

**MINUTES OF 355TH MEETING OF REGISTRATION BOARD
HELD ON 25TH MARCH, 2026**

Item No.	Detail of Item	Page No
I.	Division of Pharmaceutical Evaluation & Registration	
	Miscellaneous -----	03 – 04
	RRR Section -----	04 – 06
	Pharmaceutical Evaluation Cell (PEC) -----	07 – 86
II.	Division of Biological Evaluation & Research -----	87 – 96

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

355th meeting of Registration Board was held on 25th March, 2026 in the Committee Room, Drug Regulatory Authority of Pakistan, Prime Minister's National Health Complex Park Road, Chak Shehzad, Islamabad.

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

The meeting was attended by the following:

1.		Member
2.	Mr. Iftikhar Ahmed Choudhury, Ex-Chief Pharmacist, Hospital Pharmacist, Government of Punjab, Lahore.	Member (Virtual)
3.	Dr. Tehseen Fatima, Dow College of Biotechnology, Dow University of Health Sciences, Karachi.	Member (Virtual)
4.	Syed Adnan Rizvi, Director Drugs Testing Laboratory, Govt. of Sindh, Karachi.	Member (Virtual)
5.	Mr. Muhammad Aslam, Additional Draftsman, Law & Justice Division, Islamabad.	Member
6.	Mr. Ghulam Mujtaba, Deputy Director, Representative of IPO, Islamabad.	Member (Virtual)
7.	Ch. Zeeshan Nazir Bajar, Director, Quality Assurance & Lab Testing Division, DRAP.	Member
8.	Dr. Ghazanfar Ali Khan, Director, of Biological Evaluation & Research Division, DRAP.	Member
9.	Hafiz M. Ali Tayyab, Additional Director, Pharmaceutical Evaluation & Registration Division, DRAP.	Member/ Secretary
10.	Dr. Junaid Akhtar, Director, Drugs Testing Laboratory, Govt. of Gilgit Baltistan.	Co-Opted Member (Virtual)

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



Item No. I Division of Pharmaceutical Evaluation & Registration.

Miscellaneous

Case No. 01: Concerns Regarding the Use of Nimesulide Tablet 100mg.

Registration Board in its 269th meeting (held on 27th - 28th April, 2017) reviewed the formulation of "Nimesulide Tablet 100mg". After threadbare deliberation and keeping in view the measures adopted by the reference regulatory bodies to mitigate the risks associated with 'Nimesulide', the Board, decided as follows:

- i. *Keeping in view the approval status of Nimesulide 100mg tablet in EMA, the Registration Board approved the formulation of Nimesulide Tablets 100mg with a pack size of 15 tablets as per recommendations of EMA only for the following clinical indications as a second line choice.*
a. Treatment of acute pain b. Primary dysmenorrhea
- ii. *The information for prescribers (Summary of Product Characteristics-SmPC) and patients (Patient Information Leaflet-PIL) including clinical indications, adverse reactions and contraindications shall be same as per approval by European Medicine Agency (EMA) assessment report and the final decision of European Commission.*
- iii. *Registration Board noticed that some of the marketing authorization / registration holders are promoting and the prescribers are subsequently prescribing nimesulide for clinical indications which are not approved by EMA assessment report. These indications also include post-operative dental pain, post-surgical pain, painful extra-articular disorders and tendinitis for even more than 15 days. Registration Board deliberated those registration holders of Nimesulide 100mg tablet shall also follow above decision. In case of non-compliance, legal proceedings shall be started accordingly.*
- iv. *Registration Board decided to place above decision on DRAP's website and same shall be communicated to all stake holders.*
- v. *Registration Board advised PE&R Division to evaluate already deferred cases of formulations containing nimesulide as per the checklist approved in 251st meeting.*

Later on, Registration Board, in its 271st meeting held on (19th-20th June, 2017) revised its previous decision by correcting the pack size to "15 days" instead of "15 Tablets". The complete decision is reproduced below:

Registration Board corrected its decision recorded in the minutes of its 269th meeting as under:

“Keeping in view the approval status of Nimesulide 100mg tablet in EMA, the Registration Board approved the formulation of Nimesulide Tablets 100mg with a pack size for 15 days as per recommendations of EMA only for the following clinical indications as a second-line choice.

a) Treatment of acute pain

b) Primary dysmenorrhea”

In compliance with the above-mentioned decision, following condition is mentioned on registration letters of Nimesulide Tablet 100mg:

“The following clinical indication should appear on the label of the product at S.No.1 in bold & conspicuous manner:

Nimesulide Tablet 100mg is indicated only as a second line choice for the treatment of acute pain & Primary Dysmenorrhea.”

