as per WHO.

DENOSUMAB

Denosumab has two Reference Products (RP) with different presentations and therapeutic indications:

- **Prolia®** (denosumab 60 mg/1 mL, PFS, s.c. administration) is approved since 2010 for the treatment of bone resorption and postmenopausal osteoporosis (FDA 2010; EMA 2010). It is named Pralia® in Japan.
- **Xgeva®** (denosumab 120 mg/1.7 mL, vial, s.c. administration) is approved since 2011 in EU and 2013 in US for the treatment of bone fractures and neoplasm metastasis (EMA 2011; FDA 2013). It is named Ranmark® in Japan.

Biosimilar to Prolia Exporting Country for bulk Import (China) Local Secondary Packaging

Case # 22

Name, address of Applicant / Importer	M/s Getz Pharma (Pvt) Limited Company Address: 29-30/27, Korangi Industrial Area karachi Site Address: Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi
Details of Drug Sale License of importer	License Type: Drug Manufacture License
Name and address of marketing authorization holder (abroad)	M/s Qilu Pharmaceutical Co., Ltd. No. 8888, Lvyou Road, High-tech Zone, Jinan, Shandong Province, China
Name, address of manufacturer(s)	M/s Qilu Pharmaceutical Co., Ltd. No. 8888, Lvyou Road, High-tech Zone, Jinan, Shandong Province, China
Name of exporting country	China
Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	<u>Scanned Apostille CoPP</u> Certificate no. No. Shandong 20241260

	Certifying Authority: Shandong Provincial Medical Products Administration The COPP specifies that the product is licensed for sale in country of origin. Validity: 08-12-2026		
Details of letter of authorization / sole agency agreement	<u>Manufacturing and Supply Agreement</u> <table border="1"> <tr> <td>1. Parties</td><td> Getz Pharma (Private) Limited ("Getz Pharma") located at Plot No.: 29-30, Sector 27, Korangi Industrial Area, Karachi – 74900 Pakistan and Qilu Pharmaceutical Co., Ltd ("Supplier") registered at No.317, Xinluo Road, High-tech Zone, Jinan, Shandong Province, China and the manufacturing location at No.8888 Lvyu Road, High-tech Zone, Jinan 250104, China. </td></tr> </table> <u>Validity: 30-09-2029</u>	1. Parties	Getz Pharma (Private) Limited ("Getz Pharma") located at Plot No.: 29-30, Sector 27, Korangi Industrial Area, Karachi – 74900 Pakistan and Qilu Pharmaceutical Co., Ltd ("Supplier") registered at No.317, Xinluo Road, High-tech Zone, Jinan, Shandong Province, China and the manufacturing location at No.8888 Lvyu Road, High-tech Zone, Jinan 250104, China.
1. Parties	Getz Pharma (Private) Limited ("Getz Pharma") located at Plot No.: 29-30, Sector 27, Korangi Industrial Area, Karachi – 74900 Pakistan and Qilu Pharmaceutical Co., Ltd ("Supplier") registered at No.317, Xinluo Road, High-tech Zone, Jinan, Shandong Province, China and the manufacturing location at No.8888 Lvyu Road, High-tech Zone, Jinan 250104, China.		
Status of the applicant	Importer		
Status of application	Similar Bio therapeutic Product		
Intended use of pharmaceutical product	Domestic and Export Sales		
For imported products specify one the these	Bulk Import Local Repacking.		
Dy. No. and date of submission	Tracking ID:PPD-D2D-QXEL Application Number:86062 Receiving: 26-03-2025		
Details of fee submitted	Challan Number: 52474807937 Division: Biological Evaluation & Registration Paid Fee: 300000.0 Paid Date: 2025-03-06		
The proposed proprietary name / brand name	Denomab Solution for Injection		
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml vial contains: Denosumab 60 mg		
Dosage form of applied drug	SC Injection		
Pharmacotherapeutic Group of (API)	Drugs for treatment of bone diseases – Other drugs affecting bone structure and mineralisation, human monoclonal antibody (IgG2) ATC code: M05BX04		
Proposed Indication	For osteoporosis in post-menopausal women at high risk of fractures. In post menopausal women reduces the risk of vertebral, non vertebral and hip fractures,		
Mechanism of Action	Denosumab is a fully human monoclonal antibody of IgG2 subtype, inhibiting RANK ligand (RANKL), which is an essential factor for the formation, activation and survival of osteoclasts (see Figure 1). Inhibition of RANKL is a possible intervention point to interfere with conditions with increased bone resorption. RANKL production is increased when estrogen is decreased, as it is after menopause and in conditions of hormone ablation, leading to an increased bone resorption. Mechanism of action for denosumab. CFU-M - colony-forming unit-macrophage; OPG = Osteoprotegerin; RANK = receptor activator of nuclear factor-κB; RANKL = RANK ligand		
Reference to Finished product specifications	As per Innovators Specification		
Proposed Pack size	1ml		
Proposed unit price	As per SRO228(I)/2024.		
Shelf Life	24 Months		
Storage Conditions	Store at 2-8°C. Do not freeze.		

The status in reference regulatory authorities	Prolia 60 mg solution for injection EMA Approved. pre-filled syringe vial		
For generic drugs (me-too status)	Product Name: PROLIA Registration No: 077527 Registration Date: 2014-07-18		
Module-II (Quality Overall Summary	Firm has submitted QOS as per WHO Template. Firm has summarized information related to general properties, manufacturers, description of manufacturing process and controls, characterization, specifications analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.		
Drug Substance Part			
Name, address of drug substance manufacturer	Name and address (including block(s)/unit(s))		Responsibility
	Qilu Pharmaceutical Co., Ltd. 8888 Lvyou Road, high-tech zone, Jinan, 250104, China DUNS: 544532200 Phone: +86-531-5568-1374		Drug substance manufacturing
	Qilu Pharmaceutical Co., Ltd. 8888 Lvyou Road, high-tech zone, Jinan, 250104, China DUNS: 544532200 Phone: +86-531-5568-1374		Analysis, release and stability study of Drug Substance
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	According to ICH Q5C Stability Testing of Biotechnological/Biological Products, stability studies were conducted on Phase I/III clinical batch Drug Substance (201902001JNN) and 3 batches of Process Performance Qualification (PPQ) batches Drug Substance (202211002JNN, 202211003JNN, 202211004JNN) during clinical studies, of which long-term and accelerated stability studies were conducted on Phase I/III clinical batch Drug Substance, and comprehensive stability studies were conducted on 3 batches of PPQ batch Drug Substance, including high temperature, freeze-thaw,accelerated and long-term tests of Drug Substance.		
	Stability study	Study condition	Packaging material
	Long-term	-20°C±5°C	Disposable storage bag
	Accelerated	5°C±3°C	
			Testing interval (month)
			0, 3, 6, 9, 12, 18 (PPQ batches), 18, 24 (Clinical phase I & III batch)
			0, 1, 3, 6
Drug Product Part			
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.		

Drug Product manufacturer	Address	Responsibility	Manufacturer Information
	Qilu Pharmaceutical Co., Ltd. Unit 3300, 8888 Lvyou Road, High-tech Zone, Jinan, Shandong Province, 250104, P.R.China	Drug Product Manufacturing	Manufactured by: Qilu Pharmaceutical Co., Ltd. Registered address: No. 317, Xinluo Street, Hi-tech Zone, Jinan, Shandong Province Post Code: 250101 Tel.: 0531-83126666 Fax: 0531-83126688
	Qilu Pharmaceutical Co., Ltd. QC Unit V, 8888 Lvyou Road, High-tech Zone, Jinan, Shandong Province, 250104, P.R.China	Drug Product Release Testing, Drug Product Stability Studies	
	Qilu Pharmaceutical Co., Ltd. QC Unit III, No.849 Dongjia Town, Licheng Zone, Jinan, Shandong, P.R.China	Sterility test	
Analytical method validation/verification of product	Firm has submitted the details of analytical method validation.		
Container closure system of the drug product	2ml neutral borosilicate glass tube vials for injection, chlorobutyl rubber stopper coated with FEP (fluorinated ethylene propylene) film for injection and aluminiumplastics combination caps for antibiotics bottles were chosen to be the inner packaging material of this produc.		
Stability study data of drug product, shelf life and storage conditions	The stability studies for three batches of PPQ batches of this drug product have been completed under accelerated (25°C ± 2°C / 60% RH ± 5% RH, Upright and Inverted, the inverted condition was performed only in 1st PPQ batch), high temperature (40°C± 2°C) and photostability (Illuminance 5,000 lx, ultraviolet 90 µw/cm2 , 25°C ± 2°C) conditions, and the long-term (5°C ± 3°C) stability studies for PPQ batches are ongoing with 12-month data available to the shelf-life date..		

PART A - ADMINISTRATIVE INFORMATION

Bio similarity Studies

Reference of biosimilar guidelines	Technical guidelines for the Research , development and Evaluation of Biosimilar NMPA Interim Technical guidelines for Similarity Assessment and indication extrapolation of Biosimiliars, NMPA.
Name of the RBP	Prolia
Authorized indications for RBP	Treatment of osteoporosis in postmenopausal women.
Pharmaceutical form	Solution for injection
Quantitative composition	60mg/1ml PFS.
Route of administration	SC
Packaging/material	PFS
Package size(s)	1's PFS
License number (of RBP)	1097037
Date of authorization (of RBP)	-
Authorization (License) Holder (of RBP)	Amgen, Netherlands
Source of RBP (or other comparator) for comparability exercise	For Quality Similarity Study USA Puerto Rico.
Availability of the RBP assessment report (language)/link	NA
Comparability exercise to demonstrate similarity to RBP	Physicochemical and biological characterization study. Comparative in vitro and in vivo non-clinical studies (PK/PD study) Comparative clinical studies(PK, efficacy, safety and immunogenicity).
Indications applied for (if different to RBP)	None

PART B - SUBMITTED DATA

Quality data. State-of-the-art methods(Same composition as that of Prolia)

Characterization

A comprehensive study on the structure, physicochemical properties, biological activity and immunological characteristics was conducted with

7 batches of This products and 9 batches of innovator products in the Chinese market, and a comparability study was conducted with the main quality indicators of all 10 batches of innovator products in the Chinese market.

Nonclinical data. In vitro studies

Primary pharmacodynamics: This product is a fully human monoclonal IgG2 antibody that targets RANKL. Based on the molecular structure characteristics and mechanism of action of this product, the in vitro and in vivo pharmacodynamics were studied and compared with those of the reference listed drug (RLD)

In vitro pharmacodynamics (Volume 2): 1) Affinity of Fab fragment to RANKL; 2) Affinity of Fc fragment to neonatal Fc receptor (FcRn); 3) Effects on the differentiation of macrophages RAW 264.7 and mouse bone marrow cells into osteoclasts.

Nonclinical data. In vivo studies

In vivo pharmacodynamics: Considering that rodents are not pharmacologically relevant species, we evaluated and compared the effects of single and repeated dose(s) of this product and the RLD Denosumab on multiple bone biomarkers (type I collagen cross-linked C-telopeptide (CTX) and tartrate-resistant acid phosphatase (TRACP-5b)), and serum bone metabolism-related parameters (alkaline phosphatase (ALP), calcium ion (Ca²⁺), and phosphorus (PHOS)) in non-human primates in the pharmacokinetic and the 16-week repeat-dose toxicity studies in cynomolgus monkeys based on clinically relevant pharmacodynamic markers and test parameters. We also analyzed their effects on bone mineral density and bone mineral content in various sites of the live cynomolgus monkeys using a dual energy X-ray bone mineral density detector (USA).

Its safety pharmacology was evaluated in the 16-week repeat-dose toxicity study in cynomolgus monkeys, and compared with that of the RLD

CLINICAL STUDIES

- include relevant study data from the following (not all may be required) which have been included to demonstrate bio similarity.

- Pharmacokinetic, PK
- Pharmacodynamic, PD
- Efficacy,
- Safety,
- Immunogenicity.

A total of 2 clinical studies, including one phase I clinical study and one phase III clinical study.

The phase I clinical study (QL1206-002) is titled "A Randomized, Double-blind, Parallel Group Study to Compare the Pharmacokinetic, Safety and Pharmacodynamic of QL1206 and Prolia® in Healthy Adults".

The phase III clinical study (QL1206-004) is titled "A Multicenter, Randomized, Double-blind, Placebo-controlled Phase III Clinical Study to Evaluate the Efficacy and Safety of QL1206 in Postmenopausal Women with Osteoporosis at High Risk of Fracture"

Study Type	Study Code	Location of Appendix	Study Objectives	Study Design and Type of Control	Test Product; Dosing Regimen; Route of Administration	Number of Subjects	Diagnosed as Healthy Subjects or Patients	Treatment Duration	Study Status; Type of Appendix
Dose-ascending, Safety, Pharmacokinetic and Preliminary Pharmacodynamic Studies									
Phase I Clinical Study to Compare Pharmacokinetic, Safety and Pharmacodynamic	QL1206-002	5.3.3.1	Phase I: Primary Objective: To evaluate the PK similarity in healthy volunteers following single, subcutaneous injections of QL1206 or Prolia®. Secondary Objective: To evaluate the similarity of clinical safety and immunogenicity in healthy volunteers following single, subcutaneous injections of QL1206 or Prolia®, and to preliminarily observe the PD similarity of QL1206 and Prolia®.	Phase I: Single-center, randomized, double-blind, parallel group, active-controlled	Test Product: QL1206 Reference product: Prolia Route of administration/regimen: a single subcutaneous (SC) dose	Screened: 467 subjects Enrolled: 144 subjects QL1206 group: 72 subjects Prolia® group: 72 subjects	Healthy subjects: males or females aged ≥ 18 years and ≤ 50 years	134 days	Completed; full CSR
Phase III Clinical Study to Compare Efficacy and Safety	QL1206-004	5.3.5.1	Phase III: Primary Objective: To evaluate whether QL1206 has better efficacy than placebo in postmenopausal osteoporosis women with a high risk of fractures. Secondary Objective: To evaluate the clinical safety, immunogenicity, and PK profiles of QL1206 in postmenopausal osteoporosis women with a high risk of fractures Exploratory Objective: 1. If permitted by data, to evaluate the effect of ADA positive on the PK profiles of QL1206 in postmenopausal osteoporosis women with a high risk of fractures. 2. If permitted by data, to evaluate the relationship between QL1206 exposure and PD endpoints, efficacy, and adverse events (i.e., exposure-effect analysis) in postmenopausal osteoporosis women with a high risk of fractures.	Multicenter, randomized, double-blind, parallel group, placebo-controlled	Test group: QL1206 Control group: Prolia Route of administration/regimen: SC, once every 6 months (Q6M), 2 doses in total.	Screened: 935 subjects Enrolled: 455 subjects QL1206 group: 337 subjects Prolia® group: 118 subjects	Postmenopausal women with osteoporosis at high risk of fracture: lumbar or total hip bone mineral density (BMD) T-score ≤ -2.5 and > -4.0; with at least 1 of the following risk factors: history of fragility fracture, parent history of hip fracture, low body weight, elderly and smoking;	1 year	Completed; full CSR

Remarks of the Evaluator

- The Form 5F specifies applicant as an importer. However, the application has been filed under the Drug Manufacturing License (DML) and involves step of manufacturing i.e. secondary packaging.
- The agreement between the importer and exporter mentions the governing law of Singapore. Justification is required.

- The proposed clinical indication is the same for both strengths (60mg/ml and 70mg/1.7ml) and has been reflected accordingly in the Quality Overall Summary (QOS). Justification is needed. - Stability data for drug substance is required up to claimed shelf life (24 months). - Summary and conclusion of stability studies of drug product has not been submitted. - Details of secondary packaging material along with justification for not providing stability data with secondary packaging material - Submit BPR and secondary packaging validation as applicant is involved in secondary packaging. - In Nonclinical studies both reference products Prolia and Xgeva (RLDs) are mentioned. clarification needed on rationale and relevance.

Comments of the BE&R Division

Not Recommended till the submission of above cited documents.

Decision of 347th Meeting.

The Registration Board deferred the case for the submission of the following documents:

- The Form 5F specifies applicant as an importer. However, the application has been filed under the Drug Manufacturing License (DML) and involves step of manufacturing i.e. secondary packaging.
- The agreement between the importer and exporter mentions the governing law of Singapore. Justification is required.
- The proposed clinical indication is the same for both strengths (60mg/ml and 70mg/1.7ml) and has been reflected accordingly in the Quality Overall Summary (QOS). Justification is needed.
- Stability data for drug substance is required up to claimed shelf life (24 months).
- Summary and conclusion of stability studies of drug product has not been submitted.
- Details of secondary packaging material along with justification for not providing stability data with secondary packaging material
- Submit BPR and secondary packaging validation as applicant is involved in secondary packaging.
- In Nonclinical studies both reference products Prolia and Xgeva (RLDs) are mentioned. clarification needed on rationale and relevance.

Evaluation of the BE&R Division

S. No	Shortcomings	Getz Pharma Response
1	The Form 5F specifies applicant as an importer. However, the application has been filed under the Drug Manufacturing License (DML) and involves step of manufacturing i.e. secondary packaging.	Please note that we will bulk import Denomab (Denosumab) Injection 60mg/mL as labelled vials from M/s Qilu Pharmaceutical Co., Ltd. situated at No. 8888, Lvyou Road, High-tech Zone, Jinan, Shandong Province China and secondary packaging will be performed at Getz Pharma Facility. Therefore, we have submitted said application under the Drug Manufacturing License (DML). Please refer to Annexure - 1 for updated Form 5F.
2	The agreement between the importer and exporter mentions the governing law of Singapore. Justification is required.	Please note that in international agreements between two parties based in different countries, neutral law is selected to maintain neutrality. Qilu Pharma has selected governing law of Singapore as it is also based on common laws as that of Pakistani Law.
3	The proposed clinical indication is the same for both strengths (60mg/ml and 70mg/1.7ml) and has been reflected accordingly in the Quality Overall Summary (QOS). Justification is needed.	Please refer to Annexure - 2 for updated QOS wherein we have updated the clinical indication of Denomab (Denosumab) Injection 60mg/ml in line with innovator product.
4	Stability data for drug substance is required up to claimed shelf life (24 months).	Please refer to Annexure - 3 for updated stability data till claimed shelf life (24 months).
4	Summary and conclusion of stability studies of drug product has not been submitted.	This is to inform you that we have submitted summary and conclusion of stability studies of drug product in Module 3. Please refer to Page 722 of Module 3.
5	Details of secondary packaging material along with justification for not providing stability data with secondary packaging material.	This is to inform you that the secondary packaging material is unit carton in which labelled vials will be packed along with leaflet. Please note that Qilu Pharma has performed stability studies on PPQ batches (batch No. 202212001KJV, 202212002KJV, 202301001KJV) in which the stability study sample are packed in packaging material simulating the commercial i.e., vials are packed in carton.

6	Submit BPS as applicant is involved in secondary packaging.	Please refer to Annexure – 4 for blank Batch Packaging Record that will be used by Getz Pharma for secondary packaging of Denomab (Denosumab) Injection.
7	In Nonclinical studies both reference products Prolia and Xgeva (RLDs) are mentioned. Clarification needed on rationale and relevance.	This is to inform you that Denosumab Injection (hereinafter referred to as QL1206), developed by Qilu Pharmaceutical Co., Ltd., is a biosimilar of the marketed innovator product Prolia® (60mg:1.0ml) and Xgeva® (120mg:1.7ml). In order to evaluate the similarity in safety, and pharmacokinetic (PK) profiles between QL1206 and innovator product, several comparative studies were designed in the non-clinical pharmacodynamics and pharmacokinetics studies to compare both strengths of QL1206 with the innovator product. Furthermore, the drug substance used for both strengths of QL1206 is identical, and the innovator product also maintains consistency in this respect. Therefore, M/s Qilu Pharma has used both reference products (Prolia and Xgeva) to perform non-clinical studies against test product QL1206.

Conclusion

Lack of clarity in the comparison of clinical and non-clinical studies, as Prolia and Xgeva represent different strengths of denosumab intended for distinct clinical indications.

Decision of 348th Meeting:

The Registration Board deferred the case for the clarity in the comparison of clinical and non-clinical studies of applied strength with Prolia and Xgeva as both are different reference products intended for distinct clinical indications.

Biosimilar to Xgeva Exporting Country for bulk import(China) Local Secondary Packaging	
Case # 23	
Name, address of Applicant / Importer	M/s Getz Pharma (Pvt) Limited Company Address: 29-30/27, Korangi Industrial Area Karachi Site Address: Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi
Details of Drug Sale License of importer	License Type: Drug Manufacture License
Name and address of marketing authorization holder (abroad)	M/s Qilu Pharmaceutical Co., Ltd. No. 8888, Lvyou Road, High-tech Zone, Jinan, Shandong Province, China
Name, address of manufacturer(s)	M/s Qilu Pharmaceutical Co., Ltd. No. 8888, Lvyou Road, High-tech Zone, Jinan, Shandong Province, China
Name of exporting country	China
Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	COPP not submitted by the applicant for 70mg/ml
Details of letter of authorization / sole agency agreement	Manufacturing and Supply Agreement 1. Parties Getz Pharma (Private) Limited ("Getz Pharma") located at Plot No.: 29-30, Sector 27, Korangi Industrial Area, Karachi – 74900 Pakistan and Qilu Pharmaceutical Co., Ltd ("Supplier") registered at No.317, Xinluo Road, High-tech Zone, Jinan, Shandong Province, China and the manufacturing location at No.8888 Lvyou Road, High-tech Zone, Jinan 250104, China. Validity: 30-09-2029
Status of the applicant	Importer
Status of application	Similar Bio therapeutic Product
Intended use of pharmaceutical product	Domestic and Export Sales
For imported products specify one of these	Bulk Import Local Repackaging.
Dy. No. and date of submission	Tracking ID: 3EY-X3X-5495 Application Number: 87324 Receiving: 07-04-2025
Details of fee submitted	hallan Number: 52953914359

	Division: Biological Evaluation & Registration Paid Fee: 300000.0 Paid Date: 2025-03-06
The proposed proprietary name / brand name	Denomab Injection 120mg/1.7mL
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml vial contains: Denosumab 70 mg
Dosage form of applied drug	SC Injection
Pharmacotherapeutic Group of (API)	Drugs for treatment of bone diseases – Other drugs affecting bone structure and mineralisation, human monoclonal antibody (IgG2) ATC code: M05BX04
Therapeutic Indication	Prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with advanced malignancies involving bone (see section 5.1). Treatment of adults and skeletally mature adolescents with giant cell tumour of bone that is unresectable or where surgical resection is likely to result in severe morbidity.
Mechanism of Action	Denosumab is a fully human monoclonal antibody of IgG2 subtype, capable to inhibit the receptor activator of nuclear factor-κB (RANK) Ligand on bone cells. This antibody binds with high affinity and specificity to RANKL, thereby neutralising the ligand and inhibiting the differentiation of immature cells into osteoclasts. RANKL is a member of the tumour necrosis (TNF) group of proteins and is an essential factor for formation, activation and survival of osteoclasts. Osteoclasts are the cells responsible for bone resorption while osteoblasts are bone forming cells. Osteoprotegerin (OPG) is the naturally occurring soluble decoy receptor that binds to and blocks the action of RANKL. OPG binding to and blocking the action of RANKL leads to an increase in bone mass. Inhibition of RANKL is a possible intervention point to interfere with conditions with increased bone resorption. Figure 1. Mechanism of action for denosumab BMP = bone morphogenetic proteins, Ca²⁺ = calcium, CFU-M = macrophage colony-forming unit; ET-1 = endothelin-1, FGF = fibroblast growth factors, IGF = insulin-like growth factors, IL-1 (IL-6, IL-8) = interleukin-1 (-6, -8), M-CSF = macrophage colony-stimulating factor, PDGF = platelet-derived growth factor; PGE2 = prostaglandin E2, PTHrP = parathyroid hormone-related peptide, RANKL = RANK ligand, TGF-β = transforming growth factor β, TNFα = tumour necrosis factor α; VEGF = vascular endothelial growth factor; WNT = wingless-type protein-1
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack size	1ml
Proposed unit price	As per SRO228(I)/2024.
Shelf Life	24 Months
Storage Conditions	Store at 2-8°C. Do not freeze.
The status in reference regulatory authorities	Xgeva (Denosumab) Injection 120mg/1.7mL by M/s Amgen Limited., United Kingdom
For generic drugs (me-too status)	Brand name: Xgeva Solution for Injection 120mg/1.7mL • Manufactured by: M/s GSK Pakistan • Strength: 120mg/1.7mL • Dosage form: Solution for Injection • Registration No.: 077528
Module-II (Quality Overall Summary	Firm has submitted QOS as per WJO template. Firm has summarized information related to general properties, manufacturers, description of manufacturing process and controls, characterization, specifications analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
Drug Substance Part	

Name, address of drug substance manufacturer	Name and address (including block(s)/unit(s))		Responsibility	
	Qilu Pharmaceutical Co., Ltd. 8888 Lvyou Road, high-tech zone, Jinan, 250104, China DUNS: 544532200 Phone: +86-531-5568-1374		Drug substance manufacturing	
	Qilu Pharmaceutical Co., Ltd. 8888 Lvyou Road, high-tech zone, Jinan, 250104, China DUNS: 544532200 Phone: +86-531-5568-1374		Analysis, release and stability study of Drug Substance	
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	According to ICH Q5C Stability Testing of Biotechnological/Biological Products, stability studies were conducted on Phase I/III clinical batch Drug Substance (201902001JNN) and 3 batches of Process Performance Qualification (PPQ) batches Drug Substance (202211002JNN, 202211003JNN, 202211004JNN) during clinical studies, of which long-term and accelerated stability studies were conducted on Phase I/III clinical batch Drug Substance, and comprehensive stability studies were conducted on 3 batches of PPQ batch Drug Substance, including high temperature, freeze-thaw, accelerated and long-term tests of Drug Substance.			
	Stability study	Study condition	Packaging material	Testing interval (month)
	Long-term	-20°C±5°C	Disposable storage bag	0, 3, 6, 9, 12, 18 (PPQ batches), 18, 24 (Clinical phase I & III batch)
Accelerated	5°C±3°C	0, 1, 3, 6		
Drug Product Part				
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.			
Drug Product manufacturer	Address	Responsibility	Manufacturer Information	
	Qilu Pharmaceutical Co., Ltd. Unit 3300, 8888 Lvyou Road, High-tech Zone, Jinan, Shandong Province, 250104, P.R.China	Drug Product Manufacturing	Manufactured by: Qilu Pharmaceutical Co., Ltd. Registered address: No. 317, Xinluo Street, Hi-tech Zone, Jinan, Shandong Province Post Code: 250101 Tel.: 0531-83126666 Fax: 0531-83126688	
	Qilu Pharmaceutical Co., Ltd. QC Unit V, 8888 Lvyou Road, High-tech Zone, Jinan, Shandong Province, 250104, P.R.China	Drug Product Release Testing, Drug Product Stability Studies		
	Qilu Pharmaceutical Co., Ltd. QC Unit III, No.849 Dongjia Town, Licheng Zone, Jinan, Shandong, P.R.China	Sterility test		
Analytical method validation/verification of product	Firm has submitted the details of analytical method validation.			
Container closure system of the drug product	2ml neutral borosilicate glass tube vials for injection, chlorobutyl rubber stopper coated with FEP (fluorinated ethylene propylene) film for injection and aluminiumplastics combination caps for antibiotics bottles were chosen to be the inner packaging material of this produc.			
Stability study data of drug product, shelf life and storage conditions	The stability studies for three batches of PPQ batches of this drug product have been completed under accelerated (25°C ± 2°C / 60% RH ± 5% RH, Upright and Inverted, the inverted condition was performed only in 1st PPQ batch), high temperature (40°C ± 2°C) and photostability (Illuminance 5,000 lx, ultraviolet 90 µw/cm2 , 25°C ± 2°C) conditions, and the long-term (5°C ± 3°C) stability studies for PPQ batches are ongoing with 12-month data available to the shelf-life date.			