However, an advisory was also required to be issued and uploaded on the DRAP's website which was not done at that time.

Recently, a correspondence received from Directorate of Drugs Control Punjab, Lahore wherein decision of 17th Provincial Pharmacovigilance Committee (PPVC) has been communicated. The decision is regarding "Concerns and Recommendations Regarding the Use of Nimesulide" and it states as under:

Minutes of 355th Meeting of Registration Board (25th March, 2026)

"The Committee recommended that the said case may be forwarded to the Registration Board, DRAP with the proposal to review the registration status of "Nimesulide" in line with the International regulatory bodies or sanction its use with restriction as mandatory. Any action taken in this regard may be communicated to the Directorate of Drugs Control, Punjab.

Recommendation:

- **Risk Assessment:** Regular monitoring of liver function in patients using Nimesulide.
- **Restriction in Vulnerable Population:** Consideration of restrictions similar to those in India for children under 12 years.
- **Awareness and Education:** Healthcare providers and patients should be educated about potential risks and alternatives."

Keeping in view that the same precautionary conditions regarding use of 'Nimesulide' are still applicable, therefore, it will be appropriate to issue advisory on the same points as were decided by the Registration Board in its 269th meeting.

Decision: Registration Board decided to issue advisory to the manufacturers/ registration holders of 'Nimesulide Tablet 100mg' as decided in its 269th meeting.

RRR section

Case No.01: M/s Lahore Pharma, 9-Km Sheikhpura Road Lahore.

1.	Brand Name + Dosage Form and Strength	Ichthammol Glycerin
	Composition	Each 100gm contains: Ichthammol...10gm Glycerin.....90gm
	Tracking ID and fee details	Challan No.4126930 Rs. 38700 & Tracking ID:W34-M4V-6MZ5
	Type of form	Form-5
	Finished product specifications	British Pharmaceutical Codex (1973)
	Pack size and Demand Price	1x10's
	GMP Status	DML Renewal status yet to be verified Panel constituted by Licensing division dated 28-01-2026
	RRA status	MHRA Approved
	Remarks:	Firm has applied re-registration for Ichthammol Glycerin Reg.No.014226 due to non-submission of renewal application.
	Decision: Approved	
2.	Brand Name + Dosage Form and Strength	Lptol solution
	Composition	Each 1000ml contains:- Chloroxylenol.....50gm
	Tracking ID and fee details	Challan No. 271687477 Rs. 38700 & Tracking ID:698-DWY-1845
	Type of form	solution
	Finished product specifications	British Pharmaceutical Codex (1973)
	Pack size and Demand Price	As per SRO
	GMP Status	DML Renewal status yet to be verified Panel constituted by Licensing division dated 28-01-2026

	RRA status	Not found
	Remarks:	RRA approved formulation is 4.8% cutaneous solution (Dettol) Applied formulation is available in BP Firm has applied re-registration for Lptol solution Reg.No.014439 due to non-submission of renewal application
	Decision: Approved . Formulation shall be standardized in line with RRA along with requisite fee (as per SRO)	
3.	Brand Name + Dosage Form and Strength	Kaoline Poultice
	Composition	Each 1000ml contains:- Kaoline heavy.....527gm Boric acid.....45gm Methyl Salicylate.....2ml Peppermint oil.....0.5ml Thymol.....0.5ml Glycerin.....100gm Propylene Glycol.....325gm
	Tracking ID and fee details	Challan No. 94562247043 Rs. 38700 & Tracking ID: SY2-USR-LEQM
	Type of form	Form-5
	Finished product specifications	Not provided
	Pack size and Demand Price	As per SRO
	GMP Status	DML Renewal inspection dated 08.02.2018 & 11.04.2018
	RRA status	MHRA Approved
	Remarks:	Formulation to be standardized in line with MHRA i.e KAOLIN POULTICE BP as under: Heavy Kaolin 527.0g Thymol 0.5g Boric Acid 45.0g Peppermint Oil 0.5g Methyl Salicylate 2.0ml Applied formulation is available in BP Firm has applied re-registration for Kaoline Poultice Reg.No. 014227 due to non-submission of renewal application
	Decision: Approved . Formulation shall be standardized in line with RRA along with requisite fee (as per SRO)	