PART A - ADMINISTRATIVE INFORMATION	
Bio similarity Studies	
Reference of biosimilar guidelines	Technical guidelines for the Research , development and Evaluation of Biosimilar NMPA Interim Technical guidelines for Similarity Assessment and indication extrapolation of Biosimilars, NMPA.
Name of the RBP	Xgeva®
Authorized indications for RBP	-
Pharmaceutical form	Solution for injection
Quantitative composition	70mg/1ml PFS.
Route of administration	SC
Packaging/material	Vial
Package size(s)	1's Via
License number (of RBP)	
Date of authorization (of RBP)	-
Authorization (License) Holder (of RBP)	Amgen Inc., USA
Source of RBP (or other comparator) for comparability exercise	
Availability of the RBP assessment report (language)/link	NA
Comparability exercise to demonstrate similarity to RBP	Physicochemical and biological characterization study. Comparative in vitro and in vivo non-clinical studies (PK/PD study) Comparative clinical studies(PK, efficacy, safety and immunogenicity).
Indications applied for (if different to RBP)	None
PART B - SUBMITTED DATA	
Quality data. State-of-the-art methods	
Characterization	
A comprehensive study on the structure, physicochemical properties, biological activity and immunological characteristics was conducted with 7 batches of This products and 9 batches of innovator products in the Chinese market, and a comparability study was conducted with the main quality indicators of all 10 batches of innovator products in the Chinese market.	
Nonclinical data. In vitro studies	
Primary pharmacodynamics: This product is a fully human monoclonal IgG2 antibody that targets RANKL. Based on the molecular structure characteristics and mechanism of action of this product, the in vitro and in vivo pharmacodynamics were studied and compared with those of the reference listed drug (RLD): ✓ In vitro pharmacodynamics (Volume 2): 1) Affinity of Fab fragment to RANKL; 2) Affinity of Fc fragment to neonatal Fc receptor (FcRn); 3) Effects on the differentiation of macrophages RAW 264.7 and mouse bone marrow cells into osteoclasts	
Nonclinical data. In vivo studies	
✓ In vivo pharmacodynamics: Considering that rodents are not pharmacologically relevant species, we evaluated and compared the effects of single and repeated dose(s) of this product and the RLD Denosumab on multiple bone biomarkers (type I collagen cross-linked C-telopeptide (CTX) and tartrate-resistant acid phosphatase (TRACP-5b)), and serum bone metabolism-related parameters (alkaline phosphatase (ALP), calcium ion (Ca ²⁺), and phosphorus (PHOS)) in non-human primates in the pharmacokinetic and the 16-week repeat-dose toxicity studies in cynomolgus monkeys based on clinically relevant pharmacodynamic markers and test parameters. We also analyzed their effects on bone mineral density and bone mineral content in various sites of the live cynomolgus monkeys using a dual energy X-ray bone mineral density detector (USA)	
CLINICAL STUDIES	
- include relevant study data from the following (not all may be required) which have been included to demonstrate bio similarity.	
· Pharmacokinetic, PK · Pharmacodynamic, PD · Efficacy, · Safety, · Immunogenicity.	

StudyNo. QL1206-001																															
StudyTitle Phase 1 A Randomized, Double-blind, Parallel-group Comparative Study of Pharmacokinetics, Safety and Pharmacodynamics QL1206 and Xgeva®in HealthyAdults	<table><tr><th></th><th>Test Product</th><th>Reference Product</th></tr><tr><td>Name of Drug Product</td><td>QL1206</td><td>Denosumab Injection</td></tr><tr><td>(Proposed) Trade Name</td><td>/</td><td>Xgeva®</td></tr><tr><td>Strength</td><td>120mg/ 1.7ml</td><td>120 mg (70 mg/mL, 1.7 mL/vial)</td></tr><tr><td>Batch No.</td><td>201702001KJH</td><td>1080217</td></tr><tr><td>Manufacturer</td><td>Qilu Pharmaceutical Co., Ltd.</td><td>Amgen Manufacturing, Limited</td></tr><tr><td>Content</td><td>101%</td><td>100.1%</td></tr><tr><td>Manufacturing Date</td><td>February 16, 2017</td><td>September 16, 2016</td></tr><tr><td>Expiry Date</td><td>February 15, 2019</td><td>September 16, 2019</td></tr><tr><td>Method of administration</td><td>Subcutaneous injection</td><td>Subcutaneous injection</td></tr></table>		Test Product	Reference Product	Name of Drug Product	QL1206	Denosumab Injection	(Proposed) Trade Name	/	Xgeva®	Strength	120mg/ 1.7ml	120 mg (70 mg/mL, 1.7 mL/vial)	Batch No.	201702001KJH	1080217	Manufacturer	Qilu Pharmaceutical Co., Ltd.	Amgen Manufacturing, Limited	Content	101%	100.1%	Manufacturing Date	February 16, 2017	September 16, 2016	Expiry Date	February 15, 2019	September 16, 2019	Method of administration	Subcutaneous injection	Subcutaneous injection
	Test Product	Reference Product																													
Name of Drug Product	QL1206	Denosumab Injection																													
(Proposed) Trade Name	/	Xgeva®																													
Strength	120mg/ 1.7ml	120 mg (70 mg/mL, 1.7 mL/vial)																													
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Manufacturer	Qilu Pharmaceutical Co., Ltd.	Amgen Manufacturing, Limited																													
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Manufacturing Date	February 16, 2017	September 16, 2016																													
Expiry Date	February 15, 2019	September 16, 2019																													
Method of administration	Subcutaneous injection	Subcutaneous injection																													
Primary Objective: Toevaluate pharmacokinetic similarity in healthy volunteers following singledose,subcutaneous injectionofQL1206orXgeva®.																															
Secondary Objective: To evaluate the similarity of clinical safety and immunogenicity in healthyvolunteersfollowingsingledose,subcutaneousinjectionofQL1206or Xgeva®.Meanwhile, preliminary PD similarityofQL1206orXgeva®was observed.																															
FAS: 157 Safety set: 157 subjects PKset: 156 subjects IS: 156 PDS: 157																															
Conclusion																															
In this study, the 90%CIs of the GMRs of primary PK parameters AUC0-∞,AUC0-andCmaxofQL1206(Recombinant Anti-RANKLFullHuman Monoclonal Antibody Injection) and Xgeva® were within the equivalence interval(80.00%–125.00%), indicating that the QL1206 manufactured by Qilu PharmaceuticalCo.,Ltd.andXgeva®(DenosumabInjection,strength:120mg (70mg/mL, 1.7mL/vial))manufactured by Amgen were bioequivalent with respect to PK.The two drug products were similar in safety, immunogenicity and PD, and the safety data were consistent with those reported in previous literature.Therefore,QL1206 is considered bioequivalent to Xgeva®.																															
Study to Compare Efficacy and Safety																															
Reports of the Study to Compare Efficacy and Safety in Patients with Bone Metastases from Solid Tumors (QL1206-003)																															
PhaseIII: Multicenter, randomized, double-blind trial																															
Primary objective: To compare the efficacy of QL1206 vs. Xgeva® in patients with solid tumor bone metastases. Secondary objective: To compare the safety and immunogenicity of QL1206 vs. Xgeva® in patients with solid tumor bone metastases.																															
Exploratory objective: To evaluate the pharmacokinetic characteristics of QL1206 in patients with solid tumor bone metastases.																															
Sample Size 700 subjects Subject Population Patients with histologically or cytologically confirmed solid tumor bone metastasis																															
Study Duration Study duration for each subject is 77 weeks (4 weeks of screening, 13 weeks of double-blind treatment, 40 weeks of QL1206 treatment, and 20 weeks of follow-up).																															
Remarks of the Evaluator																															
• The applicant is classified as an importer for this application. However, the application has been filed under the Drug Marketing License (DML). • Original, legalized and valid CoPP of applied strength is required. • The agreement between the importer and exporter mentions the <i>governing law of Singapore</i> .Justification is required. • The proposed clinical indication is the same for both strengths and has been reflected accordingly in the Quality Overall Summary (QOS).Justification is needed. • Stability data for drug substance required up to full claimed shelf life (24 months). • Summary and conclusion of stability studies of drug product has not been submitted. • Details of secondary packaging material along with justification for no stability data submitted of secondary packaging site. • Nonclinical studies reference both Prolia and Xgeva (RLDs) — clarification needed on rationale and relevance. • Submit Batch Packaging Record																															
Comments of the BE&R Division																															
Not Recommended till the submission of above cited documents.																															
Decision:																															
The Registration Board deferred the case for the submission of the following documents:																															
• The Form 5F specifies applicant as an importer. However, the application has been filed under the Drug Manufacturing License (DML) and involves step of manufacturing i.e. secondary packaging. • The agreement between the importer and exporter mentions the governing law of Singapore. Justification is required. • The proposed clinical indication is the same for both strengths (60mg/ml and 70mg/1.7ml) and has been reflected accordingly in the Quality Overall Summary (QOS).Justification is needed. • Stability data for drug substance is required up to claimed shelf life (24 months). • Summary and conclusion of stability studies of drug product has not been submitted. • Details of secondary packaging material along with justification for not providing stability data with secondary .packaging material • Submit BPR and secondary packaging validation as applicant is involved in secondary packaging. • In Nonclinical studies both reference products Prolia and Xgeva (RLDs) are mentioned.clarification needed on rationale and relevance.																															
Evaluation by BE&R Division																															

S. No	Shortcomings	Getz Pharma Response
1	The applicant is classified as an importer for this application. However, the application has been filed under the Drug Marketing License (DML).	Please note that we will bulk import Denomab (Denosumab) Injection 120mg/1.7mL as labelled vials from M/s Qilu Pharmaceutical Co., Ltd. situated at No. 8888, Lvyou Road, High-tech Zone, Jinan, Shandong Province China and secondary packaging will be performed at Getz Pharma Facility. Therefore, we have submitted said application under the Drug Manufacturing License (DML). Please refer to Annexure - 1 for updated Form 5F.
2	Original, legalized and valid CoPP of applied strength is required.	Please refer to Annexure - 2 for legalized and valid CoPP of Denosumab Injection 120mg/1.7ml.
3	The agreement between the importer and exporter mentions the governing law of Singapore. Justification is required.	Please note that in international agreements between two parties based in different countries, neutral law is selected to maintain neutrality. Qilu Pharma has selected governing law of Singapore as it is also based on common laws as that of Pakistani Law.
4	The proposed clinical indication is the same for both strengths and has been reflected accordingly in the Quality Overall Summary (QOS). Justification is needed.	Please refer to Annexure - 3 for updated QOS wherein we have updated the clinical indication of Denomab (Denosumab) Injection 120mg/1.7ml in line with innovator product.
5	Stability data for drug substance required up to full claimed shelf life (24 months).	Please refer to Annexure - 4 for updated stability data till claimed shelf life (24 months).
6	Summary and conclusion of stability studies of drug product has not been submitted.	This is to inform you that we have submitted summary and conclusion of stability studies of drug product in Module 3. Please refer to Page 688 of Module 3.
7	Details of secondary packaging material along with justification for no stability data submitted of secondary packaging site.	This is to inform you that the secondary packaging material is unit carton in which labelled vials will be packed along with leaflet. Please note that Qilu Pharma has performed stability studies on PPQ batches (batch No. 202212001KJR, 202212002KJR, 202301001KJR) in which the stability study sample are packed in packaging material simulating the commercial i.e., vials are packed in carton.
8	In Nonclinical studies reference both Prolia and Xgeva (RLDs) — clarification needed on rationale and relevance.	This is to inform you that Denosumab Injection (hereinafter referred to as QL1206), developed by Qilu Pharmaceutical Co., Ltd., is a biosimilar of the marketed innovator product Prolia® (60mg:1.0ml) and Xgeva® (120mg:1.7ml). In order to evaluate the similarity in safety, and pharmacokinetic (PK) profiles between QL1206 and innovator product, several comparative studies were designed in the non-clinical pharmacodynamics and pharmacokinetics studies to compare both strengths of QL1206 with the innovator product. Furthermore, the drug substance used for both strengths of QL1206 is identical, and the innovator product also maintains consistency in this respect. Therefore, M/s Qilu Pharma has used both reference products (Prolia and Xgeva) to perform non-clinical studies against test product QL1206.
9	Submit Batch Packaging Record	Please refer to Annexure – 5 for blank Batch Packaging Record that will be used by Getz Pharma for secondary packaging of Denomab (Denosumab) Injection.
Conclusion		

Lack of clarity in the comparison of clinical and non-clinical studies, as Prolia and Xgeva represent different strengths of denosumab intended for distinct clinical indications. Moreover, clarification is required for the strength of test product and for comparison of same strength for both the applied formulations 60mg/ml and 70mg/1.7ml.

Decision of 348th Meeting:

The Registration Board deferred the case for the clarity in the comparison of clinical and non-clinical studies of applied strength with Prolia and Xgeva as both are different reference products intended for distinct clinical indications.

OMALIZUMAB							
Deferred Case (M-347)							
Exporting Country (Switzerland)							
Case # 24							
Name, address of Applicant / Importer	M/s Novartis Pharma Pakistan Ltd, 15 West Wharf, Karachi, Pakistan.						
Details of Drug Sale License of importer	License No: 015 Address: 15 West Wharf, Karachi, Pakistan. Address of Godown: C-21 S.I.T.E. Karachi. Validity: 19-01-2028. Status: License to sell drugs by way of wholesale						
Name and address of marketing authorization holder (abroad)	Novartis Europharm Limited, Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland.						
Name, address of manufacturer(s)	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332, Stein, Switzerland.						
Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	Scanned Legalized COPP of EMA Certificate No: 01/24/005664) Request:101129 Free Sale:Yes						
Details of letter of authorization / sole agency agreement	Scanned Apostille letter of authorization <u>SOLE AGENCY AGREEMENT / LETTER OF AUTHORIZATION</u> <u>AND</u> <u>RELATIONSHIP BETWEEN MARKETING AUTHORIZATION HOLDER AND MANUFACTURER</u> Dear Madam/ Sir: We do hereby confirm that Novartis Europharm Limited, with its registered office located at Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland will be the Marketing Authorization Holder and Novartis Pharma Stein AG, with its registered office located at Schaffhauserstrasse, 4332, Stein, Switzerland, will be the Manufacturer for our following products: • Xolair 75 mg solution for injection in Pre-filled Syringe. • Xolair 75 mg solution for injection in Pre-filled Pen. • Xolair 150 mg solution for injection in Pre-filled Syringe. • Xolair 150 mg solution for injection in Pre-filled Pen. Listed below is the summary of responsibilities for each company: <table border="1" style="width: 100%;"> <tr> <td>Proposed Marketing Authorization Holder</td> <td>Novartis Europharm Limited, Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland.</td> </tr> <tr> <td>Proposed Drug Product Manufacturer/ Primary & Secondary Packaging Site/ Batch Release site of Medicinal Product.</td> <td>Novartis Pharma Stein AG, Schaffhauserstrasse, 4332, Stein, Switzerland.</td> </tr> <tr> <td>Representative, Sole Agent and</td> <td>Novartis Pharma (Pakistan) Limited,</td> </tr> </table>	Proposed Marketing Authorization Holder	Novartis Europharm Limited, Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland.	Proposed Drug Product Manufacturer/ Primary & Secondary Packaging Site/ Batch Release site of Medicinal Product.	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332, Stein, Switzerland.	Representative, Sole Agent and	Novartis Pharma (Pakistan) Limited,
Proposed Marketing Authorization Holder	Novartis Europharm Limited, Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland.						
Proposed Drug Product Manufacturer/ Primary & Secondary Packaging Site/ Batch Release site of Medicinal Product.	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332, Stein, Switzerland.						
Representative, Sole Agent and	Novartis Pharma (Pakistan) Limited,						
Name of exporting country	Switzerland						
Status of the applicant	☒ Importer						
Status of application	☒ Generic Drug Product (GDP)						
Intended use of pharmaceutical product	☒ Domestic sale						
For imported products, specify one the these	☒ Finished Pharmaceutical product import						
Dy. No. and date of submission	Tracking ID:ATH-6RH-7YYN Application Number:30076 Receiving: 13-09-2024						
Details of fee submitted	Challan Number: 97560709925 Division: Biological Evaluation & Registration Paid Fee: 300000.0						

	Paid Date: 2024-07-26										
The proposed proprietary name / brand name	Xolair 75mg solution for injection in Pre-filled Pen										
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 0.5ml Pre-filled Pen contains: Omalizumab 75 mg										
Pharmaceutical form of applied drug	Solution in pre-filled pen										
Pharmacotherapeutic Group of (API)	Monoclonal antibody										
Reference to Finished product specifications	Innovator's Specifications										
Proposed Pack size	1's										
Shelf life	18months										
Proposed unit price	As per SRO										
The status in reference regulatory authorities	Xolair (TGA Approved)										
For generic drugs (me-too status)	NA										
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.										
Name, address of drug substance manufacturer	Novartis Pharma S.A.S., Centre de Biotechnologie, 8 rue de l'Industrie 68330 Huningue, France.										
Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.										
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at < -20 °C for 12 months and the accelerated stability data is conducted at 5°C ± 3°C for 3 months.										
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.										
Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.										
Container closure system of the drug product	sterile, single use, pre-fillable syringe that includes a glass syringe barrel, equipped with a staked stainless steel needle fixed to the syringe barrel with an adhesive, a rubber plunger stopper, and a rigid needle shield composed of a needle shield covered by a rigid shell.										
Stability study data of drug product, shelf life and storage conditions	Table 8-2 Proposed shelf life and storage conditions <table> <tr> <th></th><th>Xolair 300 mg/2.0 mL, 150 mg/1.0 mL, 75 mg/0.5 mL solution for injection in autoinjector</th></tr> <tr> <td>Proposed shelf life</td><td>18 months</td></tr> <tr> <td>Justification of proposed shelf life</td><td>Satisfactory long term stability data (2 – 8 °C/ambient RH) from primary stability batches as well as long term stability data from supportive stability batches and shown comparability between the unassembled and assembled material and the initially commercialized and the newly developed Xolair solution for injection products</td></tr> <tr> <td>Packaging</td><td>Primary packaging described in section 'Container closure system'</td></tr> <tr> <td>Storage requirements</td><td>Store at 2 – 8 °C; Do not freeze; Protect from light</td></tr> </table>		Xolair 300 mg/2.0 mL, 150 mg/1.0 mL, 75 mg/0.5 mL solution for injection in autoinjector	Proposed shelf life	18 months	Justification of proposed shelf life	Satisfactory long term stability data (2 – 8 °C/ambient RH) from primary stability batches as well as long term stability data from supportive stability batches and shown comparability between the unassembled and assembled material and the initially commercialized and the newly developed Xolair solution for injection products	Packaging	Primary packaging described in section 'Container closure system'	Storage requirements	Store at 2 – 8 °C; Do not freeze; Protect from light
	Xolair 300 mg/2.0 mL, 150 mg/1.0 mL, 75 mg/0.5 mL solution for injection in autoinjector										
Proposed shelf life	18 months										
Justification of proposed shelf life	Satisfactory long term stability data (2 – 8 °C/ambient RH) from primary stability batches as well as long term stability data from supportive stability batches and shown comparability between the unassembled and assembled material and the initially commercialized and the newly developed Xolair solution for injection products										
Packaging	Primary packaging described in section 'Container closure system'										
Storage requirements	Store at 2 – 8 °C; Do not freeze; Protect from light										
Remarks of the Evaluator	- Application and fee should be submitted under DSL instead of DML. - The COPP does not provide QC and Batch release site of finished product. - Submit hard copy of original or notarized Letter of authorization.										

		- The application is for the registration of generic drug product, therefore provide reference of other similar approved medicines with information pertaining to Manufacturer name, brand name, strength, composition, registration number & dosage form. - Documents/evidence for acceptable shipping conditions for finished product and & proof of shipping validation. - Stability data of drug product till claimed shelf life i.e. 18 month is required. - Module 4 Non-Clinical Data Module 4 as per DRAP CTD guidance document for Biological Products. - Module 5 Clinical Data Module 5 as per DRAP CTD guidance document for Biological Products.

Comments of BE&R

Not recommended till the submission of the above cited documents.

Previous Decision of 345th Meeting:

The Registration Board deferred the case for the submission of the following documents:

- Application and fee should be submitted under DSL instead of DML.
- The COPP does not provide QC and Batch release site of finished product.
- Hard copy of original or notarized Letter of authorization.
- The application is for the registration of generic drug product, therefore provide reference of other similar approved medicines with information pertaining to Manufacturer name, brand name, strength, composition, registration number & dosage form.
- Documents/evidence for acceptable shipping conditions for finished product and & proof of shipping validation.
- Stability data of drug product till claimed shelf life i.e. 18 months.
- Module 4 as per DRAP CTD guidance document for Biological Products.
- Module 5 as per DRAP CTD guidance document for Biological Products.

Remarks of Evaluator:

S. No	Sections	Observations	Novartis Reply
1.	Form 5F	Application and fee should be submitted under DSL instead of DML	As per your instruction, we have re-submitting revised fees on our DSL no 015 Deposit Slip no 00162363939, PKR 300,000 Dated 13/2/2025 (challan attached in Annex 1)
2.	1.3.3 a) b)	The COPP does not provide QC and Batch Release site of finished product Submit hard copy of original or notarized letter of authorization	a) QC site is not regulatory relevant as per PRV guideline 2023. However, the information pertaining to QC site can be found in 3.2.P.3.1. (highlighted & attached in Annex 2) The Batch Release site of the product is not regulatory relevant in our reference country which is the reason the batch release site (BRS) is not mentioned in CPP. However, the information pertaining to BRS site can be found in 3.2.P.3.1 (highlighted & attached in Annex 2) b) We have submitted the hard copy of original and notarized letter of authorization. (ack copy attached in Annex 3)
3.	1.4.1	The application is for the registration of generic drug product, therefore provide reference of other similar approved medicines with information pertaining to manufacturer name, brand name, strength, composition, registration number and dosage form	This application of Xolair Pre-filled pen is a line extension of our already registered product Xolair 75mg Powder for solution for injection (Registration no 088715). We are innovator of Xolair Solution for Injection (Omalizumab), no other generics are available in Pakistan. We are attaching the registration letter of our registered product (copy of registration letter attached as Annex 4)

4.	1.4.2	Documents/evidence for acceptable shipping conditions for finished product and proof of shipping validation	We have submitted application for new registration of product. The proposed product is not imported/shipped till now; therefore, no shipment documents/evidence are available.
5.	3.2.P.8.3	Stability data of drug product till claimed shelf life i.e. 18 months is required.	We are attaching 18 months stability data along with summary & conclusion, highlighted that the stability data conducted for 18 months (attached as Annex 5)
6.	Module 4	Module 4 as per DRAP CTD guidance document for Biological Products.	When a product is approved in any reference country like EMA, Module 4 is not applicable.
7.	Module 5	Module 5 as per DRAP CTD guidance document for Biological Products.	When a product is approved in any reference country like EMA, Module 5 is not applicable.

Comments of the BE&R Division

Recommended for approval, considering its status as an innovator product imported from a reference regulatory authority. This recommendation is conditional upon the submission of the following documents:

- Updated Certificate of Pharmaceutical Product (COPP) reflecting manufacturing sites in line with section 3.2.P.3.1
- Shipping validation documentation
- Modules 4 and 5 of the Common Technical Document (CTD)

Decision of 347th Meeting:

The Registration Board deferred the case for the submission of the following documents:

- Certificate of Pharmaceutical Product (COPP) reflecting manufacturing sites in line with section 3.2.P.3.1
- Shipping validation documentation.
- Modules 4 and 5 of the Common Technical Document (CTD).

Evaluation by BE&R Division

Sr. No	Queries	Applicant Reponse	Evaluation
	Certificate of Pharmaceutical Product (COPP) reflecting manufacturing sites in line with section 3.2.P.3.1	3.2.P.3.1 - Certificate of Pharmaceutical Product (COPP) reflecting manufacturing sites in line with section 3.2.P.3.1: Kindly find attached the revised notarized Certificate of Pharmaceutical Product (COPP) reflecting manufacturing sites in line with section 3.2.P.3.1. we have submitted Notarized EMA COPP previously, but EMA COPP did not contain the details of manufacturing activities. Therefore, we are providing you Notarized Swiss COPP, which fully fulfill your desired observations. Additionally, we are also providing you revised Notarized Sole Agency Agreement, as per the new COPP.	The new marketing authorization holder is M/s Novartis Pharma AG, Lichtstrasse 35, 4056 Basel. Scanned copy of original apostille COPP Certificate No. 25001328 Free sale status: Yes GMP:Yes Date: 03-04-25 Fee for change in MAH is required. Revised LOA has been submitted.
	Shipping validation documentation.	the data logger from the shipment of our previously registered Xolair 150mg solution for injection. We are also attaching our cold chain Management SOP for your reference.	-
	Modules 4 and 5 of the Common Technical Document (CTD).	Module 4 and Module 5 provided .	-

Conclusion

The applicant has submitted the Swissmedic COPP along with a change in MAH and a Letter of Authorization (LOA); however, submission of the applicable fee as per the SRO is still required.

Decision of 348th Meeting:

The Registration Board approved the formulation with shelf life of 18 months to be stored at 2-8°C as per current policy for inspection of manufacturers abroad notified vide Letter No.3-2/2005-Reg-I /Vol-II dated July 6, 2022. Registration letter will be issued on submission of requisite fee.

OMALIZUMAB
Deferred Case (M-347)
Exporting Country (Switzerland)

Case # 25

Name, address of Applicant / Importer	M/s Novartis Pharma Pakistan Ltd, 15 West Wharf, Karachi, Pakistan.						
Details of Drug Sale License of importer	License No: 015 Address: 15 West Wharf, Karachi, Pakistan. Address of Godown: C-21 S.I.T.E. Karachi. Validity: 19-01-2028. Status: License to sell drugs by way of wholesale						
Name and address of marketing authorization holder (abroad)	Novartis Europharm Limited, Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland.						
Name, address of manufacturer(s)	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332, Stein, Switzerland.						
Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	Scanned Legalized COPP of EMA Certificate No: 01/24/005664) Request:101129 Free Sale:Yes						
Details of letter of authorization / sole agency agreement	Scanned Apostille letter of authorization SOLE AGENCY AGREEMENT / LETTER OF AUTHORIZATION AND RELATIONSHIP BETWEEN MARKETING AUTHORIZATION HOLDER AND MANUFACTURER Dear Madam/ Sir: We do hereby confirm that Novartis Europharm Limited, with its registered office located at Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland will be the Marketing Authorization Holder and Novartis Pharma Stein AG, with its registered office located at Schaffhauserstrasse, 4332, Stein, Switzerland, will be the Manufacturer for our following products: • Xolair 75 mg solution for injection in Pre-filled Syringe. • Xolair 75 mg solution for injection in Pre-filled Pen. • Xolair 150 mg solution for injection in Pre-filled Syringe. • Xolair 150 mg solution for injection in Pre-filled Pen. Listed below is the summary of responsibilities for each company: <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Proposed Marketing Authorization Holder</td><td style="width: 50%;">Novartis Europharm Limited, Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland.</td></tr> <tr> <td>Proposed Drug Product Manufacturer/ Primary & Secondary Packaging Site/ Batch Release site of Medicinal Product.</td><td>Novartis Pharma Stein AG, Schaffhauserstrasse, 4332, Stein, Switzerland.</td></tr> <tr> <td>Representative, Sole Agent and</td><td>Novartis Pharma (Pakistan) Limited,</td></tr> </table>	Proposed Marketing Authorization Holder	Novartis Europharm Limited, Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland.	Proposed Drug Product Manufacturer/ Primary & Secondary Packaging Site/ Batch Release site of Medicinal Product.	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332, Stein, Switzerland.	Representative, Sole Agent and	Novartis Pharma (Pakistan) Limited,
Proposed Marketing Authorization Holder	Novartis Europharm Limited, Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland.						
Proposed Drug Product Manufacturer/ Primary & Secondary Packaging Site/ Batch Release site of Medicinal Product.	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332, Stein, Switzerland.						
Representative, Sole Agent and	Novartis Pharma (Pakistan) Limited,						
Name of exporting country	Switzerland						
Status of the applicant	☒ Importer						
Status of application	☒ Generic Drug Product (GDP)						
Intended use of pharmaceutical product	☒ Domestic sale						
For imported products, specify one the these	☒ Finished Pharmaceutical product import						
Dy. No. and date of submission	Tracking ID:W65-GUL-LZQ4 Application Number:30065						
Details of fee submitted	Challan Number: 0477665557 Division: Biological Evaluation & Registration Paid Fee: 300000.0 Paid Date: 2024-07-26						
The proposed proprietary name / brand name	Xolair 150mg solution for injection in Pre-filled Pen						
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 0.5ml Pre-filled Pen contains: Omalizumab 150mg						
Pharmaceutical form of applied drug	Solution in pre-filled pen						
Pharmacotherapeutic Group of (API)	Monoclonal antibody						

Reference to Finished product specifications	Innovator's Specifications										
Proposed Pack size	1's										
Shelf life	18months										
Proposed unit price	As per SRO										
The status in reference regulatory authorities	Xolair (TGA Approved)										
For generic drugs (me-too status)	NA										
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.										
Name, address of drug substance manufacturer	Novartis Pharma S.A.S., Centre de Biotechnologie, 8 rue de l'Industrie 68330 Huningue, France.										
Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.										
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at < -20 °C for 12 months and the accelerated stability data is conducted at 5°C ± 3°C for 3 months.										
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.										
Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.										
Container closure system of the drug product	sterile, single use, pre-fillable syringe that includes a glass syringe barrel, equipped with a staked stainless steel needle fixed to the syringe barrel with an adhesive, a rubber plunger stopper, and a rigid needle shield composed of a needle shield covered by a rigid shell.										
Stability study data of drug product, shelf life and storage conditions	Table 8-2 Proposed shelf life and storage conditions <table> <tr> <td></td><td>Xolair 300 mg/2.0 mL, 150 mg/1.0 mL, 75 mg/0.5 mL solution for injection in autoinjector</td></tr> <tr> <td>Proposed shelf life</td><td>18 months</td></tr> <tr> <td>Justification of proposed shelf life</td><td>Satisfactory long term stability data (2 – 8 °C/ambient RH) from primary stability batches as well as long term stability data from supportive stability batches and shown comparability between the unassembled and assembled material and the initially commercialized and the newly developed Xolair solution for injection products</td></tr> <tr> <td>Packaging</td><td>Primary packaging described in section 'Container closure system'</td></tr> <tr> <td>Storage requirements</td><td>Store at 2 – 8 °C; Do not freeze; Protect from light</td></tr> </table>		Xolair 300 mg/2.0 mL, 150 mg/1.0 mL, 75 mg/0.5 mL solution for injection in autoinjector	Proposed shelf life	18 months	Justification of proposed shelf life	Satisfactory long term stability data (2 – 8 °C/ambient RH) from primary stability batches as well as long term stability data from supportive stability batches and shown comparability between the unassembled and assembled material and the initially commercialized and the newly developed Xolair solution for injection products	Packaging	Primary packaging described in section 'Container closure system'	Storage requirements	Store at 2 – 8 °C; Do not freeze; Protect from light
	Xolair 300 mg/2.0 mL, 150 mg/1.0 mL, 75 mg/0.5 mL solution for injection in autoinjector										
Proposed shelf life	18 months										
Justification of proposed shelf life	Satisfactory long term stability data (2 – 8 °C/ambient RH) from primary stability batches as well as long term stability data from supportive stability batches and shown comparability between the unassembled and assembled material and the initially commercialized and the newly developed Xolair solution for injection products										
Packaging	Primary packaging described in section 'Container closure system'										
Storage requirements	Store at 2 – 8 °C; Do not freeze; Protect from light										
Remarks of the Evaluator	• Application and fee should be submitted under DSL instead of DML. • The COPP does not provide QC and Batch release site of finished product. • Submit hard copy of original or notarized Letter of authorization. • The application is for the registration of generic drug product, therefore provide reference of other similar approved medicines with information pertaining to Manufacturer name, brand name, strength, composition, registration number & dosage form. • Documents/evidence for acceptable shipping conditions for finished product and & proof of shipping validation. • Stability data of drug product till claimed shelf life i.e. 18 month is required. • Module 4 Non-Clinical Data Module 4 as per DRAP CTD guidance document for Biological Products.										