Case No.02: M/s. Convell Laboratories pharmaceutical manufacturing Saidu sharif swat Pakistan

1.	Brand Name + Dosage Form and Strength	Veldox 100 mg Tablet
	Composition	Each Tablet contains Cefpodoxime Proxetil.....100 mg
	Tracking ID and fee details	RR3-2ZL-38LV Rs.37,000/-dated: 04-july-2025 (27670563)
	Type of form	Fom-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO, 1x10 s
	GMP Status	Manufacturing facility/sections approval to be verified

RRA status	Reference formulation is approved in RRA as base
Remark of the Renewal section	Remarks: Label claim to be standardized in line with RRA along with fee as under: Each film coated tablet contains: cefepodoxime (as cefepodoxime proxetil).....100mg Firm has applied re-registration for Veldox 100 mg Tablet Reg. No. 032391 due to non submission of renewal application.
Decision: Rejected due to unavailability of relevant section/manufacturing facility	

Case No.03: M/s Welmed Pharmaceutical industries (Pvt) Ltd., Plot No. 108/1 Road No. R-2 I.E. Gadoon.

1.	Brand Name + Dosage Form and Strength	Gyrocim 400mg Tabs
	Composition	Each film coated tablet contains Moxifloxacin as HCl400
	Tracking ID and fee details	Challan No.82440877613 Rs. 38700 & Tracking ID: DEX-69G-VJYP
	Type of form	Tablet
	Finished product specifications	USP Specifications
	Pack size and Demand Price	Not provided
	GMP Status	DML renewed dated 26 th January 2026 wherein Tablet (General) section found approved
	RRA status	USFDA approved
	Remarks:	Firm has applied re-registration for Gyrocim 400mg Tabs Reg.No.096213 due to non submission of renewal application.
	Decision: Approved	
2.	Brand Name + Dosage Form and Strength	Montimed 10mg Tablets
	Composition	Each tablet contains Montelukast Sodium10.40mg eq. To Montelukast10mg
	Tracking ID and fee details	Challan No. 75763501 Rs. 38700 & Tracking ID: WGJ-MUN-SUHN
	Type of form	Tablet
	Finished product specifications	USP Specification
	Pack size and Demand Price	Not provided
	GMP Status	DML renewed dated 26 th January 2026 wherein Tablet (General) section found approved
	RRA status	USFDA approved
	Remarks:	Firm has applied re-registration for Montimed 10mg Tablets Reg.No.096901 due to nonsubmission of renewal application. Label claim to be standardized in line with RRA as Film coated tablet.
	Decision: Approved. Label claim shall be standardized in line with RRA along with requisite fee (as per SRO).	



Drug Regulatory Authority of Pakistan

(Pharmaceutical Evaluation & Registration Division)



Pharmaceutical Evaluation Cell (PEC)

Sr. No	Title	Description
1	Case Category	Any Other (Abdul Mughees)
	Name, address of Applicant.	Amgomed Office No. 4, First Floor, Ghousia Plaza, Main Jinnah Avenue, Blue Area (037/DSL(D)/PS&DC-ICT/2025)
	Application Form Dy. No / Tracking ID & date of submission	(2ZU-R2Z-2NQZ, 2025-08-19)
	Detail of Fee Submitted	300000.0, 2025-07-15,
	The proposed proprietary name / brand name	Abiraterone 500 mg
	Label Claim	Each film-coated tablet contains: Abiraterone acetate.... 500 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	60 tablets-As per SRO
	Shelf Life (Unit)	24 Year(s)30 degree
	For generic drugs (me-too Status)	Zytiga 500mg, Abytiga 500mg and Abirone
	Pharmacotherapeutic Group of (API)	Anti androgens
	Name, address of Manufacturing site:	Synthon Hispania S.L.-Caste116 1 Poligono Las Salinas 08830 Sant Boi de Llobregat, Spain-Spain
	Pharmaceutical Equivalence and Comparative Dissolution Profile	BE performed against Zytiga Batch IDZT100
	Name, address of Marketing Authorization Holder:	Amgomed Pharma, Office No. 4 First Floor, Ghausia Plaza, Jinnah Avenue, Blue Area, Islamabad, Pakistan 44000, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	EUDRA GMP
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies conducted at long-term (25C / 60 % RH) and accelerated conditions
	The status in reference regulatory authorities	EMA, USFDA
	Evaluation Remarks	
	In light of decision of 220th meeting of the Authority. Abiraterone 250 mg is already approved from the same source.	
	Decision	
	Approved	
	As per current import policy.	
2	Case Category	Any Other (Abdul Mughees)
	Name, address of Applicant.	Al Habib Pharmaceuticals. Plot 81 SMCHS BLOCK B (0414)
	Application Form Dy. No / Tracking ID & date of submission	(QZX-NN1-JWH4, 2026-01-14)