		Module 5Clinical Data	Module 5 as per DRAP CTD guidance document for Biological Products.
Comments of BE&R Not recommended till the submission of the above cited documents.			
Decision of 345th Meeting: The Registration Board deferred the case for the submission of the following documents: - Application and fee should be submitted under DSL instead of DML. - The COPP does not provide QC and Batch release site of finished product. - Hard copy of original or notarized Letter of authorization. - The application is for the registration of generic drug product, therefore provide reference of other similar approved medicines with information pertaining to Manufacturer name, brand name, strength, composition, registration number & dosage form. - Documents/evidence for acceptable shipping conditions for finished product and & proof of shipping validation. - Stability data of drug product till claimed shelf life i.e. 18 months. - Module 4 as per DRAP CTD guidance document for Biological Products. - Module 5 as per DRAP CTD guidance document for Biological Products.			
Remarks of Evaluator			
S. No	Sections	Observations	Novartis Reply
1.	Form 5F	Application and fee should be submitted under DSL instead of DML	As per your instruction, we have re-submitting revised fees on our DSL no 015 Deposit Slip no 57384855037, PKR 300,000 Dated 13/2/2025 (challan attached in Annex 1)
2.	1.3.3 a) b)	The COPP does not provide QC and Batch Release site of finished product hard copy of original or notarized letter of authorization	QC site is not regulatory relevant as per PRV guideline 2023. However, the information pertaining to QC site can be found in 3.2.P.3.1. (highlighted & attached in Annex 2) The Batch Release site of the product is not regulatory relevant in our reference country which is the reason the batch release site (BRS) is not mentioned in CPP. However, the information pertaining to BRS site can be found in 3.2.P.3.1 (highlighted & attached in Annex 2) c) We have submitted the hard copy of original and notarized letter of authorization. (ack copy attached in Annex 3)
3.	1.4.1	The application is for the registration of generic drug product, therefore provide reference of other similar approved medicines with information pertaining to manufacturer name, brand name, strength, composition, registration number and dosage form	This application of Xolair Pre-filled pen is a line extension of our already registered product Xolair 150mg Powder for solution for injection (Registration no 047599). We are innovator of Xolair Solution for Injection (Omalizumab), no other generics are available in Pakistan. We are attaching the registration letter of our registered product (copy of registration letter attached as Annex 4)
4.	1.4.2	Documents/evidence for acceptable shipping conditions for finished product and proof of shipping validation	We have submitted application for new registration of product. The proposed product is not imported/shipped till now; therefore, no shipment documents/evidence are available.
5.	3.2.P.8.3	Stability data of drug product till claimed shelf life i.e. 18 months is required.	We are attaching 18 months stability data along with summary & conclusion, highlighted that the stability data conducted for 18 months (attached as Annex 5)
6.	Module 4	Module 4 as per DRAP CTD guidance document for Biological Products.	When a product is approved in any reference country like EMA, Module 4 is not applicable.

7.	Module 5	Module 5 as per DRAP CTD guidance document for Biological Products.	When a product is approved in any reference country like EMA, Module 5 is not applicable.

Comments of the BE&R Division

Recommended for approval, considering its status as an innovator product imported from a reference regulatory authority. This recommendation is conditional upon the submission of the following documents:

- Updated Certificate of Pharmaceutical Product (COPP) reflecting manufacturing sites in line with section 3.2.P.3.1
- Shipping validation documentation
- Modules 4 and 5 of the Common Technical Document (CTD)

Decision of 347th Meeting :

The Registration Board deferred the case for the submission of the following documents:

- **Certificate of Pharmaceutical Product (COPP) reflecting manufacturing sites in line with section 3.2.P.3.1**
- **Shipping validation documentation.**
- **Modules 4 and 5 of the Common Technical Document (CTD).**

Evaluation by BE&R

Sr. No	Queries	Applicant Response	Evaluation
1	Certificate of Pharmaceutical Product (COPP) reflecting manufacturing sites in line with section 3.2.P.3.1	3.2.P.3.1 - Certificate of Pharmaceutical Product (COPP) reflecting manufacturing sites in line with section 3.2.P.3.1: Kindly find attached the revised notarized Certificate of Pharmaceutical Product (COPP) reflecting manufacturing sites in line with section 3.2.P.3.1. we have submitted Notarized EMA COPP previously, but EMA COPP did not contain the details of manufacturing activities. Therefore, we are providing you Notarized Swiss COPP, which fully fulfill your desired observations. Additionally, we are also providing you revised Notarized Sole Agency Agreement, as per the new COPP.	The new marketing authorization holder is M/s Novartis Pharma AG, Lichtstrasse 35, 4056 Basel. Scanned copy of original apostille COPP Certificate No. 25001328 Free sale status: Yes GMP: Yes Date: 03-04-25 Fee for change in MAH is required. Revised LOA has been submitted.
2	Shipping validation documentation.	the data logger from the shipment of our previously registered Xolair 150mg solution for injection. We are also attaching our cold chain Management SOP for your reference.	-
3	Modules 4 and 5 of the Common Technical Document (CTD).	Module 4 and Module 5 provided.	-

Conclusion

The applicant has submitted the Swissmedic COPP along with a change in MAH and a Letter of Authorization (LOA); however, submission of the applicable fee as per the SRO is still required

Decision of 348th Meeting:

The Registration Board approved the formulation with shelf life of 18 months to be stored at 2-8°C as per current policy for inspection of manufacturers abroad notified vide Letter No.3-2/2005-Reg-I /Vol-II dated July 6, 2022. Registration letter will be issued on submission of requisite fee.

OCRELIZUMAB	
Deferred Case-M-347	
Exporting Country(Switzerland)	
Case # 26	
Name, address of Applicant / Importer	M/s Roche Pakistan Limited, 1 st floor, 37-B, Block 6, PECHS, Karachi.

Details of Drug Sale License of importer	License No: 0375 Address: Roche Pakistan Limited, 1 st floor, 37-B, Block 6, PECHS, Karachi. Address of Godown: • R-PI, plot no. 56, sector 15, K.I.A, Karachi Validity: 07/11/2028. Status: Drug License by way of wholesale Renewal: N/A
Name and address of marketing authorization holder (abroad)	Roche Registration GmbH, Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Germany.
Name, address of manufacturer(s)	Quality Control Testing +Primary Packaging Roche Diagnostics GmbH, Sandhofer Strasse 116, 68305 Mannheim, Germany Labeling, Secondary Packaging +Release F. Hoffmann-La Roche AG Wurmisweg 4303 Kaiseraugst Switzerland Release of Finished Drug Product F. Hoffmann-La Roche AG Wurmisweg 4303 Kaiseraugst Switzerland
Name of exporting country	Switzerland
Detail of certificates attached (CoPP, Free-sale certificate, GMP certificate)	e-CPP of EMA Certificate No.: 01/24/007776 Issuance Date: 12/07/2024
Details of letter of authorization / sole agency agreement	• Product Specific authorization letter from M/s F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, CH-4070 Basel Switzerland in name of M/s Roche Pakistan Limited, Karachi dated 12-08-2024. • Copy of relationship letter indicating relation of all Roche companies with M/s F. Hoffmann-La Roche Ltd., Basel. Switzerland.
Status of the applicant	☒ Importer
Status of application	☒ New Drug Product (NDP)
Intended use of pharmaceutical product	☒ Domestic sale
For imported products, specify one the these	☒ Finished Pharmaceutical product import
Dy. No. and date of submission	Tracking ID:1UQ-G1E-BQ8W Application Number:38265 Receiving: 13-09-2024
Details of fee submitted	Challan Number: 6500987779 Division: Biological Evaluation & Registration Paid Fee: 300000.0 Paid Date: 2024-08-15
The proposed proprietary name / brand name	Ocrevus Solution for Injection 40mg/ml
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ocrelizumab 920mg/23ml
Indication	Ocrevus is indicated for the treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features (see section 5.1). Ocrevus is indicated for the treatment of adult patients with early primary progressive multiple sclerosis (PPMS) in terms of disease duration and level of disability, and with imaging features characteristic of inflammatory activity
Dosage form of applied drug	Subcutaneous Use (Solution for injection)
Pharmacotherapeutic Group of (API)	Immunosuppressants, monoclonal antibodies

	ATC code: L04AG08
Reference to Finished product specifications	Innovator's specifications
Proposed pack size	1's vial
Proposed unit price	As per SRO
Shelf life	24 months
Storage conditions	2°C - 8°C (protected from light)
The status in reference regulatory authorities	The product is registered in EMA.
For generic drugs (me-too status)	N/A
Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH guidelines. The firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
Name, address of drug substance manufacturer	Roche Diagnostics GmbH, Sandhofer Strasse 116, 68305 Mannheim Germany
Module-III Drug Substance:	The firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	18 months real time stability data at 5°C of 03 batches 06 month accelerated stability data 25°C of 03 batches
Module-III Drug Product:	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Analytical method validation/verification of product	The firm has submitted that the data from the PPQ batches demonstrate that the FDC drug product manufacturing process consistently yields drug product that meets the predetermined acceptance criteria for all quality attributes and that the in-process tests are suitable to monitor the manufacturing process.
Analytical method validation/verification of product	The firm has submitted analytical method validation studies for the applied product.
Container closure system of the drug product	50 mL, USP/Ph. Eur./JP Type I glass, borosilicate, colorless
Stability study data of drug product, shelf life and storage conditions	- Shelf life at recommended storage conditions: 2-8C, protected from light 24 month
Module-IV Non-Clinical	- Toxicology – Local Tolerance studies 03-0216-0349. Cross-reactivity of rhuMAb 2H7 (anti-CD20) with human and non-human primate (cynomolgus monkey) tissues ex vivo. September 2003. 03-0236-0349. Hemolytic potential and blood compatibility of rhuMAb 2H7. September 2003. 05-0025-1466. A pharmacokinetic, pharmacodynamic and local tolerance study of rhuMAb 2H7 (PRO70769) Administered by subcutaneous injection to cynomolgus monkeys as a single or divided dose. July 2006. 06-0367. 72-hour postdose toxicity and toxicokinetics study of rhuMAb 2H7 in male SD rats following a single subcutaneous injection. July 2006. 06-0367 A. 72-hour post-dose toxicity study of rhuMAb 2H7 in male SD rats following a single subcutaneous injection. April 2007.

		• 06-0367 B. 72-hour post-dose toxicity and toxicokinetics study of rhuMAb 2H7 in male SD rats following a single subcutaneous injection. December 2007. • 06-0367 C. 72-hour post-dose toxicity study of rhuMAb 2H7 in male SD rats following a single subcutaneous injection. December 2007. • 06-0367 D. 72-hour post-dose toxicity study of rhuMAb 2H7 in male SD rats following a single subcutaneous injection. December 2007. • 18-1377. A 72-hour single dose subcutaneous local tolerance study of ocrelizumab in male Sprague-Dawley rats. July 2018. • 18-1665. A 7-day Good Laboratory Practices single dose subcutaneous local tolerance study of 2H7 SC in male Sprague-Dawley rats. February 2019. • 18-1979. Ocrelizumab: a single dose subcutaneous local tolerance study in Göttingen mini-pigs. February 2019.
	Module-V Clinical	• The Validation History of the Method for the rhuMAb 2H7 Human Antigen ELISA • Population PK Analysis of SC and IV Ocrelizumab in Patients with Multiple Sclerosis • Clinical Study Summary [Preliminary Results] – Study OCARINA I (CN41144): A Phase Ib, open-label, multicentre study to investigate the pharmacokinetics, safety, and tolerability of subcutaneous ocrelizumab administration in patients with multiple sclerosis. February 2022. • Interim Clinical Study Report – Study OCARINA I (CN41144): A Phase Ib, open-label, multicentre study to investigate the pharmacokinetics, safety, and tolerability of subcutaneous ocrelizumab administration in patients with multiple sclerosis. June xx 2023. Report No. 1118563. • Primary Clinical Study Report – Study OCARINA II (CN42097): A Phase III, non-inferiority, randomized, open-label, parallel group, multicenter study to investigate the pharmacokinetics, pharmacodynamics, safety, and radiological and clinical • 03-0216-0349. Cross-reactivity of rhuMAb 2H7 (anti-CD20) with human and non-human primate (cynomolgus monkey) tissues ex vivo. September 2003. • 03-0236-0349. Hemolytic potential and blood compatibility of rhuMAb 2H7. September 2003. • 03-0684-0134. A repeated dose (x4) toxicity and toxicokinetic evaluation of rhuMAb 2H7 antibody (PRO70769) by intravenous administration in cynomolgus monkeys. December 2004. • 04-0192-0134. A repeat-dose (once every 3 weeks for 8 doses) toxicity and toxicokinetic evaluation of rhuMAb 2H7 (ocrelizumab) by intravenous administration in cynomolgus monkeys, with a 16-week recovery period. June 2005. • 04-1272-1342. An assessment of the effects of PRO70769 (rhuMAb 2H7) on embryofetal development when administered weekly by intravenous injection to pregnant cynomolgus monkeys. March 2006. • 05-0025-1466. A pharmacokinetic, pharmacodynamic and local tolerance study of rhuMAb 2H7 (PRO70769) Administered by subcutaneous injection to cynomolgus monkeys as a single or divided dose. July 2006. • 06-0367. 72-hour post-dose toxicity and toxicokinetics study of rhuMAb 2H7 in male SD rats following a single subcutaneous injection. July 2006. • 06-0367 A. 72-hour post-dose toxicity study of rhuMAb 2H7 in male SD rats following a single subcutaneous injection. April 2007. • 06-0367 B. 72-hour post-dose toxicity and toxicokinetics study of rhuMAb 2H7 in male SD rats following a single subcutaneous injection. December 2007. • 06-0367 C. 72-hour post-dose toxicity study of rhuMAb 2H7 in male SD rats following a single subcutaneous injection. December 2007. • 06-0367 D. 72-hour post-dose toxicity study of rhuMAb 2H7 in male SD rats following a single subcutaneous injection. December 2007. • 06-1260. An assessment of the effects of ocrelizumab (rhuMAb 2H7) on pre- and postnatal development when administered weekly by intravenous injection to pregnant cynomolgus monkeys. December 2011. • 12-0524. Ocrelizumab: 9-week intravenous administration male fertility study in the cynomolgus monkey with a 16-week recovery phase. August 2014. • 12-0525. A study of the effect of ocrelizumab, administered by intravenous injection, on female fertility in cynomolgus monkeys (Seg I). October 2014.

		15-3109. An 8-week multiple dose immunotoxicity study of ocrelizumab by intravenous injection in juvenile cynomolgus monkeys with a 9-month recovery period. September 2018. 17-1133. An assessment of the effects of ocrelizumab on embryo-fetal and pre- and postnatal development when administered once weekly for up to 23 weeks intravenously to pregnant cynomolgus monkeys. June 2020. 18-1377. A 72-hour single dose subcutaneous local tolerance study of ocrelizumab in male Sprague-Dawley rats. July 2018. 18-1665. A 7-day Good Laboratory Practices single dose subcutaneous local tolerance study of 2H7 SC in male Sprague-Dawley rats. February 2019. 18-1979. Ocrelizumab: a single dose subcutaneous local tolerance study in Göttingen mini-pigs. February 2019.

Remarks of Evaluator	Observations 1.3.2 The batch release site mentioned on COPP is “Roche Pharma AG Emil-Barell-Strasse 1,79639 Grenzach-Wyhlen, Germany” whereas on Form 5F and section 3.2.P.3.1 is “F. Hoffmann-La Roche AG Wurmisweg 4303 Kaiseraugst Switzerland”. Clarification is required. - Provide the name of exporting country. - Submit hard copy of original letter of authorization and relationship letter. - Documents/evidence for acceptable shipping conditions for finished product and & proof of shipping validation. 3.2.S.1-3.2.S.7: Submit data of API in relevant sections where you have referred to Ocrelizumab IV. 3.2.P.8.2: Submit stability data of PPQ/commercial batches till claimed shelf life i.e. 24 months. - Module 4 Non-Clinical Data a) Justification with evidence of reference guidelines were studies have not been performed for subcutaneous route. - Module 5: Clinical Data a) Justification with evidence of reference guidelines were Phase III studies have been performed on 236 subjects. However, for better demonstration of efficacy and monitoring of ADRs study participants ought to be greater than 300. b) Clarification/justification is required for performing open label studies instead of blinding. c) Reports on post marketing experience is required as product is already approved in EMA.

Comments of BE&R

Not Recommended till the submission of the above cited documents.

Previous Decision of 345th Meeting:

The Registration Board deferred the case for the submission of the following documents:

- The batch release site mentioned on COPP is “Roche Pharma AG Emil-Barell-Strasse 1,79639 Grenzach-Wyhlen, Germany” whereas on Form 5F and section 3.2.P.3.1 is “F. Hoffmann-La Roche AG Wurmisweg 4303 Kaiseraugst Switzerland”. Clarification is required.
- Name of exporting country.
- Hard copy of original letter of authorization and relationship letter.
- Documents/evidence for acceptable shipping conditions for finished product and & proof of shipping validation.
- Data of API in relevant sections (3.2.S.1-3.2. S.7) where you have referred to Ocrelizumab IV.
- Stability data of PPQ/commercial batches till claimed shelf life i.e. 24 months.
- Justification with evidence of reference guidelines were non-clinical studies have not been performed by subcutaneous route.
- Justification with evidence of reference guidelines were Phase III studies have been performed on 236 subjects. However, for better demonstration of efficacy and monitoring of ADRs study participants ought to be greater than 300.
- Clarification/justification is required for performing open label studies instead of blinding.
- Reports on post marketing experience is required as product is already approved in EMA.

Remarks of the Evaluator

Sr. NO	Observation	Applicant Response	Evaluation by BE& R
1.	The batch release site	The EMA CoPP does not specify	The applicant has

	mentioned on COPP is “Roche Pharma AG Emil-Barell-Strasse 1,79639 Grenzach-Wyhlen, Germany” whereas on Form 5F and section 3.2.P.3.1 is “F. Hoffmann-La Roche AG Wurmisweg 4303 Kaiseraugst Switzerland”. Clarification is required.	details regarding the batch release for the importing country; it only references the "batch release of the finished medicinal product in the EU" (as mentioned in the CoPP). Therefore, the designated site responsible for batch release for Pakistan is the one indicated in section 3.2.P.3.1 of the submitted dossier. (Annex-I)	submitted declaration that their batch release site will be ““F. Hoffmann-La Roche AG Wurmisweg 4303 Kaiseraugst Switzerland”. However, the batch release site listed in the COPP should match the information provided in Module 3, section 3.2.P.3.2 of the Common Technical Document (CTD). Response Received from EMA regarding clarification for batch release site on COPP. <i>“Please be advised that the batch release in the EU activity which can be mentioned in the certificates is only intended for sites located in the EU. We can issue for any site approved for the batch release in the EU for the certain product. To see which sites are approved for batch release in the EU for a certain product please consult the Annex II of the SmPC of that product published on the EMA website.”</i> Name and address of the manufacturer responsible for Roche Pharma AG Emil-Barell-Strasse 1 79639 Grenzach-Wyhlen Germany Placed before Board for consideration whether to proceed with declaration or mandate a revised COPP.
2.	Name of exporting country.	Switzerland	-
3.	Hard copy of original letter of authorization and relationship letter.	Scanned Copy Attached	-
4.	Documents/evidence for acceptable shipping conditions for finished product and & proof of shipping validation	Qualification Summary report for the Taracell Getcool Cold .	The PQ was performed (VAL-0126636) for the shipment route from F. Hoffmann-La Roche Ltd., Kaiseraugst, Switzerland (KAU) to Produtos Roche Quimicos E Farmaceuticos S.A., Anapolis, Brazil or Produtos Roche Químicos e Farmacêuticos S.A., Rio de Janeiro, Brazil.
5.	Data of API in relevant sections (3.2.S.1-3.2. S.7) where you have referred to Ocrelizumab IV.		
6.	Stability data of PPQ/commercial batches till claimed shelf life i.e.	Enclosed	Data upto 24 months for following batches has been

	24 months		submitted by the applicant. H001 H002 H003
7.	Justification with evidence of reference guidelines were non-clinical studies have not been performed by subcutaneous route.	The Applicant would like to confirm that the nonclinical strategy to support the application for subcutaneous (SC) administration of ocrelizumab leverages the available comprehensive nonclinical data packages (including pharmacology, pharmacokinetics/toxicokinetics, and toxicology) for intravenous (IV) administration of ocrelizumab, as well as local tolerability assessments upon SC administration of ocrelizumab. Additionally, a nonclinical program was carefully designed and meets all requirements to adequately characterize the pharmacology, pharmacokinetics/toxicokinetics, toxicity and local tolerability of rHuPH20 as a locally active SC permeation enhancer for biotherapeutics and in particular for ocrelizumab SC. Since the systemic exposure of ocrelizumab by the new SC route of administration is equivalent to or less than that of the approved IV route, histological evaluation was limited to locally exposed tissues (injection site) of local tolerability studies, in line with FDA guidance “Nonclinical Safety Evaluation of Reformulated Drug Products and Products Intended for Administration by an Alternate Route” (FDA 2018). Therefore, a direct comparison of the concentration tested in relevant rat and minipig models (Studies 18-1665 and 18-1979) to the proposed human drug product concentration (40 mg/mL), provided an appropriate determination of the tolerability of ocrelizumab SC formulation in the immediate local tissue environment.	Justified.
8.	Justification with evidence of reference guidelines were Phase III studies have been performed on 236 subjects. However, for better demonstration of efficacy and monitoring of ADRs study participants ought to be greater than 300.	The Applicant would like to clarify that, while 236 subjects were evaluated in the Phase III study OCARINA II (CN42097), overall, more than 300 patients were evaluated in OCARINA II and OCARINA I (CN41144), the studies contributing to the safety evaluation of ocrelizumab SC, as outlined in the Section 1.2.1 of the Summary of Clinical Safety. An updated 120-Day Safety Report is available and is provided along with this response.	Justified.

		By the time the analysis for this report was completed, ~350 patients were evaluated, as shown in Section 2.2.1 (see Table 1). The reference guideline used was ICH Topic E 1 Population Exposure: The Extent of Population Exposure to Assess Clinical Safety. Additionally, the FDA's advice was sought, and they agreed that the size of the safety database was adequate, considering the exposure size of the population sufficient. This clinical development was following the PK bridging approach, and with the demonstrated PK non-inferiority, Ocrevus SC is expected to have a similar safety profile to Ocrevus IV, which has been well characterized based on data from >400.000 patients treated with >1.5 million PYs of cumulative exposure as of Nov 2024.	
9.	Clarification/justification is required for performing open label studies instead of blinding.	The Applicant would like to clarify that the OCARINA I and OCARINA II studies supporting this application compared the IV and SC administration of ocrelizumab. OCARINA I was an exploratory study to assess the pharmacokinetics (PK) and safety of the new SC formulation. The primary endpoint of the pivotal OCARINA II study was the PK comparison of ocrelizumab after IV and SC administration. The PK measurement, i.e. ocrelizumab serum levels is, by definition, an objective endpoint, and the measurement cannot be biased in any way by an open label study conduct. Studies with PK as the primary objective are therefore indeed usually open label studies. The required time-points for collection of blood samples to characterize PK are different after IV and SC administration, as PK profiles are different after SC and IV administration. Blinding a study would have therefore required the collection of multiple additional blood samples from all patients, which is not justified, as there is no added scientific value. Blinding the studies would have imposed a big and unnecessary burden for health care providers and patients to have both formulations (SC and IV) administered concomitantly to each patient. Additionally, secondary and exploratory radiological endpoints	Justified.

		for OCARINA II were analyzed by a blinded centralized reading center, meaning the investigators could not influence the results.	
10.	Reports on post marketing experience is required as product is already approved in EMA.	The Applicant would like to confirm that Ocrevus SC has been approved in the EU on 20 June 2024. The previous PBRER (reporting period 28 March 2021 to 27 March 2024) was already submitted to the Pakistan Health Authority in June 2024 and it included Ocrevus IV data where, as per the PK bridging approach, the Applicant has characterized the safety profile of SC is similar to IV, with injection reactions (IRs) and infusion-related reactions (IRRs) being the only difference, specific to each route of administration. Therefore, the post-marketing experience with Ocrevus IV included in the PBRER 2024 is also applicable to Ocrevus SC. A new PBRER (reporting period 28 March 2024 to 27 March 2025), including SC data, is currently under preparation and will be available by June 2025, and will be submitted to the Pakistan Health Authority according to the local regulations. This will be the 1st PBRER to also include post-marketing experience with Ocrevus SC.	Justified.

Recommendation by BE& R Division

Recommended and placed before Board for consideration whether to proceed with the declaration regarding the batch release site or mandate the submission of a revised Certificate of Pharmaceutical Product (COPP).

Decision of 347th Meeting :

The Registration Board deferred the case for the submission of the following documents:

- **Original, legalized and valid Certificate of Pharmaceutical Product (COPP) of Swissmedic stating batch release site “F. Hoffmann-La Roche AG Wurmisweg 4303 Kaiseraugst Switzerland”.**

Evaluation by BE&R

Sr. No.	Query	Response	Evaluation
1	Original, legalized and valid Certificate of Pharmaceutical Product (COPP) of Swissmedic stating batch release site “F. Hoffmann-La Roche AG Wurmisweg 4303 Kaiseraugst Switzerland”.	It is to be noted that the CPP now reflects a change in the Marketing Authorization Holder (MAH), which has been changed from: Roche Registration GmbH, Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Germany to F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, 4058 Basel, Switzerland. Additionally, we would like to inform you of the updated company address in Pakistan, which has been changed from: Roche Pakistan Limited, 1st Floor, 37-B,	New DSL dated 10-01-2025 Drug License by Way of Retail Sale. License Number: 1759 Validity : 23-12-2029 Also update the address in eApp system. Original Apostille COPP Certificate No: 25001961 Free Sale Status: Yes GMP : Yes Shelf life: 24 months New MAH: F. Hoffmann-La Roche Ltd, Grenzacherstrasse 124, 4058 Basel Switzerland.

		Block 6, P.E.C.H.S, Karachi to Roche Pakistan Limited, Office #1101-1104, 11th Floor, Al-Tijarah Centre, Plot #32-1-A, Block 6, P.E.C.H.S, Karachi, Pakistan. Sr. No. Pre-Registration Variations Challan No. Fee 1. Change of MAH 05861564 150,000/- 2. Change of company address 21379028 9000/-	Bulk Manufacturing+Quality Control Testing +Primary Packaging Roche Diagnostics GmbH, Sandhofer Strasse 116, 68305 Mannheim, Germany Labeling, Secondary Packaging +Release F. Hoffmann-La Roche AG Wurmisweg 4303 Kaiseraugst Switzerland

Conclusion:

The applicant has now submitted a new Swissmedic COPP along with the updated MAH details and has provided the requisite fee.

Decision of 348th Meeting:

The Registration Board approved the formulation with shelf life of 24 months to be stored at 2-8°C as per current policy for inspection of manufacturers abroad notified vide Letter No.3-2/2005-Reg-I /Vol-II dated July 6, 2022.

ATEZOLIZUMAB	
Deferred Cases-M-347	
Case # 27	
Name, address of Applicant / Importer	M/s Roche Pakistan Limited, 1 st floor, 37-B, Block 6, PECHS, Karachi.
Details of Drug Sale License of importer	License No: 0375 Address: Roche Pakistan Limited, 1 st floor, 37-B, Block 6, PECHS, Karachi. Address of Godown: • R-PI, plot no. 56, sector 15, K.I.A, Karachi Validity: 07/11/2028. Status: Drug License by way of wholesale Renewal: N/A
Name and address of marketing authorization holder (abroad)	Roche Registration GmbH, Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Germany.
Name, address of manufacturer(s)	Manufacturer, Primary and Secondary Packaging Site: Roche Diagnostics GmbH, Sandhofer Strasse 116, 68305 Mannheim, Germany.
Name of exporting country	Switzerland
Detail of certificates attached (CoPP, Free-sale certificate, GMP certificate)	EMA e-CPP Certificate No.: 01/21/001133 Issuance Date: 02/02/2024
Details of letter of authorization / sole agency agreement	- Product Specific authorization letter from M/s F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, CH-4070 Basel Switzerland in name of M/s Roche Pakistan Limited, Karachi dated 31-08-2023. - Copy of relationship letter indicating relation of all Roche companies with M/s F. Hoffmann-La Roche Ltd., Basel. Switzerland.
Status of the applicant	☒ Importer
Status of application	☒ New Drug Product (NDP)
Intended use of pharmaceutical product	☒ Domestic sale
For imported products, specify one the these	☒ Finished Pharmaceutical product import
Dy. No. and date of submission	Tracking ID:67L-AQD-TSD6

	Application Number:2466 Receiving: 06-05-2024
Details of fee submitted	Deposited Fee = 300,000/- Deposit Slip no.8807858852 PKR 75,000 Dated 14-02-2024 Deposit Slip no.8485171119 PKR 225,000 Dated 09-04-2024
The proposed proprietary name / brand name	Tecentriq
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Atezolizumab...1875mg
Indications	Treatment of non-small cell lung cancer (NSCLC), small cell lung cancer (SCLC), hepatocellular carcinoma, melanoma, and alveolar soft part sarcoma.
Dosage form of applied drug	Subcutaneous Use (Solution for injection)
Pharmacotherapeutic Group of (API)	Antineoplastic (Monoclonal Antibodies) ATC code: L01FF05
Reference to Finished product specifications	Innovator's specifications
Proposed pack size	1's vial
Proposed unit price	As per SRO
Shelf life	24 months
Storage conditions	2°C - 8°C
The status in reference regulatory authorities	EMA Approved.
For generic drugs (me-too status)	N/A
Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH guidelines. The firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
Name, address of drug substance manufacturer	Roche Diagnostics GmbH Nonnenwald 2 82377 Penzberg Germany
Module-III Drug Substance:	The firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	36 months real time stability data at -20°C of 03 batches 06 months accelerated stability data at 5°C of 03 batches
Module-III Drug Product:	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Analytical method validation/verification of product	The firm has submitted that the data from the PPQ batches demonstrate that the FDC drug product manufacturing process consistently yields drug product that meets the predetermined acceptance criteria for all quality attributes and that the in-process tests are suitable to monitor the manufacturing process.
Analytical method validation/verification of product	The firm has submitted analytical method validation studies for the applied product.
Container closure system of the drug product	6 mL, USP/Ph. Eur./JP Type I glass, borosilicate, colorless

	Stability study data of drug product, shelf life and storage conditions	• 36 months real time stability data at 5°C of 03 batches • 06 month accelerated stability data 25°C of 03 batches
	Module-IV Non-Clinical	4.2 Study Reports 4.2.1 Pharmacology 4.2.1.1 Primary Pharmacodynamics • NC 09-0426. In Vitro Binding and Biological Activity of MPDL3280A (rhuMAb PD-L1) (Amendment 1). Genentech, March 2011 • NC 15-0984. In Vitro Binding Affinity of MPDL3280A. Genentech, June 2015 • NC 08-1033 E. Evaluation of the Anti-Tumor Efficacy of Anti-PD-L1 Monoclonal Antibody in the Syngeneic MC38.OVA Colorectal Cancer Model in C57BL-6 Mice. Genentech, February 2011 • NC 10-1883. Evaluation of the Anti-Tumor Efficacy of Anti-PD-L1 Monoclonal Antibody in the Syngeneic MC38 Colorectal Model in C57BL-6 Mice. Genentech, February 2011 • NC 08-1734 D. Evaluation of the Anti-Tumor Efficacy of Anti-PD-L1 Monoclonal Antibody in the Syngeneic CT26 Colorectal Cancer Model in Balb-c Mice. Genentech, February 2011 • NC 09-2165 I. Evaluation of the Anti-Tumor Efficacy of Anti-PD-L1 Monoclonal Antibody in the Syngeneic Cloudman S91Melanoma Model in DBA-2 Mice. Genentech, February 2011 • NC 08-0559 A 08-0559 B 08-1160. Therapeutic Efficacy and Dose Titration of Anti-PD-L1 mAb in the Lymphocytic Choriomeningitis Virus Infection Model. Genentech, June 2009 • NC 09-2500 09-2500 B 09-2501 09-2501 A. Evaluation of the Host Response to Armstrong and CL-13 Lymphocytic Choriomeningitis Virus (LCMV) Infection in Mice following Administration of a Single Dose of Anti-PD-L1 Antibody at Different Times during Infection. Genentech, March 2011 • NC 10-1394. Studies to Address Mechanism of Anti-PD-L1 Enhanced Pathology in Lymphocytic Choriomeningitis Virus (LCMV) Infection: Comparisons between Clone-13 and Armstrong Strains. Genentech, August 2010 • NC 08-1309 A. Evaluation of the Combined Effects of Adenovirus Expressed Interferon-alpha (IFN-a) and Anti-PD-L1 mAb in Mice Infected with Lymphocytic Choriomeningitis Virus (LCMV) (Amendment 1). Genentech, July 2010 • NC 15-2718. Non-Clinical Biomarker Study in Pediatric Tumor Tissue (Amendment 2). Genentech, January 2016 4.2.2 Pharmacokinetics 4.2.2.1 Analytical Methods and Validation Reports • NC 4.MPDL.1.AVR_0. 4.MPDL.1 (MPDL3280A) Cynomolgus Monkey Serum Antigen ELISA. Genentech, June 2009 • NC ICD 590. Validation of an ELISA Method for the Quantitation of MPDL3280A (Anti-PD-L1) in Cynomolgus Monkey Serum. Genentech, May 2015 • NC 4.MPDL.2.AVR_0. 4.MPDL.2 (MPDL3280A) Cynomolgus Monkey Serum ATA DIG ELISA. Genentech, July 2009 • NC ICDIM 207. Validation of an Immunoassay Method for the Detection of Antibodies to MPDL3280A (Anti-PD-L1) in Cynomolgus Monkey Serum. Genentech, May 2015 4.2.2.7 Other Pharmacokinetic Studies • NC 08-1946. Evaluation of Pharmacokinetics and Pharmacodynamics following Single-Dose Intravenous Administration of an Anti-PD-L1 Reverse Chimera Antibody (Amendment 1). Genentech, March 2011 • NC 08-0598. A Single-Dose Pharmacokinetic Study of MPDL3280A Administered by Intravenous Injection to Cynomolgus Monkeys. Genentech, June 2009 4.2.3 Toxicology 4.2.3.2 Repeat-Dose Toxicity • NC 08-0806. A 15-Day Pilot Toxicity Study of Anti-PDL1 (MPDL3280A) Administered by Intravenous Injection Once a Week for a Total of 3 Doses to Female C57BL 6 and CD-1 Mice with 4 Weeks of Recovery (Amendment 1) Genentech, July 2011 • NC 08-1148. An Eight-Week Toxicity, Toxicokinetic, and Safety Pharmacology Study of MPDL3280A Administered by Intravenous Injection or Subcutaneous Injection to Cynomolgus Monkeys, with a 12-Week Recovery Period. Genentech, November 2009

		- NC 13-3278. A 26-Week Toxicity and Toxicokinetic Study with MPDL13280A, Administered by Intravenous Injection to Cynomolgus Monkey with a 13-Week Recovery Phase. Genentech, September 2015 4.2.3.7 Other Toxicity Studies 4.2.3.7.7 Other - NC 08-1827. In Vitro Cytokine Release Study with Anti-PD-L1 Antibody in Human PBMCs (Amendment 1). Genentech, March 2011 - NC 08-1172. Hemolytic Potential Testing with MPDL3280A in Cynomolgus Monkey and Human Blood. Genentech, June 2009 - NC 08-1174. Tissue Cross-Reactivity of MPDL3280A with Human and Cynomolgus Monkey Tissues Ex Vivo. Genentech, June 2009
	Module-V Clinical	5 Clinical Study Reports 5.2 Tabular Listing of all Clinical Studies Synopses of Individual Studies - SC 5.3 Clinical Study Reports 5.3.1 Reports of Biopharmaceutic Studies 5.3.1.4 Reports of Bioanalytical and Analytical Methods for Human Studies Node Extension P251 - The Validation History of the Method for Measuring MPDL3280A (Anti-PD-L1) in Human Serum. Node Extension P252 - The Validation History of the Method for the Detection of Anti-Drug Antibodies to Atezolizumab in Human Serum Node Extension P283 - The Validation History of the Method for the Detection of Anti-rHuPH20 Binding Antibodies in Human Plasma (K3EDTA) by an Electro chemiluminescent Assay (ECLA). Node Extension P352 - The Validation History of the Method for the Quantitative Detection of Immuno-Reactive rHuPH20 in Human K3EDTA Plasma. Node Extension VHR_MPDL3280_NAb - The Validation History of the ELISA Method for the Detection of Neutralizing Antibodies to Atezolizumab in Human Serum. Node Extension P4367 - The Validation History of the Method for the Detection of Neutralizing Antibodies to rHuPH20 in Human Plasma. 5.3.3 Reports of Human Pharmacokinetic (PK) Studies 5.3.3.5 Population PK Study Reports Node Extension PopPK Report 1116054. Population Pharmacokinetics of Subcutaneous and Intravenous Administration of Single-Agent Atezolizumab (Anti-PD-L1 Antibody) in Patients with Previously Treated Locally Advanced or Metastatic Non-Small Cell Lung Cancer IMscin001 (BP40657) (Part/Phase 1/I and 2/III). Node Extension Exposure-Response Analysis Report 1116055. Exposure-Response Analyses of Subcutaneous Administration of Single-Agent Atezolizumab (Anti-PD-L1 Antibody) in Patients with Previously Treated Locally Advanced or Metastatic Non Small Cell Lung Cancer IMscin001 (BP40657) (Part/Phase 2/III). 5.3.5 Reports of Efficacy and Safety Studies - Indication: NSCLC 2L PK Safety Efficacy (Part 2 only) ADA PRO(Part 2 only) Phase Ib/III, two-part, randomized, multicenter, open-label, active controlled, Part 1: 3 arm Part 2: 2 arm
	Evaluator Remarks:	<u>Shortcomings</u> - Form 5 F: Submit data in relevant sections of Module 1 instead of referring to Annexures. - Submit original hard copy of letter of authorization and relationship letter. - Update the fee challan details of remaining fee in additional fee section of eApp.

	4. The COPP and section 1.3.1 does not provide any information about QC and batch release site of the finished product. 5. Documents/evidence for acceptable shipping conditions for finished product and & proof of shipping validation. 6. Submit stability data of PPQ batches till claimed shelf life i.e. 36 months. 7. Provide responsibilities of QC and batch release site involved in Manufacture of Atezolizumab SC Drug Product. 8. 3.2.P.8.2: Submit stability data of PPQ batches till claimed shelf life i.e. 24 months or claim shelf life of 18 months. 9. Module 4: Non-Clinical Data - Justification with evidence of reference guidelines were studies have not been performed for subcutaneous route. - Provide tabular listing of nonclinical studies by SC route along with conclusion. 10. Module 5: Clinical Data - Submit complete module 5 containing all study reports. - Clarification/justification is required for performing open label studies instead of blinding.

Comments by BE&R

Recommended subjects to submission of shortcomings.

Decision of 345th Meeting:

The Registration Board deferred the case for the submission of the following documents:

- Data in relevant sections of Module 1 instead of referring to Annexures.
- Original hard copy of letter of authorization and relationship letter.
- Update the fee challan details of remaining fee in additional fee section of eApp.
- The COPP and section 1.3.1 does not provide any information about QC and batch release site of the finished product.
- Documents/evidence for acceptable shipping conditions for finished product and & proof of shipping validation.
- Stability data of PPQ batches till claimed shelf life i.e. 36 months.
- Responsibilities of QC and batch release site involved in Manufacture of Atezolizumab SC Drug Product.
- stability data of PPQ batches till claimed shelf life i.e. 24 months or claim shelf life of 18 months.
- Justification with evidence of reference guidelines were non-clinical studies have not been performed for subcutaneous route.
- Provide tabular listing of nonclinical studies by SC route along with conclusion.
- Submit complete module 5 containing all study reports as per CTD guidance document.
- Clarification/justification is required for performing open label studies instead of double blind.

Remarks of Evaluator

Sr. No.	Queries	Company's Response	Remarks
1.	Form 5 F Submit data in relevant sections of Module 1 instead of referring to Annexures.	Enclosed in the Attachment in Annex-I.	Applicant has hyperlinked the Annexures.
2.	Submit original hard copies of the letter of authorization and relationship letter.	Enclosed in the Attachment in Annex-Ia & Ib.	eCOPP has been submitted.
3.	1.1 Update the fee challan details of the remaining fee in the additional fee section of the e-App.	Updated on e-APP.	Updated.
4.	1.3.1 The CoPP and section 1.3.1 do not provide any information about QC and batch release site of the finished product.	The QC site is the same as the manufacturing site and packaging site located at Roche Diagnostics GmbH, Sandhofer Strasse 116, 68305 Mannheim, Germany, so it was mentioned separately. The EMA CoPP does not specify details regarding the batch release for	Declaration of Batch Release site for Tecentriq SC (Atezolizumab 1875 mg/15 ml), for Roche Pakistan Limited We, Pharma Technical Regulatory, hereby declare that the following site is responsible for performing batch release for the product Tecentriq SC 1875 mg/15 ml for Roche Pakistan Limited. We confirm that this site operates in

		the importing country; it only references the "<i>batch release of the finished medicinal product in the EU</i>" (as mentioned in the CoPP). Therefore, we have enclosed a declaration letter specifying the batch release site for Pakistan. Enclosed in the Attachment in Annex-I , III and IIIa	compliance with the international guidelines on Good Manufacturing Practice (GMP) “F. Hoffmann-La Roche AG Wurmisweg 4303 Kaiseraugst Switzerland” Placed before Board for consideration whether to proceed with declaration or request a revised COPP.
5.	1.4.2 Documents/evidence for acceptable shipping conditions for finished product and proof of shipping validation.	Qualification Summary report for the Taracell Getcool Cold .	The PQ was performed (VAL-0126636) for the shipment route from F. Hoffmann-La Roche Ltd., Kaiseraugst, Switzerland (KAU) to Produtos Roche Químicos e Farmaceuticos S.A., Anapolis, Brazil or Produtos Roche Químicos e Farmacêuticos S.A., Rio de Janeiro, Brazil.
6.	3.2.S.7 Submit stability data of PPQ batches till claimed shelf life i.e. 36 months.	Enclosed in the Attachment Annex V.	24 months data of PPQ/commercial batches has been submitted. The proposed atezolizumab SC commercial drug substance shelf life at the long-term storage condition of –20°C is 36 months, which is the same as the approved drug substance shelf life for commercial atezolizumab for intravenous administration (atezolizumab IV). This proposed shelf life is supported by the long-term and accelerated stability data available to date (summarized in Table S.7.1-7), which demonstrate that little or no change is observed after 36 months at the long-term storage temperature. This 36 months’ shelf life is further supported by the end-to-end degradation assessment (refer to Section P.8.1 Stability Summary and Conclusion). Based on the above observations and the currently available long-term stability data, the PPQ batches are expected to remain within acceptance criteria at the end of the proposed shelf life of 36 months at –20°C
7.	3.2.P.3.1 Provide responsibilities of QC and batch release site involved in Manufacture of Atezolizumab SC Drug Product.	Enclosed in the Attachment in Annex III. Manufacture of Drug Product (including filling/primary packaging)	As per COPP , following are the site b) manufacturing the bulk finished f) primary packaging of the dosage form

		Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim Germany Quality Control Release , Stability Testing Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim Germany Labeling and Secondary Packaging ,Release of Finished Drug Product F. Hoffmann-La Roche AG Wurmisweg 4303 Kaiseraugst Switzerland Release of Finished Drug Product	g) secondary packaging of the product Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim Germany As Per SMPC at EMA website Name and address of the manufacturer responsible for batch release Roche Pharma AG Emil-Barell-Strasse 1 79639 Grenzach-Wyhlen GERMANY Response Received from EMA regarding clarification for batch release site on COPP. <i>“Please be advised that the batch release in the EU activity which can be mentioned in the certificates is only intended for sites located in the EU. We can issue for any site approved for the batch release in the EU for the certain product. To see which sites are approved for batch release in the EU for a certain product please consult the Annex II of the SmPC of that product published on the EMA website.”</i>
8.	3.2.P.8.2 Submit stability data of PPQ batches till claimed shelf life i.e. 24 months or claim shelf life of 18 months.	Enclosed in the Attachment in Annex VI. PPQ Batches H0001 Up to 24 mo Results to date meet the study and commercial shelf-life acceptance criteria. Changes (Tfinal time point – T0) were observed for the following: IE-HPLC: Up to 2.1% increase in the acidic region and up to 2.3% decrease in the main peak. and up to 1.5% decrease in main peak SE HPLC: Up to 0.2% increase in the sum of HMW forms and up to 0.4% decrease in main peak NR-CE-SDS: Up to 0.4% increase in the sum of pre-peaks and up to 0.7% decrease in main peak Little or no change observed in any of the other attributes tested (refer to Table P.8.1-4for the attributes tested).	Data submitted for 24 months.
9.	Module 4: Non-Clinical Data a) Justification with evidence of reference guidelines were studies have not been performed for subcutaneous route.	Please refer to Appendix 1 Explanation for the Absence of Data or Sections from the CTD of Module 2.4 Nonclinical Overview. (Annex VII)	Justifications provided in the light of ICH guidelines.
10.	b) Provide tabular listing of nonclinical studies by SC route along with conclusion.	The non-clinical studies conducted for the IV application are applicable to the SC route.	

11.	Module 5: Clinical Data a) Submit complete module 5 containing all study reports.	Please find enclosed the Module 5 documents supporting the indication for Tecentriq SC. The documents shared reflect the indication already reviewed and approved in Pakistan as part of Tecentriq 1200 mg and 840 mg, intravenous administration. (Annex VIII)	--
12.	b) Clarification/justification is required for performing open label studies instead of blinding.	Since the IMscin 001 study compared two methods of administration (Tecentriq SC vs IV), blinding the study for either HCPs and/or patients would have required administering placebo versions of both the subcutaneous and intravenous formulations and administering them concomitantly. This would have imposed a significant additional burden on HCPs and patients. On the other hand, both co-primary endpoints of the study were derived from PK samples analyzed at a central lab and therefore, even if the investigators knew the treatment allocation, they could not influence the result.	Justified following reliance pathway.

Recommendation by BE& R Division

Recommended and placed before Board for consideration whether to proceed with declaration w.r.t to batch release site or mandate a revised COPP.

Decision of M-347:

The Registration Board deferred the case for the submission of the following document:

- ✓ Original, legalized and valid Certificate of Pharmaceutical Product (COPP) of Swissmedic stating batch release site “F. Hoffmann-La Roche AG Wurmisweg 4303 Kaiseraugst Switzerland”.

Sr. No.	Query	Response	Evaluation
1	Original, legalized and valid Certificate of Pharmaceutical Product (COPP) of Swissmedic stating batch release site “F. Hoffmann-La Roche AG Wurmisweg 4303 Kaiseraugst Switzerland”.	It is to be noted that the CPP now reflects a change in the Marketing Authorization Holder (MAH), which has been changed from: Roche Registration GmbH, Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Germany to F. Hoffmann-La Roche Ltd., Grenzachstrasse 124, 4058 Basel, Switzerland. Additionally, we would like to inform you of the updated company address in Pakistan, which has been changed from: Roche Pakistan Limited, 1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi to Roche Pakistan Limited, Office #1101-1104, 11th Floor, Al-Tijarah Centre, Plot #32-1-A, Block 6, P.E.C.H.S, Karachi, Pakistan.	New DSL dated 10-01-2025 Drug License by Way of Retail Sale. License Number: 1759 Validity : 23-12-2029 Also update the address in eApp system. Original Apostille COPP Certificate No: 25001962 Free Sale Status: Yes GMP : Yes Shelf life: 24 months New MAH: F. Hoffmann-La Roche Ltd, Grenzachstrasse 124, 4058 Basel Switzerland. Bulk Manufacturing+Quality Control Testing +Primary Packaging Roche Diagnostics GmbH, Sandhofer Strasse 116,

		Sr. No. Pre-Registration Variations Challan No. Fee 1. Change of MAH 75602489177 150,000/- 2. Change of company address 42436283786 9000/-	68305 Mannheim, Germany Labeling, Secondary Packaging +Release F. Hoffmann-La Roche AG Wurmisweg 4303 Kaiseraugst Switzerland
Conclusion: The applicant has now submitted a new Swissmedic COPP along with the updated MAH details and has provided the requisite fee.			
Decision of 348th Meeting: The Registration Board approved the formulation with shelf life of 24 months to be stored at 2-8°C as per current policy for inspection of manufacturers abroad notified vide Letter No.3-2/2005-Reg-I /Vol-II dated July 6, 2022.			

Agenda Item No. 03: Registration Applications of Misc. Biological Products

Case # 1	
Name, address of Applicant / Importer	Lab Diagnostic Systems (SMC) Pvt. Ltd. Plot 36-A, PSIC SIE, Taxila Rawalpindi
Details of Drug Sale License of importer	License No: 01-374-0006-118530D Address: 36-A, PSIC, SIE, Taxila Rawalpindi Validity: 15/08/2029
Name, address of manufacturer(s) & MAH	Name: Vins Bioproducts Limited Address: Survey No. 117, Thimmapur (Village), Kothur (Mandal), Ranga Reddy (Dist.),-509325, Telangana, India.
Name of exporting country	India
Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	CoPP: Valid CoPP has been provided. LOA: Valid LOA has been provided.
Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
Dy. No. and date of submission	Form -5F Application ID: 12X-JLL-LWVD Dated: 30-01-2025
Details of fee submitted	Rs: 3,00,000 Dated: 2 nd January,2025 Deposit Slip No. 52987445224
The proposed proprietary name / brand name	TETAVIN Tetanus Antitoxin 1500 I.U B.P
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Tetanus Antitoxin 1500 I.U B.P Each ml contains: Enzyme Refined, Equine Tetanus Antitoxic Immunoglobulin fragments not less than 1500 I.U.
Dosage form of applied drug	Solution for Injection
Pharmacotherapeutic Group of (API)	Antitoxins
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack size	20 Ampoules of 1ml in 1 pack (1 mL×20 ampoules)
Proposed unit price	As per SRO
Shelf Life	24 Months
Storage Conditions	Store between 2-8°C. Do not freeze. Protect from light.

The status in reference regulatory authorities	Not provided
For generic drugs (me-too status)	Tetanus Antitoxin 1500 I.U/ml BP, MAH: Amson Vaccines & Pharma (Pvt) Ltd, Islamabad, Manufacturer: Biological E. Ltd, 18 / 1 & 3, Azamabad, Hyderabad, India
Module-II (Quality Overall Summary	Firm has submitted QOS.
Name, address of drug substance manufacturer	Name: Vins Bioproducts Limited Address: Survey No. 117, Thimmapur (Village), Kothur (Mandal), Ranga Reddy (Dist.), -509325, Telangana, India.
Module-III Drug Substance:	Firm has submitted general information, detail of manufacture, characteristics, specifications, analytical procedures, container closure system and stability studies related to drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of three batches accelerated conditions 25°C±2°C and 60% ± 5% RH for 6 months and long -term stability studies of three batches at 2° C-8° C for 24 months.
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Container closure system of the drug product	The primary packaging includes flint USP Type 1 glass ampoule.
Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of three batches at accelerated conditions 25°C±3°C and 60% ± 5% RH for 6 months and real time stability studies of three batches at 5± 3°C for 24 Months. Depicting shelf life of 24 Months.
Module-IV Non-Clinical	Potency determination animal study provided.
Module-V Clinical	Not provided-Literature regarding in-vitro determination of tetanus immunity provided.
Remarks of Evaluator	• RRA approval status not provided. • The CoPP provided is not legalized. • LOA provided is not legalized. • CoPP mentions that the product is licensed to be placed on market of exporting country while product approval letter & product specific GMP certificate mention that the product is for export purpose. • Product specific GMP certificate of M/s Vins Bioproducts Limited submitted does not mention the drug substance manufacturing facility. • GMP certificate of M/s Shantha, claimed toxoid producer, has not been provided. • Finished product specifications need clarification as In-house as well as BP specifications, have been mentioned in product specification sheet. • Toxicity studies not provided in module IV.

		• Clinical studies data (module-V) not provided.																								
	Decision of 345 th RB meeting	The Registration Board deferred the case for rectification of following deficiencies in the application; • RRA approval status not provided. • The CoPP provided is not legalized. • LOA provided is not legalized. • CoPP mentions that the product is licensed to be placed on market of exporting country while product approval letter & product specific GMP certificate mention that the product is for export purpose. • Product specific GMP certificate of M/s Vins Bioproducts Limited submitted does not mention the drug substance manufacturing facility. • GMP certificate of M/s Shantha, claimed toxoid producer, has not been provided. • Finished product specifications need clarification as In-house as well as BP specifications, have been mentioned in product specification sheet. • Toxicity studies not provided in module IV. • Clinical studies data (module-V) not provided.																								
Evaluation by BE&R: The firm has submitted a reply which is tabulated below;																										
	<table><tr><th>Sr.No.</th><th>Deficiencies</th><th>Response of the firm</th><th>Remarks of evaluator</th></tr><tr><td>1</td><td>RRA approval status not provided</td><td>We have asked this information from manufacturer; we will submit that.</td><td>RRA approval status not provided yet.</td></tr><tr><td>2</td><td>The CoPP provided is not legalized.</td><td>Legalized COPP is attached in Annexure-I</td><td>Ministry of Foreign Affairs attested COPP is provided.</td></tr><tr><td>3</td><td>CoPP mentions that the product is licensed to be placed on market of exporting country while product approval letter & product specific GMP certificate mention that the product is for export purpose.</td><td>Manufacturer has shared domestic manufacturing licenses for Tetanus Antitoxin. The relevant license is attached in Annexure-III.</td><td>The firm has submitted License Retention Certificate along with List of products under Form 28D. The applied product “TETANUS ANTITOXIN 1500I.U BP (1ml LIQUID AMPOULE)” is mentioned in the list and the list shows that the product is registered for Export purpose.</td></tr><tr><td>4</td><td>Product specific GMP certificate of M/s Vins Bioproducts Limited submitted does not mention the drug substance manufacturing facility.</td><td>Declaration regarding this is attached for your reference in Annexure-IV.</td><td>The firm has submitted a declaration from M/s Vins Bioproducts Limited which states that; “We would like to inform you that Vins Bioproducts Limited holds a GMP certificate in accordance with Schedule M, as stipulated by the Drugs and Cosmetics Act. This certification is applicable to both Drug Substances and Drug product manufacturing processes. Hence, Product specific GMP certificate is not required for the manufacturing of Drug Substances at our facility.”</td></tr><tr><td>5</td><td>GMP certificate of M/s Shantha, claimed</td><td>We will share as soon as we receive it form principle.</td><td>Not submitted yet.</td></tr></table>	Sr.No.	Deficiencies	Response of the firm	Remarks of evaluator	1	RRA approval status not provided	We have asked this information from manufacturer; we will submit that.	RRA approval status not provided yet.	2	The CoPP provided is not legalized.	Legalized COPP is attached in Annexure-I	Ministry of Foreign Affairs attested COPP is provided.	3	CoPP mentions that the product is licensed to be placed on market of exporting country while product approval letter & product specific GMP certificate mention that the product is for export purpose.	Manufacturer has shared domestic manufacturing licenses for Tetanus Antitoxin. The relevant license is attached in Annexure-III.	The firm has submitted License Retention Certificate along with List of products under Form 28D. The applied product “TETANUS ANTITOXIN 1500I.U BP (1ml LIQUID AMPOULE)” is mentioned in the list and the list shows that the product is registered for Export purpose.	4	Product specific GMP certificate of M/s Vins Bioproducts Limited submitted does not mention the drug substance manufacturing facility.	Declaration regarding this is attached for your reference in Annexure-IV.	The firm has submitted a declaration from M/s Vins Bioproducts Limited which states that; “We would like to inform you that Vins Bioproducts Limited holds a GMP certificate in accordance with Schedule M, as stipulated by the Drugs and Cosmetics Act. This certification is applicable to both Drug Substances and Drug product manufacturing processes. Hence, Product specific GMP certificate is not required for the manufacturing of Drug Substances at our facility.”	5	GMP certificate of M/s Shantha, claimed	We will share as soon as we receive it form principle.	Not submitted yet.	
Sr.No.	Deficiencies	Response of the firm	Remarks of evaluator																							
1	RRA approval status not provided	We have asked this information from manufacturer; we will submit that.	RRA approval status not provided yet.																							
2	The CoPP provided is not legalized.	Legalized COPP is attached in Annexure-I	Ministry of Foreign Affairs attested COPP is provided.																							
3	CoPP mentions that the product is licensed to be placed on market of exporting country while product approval letter & product specific GMP certificate mention that the product is for export purpose.	Manufacturer has shared domestic manufacturing licenses for Tetanus Antitoxin. The relevant license is attached in Annexure-III.	The firm has submitted License Retention Certificate along with List of products under Form 28D. The applied product “TETANUS ANTITOXIN 1500I.U BP (1ml LIQUID AMPOULE)” is mentioned in the list and the list shows that the product is registered for Export purpose.																							
4	Product specific GMP certificate of M/s Vins Bioproducts Limited submitted does not mention the drug substance manufacturing facility.	Declaration regarding this is attached for your reference in Annexure-IV.	The firm has submitted a declaration from M/s Vins Bioproducts Limited which states that; “We would like to inform you that Vins Bioproducts Limited holds a GMP certificate in accordance with Schedule M, as stipulated by the Drugs and Cosmetics Act. This certification is applicable to both Drug Substances and Drug product manufacturing processes. Hence, Product specific GMP certificate is not required for the manufacturing of Drug Substances at our facility.”																							
5	GMP certificate of M/s Shantha, claimed	We will share as soon as we receive it form principle.	Not submitted yet.																							

		toxoid producer, has not been provided.		
6	Finished product specifications need clarification as In house as well as BP specifications, have been mentioned in product specification sheet.	It was a typographical error, our product complies with the BP Specifications	-	
7	Toxicity studies not provided in module IV.	Attached as Annexure-V	Firm has submitted 28 days Repeat Dose Toxicity Study of Tetanus Antitoxin 1500IU/ml in 60 rats (30 males and 30 females).	
8	Clinical studies data (module-V) not provided.	Attached as Annexure-VI	Firm has submitted a clinical study report of study title "Safety of Equine Tetanus Antitoxin for Prophylactic Use in Ethiopia: A multicenter Retrospective study". The study was a multi-site retrospective cohort study. A total of 1123 patients were included from 11 public healthcare facilities. Out of 1123 patients in the study, 1120 patients had taken the TAT dose of 3000IU and 3 patients had taken the TAT dose of 1500IU.	
Concluding Remarks by BE&R: The reply of the firm is still deficient for submission of following, • RRA approval status. • Registration status in country of origin whether for export purpose or both domestic and export purpose. • GMP certificate of M/s Shantha claimed toxoid producer. It is further stated that the applied product is already approved in the name of M/s Bristol Mayer Biotech Pakistan in 339th meeting of Registration Board as per following details; <i>Tetanus Antitoxin 1500 IU BP</i> <i>Each ml contains;</i> <i>Enzyme Refined, Equine Tetanus Antitoxin Immunoglobulin fragments..... NLT 1500 IU</i> <i>(1 ml liquid ampoule)</i>				
Decision of 348th RB meeting: Registration Board after detailed deliberation deferred the case for clarification from the applicant as the applied product is already approved in the name of M/s Bristol Mayer Biotech Pakistan in 339th meeting of Registration Board. The Board advised the applicant to submit valid product specific letter of authorization and further clarification from MAH about the marketing rights given to M/s Bristol Mayer Biotech Pakistan.				