	Detail of Fee Submitted	313500, 2025-09-03,
	The proposed proprietary name / brand name	EPOSIDE Injection USP 100mg/5ml
	Label Claim	Each vial contains 100mg/5ml of etoposide. (20mg/ml)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1s, 5s, 10s, 15s,-As per SRO
	Shelf Life (Unit)	24 Year(s)Store Below 30 c
	For generic drugs (me-too Status)	Product Name: Sedol 100mg/5ml Injection Company Name: Venus Remedies Limited, India (Imported by: Helix Pharma (Pvt)., Ltd.) Dosage Form: Vial Label Claim: Each Vial contains: Etoposide 100mg/5ml Inje
	Pharmacotherapeutic Group of (API)	MAC-CHEM PRODUCTS (INDIA) PVT. LTD. INDIA ADDRESS: N-211/2/10, M.I.D.C. Tarapur, Boisar, Dist. Palghar 401506 Maharashtra State, INDIA
	Name, address of Manufacturing site:	NAPROD LIFE SCIENCES PVT. LTD.- NAPROD LIFE SCIENCES PVT. LTD. PLOT NO. G-17/1, MIDC, TARAPUR, BOISAR, DIST. PALGHAR 401506 MAHARASHTRA STATE, INDIA.-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference Product: EUNADES®CS (Etoposide Injection 100mg/5ml) Manufactured By: PFIZER Batch No: HP40B
	Name, address of Marketing Authorization Holder:	Al Habib Pharmaceuticals, Plot 81, Block B, SMCHS, Karachi , Pakistan, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	GMP issued by OGYEI Hungry (verification from EudraGMP pending)
	Details of Authorization Letter :	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches at accelerated and long-term (25C) conditions
	The status in reference regulatory authorities	Abbreviated New Drug Application (ANDA): 074513 Company: ACCORD HLTHCARE Drug Name: ETOPOSIDE Active Ingredients: ETOPOSIDE Strength: 20mg/ml Dosage form/Route: Injectable;Injection Marketing Status: Prescription RLD: No REFERENCE AUTHORITY: US-FDA E-LINK: <a href="https://www.accessdata.fda.gov/scripts/cder/daf/in
event=overview.process&A pplNo=074513">https://www.accessdata.fda.gov/scripts/cder/daf/in event=overview.process&A pplNo=074513
	Evaluation Remarks	
	In light of decision of 220th meeting of the Authority. The applicaiton fulfills codal formalities subject to submission of legalized CoPP.	
	Decision	
	Approved	
	Approved subject to submission of legalized CoPP and as per current import policy.	
3	Case Category	Any Other (Abdul Mughees)
	Name, address of Applicant.	Genix Pharma (Pvt) Ltd , Plot No. 44-45-B, Korangi Creek Road, Karachi (0640)
	Application Form Dy. No / Tracking ID & date of submission	(S7S-4Y5-8J5P, 2026-02-04)

	Detail of Fee Submitted	300000, 13500 2025-04-18, 2025-11-17
	The proposed proprietary name / brand name	Nunilo Capsule 50mg
	Label Claim	Each capsule contains: Nilotinib.....50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	56's-As per SRO
	Shelf Life (Unit)	2 Year(s)15°C - 30°C
	For generic drugs (me-too Status)	Tasigna Capsule 50mg
	Pharmacotherapeutic Group of (API)	L01EA03: BCR-ABL tyrosine kinase inhibitors
	Name, address of Manufacturing site:	Shilpa Medicare Limited -Plot No. S-20 to S26, Pharmaceutical formulations SEZ, TSIIC, Green Industrial Park, Polepally, Jadcherla, Telangana, 509301, India -India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Tasigna Capsule
	Name, address of Marketing Authorization Holder:	Genix Pharma (Pvt) Ltd. Karachi, 44,45-B Korangi Creek Road, Karachi 75190 Pakistan , Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	GMP certificate issued by BASG Germany valid upto three years from 26/01/02024, with hard capsule section
	Details of Authorization Letter :	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted on long-term and accelerated conditions
	The status in reference regulatory authorities	Tasigna Capsule 50mg
	Evaluation Remarks	
	In light of decision of 220th meeting of the Authority. Shilpa product contains Nilotinib base instead of Nilotinib hydrochloride. However, the Board has already approved Nunilo 150 and 200mg strengthes from same source.	
4	Decision	
	Approved	
	As per current import policy.	
	Case Category	Any Other (Abdul Mughees)
	Name, address of Applicant.	My Body Healer (Private) Limited Office No. 104 & 105, 1st Floor, Plot No. 54-C, Al Murtaza Commercial Lane-2, Phase VIII, DHA, Karachi (670)
	Application Form Dy. No / Tracking ID & date of submission	(83M-N89-95X9, 2026-02-18)
	Detail of Fee Submitted	300000, 13500 2025-03-25, 2025-11-17
	The proposed proprietary name / brand name	Letrozest 2.5mg Tablets
	Label Claim	Each film coated tablet contains: Letrozole 2.5mg
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	1x10's & 3x10's-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Grudiz 2.5mg Tablets by Sami Pharmaceuticals (Pvt.) Limited
	Pharmacotherapeutic Group of (API)	Non- Steroidal Type II Aromatase Inhibitor

	Name, address of Manufacturing site:	Pharmacare Premium Ltd.-HHF003. Hal Far Industrial Estate, Birzebbugia, BBG3000, Malta.-Malta
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The comparative dissolution profiles of Letrozole tablets USP 2.5 mg of scale up batch with Femara® 2.5 mg tablets in 0.1N HCL, pH .4.5 Acetate buffer and pH 6.8 phosphate buffer
	Name, address of Marketing Authorization Holder:	My Body Healer (Private) Limited, Office No. 104 & 105, 1 Floor, Plot No. 54-C, Al Murtaza Commercial Lane-2, Phase VIII, DHA, Karachi., Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	FP Manufacturer EUDRA GMP
	Details of Authorization Letter :	Not applicable.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Femara 2.5mg Tablets by Novartis Ireland Limited, MHRA UK
	Evaluation Remarks	
	In light of decision of 220 meeting of the Authority	
	Decision	
	Approved	
	As per current import policy.	
5	Case Category	Any Other (Abdul Mughees)
	Name, address of Applicant.	Al Habib Pharmaceuticals. Plot 81 SMCHS BLOCK B (0414)
	Application Form Dy. No / Tracking ID & date of submission	(979-BYH-U7WT, 2026-03-18)
	Detail of Fee Submitted	313500, 2025-11-10,
	The proposed proprietary name / brand name	CARAPLATIN
	Label Claim	For 450 mg/45 mL Each mL contains: Carboplatin Ph. Eur. 10 mg Water for injection Ph. Eur. q.s. Excipients q.s
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Manufacturer name: Helix Pharma Private Limited Brand name : Carbol Strength: 450mg Composition : Each 45ml contains Carboplatin BP 450mg Registration number: 072506 Dosage form: Injection Pack size:
	Pharmacotherapeutic Group of (API)	HETERO LABS LIMITED, Unit-I, Sy.No.10, I.D.A., Gaddapotharam Village, Jinnaram Mandal, Sangareddy District,Pincode 502319,Telangana State, INDIA
	Name, address of Manufacturing site:	JODAS EXPOIM PVT. LTD.-Plot No. 55, Phase III, Biotech Park, Karkapatla Village, Markook Mandal, Siddipet District, Telangana, India-502279-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided

	Name, address of Marketing Authorization Holder:	Al Habib Pharmaceuticals, Plot 81, Block B, SMCHS, Karachi , Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Provided
	Details of Authorization Letter :	Provided
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
	The status in reference regulatory authorities	CARBOPLATIN 450MG/45ML (10MG/ML) Injection ; Accord Healthcare Limited, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom : MHRA APPROVED PL 20075/0028
	Evaluation Remarks	
	In light of decision of 220th meeting of the Authority. The applicant shall submit valid legalized CoPP and letter of Authorization.	
	Decision	
	Approved	
	Approved subject to submission of legalized CoPP, letter of Authorization and as per current import policy.	
6	Case Category	Any Other (Abdul Mughees)
	Name, address of Applicant.	Al Habib Pharmaceuticals. Plot 81 SMCHS BLOCK B (0414)
	Application Form Dy. No / Tracking ID & date of submission	(GRL-8MT-RP1J, 2026-03-18)
	Detail of Fee Submitted	313500, 2025-11-10,
	The proposed proprietary name / brand name	CARAPLATIN
	Label Claim	For 150 mg/15 mL Each mL contains: Carboplatin Ph. Eur. 10 mg Water for injection Ph. Eur. q.s. Excipients q.s.
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Manufacturer name: Helix Pharma Private Limited Brand name : Carbol Strength: 150mg Composition : Each 15ml contains Carboplatin BP 150mg Registration number: 072505 Dosage form: Injection Pack size:
	Pharmacotherapeutic Group of (API)	HETERO LABS LIMITED, Unit- I, Sy.No.10, I.D.A., Gaddapotharam Village, Jinnaram Mandal, Sangareddy District, Pincode 502319, Telangana State, INDIA
	Name, address of Manufacturing site:	JODAS EXPOIM PVT. LTD.-Plot No. 55, Phase III, Biotech Park, Karkapatla Village, Markook Mandal, Siddipet District, Telangana, India- 502279-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
	Name, address of Marketing Authorization Holder:	Al Habib Pharmaceuticals, Plot 81, Block B, SMCHS, Karachi , Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Provided
	Details of Authorization Letter :	Provided

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
	The status in reference regulatory authorities	CARBOPLATIN 150MG/15ML (10MG/ML) Injection ; Accord Healthcare Limited, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom : MHRA APPROVED PL 20075/0028
	Evaluation Remarks	
	In light of decision of 220th meeting of the Authority. The applicant shall submit valid legalized CoPP and letter of Authorization.	
	Decision	
	Approved	
	Approved subject to submission of legalized CoPP, letter of Authorization and as per current import policy.	
7	Case Category	Any Other (Abdul Mughees)
	Name, address of Applicant.	Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan (01-374-0006-118530D)
	Application Form Dy. No / Tracking ID & date of submission	(LJ6-L25-YP14, 2026-03-19)
	Detail of Fee Submitted	300000.0, 2025-06-23,
	The proposed proprietary name / brand name	ANESPRO 200mg/20ml
	Label Claim	Propofol Injectable Emulsion 200mg/20ml
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	24 MonthStore between 4° to 25°C (40° to 77°F). Do not freeze.
	For generic drugs (me-too Status)	Brand Name: PROPOFOL Dosage Form & Strength: Intravenous injection — Propofol 10 mg/mL (1%) Pack Size: 20 mL vials, sold in packs of 5 (i.e., “20 mL × 5 vials”) Composition: Each mL contains 10 mg of
	Pharmacotherapeutic Group of (API)	Anesthetic
	Name, address of Manufacturing site:	Nanjing King-Friend Biochemical Pharmaceutical Co.-No. 16 Xuefu Road Nanjing High & New Technology Development Zone Nanjing, Jiangsu, 210061, P. R. China-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	TPropofol Injectable Emulsion, USP is a generic version of the RLD DIPRIVAN®, approved under US NDA 019627. It is a sterile oil-in-water emulsion, where Propofol and soybean oil form the oil phase, and excipients like glycerol, sodium hydroxide, and disodium edetate form the aqueous phase. Propofol is freely soluble in the oil phase, and excipients are fully soluble in the aqueous phase; thus, no further solubility studies were necessary. pH impact studies using varying sodium hydroxide concentrations confirmed product stability and compliance with the RLD pH range of 7.0–8.5.
	Name, address of Marketing Authorization Holder:	Nanjing King-Friend Biochemical Pharmaceutical Co., No. 16 Xuefu Road Nanjing