Case#2		
	Name, address of Applicant / Importer	Lab Diagnostic Systems (SMC) Pvt. Ltd. Plot 36-A, PSIC SIE, Taxila Rawalpindi
	Details of Drug Sale License of importer	License No: 01-374-0006-118530D Address: 36-A, PSIC, SIE, Taxila Rawalpindi

	Validity: 15/08/2029
Name, address of manufacturer(s) & MAH	Name: Vins Bioproducts Limited Address: Survey No. 117, Thimmapur (Village), Kothur (Mandal), Ranga Reddy (Dist.),-509325, Telangana, India.
Name of exporting country	India
Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	CoPP: Valid CoPP has been provided. LOA: Valid LOA has been provided.
Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
Dy. No. and date of submission	Form -5F Application ID: D9J-N52-7Z6U Dated: 31-01-2025
Details of fee submitted	Rs: 3,00,000 Dated: 18/2/2024 Deposit Slip No. 31555199874
The proposed proprietary name / brand name	GLOBURAB (Rabies Antiserum 1000 I.U I.H.S, 5ml Vial)
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Enzyme Refined , Equine Antirabies immunoglobulin fragments not less than 200 I.U.
Dosage form of applied drug	Solution for Injection
Pharmacotherapeutic Group of (API)	Rabies Vaccine
Reference to Finished product specifications	In-house Specifications
Proposed Pack size	5ml Liquid Vial
Proposed unit price	As per SRO
Shelf Life	24 Months
Storage Conditions	Store between 2-8°C. Do not freeze. Protect from light.
The status in reference regulatory authorities	FAVIRAB 1000IU/5ml (Rabies Immunoglobulin) MAH: Sanofi Pasteur SA ANSM APPROVED
For generic drugs (me-too status)	---
Module-II (Quality Overall Summary)	Firm has submitted QOS.
Name, address of drug substance manufacturer	Name: Vins Bioproducts Limited

	Address: Survey No. 117, Thimmapur (Village), Kothur (Mandal), Ranga Reddy (Dist.),-509325, Telangana, India.
Module-III Drug Substance:	Firm has submitted general information, detail of manufacture, characteristics, specifications, analytical procedures, container closure system and stability studies related to drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of three batches at accelerated conditions 25°C±2°C and 60% ± 5% RH for 6 months and long -term stability studies data of three batches at 2° C-8° C for 24 months.
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Container closure system of the drug product	5 mL flint 20 mm molded glass vials, 20 mm bromobutyl rubber stoppers, and 20 mm diameter aluminum flip-off seals.
Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of three batches at accelerated conditions 25°C±2°C and 60% ± 5% RH for 6 months and long -term stability studies of four batches at 2°C-8°C for 24 Months.
Module-IV Non-Clinical	Not provided-Just table of contents provided.
Module-V Clinical	Not provided-Reference of literature provided.
Remarks of Evaluator	• The CoPP provided is not legalized. • LOA provided is not legalized. • CoPP mentions that the product is licensed to be placed on market of exporting country while product approval letter & product specific GMP certificate mention that the product is for export purpose. • Product specific GMP certificate of M/s Vins Bioproducts Limited submitted does not mention the drug substance manufacturing facility. • Pre-clinical studies (Module-IV) has not been provided. • Clinical studies (Module-V) of the applied product has not been provided.
Decision of 345 th RB meeting	The Registration Board deferred the case for rectification of following deficiencies in the application; • The CoPP provided is not legalized. • LOA provided is not legalized. • CoPP mentions that the product is licensed to be placed on market of exporting country while product approval letter & product specific GMP certificate mention that the product is for export purpose. • Product specific GMP certificate of M/s Vins Bioproducts Limited submitted does not mention the drug substance manufacturing facility. • Pre-clinical studies (Module-IV) has not been provided.

		• Clinical studies (Module-V) of the applied product has not been provided.	
Evaluation by BE&R: The firm has submitted a reply which is tabulated below;			
Sr.No.	Deficiencies	Response of the firm	Remarks of evaluator
1	The CoPP provided is not legalized.	Please find the attached COPP in Annexure-I.	Ministry of Foreign Affairs attested COPP is provided.
2	LOA provided is not legalized.	Please find the attached Legalized LOA in Annexure-I.	Ministry of Foreign Affairs attested LOA is provided
3	CoPP mentions that the product is licensed to be placed on market of exporting country while product approval letter & product specific GMP certificate mention that the product is for export purpose.	Manufacturer has shared domestic manufacturing licenses for Rabies, Diphtheria Antitoxin, and Tetanus Antitoxin. The relevant license is submitted.	The firm has submitted License Retention Certificate along with List of products under Form 28D. The list contains “Rabies Antiserum 1000IU I.H.S (5ml Liquid vial)” with the brand name VINRAB which is approved for domestic use. However, the brand name of applied product is GLOBURAB. Clarification required.
4	Product specific GMP certificate of M/s Vins Bioproducts Limited submitted does not mention the drug substance manufacturing facility.	Declaration regarding this is attached for your reference in Annexure-III	The firm has submitted a declaration from M/s Vins Bioproducts Limited which states that; “We would like to inform you that Vins Bioproducts Limited holds a GMP certificate in accordance with Schedule M, as stipulated by the Drugs and Cosmetics Act. This certification is applicable to both Drug Substances and Drug product manufacturing processes. Hence, Product specific GMP certificate is not required for the manufacturing of Drug Substances at our facility.”
5	Pre-clinical studies (Module-IV) has not been provided.	Please find the enclosed Pre-Clinical Study in Annexure-IV.	Firm has submitted Module-IV including single dose and repeat dose Toxicity studies.
6	Clinical studies (Module-V) of the applied product has not been provided.	Please find the enclosed Clinical Study in Annexure-V.	Firm has submitted Literature references. Phase III Clinical studies and complete data is required.
Concluding remarks by BE&R: The reply of the firm is still deficient for submission of following, • Phase-III clinical data. • Registration status of applied product in country of origin whether for export purpose or both domestic and export purpose.			

	It is further stated that the applied product is already registered in the name of M/s Bristol Mayer Biotech Pakistan with brand name “Vinrab” and approval was granted in 339th meeting of Registration Board as per following details; <i>Vinrab 1000IU Injection</i> <i>Each ml contains;</i> <i>Antirabies Immunoglobulin fragments....NLT 200IU</i> <i>(1's x 5ml Vial)</i>
	Decision of 348th RB meeting: Registration Board after detailed deliberation deferred the case for clarification from the applicant as the applied product is already approved in the name of M/s Bristol Mayer Biotech Pakistan in 339th meeting of Registration Board. The Board advised the applicant to submit valid product specific letter of authorization and further clarification from MAH about the marketing rights given to M/s Bristol Mayer Biotech Pakistan.

Case # 3	
Name, address of Applicant / Importer	Lab Diagnostic Systems (SMC) Pvt. Ltd. Plot 36-A, PSIC SIE, Taxila Rawalpindi
Details of Drug Sale License of importer	License No: 01-374-0006-118530D Address: 36-A, PSIC, SIE, Taxila Rawalpindi Validity: 15/08/2029
Name, address of manufacturer(s) & MAH	Name: Virchow Biotech Pvt. Ltd Manufacturing Address: Survey No. 172 Part, Gagillapur (V), Dudigal-Gandimaisamma (M), Medchal Malkajgiri (D), Telangana state-500043, India.
Name of exporting country	India
Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	COPP: Valid COPP has been submitted. GMP: Valid GMP certificate has been submitted. LOA: LOA has been submitted.
Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
Dy. No. and date of submission	Form -5F Application ID: ZQR-ZY9-H322 Dated:30-01-2025
Details of fee submitted	Rs: 3,00,000 Dated: 16/08/2024 Deposit Slip No. 8347000177
The proposed proprietary name / brand name	Viglobulin 50ml

Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Human Immunoglobulin 50g/Lit, Maltose 100g/Lit, Water for Injection
Dosage form of applied drug	Injectable Solution
Pharmacotherapeutic Group of (API)	Normal human Immunoglobulins
Reference to Finished product specifications	BP Specifications
Proposed Pack size	50ml
Proposed unit price	As per SRO
Shelf Life	36 Months
Storage Conditions	Store between 2-8°C. Do not freeze.
The status in reference regulatory authorities	Flebogamma DIF 5% by Instituto Griflos, SA-USFDA
For generic drugs (me-too status)	Brand Name: BIAVEN 5% w/v, Generic Name: Immunoglobulin 5%w/v Manufactured by: Amson Vaccines & Pharma Pvt. Ltd Dosage Form: Injection, Pack Size: 50ml
Module-II (Quality Overall Summary)	Firm has submitted QOS.
Name, address of drug substance manufacturer	Name: Virchow Biotech Pvt. Ltd Manufacturing Address: Survey No. 172 Part, Gagillapur (V), Dudigal-Gandimaisamma (M), Medchal Malkajgiri (D), Telangana state-500043, India.
Module-III Drug Substance:	Firm has submitted general information, detail of manufacture, characteristics, specifications, analytical procedures, container closure system and stability studies related to drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of three batches at accelerated conditions 25°C±2°C and 60% + 5% RH for 6 months and long -term stability studies of four batches at 5°C±3°C for 18 months. Shelf life of drug substance is 12 months.
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Container closure system of the drug product	USP type I glass vial (50ml), stoppered with rubber stoppers with aluminum flip-off seals. Pack Size: 50ml
Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of three batches at accelerated conditions 25°C±2°C and 60% + 5% RH for 6 months and long -term stability studies of three batches at 5°C±3°C for 36 months for one batch and 24 months for two batches.
Module-IV Non-Clinical	Not provided-Reference of literature provided.
Module-V Clinical	Not provided-Reference of literature provided.
Remarks of Evaluator	CoPP provided is not legalized. Product specific GMP certificate has been submitted which is not legalized. Copp mentions that the product is licensed to be placed on market of exporting country while the approval letter of the product issued by DCA mentions only export market. GMP certificate also mentions that the products manufactured are for export purpose. GMP certificate does not mention information pertaining to Drug Substance manufacture.

Justification of in-house specification ranges of different tests given for drug product, is required while BP Specs. Has been mentioned in CoPP.

In case of drug product, long term stability studies data of 24 months has been provided for two batches and data of 36 months has been provided for one batch. Data of 36 months for three batches is required.

The said case was previously discussed in 345th meeting of the Registration Board and the Board has decided as under:

Decision:

The Registration Board deferred the case for rectification of following deficiencies in the application;

- ***CoPP provided is not legalized.***
- ***Product specific GMP certificate has been submitted which is not legalized.***
- ***Copp mentions that the product is licensed to be placed on market of exporting country while the approval letter of the product issued by DCA mentions only export market. GMP certificate also mentions that the products manufactured are for export purpose.***
- ***GMP certificate does not mention information pertaining to Drug Substance manufacture.***
- ***Justification of in-house specification ranges of different tests given for drug product, is required while BP Specs. Has been mentioned in CoPP.***
- ***In case of drug product, long term stability studies data of 24 months has been provided for two batches and data of 36 months has been provided for one batch. Data of 36 months for three batches is required.***

Now the firm has submitted their response which is as under:

Deficiency	Firms response
Product specific GMP certificate has been submitted which is not legalized	Notarized GMP Submitted
CoPP mentions that the product is licensed to be placed on market of exporting country while the approval letter of the product issued by DCA mentions only export market. GMP certificate also mentions that the products manufactured are for export purpose	We would like to clarify that the product under the brand name Viglobulin is possessing a product license to be manufactured for the export market and that license can be used for exporting countries. A copy of the product license of Viglobulin is submitted
GMP certificate does not mention information pertaining to Drug Substance manufacture.	justification letter from the manufacturer is submitted which states that both API and the finished product are being manufactured at the same site.
Justification of in-house specification ranges of different tests given for drug product, is required while BP Specs. has been mentioned in CoPP.	We would like to clarify that the product complies with the BP specifications as per the prescribed parameter methodology and acceptance criteria, hence it is claimed as BP in COPP and other legal documents. However, there are certain tests that are essential considering the biological nature of product and performed as per CDSCO regulation of biological product hence it is claimed as inhouse for this test only. justification letter from the manufacturer is submitted.
Real time stability studies data of three batches for 36 months is required.	36 Months stability data for three batches is submitted.

Decision: Keeping in view valid legalized CoPP indicating product availability in country of origin, Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	

Case # 04	
Name, address of Applicant / Importer	Lab Diagnostic Systems (SMC) Pvt. Ltd. Plot 36-A, PSIC SIE, Taxila Rawalpindi
Details of Drug Sale License of importer	License No: 01-374-0006-118530D Address: 36-A, PSIC, SIE, Taxila Rawalpindi Validity: 15/08/2029
Name, address of manufacturer(s) & MAH	Name: Virchow Biotech Pvt. Ltd Manufacturing Address: Survey No. 172 Part, Gagillapur (V), Dudigal-Gandimaisamma (M), Medchal Malkajgiri (D), Telangana state-500043, India.
Name of exporting country	India
Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	COPP: Valid COPP has been submitted. GMP: Valid GMP certificate has been submitted. LOA: LOA has been submitted.
Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
Dy. No. and date of submission	Form -5F ID: 9ZA-HWV-NHHD Dated:17-02-2025
Details of fee submitted	Rs: 3,00,000 Dated: 16/08/2024 Deposit Slip No. 4762941445
The proposed proprietary name / brand name	Viglobulin 100ml
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Human Immunoglobulin 50g/Lit, Maltose 100g/Lit, Water for Injection
Dosage form of applied drug	Injectable Solution
Pharmacotherapeutic Group of (API)	Normal human Immunoglobulins
Reference to Finished product specifications	BP
Proposed Pack size	100ml
Proposed unit price	As per SRO
Shelf Life	36 Months
Storage Conditions	Store between 2-8°C. Do not freeze.
The status in reference regulatory authorities	Flebogamma DIF 5% by Instituto Griflos, SA-USFDA

For generic drugs (me-too status)	Gama Globlin 5% w/v Manufactured by: Genesis Pharma
Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to general properties, manufacturers, description of manufacturing process and controls, characterization, specifications analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
Name, address of drug substance manufacturer	Name: Virchow Biotech Pvt. Ltd Manufacturing Address: Survey No. 172 Part, Gagillapur (V), Dudigal-Gandimaisamma (M), Medchal Malkajgiri (D), Telangana state-500043, India.
Module-III Drug Substance:	Firm has submitted general information, detail of manufacture, characteristics, specifications, analytical procedures, container closure system and stability studies related to drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of three batches at accelerated conditions 25°C±2°C and 60% + 5% RH for 6 months and long -term stability studies of four batches at 5°C±3°C for 18 months. Shelf life of drug substance is 12 months.
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Container closure system of the drug product	USP type I glass vial (50ml), stoppered with rubber stoppers with aluminum flip-off seals. Pack Size: 100ml
Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of three batches at accelerated conditions 25°C±2°C and 60% + 5% RH for 6 months and long -term stability studies of three batches at 5°C±3°C for 36 months for one batch and 24 months for two batches.
Module-IV Non-Clinical	Not provided-Reference of literature provided.
Module-V Clinical	Not provided-Reference of literature provided.
Remarks of Evaluator	Product specific GMP certificate has been submitted which is not legalized. Copp mentions that the product is licensed to be placed on market of exporting country while the approval letter of the product issued by DCA mentions only export market. GMP certificate also mentions that the products manufactured are for export purpose. GMP certificate does not mention information pertaining to Drug Substance manufacture. Justification of in-house specification ranges of different tests given for drug product, is required while BP Specs. has been mentioned in CoPP. Real time stability studies data of three batches for 36 months is required.
Evaluator Remarks:	

The said case was previously discussed in 345th meeting of the Registration Board and the Board has decided as under:

Decision:

The Registration Board deferred the case for rectification of following deficiencies in the application;

- ***CoPP provided is not legalized.***
- ***Product specific GMP certificate has been submitted which is not legalized.***
- ***Copp mentions that the product is licensed to be placed on market of exporting country while the approval letter of the product issued by DCA mentions only export market. GMP certificate also mentions that the products manufactured are for export purpose.***
- ***GMP certificate does not mention information pertaining to Drug Substance manufacture.***
- ***Justification of in-house specification ranges of different tests given for drug product, is required while BP Specs. Has been mentioned in CoPP.***
- ***In case of drug product, long term stability studies data of 24 months has been provided for two batches and data of 36 months has been provided for one batch. Data of 36 months for three batches is required.***

Now the firm has submitted their response which is as under:

Deficiency	Firms response
Product specific GMP certificate has been submitted which is not legalized	Notarized GMP Submitted
CoPP mentions that the product is licensed to be placed on market of exporting country while the approval letter of the product issued by DCA mentions only export market. GMP certificate also mentions that the products manufactured are for export purpose	We would like to clarify that the product under the brand name Viglobulin is possessing a product license to be manufactured for the export market and that license can be used for exporting countries. A copy of the product license of Viglobulin is submitted
GMP certificate does not mention information pertaining to Drug Substance manufacture.	justification letter from the manufacturer is submitted which states that both API and the finished product are being manufactured at the same site.
Justification of in-house specification ranges of different tests given for drug product, is required while BP Specs. has been mentioned in CoPP.	We would like to clarify that the product complies with the BP specifications as per the prescribed parameter methodology and acceptance criteria, hence it is claimed as BP in COPP and other legal documents. However, there are certain tests that are essential considering the biological nature of product and performed as per CDSCO regulation of biological product hence it is claimed as inhouse for this test only. justification letter from the manufacturer is submitted.
Real time stability studies data of three batches for 36 months is required.	36 Months stability data for three batches is submitted.

Decision:

Keeping in view valid legalized CoPP indicating product availability in country of origin, Registration Board approved the product subject to compliance of current Import Policy for finished drugs.

Case # 05		
Name, address of Applicant / Importer	Lab Diagnostic Systems (SMC) Pvt. Ltd. Plot 36-A, PSIC SIE, Taxila Rawalpindi	
Details of Drug Sale License of importer	License No: 01-374-0006-118530D Address: 36-A, PSIC, SIE, Taxila Rawalpindi Validity: 15/08/2029	
Name, address of manufacturer(s) & MAH	Name: Vins Bioproducts Limited Address: Survey No. 117, Thimmapur (Village), Kothur (Mandal), Ranga Reddy (Dist.),-509325, Telangana, India.	
Name of exporting country	India	
Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	CoPP: Valid CoPP has been provided. LOA: Valid LOA has been provided.	
Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)	
Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)	
Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales	
For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only	
Dy. No. and date of submission	Form -5F Application ID: PGA-AMD-G2RP Dated: 30-01-2025	
Details of fee submitted	Rs: 3,00,000 Dated: 12th November,2024 Deposit Slip No. 228655001	
The proposed proprietary name / brand name	Diphtheria Antitoxin 10000 I.U B.P	
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Diphtheria Antitoxin 10000 I.U B.P Each mL contains: Enzyme refined, equine Diphtheria Antitoxic immunoglobulin fragments not less than 1000 I.U.	
Dosage form of applied drug	Solution for Injection	
Pharmacotherapeutic Group of (API)	Antitoxins and Immunologic	
Reference to Finished product specifications	British Pharmacopeia	
Proposed Pack size	10ml Liquid Vial	
Proposed unit price	As per SRO	
Shelf Life	24 Months	
Storage Conditions	Store between 2-8°C. Do not freeze. Protect from light.	
The status in reference regulatory authorities	Diphtheria Antitoxin 10000I.U B.P (10ml Liquid Vial) Manufacturer: VINS BIOPRODUCTS LIMITED ANSM Approved	
For generic drugs (me-too status)	Diphtheria Antitoxin 10000 IU/ml Dosage form: Injection Strength: 1000IU/ml MAH: Hakimsons Impex (Pvt) Ltd.	
Module-II (Quality Overall Summary)	Firm has submitted QOS.	

Name, address of drug substance manufacturer	Name: Vins Bioproducts Limited Address: Survey No. 117, Thimmapur (Village), Kothur (Mandal), Ranga Reddy (Dist.),-509325, Telangana, India.
Module-III Drug Substance:	Firm has submitted general information, detail of manufacture, characteristics, specifications, analytical procedures, container closure system and stability studies related to drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of three batches at accelerated conditions 25°C±2°C and 60% + 5% RH for 6 months and long -term stability studies data of three batches at 2° C-8° C for 24 months.
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Container closure system of the drug product	10mL USP Type-1 clear glass vial with 20 mm Bromo butyl stopper having Aluminum flip off seal.
Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of three batches at accelerated conditions 25°C±2°C and 60% + 5% RH for 6 months and long -term stability studies data of three batches at 2°C-8°C for 24 Months.
Module-IV Non-Clinical	Potency determination animal study provided.
Module-V Clinical	A study titled "To Study the Adverse Events following the administration of Diphtheria Antitoxin (Equine Source), 10000 IU /10 ml, in probable and confirmed diphtheria cases at SRRITCD Hospital, Hyderabad" has been submitted.
Remarks of Evaluator	The CoPP provided is not legalized. LOA provided is not legalized. CoPP mentions that the product is licensed to be placed on market of exporting country while product approval letter & product specific GMP certificate mention that the product is for export purpose. Product specific GMP certificate of M/s Vins Bioproducts Limited submitted does not mention the drug substance manufacturing facility. Toxicity studies not provided in module IV. Clinical studies data (module-V) depicting efficacy of the product, has not been provided.
Evaluator's remarks: The said case was previously discussed in 345 th meeting of the Registration Board and the Board has decided as under: Decision: <i>The Registration Board deferred the case for rectification of following deficiencies in the application;</i> • <i>The CoPP provided is not legalized.</i> • <i>LOA provided is not legalized.</i> • <i>CoPP mentions that the product is licensed to be placed on market of exporting country while product approval letter & product specific GMP certificate mention that the product is for export purpose.</i>	

- *Product specific GMP certificate of M/s Vins Bioproducts Limited submitted does not mention the drug substance manufacturing facility.*
- *Toxicity studies not provided in module IV.*
- *Clinical studies data (module-V) depicting efficacy of the product, has not been provided.*

Now the firm has submitted following response:

Deficiencies	Firm's response
The CoPP provided is not legalized.	Legalized COPP Submitted
LOA provided is not legalized.	Legalized LOA Submitted
CoPP mentions that the product is licensed to be placed on market of exporting country while product approval letter & product specific GMP certificate mention that the product is for export purpose.	Declaration regarding this is submitted.
Product specific GMP certificate of M/s Vins Bioproducts Limited submitted does not mention the drug substance manufacturing facility.	Manufacturer has shared domestic manufacturing licenses for Rabies, Diphtheria Antitoxin, and Tetanus Antitoxin. The relevant license is submitted.
Toxicity studies not provided in module IV.	Toxicity studies in module IV submitted in DRAP.
Clinical studies data (module-V) depicting efficacy of the product, has not been provided. Clinical safety study provided involved only 203 subjects out of which six reported fourteen (14) adverse events immediately or within 24 hours of administration.	Clinical studies submitted in DRAP.

Decision:

Keeping in view valid legalized CoPP indicating product availability in country of origin, Registration Board approved the product subject to compliance of current Import Policy for finished drugs.

Case # 06

Name, address of Applicant / Importer	M/s Macter International Limited. F-216, S.I.T.E., Karachi-Pakistan.
Status of Applicant	☒ Manufacturer ☐ Importer ☐ Bulk Import & Local Repack ☐ Is involved in none of the above
Name, address of manufacturer(s)	M/s Macter International Limited. F-216,S.I.T.E., Karachi-Pakistan.