		High & New Technology Development Zone Nanjing, Jiangsu, 210061, P. R. China, China
	Details of Certificates (CoPP/FSC/cGMP):	Valid
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies of Propofol, USP drug substance are carried out by drug substance manufacturer, Bachem SA, Succursale de Vionnaz under long term condition (5±3°C and 25°C/60% RH for 60 months) and accelerated condition (40°C/75% RH for 6 months) as per ICH.
	The status in reference regulatory authorities	Brand Name: DIPRIVAN Propofol Injectable Emulsion, USP, 200 mg/20 mL Dosage Form: Injection Manufactured by: Fresenius Kabi USA, LLC 6 Lake Zurich, IL 60047 USFDA Approved
	Evaluation Remarks	
	In light of decision of 220 meeting of the Authority. The same product from the following manufacturer is available in the Orange Book, US FDA. The applicant needs to provide legalized letter of authorization.	
	Nanjing King-Friend Biochemical Pharmaceutical Co.	No. 16 Xuefu Road Nanjing High & New Technology Development Zone Nanjing, Jiangsu, 210061, P. R. China
	Decision	
	Approved	
	As per current import policy.	
8	Case Category	Any Other (Abdul Mughees)
	Name, address of Applicant.	Himmel Pharmaceuticals Private Limited Ground Floor, 6- Judicial Colony phase-1 (Ext.) Shahrah Nazaria e Pakistan, (05-352-0065-016174D)
	Application Form Dy. No / Tracking ID & date of submission	(TXR-Z3H-9Y53, 2026-02-26)
	Detail of Fee Submitted	313500, 2025-09-22,
	The proposed proprietary name / brand name	Paclitaxel for Injection
	Label Claim	Each vial contains paclitaxel 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1s-Free of Cost
	Shelf Life (Unit)	3 Year(s)10-30 degree Celcius uopened vial
	For generic drugs (me-too Status)	Nab Xelpac Injection
	Pharmacotherapeutic Group of (API)	Antineoplastic agents
	Name, address of Manufacturing site:	CSPC Ouyi Pharmaceutical Co., Ltd.-No.88 Yangzi Road, Economic and Technological Development Zone, Shijiazhuang, Hebei, China- China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Abraxane 5 mg/ml powder for dispersion for infusion.
	Name, address of Marketing Authorization Holder:	CSPC Ouyi Pharmaceutical Co., Ltd., No.88 Yangzi Road, Economic and Technological Development Zone, Shijiazhuang, Hebei, China, China
	Details of Certificates (CoPP/FSC/cGMP):	Hebei Province Medical Products Administration GMP Compliance Inspection Notice for

		Pharmaceutical Products Code: JiHuaYaoFuJian 2022091 dated Sep.16, 2022- Sep.21, 2022
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted at long-term and accelerated conditions
	The status in reference regulatory authorities	Abraxane 5 mg/ml powder for dispersion for infusion.
	Evaluation Remarks	
	In light of the decision of the 220 meeting of the Authority	
	Decision	
	Deferred	
	Deferred for evidence of approval of Albumin source used in the formulation including details on provision of Albumin from specified source within country of origin and other countries	
9	Case Category	Any Other (Abdul Mughees)
	Name, address of Applicant.	Sohail Corporation plot # 7, SR-5, Serai Quarters (Techno City), WH-42, Karachi Pakistan. (238)
	Application Form Dy. No / Tracking ID & date of submission	(TVP-2U1-752B, 2026-02-18)
	Detail of Fee Submitted	313500, 2025-10-22,
	The proposed proprietary name / brand name	Metronidazole Injection 500mg/100ml (0.5% W/V)
	Label Claim	Each 100ml vial contains: 500mg of Metronidazole. B.P. (0.5% W/V).
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's (100ml vial)-Controlled
	Shelf Life (Unit)	36 MonthKeep the bottle in the outer carton in order to protect from light.The bottles are for single use only. Discard any unused portion. Do not reconnect partially used containers. Any unused product or
	For generic drugs (me-too Status)	Manufacturer/Registration holder: Hoechst Pakistan Limited. • Brand name: Flagyl Injection 500mg/100ml • Strength: 100 ml: 500mg • Dosage form: Injection. • Registration number: 005102.
	Pharmacotherapeutic Group of (API)	API: Metronidazole.(Antiamoebic and Anti-infective) Pharmacotherapeutic group: Anti-bacterials for systemic use: imidazole derivatives. ATC code: J01XD01.
	Name, address of Manufacturing site:	Shandong Hualu Pharmaceutical Co., Ltd.-No.1 Hualu Road, Zhenxing Street, Chiping District, Liaocheng City, Shandong Province.-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Valid Pharmaceutical Equivalence attached in Module 3
	Name, address of Marketing Authorization Holder:	M/s; Sohail Corporation, Address: Plot no 7, (Serai Quarters) SR-5, Techno City, Warehouse No 42, 6th Floor, Karachi. , Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Valid GMP Inspection Report of Manufacturer issued by Shandong Provincial Drug Supervision and Administration Bureau attached herewith