GMP of manufacturer & Evidence of Section	DML No. 000141 Address: F-216,S.I.T.E., Karachi-Pakistan. Evidence of section: Liquid and Lyophilized rDNA Technology Products (Biological) Section (F.2-13/95-Lic (Vol-IV), dated 19-07-2012 GMP: Valid up to 30-06-2027
Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
For imported products, specify one the these	Not Applicable Ready to fill bulk Import, Local Packing
Dy. No. and date of submission	Tracking ID: WZU-4LW-9YSG Date of Submission: 28-04-2025
Details of fee submitted	Challan No. 2693879626 Amount: 300,000/- Date of submission: 15-04-2025
The proposed proprietary name / brand name	Mac-Epo 2000 IU / 1 mL solution for injection in a pre-filled syringe
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each pre-filled syringe of 1 mL contains: Epoetin alfa 2000IU
Pharmaceutical form of applied drug	Solution For Injection in PFS (For Intravenous or Subcutaneous use only)
Pharmacotherapeutic Group of (API)	Anti-anemic preparations Human Erythropoietin ATC Code: B03XA01
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack size	1's
Proposed unit price	As per SRO
Shelf Life	03 Years
Storage conditions	2 – 8 °C
The status in reference regulatory authorities	EPOGEN (Amgen Inc. USA)
For generic drugs (me-too status)	Epoetin Alfa Solution for injection by AJM Pharma
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Elucidation of Structure, impurities specifications,

		analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product are submitted.
	Name, address of drug substance manufacturer	Name: Kexing Biopharmaceutical Co. Ltd Address: No. 2666, Chuangye Road, Bucun Subdistrict, Zhangqiu, Jinan, Shandong, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, elucidation of structure impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of drug substance at long term & on-going The long-term stability data was conducted at 2 to 8°C for 24 months. The ongoing stability was also conducted at 2 to 8°C for 24 Months. Batch Numbers for Long-term: 11-GCSF-028-016 11-GCSF-029-017 11-GCSF-030-018 Batch Numbers for Ongoing: 15-GCSF-042-027 15-GCSF-045-032 15-GCSF-047-035 15-GCSF-049-039 15-GCSF-055-049
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Data as per guidelines of 278th meeting of Registration Board; i) For Bulk Concentrate Import, Local formulation Filling	
	The firm shall provide legalized GMP certificate of biological drug substance manufacturer abroad (who will provide concentrate / ready to fill bulk of biological drug to Pakistani manufacturers for	GMP Compliance Inspection report Dated: 05 May, 2023 No. 2023116 GMP Issued by: National Administration of Drugs, Foods, and Medical Devices (ANMAT) Argentina

further processing) as an evidence that the manufacturer is an authorized manufacturer of biological drug in the country of origin.	
The firms shall provide legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ ready to fill bulk after submission of data to the concerned regulatory authority.	Firm has submitted the COPP bearing No. Shandong20251043, valid upto 23-01-2027, for product Human Erythropoietin 2000IU/1ml pre-filled syringe, manufactured by same source M/s Kexing Biopharmaceutical Co. Ltd, No. 2666, Chuangye Road, Bucun Subdistrict, Zhangqiu, Jinan, Shandong, China
The firm shall provide the lot release certificate of the finished product manufactured by same bulk concentrate/ ready to fill from country of export (If applicable).	Not Applicable
The firm shall provide the 6 months accelerated and real time stability studies for drug substance	Firm has submitted stability study data of drug substance at long term & on-going The long-term stability data was conducted at $5\pm 3^{\circ}\text{C}$ for 12 months. Accelerated testing at $25\pm 2^{\circ}\text{C}/60\pm 5\%\text{RH}$ for 6 months. Batch Numbers for Long-term: 201309001 201309002 201309003 Batch Numbers for Ongoing: 201309001 201309002 201309003
The firm shall provide the agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.	Not Applicable
Regular monitoring through pharmacovigilance reporting system shall be observed through proper pharmacovigilance cell of the manufacturer and report will be forwarded to the National Pharmacovigilance Centre, Division of Pharmacy Services and Biological Division of DRAP. In case of any severe adverse event, immediate mandatory reporting procedure shall be followed.	Firm have submitted undertaking & SOP as detailed in 278th meeting of Registration Board by the local manufacturer.
The firm shall inform DRAP if there shall be any adverse event or ADR reporting from the country of manufacture of concentrate/ready to fill bulk	Firm have submitted undertakings as detailed in 278th meeting of Registration Board by the local manufacturer.

	and finished product as required vide Rules 30 of Drug (LR&A) Rule.																	
	If any of the conditions is not fulfilled or public health risk reported at any stage, the drug registration shall stand cancelled with immediate effect.	Firm have submitted undertakings as detailed in 278th meeting of Registration Board by the local manufacturer.																
	All the provisions as contained in the Drugs Act, 1976 and rules made there under including provisions of Lot Release certification from National Control Laboratory for Biologicals shall be strictly adhered to.	Firm have submitted undertaking as detailed in 278th meeting of Registration Board by the local manufacturer.																
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative Studies are attached.																
	Analytical method validation/verification of product	Method verification studies have submitted including Specificity, precision, intermediate precision, Repeatability solution stability.																
	Container closure system of the drug product	1 ml USP type-1 glass prefilled syringe Clear Glass Barrel, Rubber Plunger																
	Documents for the procurement of API with approval from DRAP	Submitted																
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 03 batches. The accelerated stability study data is conducted at 25°C ± 2°C for 6 months, for following batches: <table><tr><td>Batch No.</td><td>Batch Size</td></tr><tr><td>EPO PFS 01A</td><td>100 PFS</td></tr><tr><td>EPO PFS 02A</td><td>100 PFS</td></tr><tr><td>EPO PFS 03A</td><td>100 PFS</td></tr></table> The real time stability study data is conducted at 5°C ± 3°C for 6 months for following batches: <table><tr><td>Batch No.</td><td>Batch Size</td></tr><tr><td>EPO PFS 01A</td><td>100 PFS</td></tr><tr><td>EPO PFS 02A</td><td>100 PFS</td></tr><tr><td>EPO PFS 03A</td><td>100 PFS</td></tr></table>	Batch No.	Batch Size	EPO PFS 01A	100 PFS	EPO PFS 02A	100 PFS	EPO PFS 03A	100 PFS	Batch No.	Batch Size	EPO PFS 01A	100 PFS	EPO PFS 02A	100 PFS	EPO PFS 03A	100 PFS
Batch No.	Batch Size																	
EPO PFS 01A	100 PFS																	
EPO PFS 02A	100 PFS																	
EPO PFS 03A	100 PFS																	
Batch No.	Batch Size																	
EPO PFS 01A	100 PFS																	
EPO PFS 02A	100 PFS																	
EPO PFS 03A	100 PFS																	
	MODULE- IV	The firm has provided pharmacological, pharmacokinetics and toxicological study reports including the single dose and repeat dose toxicity studies in animals.																
	MODULE- V	The firm has provided clinical study reports																

Remarks:

Decision:

The Registration Board approved the product 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 # 07

Name, address of Applicant / Importer	M/s Macter International Limited. F-216, S.I.T.E., Karachi-Pakistan.
Status of Applicant	☒ Manufacturer ☐ Importer ☐ Bulk Import & Local Repack ☐ Is involved in none of the above
Name, address of manufacturer(s)	M/s Macter International Limited. F-216,S.I.T.E., Karachi-Pakistan.
GMP of manufacturer & Evidence of Section	DML No. 000141 Address: F-216,S.I.T.E., Karachi-Pakistan. Evidence of section: Liquid and Lyophilized rDNA Technology Products (Biological) Section (F.2-13/95-Lic (Vol-IV), dated 19-07-2012 GMP: Valid up to 30-06-2027
Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
For imported products, specify one the these	Not Applicable Ready to fill bulk Import, Local Packing
Dy. No. and date of submission	Tracking ID: D1R-1GM-8QE3 Date of Submission: 28-04-2025
Details of fee submitted	Challan No. 4318326317 Amount: 300,000/- Date of submission: 15-04-2025
The proposed proprietary name / brand name	Mac-Epo 4000 IU / 1 mL solution for injection in a pre-filled syringe
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each pre-filled syringe of 1 mL contains: Epoetin alfa 4000IU
Pharmaceutical form of applied drug	Solution For Injection in PFS (For Intravenous or Subcutaneous use only)
Pharmacotherapeutic Group of (API)	Anti-anemic preparations Human Erythropoietin ATC Code: B03XA01
Reference to Finished product specifications	As per Innovators Specification

Proposed Pack size	1's
Proposed unit price	As per SRO
Shelf Life	03 Years
Storage conditions	2 – 8 °C
The status in reference regulatory authorities	EPOGEN (Amgen Inc. USA)
For generic drugs (me-too status)	Epoetin Alfa Solution for injection by AJM Pharma
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Elucidation of Structure, impurities specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product are submitted.
Name, address of drug substance manufacturer	Name: Kexing Biopharmaceutical Co. Ltd Address: No. 2666, Chuangye Road, Bucun Subdistrict, Zhangqiu, Jinan, Shandong, China.
Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, elucidation of structure impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of drug substance at long term & on-going The long-term stability data was conducted at 2 to 8°C for 24 months. The ongoing stability was also conducted at 2 to 8°C for 24 Months.
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

Data as per guidelines of 278th meeting of Registration Board; i) For Bulk Concentrate Import, Local formulation Filling	
The firm shall provide legalized GMP certificate of biological drug substance manufacturer abroad (who will provide concentrate / ready to fill bulk of biological drug to Pakistani manufacturers for further processing) as an evidence that the manufacturer is an authorized manufacturer of biological drug in the country of origin.	GMP Compliance Inspection report Dated: 05 May, 2023 No. 2023116 GMP Issued by: National Administration of Drugs, Foods, and Medical Devices (ANMAT) Argentina
The firms shall provide legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ ready to fill bulk after submission of data to the concerned regulatory authority.	Firm has submitted the COPP bearing No. Shandong20251044, valid upto 23-01-2027, for product Human Erythropoietin 4000IU/1ml pre-filled syringe, manufactured by same source M/s Kexing Biopharmaceutical Co. Ltd, No. 2666, Chuangye Road, Bucun Subdistrict, Zhangqiu, Jinan, Shandong, China
The firm shall provide the lot release certificate of the finished product manufactured by same bulk concentrate/ ready to fill from country of export (If applicable).	Not Applicable
The firm shall provide the 6 months accelerated and real time stability studies for drug substance	Firm has submitted stability study data of drug substance at long term & on-going The long-term stability data was conducted at $5\pm 3^{\circ}\text{C}$ for 12 months. Accelerated testing at $25\pm 2^{\circ}\text{C}/60\pm 5\%\text{RH}$ for 6 months. Batch Numbers for Long-term: 201309001 201309002 201309003 Batch Numbers for Ongoing: 201309001 201309002 201309003
The firm shall provide the agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.	Not Applicable
Regular monitoring through pharmacovigilance reporting system shall be observed through proper pharmacovigilance cell of the manufacturer and report will be forwarded to the National Pharmacovigilance Centre, Division of Pharmacy Services and Biological Division of DRAP. In	Firm have submitted undertaking & SOP as detailed in 278th meeting of Registration Board by the local manufacturer.

	case of any severe adverse event, immediate mandatory reporting procedure shall be followed.																	
	The firm shall inform DRAP if there shall be any adverse event or ADR reporting from the country of manufacture of concentrate/ready to fill bulk and finished product as required vide Rules 30 of Drug (LR&A) Rule.	Firm have submitted undertakings as detailed in 278th meeting of Registration Board by the local manufacturer.																
	If any of the conditions is not fulfilled or public health risk reported at any stage, the drug registration shall stand cancelled with immediate effect.	Firm have submitted undertakings as detailed in 278th meeting of Registration Board by the local manufacturer.																
	All the provisions as contained in the Drugs Act, 1976 and rules made there under including provisions of Lot Release certification from National Control Laboratory for Biologicals shall be strictly adhered to.	Firm have submitted undertaking as detailed in 278th meeting of Registration Board by the local manufacturer.																
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative Studies are attached.																
	Analytical method validation/verification of product	Method verification studies have submitted including Specificity, precision, intermediate precision, Repeatability solution stability.																
	Container closure system of the drug product	1 ml USP type-1 glass prefilled syringe Clear Glass Barrel, Rubber Plunger																
	Documents for the procurement of API with approval from DRAP	Submitted																
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 03 batches. The accelerated stability study data is conducted at 25°C ± 2°C for 6 months, for following batches: <table><tr><td>Batch No.</td><td>Batch Size</td></tr><tr><td>EPO PFS 01B</td><td>100 PFS</td></tr><tr><td>EPO PFS 02B</td><td>100 PFS</td></tr><tr><td>EPO PFS 03B</td><td>100 PFS</td></tr></table> The real time stability study data is conducted at 5°C ± 3°C for 6 months for following batches: <table><tr><td>Batch No.</td><td>Batch Size</td></tr><tr><td>EPO PFS 01B</td><td>100 PFS</td></tr><tr><td>EPO PFS 02B</td><td>100 PFS</td></tr><tr><td>EPO PFS 03B</td><td>100 PFS</td></tr></table>	Batch No.	Batch Size	EPO PFS 01B	100 PFS	EPO PFS 02B	100 PFS	EPO PFS 03B	100 PFS	Batch No.	Batch Size	EPO PFS 01B	100 PFS	EPO PFS 02B	100 PFS	EPO PFS 03B	100 PFS
Batch No.	Batch Size																	
EPO PFS 01B	100 PFS																	
EPO PFS 02B	100 PFS																	
EPO PFS 03B	100 PFS																	
Batch No.	Batch Size																	
EPO PFS 01B	100 PFS																	
EPO PFS 02B	100 PFS																	
EPO PFS 03B	100 PFS																	
	MODULE- IV	The firm has provided pharmacological, pharmacokinetics and toxicological study reports including the single dose and repeat dose toxicity studies in animals.																

MODULE- V	The firm has provided clinical study reports
Remarks: Decision: The Registration Board approved the product 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 # 08		
	Name, address of Applicant / Importer	M/s Macter International Limited. F-216, S.I.T.E., Karachi-Pakistan.
	Status of Applicant	☒ Manufacturer ☐ Importer ☐ Bulk Import & Local Repack ☐ Is involved in none of the above
	Name, address of manufacturer(s)	M/s Macter International Limited. F-216,S.I.T.E., Karachi-Pakistan.
	GMP of manufacturer & Evidence of Section	DML No. 000141 Address: F-216,S.I.T.E., Karachi-Pakistan. Evidence of section: Liquid and Lyophilized rDNA Technology Products (Biological) Section (F.2-13/95-Lic (Vol-IV), dated 19-07-2012 GMP: Valid up to 30-06-2027
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	Not Applicable Ready to fill bulk Import, Local Packing
	Dy. No. and date of submission	Tracking ID: 32X-XWZ-ZUVZ Date of Submission: 28-04-2025
	Details of fee submitted	Challan No. 88682349551 Amount: 300,000/- Date of submission: 15-04-2025
	The proposed proprietary name / brand name	Mac-Epo 10,000 IU / 1 mL solution for injection in a pre-filled syringe
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each pre-filled syringe of 1 mL contains: Epoetin alfa 10,000IU

Pharmaceutical form of applied drug	Solution For Injection in PFS (For Intravenous or Subcutaneous use only)
Pharmacotherapeutic Group of (API)	Anti-anemic preparations Human Erythropoietin ATC Code: B03XA01
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack size	1's
Proposed unit price	As per SRO
Shelf Life	03 Years
Storage conditions	2 – 8 °C
The status in reference regulatory authorities	EPOGEN (Amgen Inc. USA)
For generic drugs (me-too status)	Epoetin Alfa Solution for injection by AJM Pharma
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Elucidation of Structure, impurities specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product are submitted.
Name, address of drug substance manufacturer	Name: Kexing Biopharmaceutical Co. Ltd Address: No. 2666, Chuangye Road, Bucun Subdistrict, Zhangqiu, Jinan, Shandong, China.
Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, elucidation of structure impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of drug substance at long term & on-going The long-term stability data was conducted at 2 to 8°C for 24 months. The ongoing stability was also conducted at 2 to 8°C for 24 Months.

Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Data as per guidelines of 278th meeting of Registration Board; i) For Bulk Concentrate Import, Local formulation Filling	
The firm shall provide legalized GMP certificate of biological drug substance manufacturer abroad (who will provide concentrate / ready to fill bulk of biological drug to Pakistani manufacturers for further processing) as an evidence that the manufacturer is an authorized manufacturer of biological drug in the country of origin.	GMP Compliance Inspection report Dated: 05 May, 2023 No. 2023116 GMP Issued by: National Administration of Drugs, Foods, and Medical Devices (ANMAT) Argentina
The firms shall provide legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ ready to fill bulk after submission of data to the concerned regulatory authority.	Firm has submitted the COPP bearing No. Shandong20251043, valid upto 23-01-2027, for product Human Erythropoietin 10000IU/1ml pre-filled syringe, manufactured by same source M/s Kexing Biopharmaceutical Co. Ltd, No. 2666, Chuangye Road, Bucun Subdistrict, Zhangqiu, Jinan, Shandong, China
The firm shall provide the lot release certificate of the finished product manufactured by same bulk concentrate/ ready to fill from country of export (If applicable).	Not Applicable
The firm shall provide the 6 months accelerated and real time stability studies for drug substance	Firm has submitted stability study data of drug substance at long term & on-going The long-term stability data was conducted at $5\pm 3^{\circ}\text{C}$ for 12 months. Accelerated testing at $25\pm 2^{\circ}\text{C}/60\pm 5\%\text{RH}$ for 6 months. Batch Numbers for Long-term: 201309001 201309002 201309003 Batch Numbers for Ongoing: 201309001 201309002 201309003
The firm shall provide the agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in	Not Applicable

manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.									
Regular monitoring through pharmacovigilance reporting system shall be observed through proper pharmacovigilance cell of the manufacturer and report will be forwarded to the National Pharmacovigilance Centre, Division of Pharmacy Services and Biological Division of DRAP. In case of any severe adverse event, immediate mandatory reporting procedure shall be followed.	Firm have submitted undertaking & SOP as detailed in 278th meeting of Registration Board by the local manufacturer.								
The firm shall inform DRAP if there shall be any adverse event or ADR reporting from the country of manufacture of concentrate/ready to fill bulk and finished product as required vide Rules 30 of Drug (LR&A) Rule.	Firm have submitted undertakings as detailed in 278th meeting of Registration Board by the local manufacturer.								
If any of the conditions is not fulfilled or public health risk reported at any stage, the drug registration shall stand cancelled with immediate effect.	Firm have submitted undertakings as detailed in 278th meeting of Registration Board by the local manufacturer.								
All the provisions as contained in the Drugs Act, 1976 and rules made there under including provisions of Lot Release certification from National Control Laboratory for Biologicals shall be strictly adhered to.	Firm have submitted undertaking as detailed in 278th meeting of Registration Board by the local manufacturer.								
Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative Studies are attached.								
Analytical method validation/verification of product	Method verification studies have submitted including Specificity, precision, intermediate precision, Repeatability solution stability.								
Container closure system of the drug product	1 ml USP type-1 glass prefilled syringe Clear Glass Barrel, Rubber Plunger								
Documents for the procurement of API with approval from DRAP	Submitted								
Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 03 batches. The accelerated stability study data is conducted at $25^{\circ}\text{C} \pm 2^{\circ}\text{C}$ for 6 months, for following batches: <table> <tr> <td>Batch No.</td><td>Batch Size</td></tr> <tr> <td>EPO PFS 01C</td><td>100 PFS</td></tr> <tr> <td>EPO PFS 02C</td><td>100 PFS</td></tr> <tr> <td>EPO PFS 03C</td><td>100 PFS</td></tr> </table> The real time stability study data is conducted at	Batch No.	Batch Size	EPO PFS 01C	100 PFS	EPO PFS 02C	100 PFS	EPO PFS 03C	100 PFS
Batch No.	Batch Size								
EPO PFS 01C	100 PFS								
EPO PFS 02C	100 PFS								
EPO PFS 03C	100 PFS								

		5°C ± 3°C for 6 months for following batches: Batch No. Batch Size EPO PFS 01C 100 PFS EPO PFS 02C 100 PFS EPO PFS 03C 100 PFS
	MODULE- IV	The firm has provided pharmacological, pharmacokinetics and toxicological study reports including the single dose and repeat dose toxicity studies in animals.
	MODULE- V	The firm has provided clinical study reports

Remarks:

Decision:

The Registration Board approved the product 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 # 09		
	Name, address of Applicant / Importer	M/s SAC BIO PHARMA , BVI 727, Model Town B, Karbala Road, Bahawalpur.
	Details of Drug Sale License of importer	M/s SAC BIO PHARMA, BVI 727, Model Town B, Karbala Road, Bahawalpur. License No.: 03-312-0162-110919D Valid till: 27.10.2028
	Name and address of marketing authorization holder (abroad)	M/s United Biotech (P) Limited, Bagbania, Baddi-Nalagarh Road, Distt. Solan, Himachal Pradesh (174 101), India.
	Name, address of manufacturer(s)	M/s United Biotech (P) Limited, Bagbania, Baddi-Nalagarh Road, Distt. Solan, Himachal Pradesh (174 101), India.
	Name of exporting country	India
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Firm has attached CoPP (HFW-H(DRUGS) 427/05/25-95) valid up to 21-02-2026 issued by Office of State Drug Controller, Licensing and Controlling Authority, Health and Family Welfare Department, Himachal Pradesh, India. The CoPP specifies that the product is licensed to be placed for use in the exporting country as well as the product is actually in the market in exporting country. The CoPP confirms the GMP status of the manufacturing site through periodic inspection Once a year. (Original Legalized and Valid COPP is required.)

Details of letter of authorization / sole agency agreement	The firm has provided LOA dated 25-07-2023 which is valid for 05 years.
Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
Dy. No. and Date of submission	E-app Tracking ID: QQG-QDV-U5N2 Application No: 1480 Receiving Date: 22-01-2024
Details of fee submitted	Deposit Slip No. 1370759962 of Rs.150,000/-dated 29-12-2023. Deposit Slip No. 6495426958 , dated 18-02-2025 of Rs. 150,000 has been paid.
The proposed proprietary name / brand name	CHORIOTEC 5000 IU (Chorionic Gonadotrophin for Injection BP 5000IU) (Lyophilized)
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Combi-pack contains: Each vial contains: Chorionic Gonadotrophin BP.....5000 IU Excipient..... q.s. Each ampoule of solvent contains; Sterile water for Injections BP..... 2ml
Pharmaceutical form of applied drug	Lyophilized Powder for injection; and solvent for parenteral use
Pharmacotherapeutic Group of (API)	Hormone. Code ATC: G03GA01.
Reference to Finished product specifications	BP Specifications
Proposed Pack size	1's vial (lyophilized part) + 1's ampoule (solvent)
Proposed unit price	As per latest SRO
Shelf Life	2 years (24 Months)
Storage Condition	Store below 25°C. All other already approved products of chorionic gonadotropin are stored at 2-8°C.
The status in reference regulatory authorities	Not provided
For generic drugs (me-too status)	IVF-C 5000 IU (Galaxy Pharma (Pvt) Ltd., Karachi) Reg. No.: 039811 (The diluent is Sodium Chloride in approved products while the applied product is with WFI).
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of

		manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	Name of manufacturer: Shanghai Techwell Biopharmaceutical Co., Ltd (Herein referred to as "Techwell") Address of manufacturer: No. 4258, Jindu Road, Minhang District, Shanghai 201108, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 pilot scale batches as under: Long term testing conditions: Batch No: 010401, 010402, 010403 at 2-8°C for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Provided
	Container closure system of the drug product	White to off-white lyophilized powder filled in a 2ml clear moulded glass vial stoppered and sealed with 13mm flip off seal green color having embossed "United Biotech" labelled & placed along with sterile WFI and placed in a plastic tray. Such single plastic tray packed in a printed mono carton along with insert.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 03 batches. Stability studies were conducted on three batches of CHLC5E1, CHLC5E2, CHLC5E3. Real time stability at 25°C±2°C/60%± 5%RH for 24 months and Accelerated stability at 40°C ± 2°C & RH 75% ± 5% for 6 months.
	Module IV	Toxicological data including single dose and repeat dose toxicity studies are not provided. Genotoxicity, carcinogenicity, reproductive and developmental toxicity not provided.
	Module V	Clinical trial data of the product is not provided. The data provided is of some other product.

The said case was considered by the Board in 345th meeting and the Board had decided as under:

Decision: Registration Board deferred for submission of following documents/clarification:

- i. *Fee challan is of Rs.150000 instead of Rs.30000 as per SRO 1872(I)/2023 dated 29-12-2023. Differential fee is required to be submitted by the applicant.*
- ii. *COPP is not legalized and was valid till 22-02-2024. Valid legalized COPP is required.*

- iii. *Product specific LOA is not provided.*
- iv. *Evidence of approval of applied product in any reference regulatory authority is not provided.*
- v. The diluent is Sodium Chloride in already approved products of chorionic gonadotropin while the applied product is with WFI. Clarification required.
- vi. GMP certificate of Drug product manufacturer is not legalized and was valid till 22-02-2024. Valid legalized GMP certificate is required.
- vii. The finished product manufacturer does not have biological section as per GMP certificate. Clarification required.
- viii. Module 1 is not as per CTD guidelines/format. Complete Module 1 as per CTD format is required.
- ix. All other already approved products of chorionic gonadotropin are stored at 2-8°C. while the storage condition of applied product is below 25°C. Clarification required.
- x. GMP certificate of drug substance manufacturer is required.
- xi. Process development of DS and its validation is not provided.
- xii. 20% overage is added in the formulation. Proper justification is required in comparison with the Innovator.
- xiii. Real time and accelerated stability data of 3 commercial batches of drug substance is required.
- xiv. Adventitious agent safety evaluation under Module 3.2.A.2 is not provided.
- xv. Analytical method verification of drug product is required under Module 3.2.P.5.3.
- xvi. Diluent COA and stability is not provided.
- xvii. In-use stability data is not provided.
- xviii. Compatibility of product with container closure system is required under Module 3.2.P.2.6.
- xix. Virus removal/inactivation studies is not provided.
- xx. Toxicological data including single dose and repeat dose toxicity studies are not provided in Module 4.
- xxi. Genotoxicity, carcinogenicity, reproductive and developmental toxicity not provided.
- xxii. Clinical trial data of the product in Module 5 is required.

Now the firm has submitted their response as under:

Shortcomings	Response of the Firm
Fee challan is of Rs.150000 instead of Rs.30000 as per SRO 1872(I)/2023 dated 29-12-2023. Differential fee is required to be submitted by the applicant.	The remaining amount of Rs. 150,000 has been paid. Receipt No. 6495426958, dated 18-02-2025
COPP is not legalized and was valid till 22-02-2024. Valid legalized COPP is required.	We have Attached the new copp with Pakistan embassy receipt and we have also given the new COPP for legalization at the Pakistan Embassy. As soon as we receive it from the Pakistan Embassy, we will send it to you.
Product specific LOA is not provided.	The letter of Authorization, because we have to submit other products to the regulatory authority to import them, that's why they have given us All products Authorization letter. Letter of authorization is attached
Evidence of approval of applied product in any reference regulatory authority is not provided.	Evidence of approval of product in India, Sri Lanka, Nepal and Turkmenistan have been provided.
The diluent is Sodium Chloride in already approved products of chorionic gonadotropin while the applied product is with WFI. Clarification required.	No clarification has been provided. The firm has attached COAs and Stability Studies Data of sodium chloride 0.9%

GMP certificate of Drug product manufacturer is not legalized and was valid till 22-02-2024. Valid legalized GMP certificate is required.	The firm has provided GMP Certificate of M/s United Biotech valid till 21-02-2026 however the Biological Section is not mentioned on the said Certificate.
The finished product manufacturer does not have biological section as per GMP certificate. Clarification required.	The firm has provided evidence of approval of Biological Section dated 22-02-2021.
Module 1 is not as per CTD guidelines/format. Complete Module 1 as per CTD format is required.	The firm has provided Module 1 as per CTD Guidelines
All other already approved products of chorionic gonadotropin are stored at 2-8°C. while the storage condition of applied product is below 25°C. Clarification required.	The firm has given the statement that their product has good stability at 25 °C
GMP certificate of drug substance manufacturer is required.	The firm has provided GMP Certificate of M/s Shanghai Techwell Biopharmaceuticals valid till 25-12-2027
Process development of DS and its validation is not provided.	The firm has provided Process development of DS and its validation
20% overage is added in the formulation. Proper justification is required in comparison with the Innovator.	The firm has provided justification letter from manufacturer which is reproduced as under: Subject: Registration of CHORIOTEC 5000(Chorionic Gonadotrophin for Injection BP 5000IU) Regarding: Justification for taking overage '20%' in formulation We, United Biotech (P) Limited presented our formulation of CHORIOTEC 5000(Chorionic Gonadotrophin for Injection BP 5000IU) for registration in which 20% overage has been used, for which justification is needed. So we are hereby clarifying reason for taking overage '20%' in formulation. Amount of Overage: 20.0% Reason for Overage: There were processing losses during many steps of manufacturing process i.e. weighing, mixing, solution preparation, filtration, filling which results in potency loss of in final formulated product. Justification for Overage: To compensate the loss during formulation processing and to maintain the potency of final formulated product, inclusion of 20.0% overage was necessary. Hence, 20.0% overage was added in order to compensate for degradation. Thanking You. For United Biotech (P) Limited
Real time and accelerated stability data of 3 commercial batches of drug substance is required.	Stability data has been provided with storage condition of 2 – 8 °C
Adventitious agent safety evaluation under Module 3.2.A.2 is not provided.	The firm has provided following clarification from the manufacturer: Dear Sir, We certify that the material, CHORIOTEC 5000: Chorionic Gonadotrophin for Injection BP 5000IU (Lyophilized) supplied from our site contains no ingredients of animal's origin and no material derived

		from, or exposed to animals affected by, or under quarantine for Transmitting Animal Spongiform Encephalopathy (TSE) / Bovine Spongiform Encephalopathy (BSE), GMO (Genetically Modified Organism). The product is produced in facility where no animal, animal products, animal byproducts, veterinary vaccines or animal pathogens are maintained and are packed in a packaging that can be identified as to the nature of the products and the country of origin.	
	Analytical method verification of drug product is required under Module 3.2.P.5.3.	Provided	
	Diluent COA and stability is not provided.	COA of WFI 2ml has been provided	
	In-use stability data is not provided.	Provided	
	Compatibility of product with container closure system is required under Module 3.2.P.2.6.	Only specifications have been provided	
	Virus removal/inactivation studies is not provided.	The firm has provided following justification: Subject: Justification for not providing virus removal / inactivation studies We United Biotech (P) Limited established in Bagbania Baddi-Nalagarh Road District Solan (HP) INDIA; hereby declare that our productt: Chorionic Gonadotrophin for Injection BP 5000IU (Lyophilized) (CHORIOTEC 5000) is a gonadotrophin with its primary mode of action as: 1. It stimulates the production of gonadal steroid hormones by stimulating the interstitial cells (Leydig cells) of the testis to produce androgens and the corpus luteum of the ovaries to produce progesterone. 2. In males its action is predominantly steroidogenic while in female it is predominantly luteinizing. They have no mechanism of action to inactivate or kill or eliminate any virus, therefore any study related to the same could not be provided.	
	Toxicological data including single dose and repeat dose toxicity studies are not provided in Module 4.	Only summary has been provided	
	Genotoxicity, carcinogenicity, reproductive and developmental toxicity not provided.	Only summary has been provided	
	Clinical trial data of the product in Module 5 is required	References of clinical studies conducted on products of other manufacturers have been provided.	
Decision: The Registration deferred the case for submission of above-mentioned shortcoming documents/information.			



Drug Regulatory Authority of Pakistan

Biological Evaluation & Research Division



Registration Board 348 Meeting Additional/Supplementary Minutes:

Agenda Item 04.01. Applications for Registration of Imported Veterinary Biological Products (E-app)

Sr. No	Title	Description
1	Case Category	Import (Muhammad Ashfaq)
	Name, address of Applicant.	Mian Traders Railways Road, Morre Eminabad (09-341-0135)
	Application Form Dy. No / Tracking ID & date of submission	(36J-D4E-MEW9, 2024-09-04)
	Detail of Fee Submitted	300000.0, 2024-09-04,
	The proposed proprietary name / brand name	SANAVAC ND G7
	Label Claim	Each dose contains: Inactivated Newcastle Disease Virus Genotype VII $\geq 10^{8.5}$ EID ₅₀ before inactivation.
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	500 ml / 1000 Doses-De-Controlled
	Shelf Life (Unit)	2 Year(s)2 - 8°C
	For generic drugs (me-too Status)	Medivac ND G7 B
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	M/s PT. Sanbio Laboratories-Jl. Melati Desa Wanaherang RT/RW 02/09, Kecamatan Gunung Putri Kabupaten Bogor, Provinsi Jawa Barat-Indonesia
	Name, address of Marketing Authorization Holder:	M/s PT Sanbio Laboratories, Jl. Melati Desa Wanaherang RT/RW 02/09, Kecamatan Gunung Putri Kabupaten Bogor Provinsi Jawa Barat , Indonesia
	Details of Certificates (CoPP/FSC/cGMP):	Valid Legalized FSC & GMP certificate has been submitted.
	Details of Authorization Letter :	Notarized LOA from MAH submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies data of three batches has been submitted.
Evaluation Remarks		
The Registration Board in its 347th meeting deferred the case due to following deficiencies in the application;1. The notarized product specific Letter of Authorization from MAH in country of origin, has not been providedThe applicant has submitted notarized product specific Letter of Authorization from MAH in country of origin.		
Decision		
Approved		

	Keeping in view the legalized GMP & FSC indicating product availability in the country of origin, the Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.	
2	Case Category	Import (Muhammad Ashfaq)
	Name, address of Applicant.	TCBP-FMD UVAS RAVI CAMPUS TCBP-FMDUVAS RAVI CAMPUS PATTOKI (000969)
	Application Form Dy. No / Tracking ID & date of submission	(44X-MUR-3L5L, 2025-02-26)
	Detail of Fee Submitted	37000.0, 2025-02-21,
	The proposed proprietary name / brand name	UVAC-FMD vaccine
	Label Claim	UVAC-FMD vaccine is trivalent vaccine containing FMD virus strains of 'O' 'A' 'Asia-1'. as per B.P specifications each dose must not be less than 3PD50.so, each FMD virus strain must not be less than 3PD50.
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)2 - 8 C
	For generic drugs (me-too Status)	TCBP-UVAS RAVI CAMPUS
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	Name, address of Marketing Authorization Holder:	, ,
	Details of Certificates (CoPP/FSC/cGMP):	granting licence
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	The Registration Board in its 347th meeting, deferred the case due to deficiencies in the application. The response of the applicant is as under;	
	Deficiency	Response
	An unsigned stability studies report of one batch for 36 months & second batch for 9 months has been submitted. Stability studies protocol along with complete stability studies data of three batches is required to be submitted	The applicant has submitted signed stability studies report of three batches; two batches report is of 30 months, and third batch's report is of 9 months. For third batch, the applicant has attached letter of commitment. Stability studies protocol has also been submitted.
	Safety and efficacy studies data of the applied product, has not been submitted	The applicant has submitted safety studies data as per B.P requirement and efficacy studies data as per O.I.E standards.
	Decision	
	Approved	
	Keeping in view the valid DML & availability of manufacturing facility, the Registration Board approved the product.	
3	Case Category	Import (Muhammad Ashfaq)
	Name, address of Applicant.	Mian Traders Railways Road, Morre Eminabad (09-341-0135)
	Application Form Dy. No / Tracking ID & date of submission	(8NZ-GJR-R3YD, 2024-12-05)

	Detail of Fee Submitted	300000.0, 2024-11-28,
	The proposed proprietary name / brand name	SANAVAC CLONE/H120
	Label Claim	Each dose contains; Live Newcastle Disease Virus Clone strain $\geq 10^6.5$ EID ₅₀ Infectious Bronchitis serotype Massachusetts strain H120 $\geq 10^2.5$ EID ₅₀
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1000 DOSES-De-Controlled
	Shelf Life (Unit)	2 Year(s) 2-8°C
	For generic drugs (me-too Status)	Strains are registered
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	M/s PT Sanbio Laboratories-Jl. Melati Desa Wanaherang RT/RW 02/09, Kecamatan Gunung Putri Kabupaten Bogor, Provinsi Jawa Barat-Indonesia
	Name, address of Marketing Authorization Holder:	M/s PT Sanbio Laboratories, Jl. Melati Desa Wanaherang RT/RW 02/09, Kecamatan Gunung Putri Kabupaten Bogor, Provinsi Jawa Barat, Indonesia
	Details of Certificates (CoPP/FSC/cGMP):	Legalized FSC has been Submitted. Valid legalized GMP certificate has been submitted.
	Details of Authorization Letter :	Notarized LOA from MAH has been submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies data of three batches has not been submitted.
	Evaluation Remarks	
	The Registration Board in its 347th meeting deferred the case due to deficiencies in the application. The response of the applicant is as under;	
	Deficiency	Response
	Notarized Letter of Authorization from MAH, has not been provided	The applicant has submitted notarized LOA from MAH.
	Free sale certificate of Sinavac ND G7 has been attached instead of applied product.	The applicant has submitted legalized FSC of the product.
	The name of MAH in country of origin is required to be mentioned in online application	The name of MAH has been added in the online application.
	The address of Manufacturer is required to be corrected in online application as per GMP certificate	The address of the manufacturer has been corrected in online application.
	Decision	
	Approved	
	Keeping in view the legalized GMP & FSC indicating product availability in the country of origin, the Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.	
4	Case Category	Import (Muhammad Ashfaq)
	Name, address of Applicant.	Vetline International 939-A, Block-J, Phase-1, LDA Avenue-1, Lahore (05-352-0066)
	Application Form Dy. No / Tracking ID & date of submission	(8SG-TUL-7XNG, 2024-07-06)
	Detail of Fee Submitted	300000.0, 2024-07-02,

The proposed proprietary name / brand name	QVAC ND(G7)+H9
Label Claim	Each Dose of vaccine contains: Newcastle Disease Virus A-VII Strain $\geq 10^{8.0}$ EID50 before inactivation & Avian Influenza Virus (H9 Subtype) Strain before inactivation $\geq 10^{8.0}$ EID50.
Reference to Finished product specifications	Manufacturer Specification
Proposed Pack Size	500ml-De-Controlled
Shelf Life (Unit)	24 Month(s)2-8°C
For generic drugs (me-too Status)	Gallimune H9+ND, Vaksimune NDL Inaktif, MEFLUVAC H9+ND7 Rinnovac ELI-7
Pharmacotherapeutic Group of (API)	Veterinary Vaccine
Name, address of Manufacturing site:	QYH NANJING BIOTECH COMPANY LIMITED -NO. 35 XIANGFENG ROAD, JIANGNING SUB-DISTRICT, JIANGNING DISTRICT, NANJING CITY, P. R. China-China
Name, address of Marketing Authorization Holder:	QYH Biotech Company Limited, Building No.20, Part 11, ABP, No. 188, Southwest 4th Ring Road, Fengtai District, Beijing, China., China
Details of Certificates (CoPP/FSC/cGMP):	Valid legalized FSC & GMP certificate has been submitted.
Details of Authorization Letter :	Legalized POA from MAH has been submitted.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies data of three batches has been submitted.
Evaluation Remarks	
The Registration Board in its 347th meeting deferred the case due to deficiencies in the application. The response of the applicant is as under;	
Deficiency	Response
The Address of MAH mentioned in POA & online application, has not been mentioned in FSC.	The applicant has submitted letter of Declaration from QYH Biotech Company Limited that QYH NANJING BIOTECH COMPANY LIMITED is their wholly owned Subsidiary.
Decision	
Approved	
Keeping in view the legalized GMP & FSC indicating product availability in the country of origin, the Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.	
5	Case Category
	Import (Muhammad Ashfaq)
	Name, address of Applicant.
	Mian Traders Railways Road, Morre Eminabad (09-341-0135)
	Application Form Dy. No / Tracking ID & date of submission
	(91N-6P3-9LN7, 2024-12-04)
	Detail of Fee Submitted
	300000.0, 2024-11-28,
	The proposed proprietary name / brand name
	SANAVAC ND G7 AI PLUS H9
	Label Claim
	Each dose contains; Inactivated Newcastle Disease Virus Genotype VII $\geq 10^{9.5}$ EID50 before inactivation Avian Influenza virus subtype H5N1 clade 2.3.2 $\geq 10^{8.5}$ EID50 before inactivation

	Avian Influenza virus subtype H9N2 $\geq 10^{8.5}$ EID50 before inactivation.
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1000 DOSES-De-Controlled
Shelf Life (Unit)	2 Year(s)2-8°C
For generic drugs (me-too Status)	Strains are registered
Pharmacotherapeutic Group of (API)	Veterinary Vaccine
Name, address of Manufacturing site:	M/s PT. Sanbio Laboratories-Jl. Melati Desa Wanaherang RT/RW 02/09, Kecamatan Gunung Putri Kabupaten Bogor, Provinsi Jawa Barat-Indonesia
Name, address of Marketing Authorization Holder:	M/s PT. Sanbio Laboratories, Jl. Melati Desa Wanaherang RT/RW 02/09, Kecamatan Gunung Putri Kabupaten Bogor, Provinsi Jawa Barat, Indonesia
Details of Certificates (CoPP/FSC/cGMP):	Legalized FSC has been submitted. Valid legalized GMP submitted.
Details of Authorization Letter :	Notarized LOA has been submitted.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies data of three batches has been submitted.
Evaluation Remarks	
The Registration Board in its 347th meeting deferred the case due to deficiencies in the application. The response of the applicant is as under;	
Deficiency	Response
Legalized Free Sale certificate of the product, has not been provided.	The applicant has submitted legalized FSC of the product.
Notarized Letter of Authorization from MAH, has not been provided.	The applicant has submitted notarized LOA from MAH.
The name of MAH in country of origin is required to be mentioned in online application	The name of MAH has been mentioned in online application.
Decision	
Approved	
Keeping in view the legalized GMP & FSC indicating product availability in the country of origin, the Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.	
6	Case Category
	Import (Muhammad Ashfaq)
	Name, address of Applicant.
	CLOUD AGRI PAKISTAN 45-A2 JOHAR TOWN LAHORE (2029-02)
	Application Form Dy. No / Tracking ID & date of submission
	(BME-BJ6-3VSE, 2024-12-22)
	Detail of Fee Submitted
	300000.0, 2024-12-05,
	The proposed proprietary name / brand name
	BIORABIA VACCINE
	Label Claim
	Each ml contains; Inactivated rabies virus antigen, Pasteur Strain PV ≥ 1 IU
	Reference to Finished product specifications
	Manufacturer Specification
	Proposed Pack Size
	1 ML-De-Controlled,10 X 1 ML-De-Controlled,12 X 1 ML-De-Controlled,25 X 1 ML-De-Controlled,50 X 1 ML-De-Controlled

Shelf Life (Unit)	24 Month(s)4-6 oC
For generic drugs (me-too Status)	Strain already registered.
Pharmacotherapeutic Group of (API)	Veterinary Vaccine
Name, address of Manufacturing site:	BIOGENESIE BAGO-RUTA PANAMERICANA, 38.5 KM. (B16191EA) GARIN, BUENOS AIRES, ARGENTINA.-Argentina
Name, address of Marketing Authorization Holder:	BIOGENESIE BAGO, RUTA PANAMERICANA, 38.5 KM. (B16191EA) GARIN, BUENOS AIRES, ARGENTINA., Argentina
Details of Certificates (CoPP/FSC/cGMP):	FSC Submitted is not legalized and mentions that the product is registered for export purpose. GMP certificate submitted is not legalized.
Details of Authorization Letter :	Legalized LOA from MAH has been submitted
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies data of three batches has been submitted.
Evaluation Remarks	
The Registration Board in its 347th meeting deferred the case due to deficiencies in the application. The response of the applicant is as under;	
Deficiency	Response
The FSC mentions that this product is registered in the ARGENTINE REPUBLIC as product for export.	We would like to clarify that the rabies vaccine is officially registered in its country of origin (Argentina). Initially, the product was registered through the issuance of two separate certificates, one for pets (under BGOVAC RABIA trade name) and another for large animals (under RABIA PARESIANTE trade name), despite the fact that the technical specifications are fully identical. For marketing purposes, and to facilitate a faster export registration process, the targeted animal species were later combined under a single registration (under Biorabia trade name) dedicated to export use. This approach has been adopted in several countries, such as Jordan, where the unified registration is accepted. Please find attached: · The registration certificates from Argentina for the rabies vaccine for both large animals (Rabia Paresiante) and pets (Bagovac Rabia) · The combined registration certificate from Argentina for all target species (Biorabia) · A copy of the registration certificate of Biorabia from Jordan
The FSC & GMP certificate are not legalized	The applicant has submitted legalized FSC & GMP certificate of the manufacturer.
Safety & efficacy studies data, has not been provided	The applicant has submitted safety & efficacy studies data of the product.
Decision	
Deferred	

	The Registration Board deferred the case for submission of revised FSC by the applicant, mentioning that the product is on free sale in the country of origin.	
7	Case Category	Import (Muhammad Ashfaq)
	Name, address of Applicant.	Mian Traders Railways Road, Morre Eminabad (09-341-0135)
	Application Form Dy. No / Tracking ID & date of submission	(GAV-9XU-17E9, 2024-12-04)
	Detail of Fee Submitted	300000.0, 2024-11-28,
	The proposed proprietary name / brand name	SANAVAC ND LS
	Label Claim	Each dose contains: Live Newcastle Disease Virus, Lasota strain $\geq 10^{6.5}$ EID50.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000 DOSES-De-Controlled
	Shelf Life (Unit)	2 Year(s)2-8°C
	For generic drugs (me-too Status)	VAKSIMUNE NDLS
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	M/s PT. Sanbio Laboratories-Jl. Melati Desa Wanaherang RT/RW 02/09, Kecamatan Gunung Putri Kabupaten Bogor, Provinsi Jawa Barat- Indonesia
	Name, address of Marketing Authorization Holder:	M/s PT. Sanbio Laboratories, Jl. Melati Desa Wanaherang RT/RW 02/09, Kecamatan Gunung Putri Kabupaten Bogor, Provinsi Jawa Barat, Indonesia
	Details of Certificates (CoPP/FSC/cGMP):	Legalized FSC has been submitted. Valid legalized GMP, has been submitted.
	Details of Authorization Letter :	Notarized LOA from MAH has been submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies data of three batches has been submitted.
	Evaluation Remarks	
	The Registration Board in its 347th meeting deferred the case due to deficiencies in the application. The response of the applicant is as under;	
	Deficiency	Response
	Notarized Letter of Authorization from MAH, has not been provided	The applicant has submitted notarized LOA from MAH.
	Free sale certificate of Sinavac ND G7 has been attached instead of applied product.	The applicant has submitted legalized FSC of the product.
	The name of MAH in country of origin is required to be mentioned in online application	The name of MAH has been added in the online application.
	The address of Manufacturer is required to be corrected in online application as per GMP certificate	The address of the manufacturer has been corrected in online application.
	Decision	
	Approved	
	Keeping in view the legalized GMP & FSC indicating product availability in the country of origin, the Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.	
8	Case Category	Import (Muhammad Ashfaq)

	Name, address of Applicant.	Mian Traders Railways Road, Morre Eminabad (09-341-0135)
	Application Form Dy. No / Tracking ID & date of submission	(NZD-JDU-DSLS, 2024-12-04)
	Detail of Fee Submitted	300000.0, 2024-11-28,
	The proposed proprietary name / brand name	SANAVAC ND CLONE
	Label Claim	Each dose contains; Live Newcastle Disease virus of Clone N-79 $\geq 10^{6.5}$ EID50.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000 DOSES-De-Controlled
	Shelf Life (Unit)	2 Year(s)2-8°C
	For generic drugs (me-too Status)	NOBILIS ND CLONE 30
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine.
	Name, address of Manufacturing site:	M/s PT. Sanbio Laboratories-Jl. Melati Desa Wanaherang RT/RW 02/09, Kecamatan Gunung Putri Kabupaten Bogor, Provinsi Jawa Barat-Indonesia
	Name, address of Marketing Authorization Holder:	M/s PT. Sanbio Laboratories, Jl. Melati Desa Wanaherang RT/RW 02/09, Kecamatan Gunung Putri Kabupaten Bogor, Provinsi Jawa Barat, Indonesia
	Details of Certificates (CoPP/FSC/cGMP):	Valid legalized FSC & GMP has been submitted.
	Details of Authorization Letter :	Notarized LOA from MAH has been submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies data of three batches has been submitted.
	Evaluation Remarks	
	The Registration Board in its 347th meeting deferred the case due to deficiencies in the application. The response of the applicant is as under;	
	Deficiency	Response
	Notarized Letter of Authorization from MAH, has not been provided	The applicant has submitted notarized LOA from MAH.
	The name of MAH in country of origin is required to be mentioned in online application	The name of MAH has been added in the online application.
	The address of Manufacturer is required to be corrected in online application as per GMP certificate	The address of the manufacturer has been corrected in online application.
	Decision	
	Approved	
	Keeping in view the legalized GMP & FSC indicating product availability in the country of origin, the Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.	
9	Case Category	Import (Muhammad Ashfaq)
	Name, address of Applicant.	Huzaifa International commercial area, aziz bhatti town, Sargodha (08-384-0120)
	Application Form Dy. No / Tracking ID & date of submission	(Z5U-WN6-L676, 2025-02-24)
	Detail of Fee Submitted	75000.0, 2024-05-16,

The proposed proprietary name / brand name	Aftosera (Polyclonal hyper-immune serum for FMD)
Label Claim	Each 10 ml Dose contains: Specific IgG antibody titer of atleast 1/40 for FMDV O serotype:100 TCID50 Titer, Specific IgG antibody titer of atleast 1/40 for FMDV A serotype: 100 TCID50 Titer & Specific IgG antibody titer of atleast 1/40 for FMDV Asia-1 (Sindh-08) serotype: 100 TCID50 Titer
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	50 ml-De-Controlled
Shelf Life (Unit)	24 Month(s)2-8 °C
For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	Veterinary Immunoglobulins
Name, address of Manufacturing site:	VETAL HAYVAN SAĞLIĞI (Vetal Animal Health Products-Organize Sanayi Bolgesi, Petrol Mah.14 cad. No.1, ADIYAMAN / TURKEY-Turkey
Name, address of Marketing Authorization Holder:	VETAL HAYVAN SAĞLIĞI (Vetal Animal Health Products, Organize Sanayi Bolgesi, Petrol Mah.14 cad. No.1, ADIYAMAN / TURKEY, Turkey
Details of Certificates (CoPP/FSC/cGMP):	Valid legalized FSC & GMP has been submitted.
Details of Authorization Letter :	LOA from MAH has been submitted.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies data of three batches has been submitted.
Evaluation Remarks	
The Registration Board in its 347th meeting, deferred the case due to deficiencies in the application. The response of the applicant is as under;	
Deficiency	Response
Justification regarding protection against FMD in cattle using subtype titre of 1:40 in antisera, is required.	A neutralizing antibody titer of 1:40 is considered sufficient to confer protective immunity against Foot-and-Mouth Disease (FMD) in cattle, particularly in the context of passive immunization via antiserum. Scientific Justification and References: · Several peer-reviewed studies and international guidelines indicate that neutralizing titres between 1:32 and 1:45 are strongly associated with protection from clinical disease in challenge studies. · A titre of 1:40 falls within this range and has been demonstrated to significantly reduce clinical signs and virus spread. · It is also stated that a titre of 1:40 is the definitive result in the context of serological diagnosis of FMD. Doubtful titre range is greater than 1/11 but less than or equal to 1/32 are considered doubtful and recorded as “inconclusive” according to Detection of antibodies against vesicular and related viruses by the virus neutralisation test (VNT) STANDARD OPERATING PROCEDURE of FMD reference laboratory. Key References: Doel, T.R. (2003) “Neutralising antibody titers of 1:32 or higher are associated

	with clinical protection.” Virus Research, 91(1), 81–99. Barnett, P.V. et al. (2003) “Titers of 1:40 and above significantly reduce clinical signs in vaccinated cattle.” Vaccine, 21(25–26), 3680–3688. Paton, D.J. et al. (2006) “A log₁₀ reciprocal titer of ~1.6 (~1:40) correlates with approximately 75–85% protection.” Rev. sci. tech. Off. int. Epiz., 25(3), 1197–1210. WOAHO/OIE Terrestrial Manual – FMD Chapter Indicates that neutralizing titers ≥1:32–1:45 are consistent with clinical protection in challenge trials.
Information regarding antigen types and subtypes used with relevance to Pakistan, is required.	According to FMD-WRL Pakistan is part of pool-3 (Turkey is also part of the same pool) regarding FMD virus outbreak categorization (Ref: https://www.wrlfmd.org/). According to FMD-WRL; the recommended FMD virus/ antigen types and subtypes for Pakistan are as following and same are being used in preparation of Aftosera: FMD Antigen O – Subtype Pan Asia-1 FMD Antigen A – Subtype Iran 05 FMD Antigen Asia-1 – Subtype Sindh-08
Information pertaining to standardization of protective doses for cattle, sheep & goat, is required.	The standardization of dose potency is established with our in-house studies designed in alignment with international standards as detailed below; · When animals were challenged with 10^{7.375} BID₅₀/ml of FMDV, the protective efficacy was measured at 50%, under high-exposure conditions. · When challenged with a standard-dose of 10⁴ BID₅₀/ml, which reflects typical field exposure, the protective efficacy increased to 95%. The dose potency adjusted accordingly
Justification of suitability of 10ml subcutaneous dose in cattle is required.	According to our studies performed in R&D laboratories of VETAL Animal Health Products Inc., AFTOSERA- hyper-immune serum is a very effective and rapid antibody-based therapy for FMD. Based on these studies, we present a new therapeutic product obtained after immunization of cattle with the inactivated FMD virus serotypes. The 10 ml dose for cattle has been adjusted after thorough clinical safety trials and R&D. Aftosera is in use in Turkey, Iraq, Syria, Iran, and gulf countries from many years with the recommended dose with safety and efficacy. Complaint regarding dose volume never received by the manufacturer.
The Registration Board further referred the case to Sub-committee on Veterinary Drugs for expert opinion regarding immunological relevance and need of applied product in Pakistan. The Sub-committee has recommended the product for grant of registration.	
Decision	
Approved	

Keeping in view the recommendations of the Sub-committee on Veterinary Drugs, legalized GMP & FSC indicating product availability in the country of origin, the Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.

Agenda Item No. 04.02: Applications for Registration of Imported Veterinary Biological Products-Hard (Deferred in Various Meetings)

Case # 01		
	Name and address of Importer	M/s Mustafa Brothers , P-186-D, People Colony No. 1, District Faisalabad.
	Detail of DSL	CDSL No: 06-331-0168-031770D Expiry Date: 21-06-2027 Place: Faisalabad
	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy. No. 7602 (R&I) Dated 29-05-2019 Rs. 100,000/-, Date: 27-05-2019, Challan No. 0291630
	Name of Manufacturer & MAH/PLH	Federal Governmental Budgetary Institution “Federal Centre for Animal Health” (FGBI”ARRIAH”) 600901, Russia, Vladimir region, Vladimir, microrayonYur’ evets
	Name of exporting country	Russian Federation
	Brand Name + Dosage Form + Strength	ARRIAH ND (Inactivated Emulsion Vaccine Against Newcastle Disease) Each dose contains; Newcastle disease virus (La-Sota strain) at least....7.5 lg EID ₅₀
	Composition	Each dose contains; Newcastle disease virus (La-Sota strain) at least....7.5 lg EID ₅₀
	Finished product specifications	Manufacturer Specifications
	Pharmacological Group	Poultry Vaccine
	Shelf life	18 months (2 °C -8 °C)
	Products already registered in Pakistan	Medivac ND Emulsion by Hilton Provac AIK by Huzaifa International
	Demanded Price / Pack size	Decontrolled/ 5,000 Doses (500mL Vial)
	Certificates Submitted	FSC: Original, Valid, Legalized FSC has been submitted. GMP: Valid legalized GMP certificate issued by Federal Service for Veterinary & Phytosanitary surveillance, has been submitted.
	Remarks of the Evaluator: The case was deferred in 292 nd meeting of the Board for following deficiencies; a. Complete stability study data. b. Evidence of authorization of Rosstandart-Certification Body of Management Systems Moscow (Voluntary Certification System) for issuance of GMP certificate by Federal Service for Veterinary and Phytosanitary Surveillance, Russia. The firm has responded as under;	
	Deficiency	Response
	Complete stability study data	The firm has submitted stability studies data of three batches.
	Evidence of authorization of Rosstandart-Certification Body of Management Systems Moscow (Voluntary Certification System) for issuance of GMP certificate by Federal Service	Valid legalized GMP certificate issued by Federal Service for Veterinary & Phytosanitary surveillance, has been submitted.

	for Veterinary and Phytosanitary Surveillance, Russia	
	Decision: Keeping in view the legalized GMP & FSC indicating product availability in the country of origin, the Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.	

Case # 02		
	Name and address of Importer	M/s Mustafa Brothers, P-186-D, People Colony No. 1, District Faisalabad.
	Detail of DSL	CDSL No: 06-331-0168-031770D Expiry Date: 21-06-2027 Place: Faisalabad
	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy. No. 7601 (R&I) Dated 29-05-2019 Rs. 100,000/- 27-05-2019
	Name of Manufacturer & MAH/PLH	Federal Governmental Budgetary Institution "Federal Centre for Animal Health" (FGBI"ARRIAH") 600901, Russia, Vladimir region, Vladimir, microrayon Yur' evets
	Name of exporting country	Russian Federation
	Brand Name + Dosage Form + Strength	ARRIAH H9N2 + ND (Combined Inactivated Emulsion Vaccine Against Avian Influenza (H9N2) and Newcastle Disease) Each ml contains; Avian Influenza Virus (strain H9N20 at least 9.0 log EID ₅₀ Newcastle disease Virus (La-Sota strain) at least....9.0 lg EID ₅₀
	Composition	Each ml contains; Avian Influenza Virus (strain H9N20 at least 9.0 log EID ₅₀ Newcastle disease Virus (La-Sota strain) at least....9.0 lg EID ₅₀
	Finished product specifications	Manufacturer Specs.
	Pharmacological Group	Poultry Vaccine
	Shelf life	18 months (2 °C -8 °C)
	Products already registered in Pakistan	Newcastle Disease & Avian Influenza disease Vaccine by Vetline International
	Demanded Price / Pack size	Decontrolled/ 1000 Doses
	Certificates Submitted	FSC: Original, Valid, Legalized FSC has been submitted. GMP: Valid legalized GMP certificate issued by Federal Service for Veterinary & Phytosanitary surveillance, has been submitted.
	Remarks of the Evaluator: The case was deferred in 292 nd meeting of the Board for following deficiencies; a. Clinical Trial data b. Stability study data. c. Evidence of authorization of Rosstandart-Certification Body of Management Systems Moscow	

(Voluntary Certification System) for issuance of GMP certificate by Federal Service for Veterinary and Phytosanitary Surveillance, Russia. d. Pharmacopoeial reference of finished product specifications. The firm has responded as under;	
Deficiency	Response
Clinical Trial data	The applicant has submitted clinical trial data of the product.
Stability study data	The applicant has submitted stability studies data of three batches of product
Evidence of authorization of Rosstandart-Certification Body of Management Systems Moscow (Voluntary Certification System) for issuance of GMP certificate by Federal Service for Veterinary and Phytosanitary Surveillance, Russia	Valid legalized GMP certificate issued by Federal Service for Veterinary & Phytosanitary surveillance, has been submitted
Pharmacopoeial reference of finished product specifications.	The applicant has submitted product specification as manufacturer specificatins.
Decision: Keeping in view the legalized GMP & FSC indicating product availability in the country of origin, the Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.	

Case # 03		
Name and address of Importer	M/s Mustafa Brothers , P-186-D, People Colony No. 1, District Faisalabad.	
Detail of DSL	CDSL No: 06-331-0168-031770D Expiry Date: 21-06-2027 Place: Faisalabad	
Type of Form Dy. No. Date of Application Fee submitted	Dy. No. 32428 R&I Dated 29-11-2021 Rs. 75,000/- (Slip No. 557604810169) Firm has submitted fee challan of differential fee of Rupee 75000/- Slip No. (13860179271).	
Name of Manufacturer & MAH/PLH	M/s. Vira Vaccine Shaya Co., Blue Glass Building After Khajenasir Toosi Blvd, Sepher Industrial district, Nazarabad, Alborz province, Iran	
Name of exporting country	IRAN	
Brand Name + Dosage Form + Strength	Vira- Peste®	
Composition	Each dose contains: Lyophilized dried suspension containing “peste des petitis ruminants (PPR) virus Nigerian 75/I” strain 10^{2.5} TCID₅₀. Diluent (Solvent): 0.9% sterile isotonic sodium chloride solution (saline solution)	
Finished product specifications	Manufacturer’s specifications	
Pharmacological Group	Viral Vaccine	
Shelf life	2 years (2 0C- 8 0C)	
Products already registered in Pakistan	PESTVAC K by Huzaifa International	
Demanded Price / Pack	100doses/vial	

size	Diluent: 100ml
Certificates Submitted	1. Free sale certificate (No.30/96352) dated December, 2022 issued by Ministry of Agriculture Veterinary Organization is submitted by the firm. 2. Original Legalized product specific translated distribution agreement is submitted by the firm. 3. Copy of valid GMP Certificate of manufacturer has been submitted.
Remarks of the Evaluator: The case was deferred in 329 th meeting of the Board for following deficiencies; a. Submit analytical method for test/analysis of applied product. b. Stability data of the product on all parameters as mentioned in finished product specifications is required as in submitted data only virus titter and moisture content is determined. The firm has responded as under;	
Deficiency	Response
Submit analytical method for test/analysis of applied product.	The firm has submitted the analytical method for test/analysis of applied product.
Stability data of the product on all parameters as mentioned in finished product specifications is required as in submitted data only virus titter and moisture content is determined.	The firm has submitted stability studies data of three batches of the product with parameters as mentioned in finished product specifications.
Copy of valid GMP Certificate of manufacturer has been submitted which is not legalized.	
Decision: Keeping in view the valid GMP & FSC indicating product availability in the country of origin, the Registration Board approved the product subject to compliance to the current Import Policy for finished drugs and submission of legalized GMP certificate by the applicant.	

Case # 04	
Name and address of Importer	M/s Mustafa Brothers , P-186-D, People Colony No. 1, District Faisalabad.
Detail of DSL	CDSL No: 06-331-0168-031770D Expiry Date: 21-06-2027 Place: Faisalabad
Type of Form Dy. No. Date of Application Fee submitted	Dy. No. 32429 R&I Dated 29-11-2021 Rs. 75,000/- (Slip No. 16918330679) Firm has submitted fee challan of differential fee of Rupee 75000/- Slip No. (16918330679).
Name of Manufacturer & MAH/PLH	M/s. Vira Vaccine Shaya Co., Blue Glass Building After Khajenasir Toosi Blvd, Sepher Industrial district, Nazarabad, Alborz province, Iran
Name of exporting country	IRAN
Brand Name + Dosage Form + Strength	Vira- Etyvax®
Composition	Each dose contains: Live attenuated Echyma Virus > 10 ^{4.5} TCID ₅₀ . Diluent (Solvent): Sodium chloride.... 0.9%.
Finished product specifications	Manufacturer's Specifications
Pharmacological Group	Biological Vaccine
Shelf life	24 Months (2°C- 8°C)
Products already	Not available

registered in Pakistan	
Demanded Price / Pack size	50doses/vial Diluent: 50ml
Certificates Submitted	1. Free sale certificate (No. 1401/33728) dated January 18, 2023 valid till 06.01.2025 issued by Veterinary organization of the country Albroz General Veterinary Department is submitted by the firm. 2. Original Legalized product specific translated distribution agreement is submitted by the firm. 3. Copy of valid GMP Certificate of manufacturer has been submitted.
Remarks of the Evaluator: The case was deferred in 329 th meeting of the Board for following deficiencies; a. Submit analytical method for test/analysis of applied product. b. Stability data of the product on all parameters as mentioned in finished product specifications is required as in submitted data only virus titter and moisture content is determined. The firm has responded as under;	
Deficiency	Response
Submit analytical method for test/analysis of applied product.	The firm has submitted the analytical method for test/analysis of applied product.
Stability data of the product on all parameters as mentioned in finished product specifications is required as in submitted data only virus titter and moisture content is determined.	The firm has submitted stability studies data of three bathes of the product with parameters as mentioned in finished product specifications.
Copy of valid GMP Certificate of manufacturer has been submitted which is not legalized. Moreover, the as per available record, me-too is not registered in Pakistan.	
Decision: The Registration Board referred the product to Ministry of National Food Security & Research, Islamabad, for comments regarding the need of vaccine, prevalence of disease and immunological relevance of the strain in Pakistan.	

Case # 05	
Detail of DSL	M/s Snam Pharma, 61-Block G, Phase-I, DHA, Lahore Cantt, District Lahore. DSL # 05-352-0058-036985D Valid till: 14 November, 2027.
Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy. No. 362 Dated 07 th September 2023 Rs. 150,000/- Date: 05-09-2023, Challan No. 48003524344
Name of Manufacturer & MAH	Manufacturer: Bioveta, a.s., Komenskeho 212, 683 23 Ivanovice na Hane, Czech Republic MAH: Bioveta, a.s., Komenskeho 212, 683 23 Ivanovice na Hane, Czech Republic
Name of exporting country	Czech Republic
Brand Name + Dosage Form + Strength	ORNIBRON H120+D274, lyophilisate for suspension for chicken Lyophilizate for suspension for domestic fowl Active substances:

		Virus bronchitidis infectiosae avium, strain H120 min. $10^{3.0}$ EID ₅₀ - max. $10^{4.8}$ EID ₅₀ Virus bronchitidis infectiosae avium, strain D274 min. $10^{3.0}$ EID ₅₀ - max. $10^{4.8}$ EID ₅₀
Composition		One vaccination dose contains: Active substances: Virus bronchitidis infectiosae avium, strain H120 min. $10^{3.0}$ EID ₅₀ - max. $10^{4.8}$ EID ₅₀ Virus bronchitidis infectiosae avium, strain D274 min. $10^{3.0}$ EID ₅₀ - max. $10^{4.8}$ EID ₅₀ * EID ₅₀ – 50% infection dose for chicken embryos
Finished product specifications		Manufacturer's Specifications
Pharmacological Group		Live Viral Veterinary Vaccine
Shelf life		30 months (2°C - 8°C)
International availability		Czech Republic, Armenia, Azerbaijan, Egypt, Jordan, Uzbekistan, Moldova, Belarus, United Arab Emirates.
Products already registered in Pakistan		Poulvac IB Primer (017058)-Hitech Pharmaceuticals.
Demanded Price / Pack size		De-controlled 10's x 1000 doses
Certificates Submitted		CoPP: Original, Valid, Legalized CoPP has been provided. GMP: Legalized copy of valid GMP certificate has been provided. LOA: Copy of LOA issued by Sales Representative of MAH, has been provided.
Evaluator Remarks: The Registration Board in its 344 th meeting referred the case to sub-committee on veterinary drugs for the expert opinion of expert working group (EWG) on veterinary drugs regarding immunological relevance and need of applied strains in Pakistan. Moreover, the Board directed to ask the applicant for rectification of following deficiencies in their application; The copy of LOA provided, has been issued by Sales Representative of MAH and is not legalized. Now the firm has submitted evidence of me-too registered in Pakistan. Legalized LOA has been submitted by the firm and clarification letter from MAH holder stating that Sales Representative of MA is authorized to issue LOA, has also been submitted.		
Decision: Keeping in view the valid GMP & CoPP indicating product availability in the country of origin, the Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.		

Case # 06		
	Name and address of Importer	M/s Snam Pharma 61-G, Phase-1, Commercial Area, DHA, Lahore
	Detail of DSL	M/s Snam Pharma, 61-Block G, Phase-I, DHA, Lahore Cantt, District Lahore. DSL # 05-352-0058-036985D Valid till: 14 November, 2027.
	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy.No. 6352 Dated: 6 th March 2023 Rs. 150,000/-, Date: 15-02-2023, Challan No. 9372558401
	Name of Manufacturer &	Manufacturer: Tianjin Ringpu Bio-Technology Co., Ltd.

MAH	Address: Airport Economic Zone Branch, No.168, Huanhe South Road, Airport Economic Zone, Tianjin, China, Postal code: 300381 MAH: Tianjin Ringpu Bio-Technology Co., Ltd. Address: No. 1 Dongjiu Road, Tianjin Free Trade Area (Airport Economic Area), Tianjin
Name of exporting country	China
Brand Name + Dosage Form + Strength	RINVAC AI Each 0.1ml contains; Inactivated avian influenza virus (H9N2 subtype) Sy strain.. $\geq 10^{8.0}$ EID ₅₀ before inactivation.
Composition	Each 0.1ml contains; Inactivated avian influenza virus (H9N2 subtype) Sy strain.. $\geq 10^{8.0}$ EID ₅₀ before inactivation
Finished product specifications	Manufacturer's Specifications
Pharmacological Group	Inactivated Viral Veterinary Vaccine
Shelf life	24 months (2°C - 8°C)
International availability	China
Products already registered in Pakistan	Strain is registered.
Demanded Price / Pack size	De-controlled 500 ml/Bottle
Certificates Submitted	FSC: Original, Valid, Legalized FSC has been provided. GMP: Legalized copy of valid GMP certificate has been provided. LOA: Legalized copy of LoA from MAH has been provided.
Remarks of the Evaluator: The Registration Board in its 345 th meeting referred the case to sub-committee on veterinary drugs for the expert opinion of expert working group (EWG) on veterinary drugs regarding immunological relevance and need of applied strains in Pakistan. The sub-committee has recommended the product for grant of registration.	
Decision: Keeping in view the recommendations of sub-committee on veterinary drugs, valid GMP & FSC indicating product availability in the country of origin, the Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.	

Case # 07		
	Name and address of Importer	M/s Hilton Pharma Pvt. Ltd. Plot No. 13-14 & 43 Sector 15 Korangi Industrial Area Karachi.
	Detail of DSL	M/s Hilton Pharma Pvt Ltd. P Plot No. 13-14 & 43 Sector 15 Korangi Industrial Area Karachi. DSL # 0647 Valid till: 29-06-2029
	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Fee Submitted: Rs. 75,000/- dated 12-10-2021 (Slip#6778804) Differential fee submitted: Rs. 225,000/- dated 27.1.24 (Slip#90397902291)
	Name of MAH & Manufacturer	PT MEDION FARMA JAYA, Jl. Raya Batujajar No 29, Cimareme, Ngamprah, Bandung Barat –

	Indonesia.
Name of exporting country	Indonesia.
Brand Name + Dosage Form + Strength	Medivac ND G7-EDS-IB Emulsion (Inactivated Vaccine for Poultry) Each dose contains; Inactivated Newcastle Disease Virus of MD15 Strain (MD15 strain identical to genotype VII.2 group).....at least 10^7 EID ₅₀ Inactivated Adenovirus 127 virus, Mc Ferran strain....at least 1000 HA unit Inactivated Infectious Bronchitis virus, Massachusetts 41 strain.....at least $10^{4.5}$ EID ₅₀
Composition	Each dose contains; Inactivated Newcastle Disease Virus of MD15 Strain (MD15 strain identical to genotype VII.2 group).....at least 10^7 EID ₅₀ Inactivated Adenovirus 127 virus, Mc Ferran strain....at least 1000 HA unit Inactivated Infectious Bronchitis virus, Massachusetts 41 strain.....at least $10^{4.5}$ EID ₅₀
Finished Product Specifications	Innovator's Specifications
Pharmacological Group	Inactivated emulsion vaccine
Shelf life	18 Months (2-8°C)
Me-too Availability	Strains are registered.
Demanded Price / Pack size	De-controlled/500ml
Certificates Submitted	CoPP: Valid legalized CoPP has been submitted GMP: Legalized copy of valid GMP certificate has been provided. LOA: Authorization letter submitted
Remarks of the Evaluator: The Registration Board in its 339th meeting, deferred the case due to deficiencies in the application. The response of the applicant is as under	
Deficiency	Response
Original legalized COPP is not provided. Scanned copy is attached in dossier.	Valid legalized CoPP has been submitted.
Product specific Letter of Authorization is not provided.	LOA from MAH has been submitted.
Fee paid is Rs.75000/- under the head of new drug molecule while the applied product is not a new drug. Remaining fee is not submitted yet.	Differential fee Challan of Rs. 225,000/- has been deposited.
Pack size and Batch size are not mentioned in stability data.	The stability studies data of three batches with Batch Numbers & pack size has been submitted by the applicant.
Mc Ferran strain of Adenovirus is not	Adenovirus 127 Mc Ferran strain used in

	registered before as per data available.	Medivac ND G7-EDS-IB Emulsion is actually the same with Adenovirus 127 strain or Egg Drop Syndrome/ Fowl Adenovirus (FAV) 127. Furthermore Adenovirus 127 strain or Egg Drop Syndrome/ Fowl Adenovirus (FAV) 127 is registered and available in Pakistan.
	Decision: Keeping in view the valid GMP & CoPP indicating product availability in the country of origin, the Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.	

Case # 08		
	Name and address of Importer	M/s Saadat International 117-Habittat Apartments, Shadman-II, Jail Road, Lahore.
	Detail of DSL	M/s Saadat International, 117-Habittat Apartments, Shadman-II, Jail Road, Laore DSL # 05-352-0063-102851D Valid till: 24 Febrary 2028
	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy. No. Dated 23rd May 2023 Rs. 150,000/-, Date: 18-05-2023, Challan No. 804748641
	Name of MAH & Manufacturer	Manufacturer: LABORATOIRE BIOLUZ Zone Industrielle de Jalday, 64500 St Jean de Luz-France MAH: BOEHRINGER INGELHEIM ANIMAL HEALTH FRANCE, 29 AVENUE TONY GARNIER, 69007, LYON, FRANCE.
	Name of exporting country	France.
	Brand Name + Dosage Form + Strength	STERILE DILUENT 400ml Each 1 ML contains: Sucrose ----- 51.25 mg Casein Hydrolysate ----- 15.00 mg Dipostassium phosphate..... 1.25 mg Postassium dihydrogen phosphate..... 0.46 mg Phenol red..... 10 µg Hydochloric acid concentrate q.s. 6.9 ≤ pH ≤ 7.3 Sodium hydrochloride -----q.s. 6.9 ≤ pH ≤ 7.3 Water for injection.....q.s. 1 ml
	Composition	Each 1 ML contains: Sucrose ----- 51.25 mg Casein Hydrolysate ----- 15.00 mg Dipostassium phosphate..... 1.25 mg Postassium dihydrogen phosphate..... 0.46 mg Phenol red..... 10 µg Hydochloric acid concentrate q.s. 6.9 ≤ pH ≤ 7.3 Sodium hydrochloride -----q.s. 6.9 ≤ pH ≤ 7.3 Water for injection.....q.s. 1 ml

	Finished Product Specifications	In-house Specs
	Pharmacological Group	Veterinary Vaccine Diluent
	Shelf life	24 months (Store at room temperature, Avoid freezing or excessive temperature)
	Me-too Availability	Not registered.
	Demanded Price / Pack size	De-controlled/400ml
	Certificates Submitted	FSC: Original/Legalized, Valid, Legalized FSC has been provided. GMP: Original/Legalized copy of valid GMP certificate has been provided. LOA: LOA issued by MAH, has been provided

Remarks of the Evaluator: The Registration Board in its 345 th meeting, deferred the case due to deficiencies in the application. The response of the applicant is as under																										
Deficiency	Response																									
The LOA has been issued by M/s BOEHRINGER INGELHEIM VETMEDICA GMBH, Binger STrabe 173 55216 Ingelheim an Rhein Germany while MAH mentioned on Certificate of Origin & Free Sale is BOEHRINGER INGELHEIM ANIMAL HEALTH FRANCE, 29 AVENUE TONY GARNIER, 69007, LYON, FRANCE	The LOA has been issued by the parent Boehringer Ingelheim Vetmedica GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein Germany, which is the parent company. However, MAH has been issued in favor of the subsidiary Boehringer Ingelheim Animal Health France, situated at 29 Avenue Tony Garnier 69007 Lyon, France																									
Justification of submission of application of the product as Biological Product, is required since the product does not contain any active ingredient of biological origin.	The said Sterile Diluent 400ml is used for the suspension of the cell associated frozen vaccines. The same list of the frozen vaccines was mentioned in the initial application (form 5A) for your kind review & consideration.																									
	<table><tr><th colspan="3">List of registered drugs/Frozen Vaccines</th></tr><tr><th>Sr. No.</th><th>Product Name</th><th>Reg. No.</th></tr><tr><td>1</td><td>Vaxxitek HVT+IBD-2000ds</td><td>057114</td></tr><tr><td>2</td><td>Newxxitek HVT+ND-2000ds</td><td>099511</td></tr><tr><td>3</td><td>Prevexxion RN-2000ds</td><td>098498</td></tr><tr><td>4</td><td>Vaxxitek HVT+IBD+ND-1000ds</td><td>115148</td></tr><tr><td>5</td><td>Vaxxitek HVT+IBD+ND-2000ds</td><td>115149</td></tr><tr><td>6</td><td>Vaxxitek HVT+IBD+ND-4000ds</td><td>115150</td></tr></table>		List of registered drugs/Frozen Vaccines			Sr. No.	Product Name	Reg. No.	1	Vaxxitek HVT+IBD-2000ds	057114	2	Newxxitek HVT+ND-2000ds	099511	3	Prevexxion RN-2000ds	098498	4	Vaxxitek HVT+IBD+ND-1000ds	115148	5	Vaxxitek HVT+IBD+ND-2000ds	115149	6	Vaxxitek HVT+IBD+ND-4000ds	115150
	List of registered drugs/Frozen Vaccines																									
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5	Vaxxitek HVT+IBD+ND-2000ds	115149																								
6	Vaxxitek HVT+IBD+ND-4000ds	115150																								
	The independent registration of the said diluent is inevitable due to the following challenges;																									
	• It is supplied from France however all above list of vaccines are sourced from USA, so its comb pack is not possible. • Since all the above vaccines are to be stored/submerged in the liquid Nitrogen cylinders at/below temperature of -196^oC so the diluent cannot be packed/stored/shipped along with the vaccines as the storage conditions of Sterile Diluent is +30^oC																									
Decision: The Registration Board after threadbare deliberation, rejected the application with the advice that the applicant may submit PRV application with relevant documents for approval of attachment of diluent with vaccine.																										

Case # 09		
Name and address of Importer	M/s Forward Solutions, Plot No. 19-B, Qazalbash Chowk, Abdul Sattar Edhi Road, Lahore	
Detail of DSL	M/s Forward Solutions, Forward Solutions, Plot No. 19-B, Qazalbash Chowk, Abdul Sattar Edhi Road, District Lahore DSL # 05-352-0066-028137D Valid till: 10 th February, 2029.	
Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy. No. 000 Dated 24 th September, 2013 Rs. 100,000/-, (Challan No. 005655 (Rs. 50000/- dated: 20-05-2013, Rs. 50000/- dated: 10-09-2013))	
Name of Manufacturer & MAH/PLH	MAH: M/s Fatro S.p.A, Via Emilia, 285 – 40064 Ozzano Emilia (Bologna) Italy. Manufacturer: M/s Fatro S.p.A, Via Molino Emili, 2 – 25030 Macclodio (BS) – Italy.	
Name of exporting country	Italy	
Brand Name + Dosage Form + Strength	G-OLVAC (Inactivated Oil Emulsified Vaccine) Each dose contains; Inactivated Newcastle Disease virus (La-Sota): not less than 10 ^{8.5} EID ₅₀ . Inactivated infectious bursal Disease virus (NEV 39): not less than 10 ^{5.5} EID ₅₀ .	
Composition	Each dose contains; Inactivated Newcastle Disease virus (La-Sota): not less than 10 ^{8.5} EID ₅₀ . Inactivated infectious bursal Disease virus (NEV 39): not less than 10 ^{5.5} EID ₅₀ .	
Finished product specifications	Manufacturer Specs.	
Pharmacological Group	Inactivated Veterinary Vaccine	
Shelf life	24 Months (2°C - 8°C)	
International availability	Italy	
Products already registered in Pakistan	Not Registered	
Demanded Price / Pack size	De-controlled/1000 doses (500 ml Vial)	
Certificates Submitted	CoPP: Original, Valid, Legalized CoPP has been submitted on 6 th December, 2021. GMP: Legalized copy of valid GMP certificate has been submitted on 30 th May, 2024 LOA: Copy of LOA has been provided.	
Remarks of the Evaluator: The Registration Board in its 292 nd meeting, deferred the case due to deficiencies in the application. The response of the applicant is as under;		
Deficiency		Response
Deferred for clarification by the firm for non-availability of the formulation by the regulatory authority in the country of the origin		Valid legalized CoPP has been submitted by the applicant confirming the availability of product in country of origin.

	As per available record, Inactivated infectious bursal Disease virus (NEV 39) is not already registered.
	Decision: The Registration Board, referred the product to Ministry of National Food Security & Research, Islamabad, for comments regarding the need of vaccine, prevalence of disease and immunological relevance of the strain in Pakistan.

Case # 10	
Name and address of Importer	M/s Forward Solutions, Plot No. 19-B, Qazalbash Chowk, Abdul Sattar Edhi Road, Lahore
Detail of DSL	M/s Forward Solutions, Plot No. 19-B, Qazalbash Chowk, Abdul Sattar Edhi Road, District Lahore DSL # 05-352-0066-028137D Valid till: 10 th February, 2029.
Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy. No. 000 Dated: 12 th April, 2017 Rs. 100,000/-, (Challan No. 0592569, dated: 10 th April, 2017)
Name of Manufacturer & MAH/PLH	MAH: M/s Fatro S.p.A, Via Emilia, 285 – 40064 Ozzano Emilia (Bologna) Italy. Manufacturer: M/s Fatro S.p.A, Via Molino Emili, 2 – 25030 Macclodio (BS) – Italy.
Name of exporting country	Italy
Brand Name + Dosage Form + Strength	AI-VAC H9 Each dose contains; Inactivated Avian Influenza (subtype H9N2) virus: not less than 10 ^{7.5} EID ₅₀
Composition	Each dose contains; Inactivated Avian Influenza (subtype H9N2) virus: not less than 10 ^{7.5} EID ₅₀
Finished product specifications	Manufacturer Specs.
Pharmacological Group	Inactivated Veterinary Vaccine
Shelf life	24 months (2°C - 8°C)
International availability	Italy
Products already registered in Pakistan	JOVA ZEIT 7 Vaccine
Demanded Price / Pack size	De-controlled 500 ml vial
Certificates Submitted	CoPP: Original, Valid, Legalized CoPP has been provided. GMP: Legalized copy of valid GMP certificate has been submitted on 30 th May, 2024 LOA: Copy of LOA has been provided.
Remarks of the Evaluator: The Registration Board in its 282 nd meeting, deferred the case due to deficiencies in the application. The response of the applicant is as under;	

Deficiency	Response
Change of address and proprietorship on DSL for all the products.	The applicant has submitted copy of valid DSL with updated address.
Clarification regarding non availability of product in country of origin as per submitted CoPPs.	The applicant has submitted clarification letter from MAH abroad declaring that vaccine is manufactured for export purpose only because there is no Avian Influenza Virus sub-type H9N2 outbreaks in chicken in Italy.
Decision: Keeping in view the valid GMP, prevalence of Avian Influenza (subtype H9N2) in Pakistan and import of product from reference country, the Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.	

Agenda Item No. 04.03: Applications for Registration of Locally Manufactured Veterinary Biological Products-Hardcopy Applications (Deferred in Various Meetings)

Case # 01		
	Name and address of product manufacturer (Applicant)	M/s Intervac Pvt. Ltd., 18 Km Lahore Sheikhpura Road , Sheikhpura Pakistan
	Brand Name +Dosage Form + Strength	INTERVAC 2 COMBO VACCINE
	Composition	Each Dose of 0.25ml Contains; Inactivated Newcastle Disease (LaSota strain) Virus. $\geq 10^9$ EID ₅₀ Inactivated Avian Infectious Bronchitis (H120 strain) Virus. $\geq 10^{6.5}$ EID ₅₀
	Pharmacological Group	Veterinary vaccine
	Finished Product Specification	Manufacturer's Specs
	Type of Form, Diary No. Date of R& I & fee	Dy no. 25861 Dated: 17-09-2021 Rs. 30,000/- (Slip # 20154971088)
	Shelf Life	12 months (2-8°C)
	Document Details	Copy of GMP certificate dated 21-03-2024 has been submitted with Veterinary Vaccine Section.
	Pack size & Demanded Price	1000 doses (300ml)/Decontrolled
	Products already registered in Pakistan	GALLIMMUNE 204 ND+IB SAADAT INTRNATIONAL
Remarks of Evaluator: The case was deferred in 324 th meeting due to deficiency in application. The response of the applicant is as under;		
Deficiency		Reponse
Deferred for confirmation of viral strain in applied vaccine composition.		The applicant has submitted detail of strains as under; Each Dose 0.25ml Contains Inactivated Newcastle Disease (LaSota strain) Virus. $\geq 10^9$ EID ₅₀ Inactivated Avian Infectious Bronchitis (H120 strain) Virus. $\geq 10^{6.5}$ EID ₅₀
Decision: Keeping in view the availability of manufacturing facility with valid GMP, the Registration Board approved the product.		

Case # 02		
	Name and address of product manufacturer (Applicant)	M/s Intervac Pvt. Ltd. 18 Km Lahore Sheikhpura Road , Sheikhpura Pakistan
	Brand Name +Dosage Form + Strength	INTERVAC 3 COMBO OIL BASED VACCINE

Composition	Each Dose 0.3ml Contains: Inactivated Newcastle disease virus, strain Lasota, at least....10 ⁷ EID ₅₀ Inactivated Infectious Bronchitis virus, strain H 120, at least....10 ⁵ EID ₅₀ Inactivated Egg Drop Syndrome (strain EDS '76) at least.....10 ⁹ EID ₅₀
Pharmacological Group	Veterinary vaccine
Finished Product Specification	Manufacturer's Specs
Type of Form, Diary No. Date of R& I & fee	Dy no. 25860 Dated: 17-09-2021 Rs.30,000/- (Slip # 3566017876)
Shelf Life	12 months (2°C-8°C)
Document Details	Copy of GMP certificate dated 21-03-2024 has been submitted with Veterinary Vaccine Section.
Pack size & Demanded Price	1000 doses (300ml)/Decontrolled
Products already registered in Pakistan	GALLIMUNE 302 ND+IB+EDS SAADAT INTRNATIONAL
Remarks of Evaluator: The case was deferred in 324 th meeting due to deficiency in application. The response of the applicant is as under;	
Deficiency	Reponse
Evidence of already registered product for applied product	Gallimune 302 ND + IB +EDS Vaccine Registration No. 049594
Confirmation of strain of Egg Drop Syndrome in applied vaccine composition	The applicant has submitted detail of strains as under; Each Dose 0.3ml Contains: Inactivated Newcastle disease virus, strain Lasota, at least....10 ⁷ EID ₅₀ Inactivated Infectious Bronchitis virus, strain H 120, at least....10 ⁵ EID ₅₀ Inactivated Egg Drop Syndrome (strain EDS '76) at Least.....10 ⁹ EID ₅₀
Decision: Keeping in view the availability of manufacturing facility with valid GMP, the Registration Board approved the product.	

Case # 03	
Name and address of product manufacturer (Applicant)	M/S Intervac Pvt. Ltd. 18 Km Lahore Sheikhpura Road , Sheikhpura Pakistan
Brand Name +Dosage Form + Strength	INTERVAC ND+IB+IBD OIL BASED VACCINE

Composition	Each Dose 0.3ml Contains: Inactivated Newcastle disease virus, strain Lasota, at least.... 10^7 EID ₅₀ Inactivated Infectious Bronchitis virus, strain H 120, at least.... 10^5 EID ₅₀ Inactivated Avian Infectious Bursal Disease (IBD) strain D-78 $\geq 10^{4.0}$ EID ₅₀
Pharmacological Group	Veterinary vaccine
Finished Product Specification	Manufacturer's Specs
Type of Form, Diary No. Date of R& I & fee	Dy No. 25859 Dated: 17-09-2021 Rs. 30,000/- (Slip # 8893423)
Shelf Life	12 months (2°C-8°C)
Document Details	Copy of GMP certificate dated 21-03-2024 has been submitted with Veterinary Vaccine Section.
Pack size & Demanded Price	1000 doses (300ml)/Decontrolled
Products already registered in Pakistan	BIGOPEST ND+IB+IBD of SAADAT INTRNATIONAL
Remarks of Evaluator: The case was deferred in 324 th meeting due to deficiency in application. The response of the applicant is as under;	
Deficiency	Reponse
Evidence of already registered product for applied product	Bigopest Injection Inactivated Vaccine Registration No. 011480
Confirmation of strain of Avian Infectious Bursal Disease in applied vaccine composition	The applicant has submitted detail of strains as under; Each Dose 0.3ml Contains: Inactivated Newcastle disease virus, strain Lasota, at least.... 10^7 EID ₅₀ Inactivated Infectious Bronchitis virus, strain H 120, at least.... 10^5 EID ₅₀ Inactivated Avian Infectious Bursal Disease (IBD) strain D-78 $\geq 10^{4.0}$ EID ₅₀
Decision: Keeping in view the availability of manufacturing facility with valid GMP, the Registration Board approved the product.	

Case # 04	
Name and address of product manufacturer (Applicant)	M/S Intervac Pvt. Ltd. 18 Km Lahore Sheikhpura Road , Sheikhpura Pakistan
Brand Name +Dosage Form + Strength	INTERVAC SHEEP POX VACCINE
Composition	Each Dose Contains: Freeze-dried attenuated sheep pox virus strain RM/65.... not less than $10^{2.5}$ TCID ₅₀

Pharmacological Group	Veterinary vaccine
Finished Product Specification	Manufacturer's Specs
Type of Form, Diary No. Date of R& I & fee	Dy No. 25858 Dated: 17-09-2021 Rs. 30,000/- (Slip #5102768612)
Shelf Life	She2 years (2°C-8°C)
Document Details	Copy of GMP certificate dated 21-03-2024 has been submitted with Veterinary Vaccine Section.
Pack size & Demanded Price	1000 doses (300ml)/Decontrolled
Products already registered in Pakistan	JOVIVAC JOVAC (Jordan Bio Industry Centre)
Remarks of Evaluator; The case was deferred in 324 th meeting due to decieny in application. The response of the applicant is as under;	
Deficiency	Reponse
Evidence of already registered product for applied product	JOVIVAC Company JOVAC (Jordan Bio Industry Center)
Confirmation of lyophilized facility for manufacturing of applied vaccine	The applicant has submitted GMP certificate as evidence. However, facility of lyophilization has not been separately mentioned in GMP certificate.
Decision: The Registration Board deferred the case for submission of evidence of availability of lyophilization facility for manufacturing of applied vaccine.	

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

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