	Details of Authorization Letter :	GMP certificate of Drug Substance attached in Module 3 (3.2.S.2.1 Manufacture)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	The stability studies of 3 batches of Metronidazole was carried out separately (API) including accelerated test, long-term test and enforced degradation test (Light exposure, High-temperature, High-humidity) according to the storage condition and testing frequency required in ICH guidance and attached in Module 3 (3.2.S.7.3 Stability Data).
	The status in reference regulatory authorities	TGA Approved
	Evaluation Remarks	
	In light of the decision of 220 meeting of the Authority. Legalized sole agency agreement shall be submitted. Valid GMP certificate shall be submitted.	
	Decision	
	Approved	
	Approved subject to submission of legalized sole agency agreement, valid GMP certificate of Finished Drug Product manufacturer and as per current import policy.	
10	Case Category	Any Other (Abdul Mughees)
	Name, address of Applicant.	AJ Mirza Pharma Pvt Ltd 1st Floor, Shafi Court, Merewether Road, Civil Lines. Karachi–Pakistan. (235)
	Application Form Dy. No / Tracking ID & date of submission	(HD6-YUN-RXXL, 2026-03-19)
	Detail of Fee Submitted	300000.0, 13500 2025-04-14, 2025-09-19
	The proposed proprietary name / brand name	LEUNIB 150mg Capsule
	Label Claim	Each capsule contains : Nilotinib Hydrochloride Monohydrate is equivalent to Nilotinib.....150mg
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	10's-As per SRO, 120's-As per SRO
	Shelf Life (Unit)	24 MonthBelow 30°C
	For generic drugs (me-too Status)	TASIGNA 150mg Capsule
	Pharmacotherapeutic Group of (API)	M/s Dr.Reddy's Laboratories Limited
	Name, address of Manufacturing site:	M/s Dr.Reddy's Laboratories Limited-Formulation Technical Operations - Unit-VII P1 to P9 & Q1 to Q5, Phase - III, VSEZ, Duvvada, Visakhapatnam, Andhra Pradesh 530 046, India-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Name, address of Marketing Authorization Holder:	A.J. Mirza Pharma (Pvt.) Ltd., 1st Floor, Shafi Court, Merewether Road, Civil Lines. Karachi–Pakistan., Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	GMP Certified
	Details of Authorization Letter :	COA Enclosed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 18 months long term data available
	The status in reference regulatory authorities	USFDA
	Evaluation Remarks	

In light of decision of the 220 meeting of the Authority. Legalized CoPP shall be submitted.		
Decision		
Approved		
Approved subject to submission of legalized CoPP and as per current import policy.		
11	Case Category	Any Other (Abdul Mughees)
	Name, address of Applicant.	AJ Mirza Pharma Pvt Ltd 1st Floor, Shafi Court, Merewether Road, Civil Lines. Karachi–Pakistan. (235)
	Application Form Dy. No / Tracking ID & date of submission	(UL9-57P-EQPA, 2026-03-19)
	Detail of Fee Submitted	300000.0, 13500.0 2025-04-14, 2025-08-19
	The proposed proprietary name / brand name	LEUNIB 200mg Capsule
	Label Claim	Nilotinib Hydrochloride Monohydrate is equivalent to Nilotinib..... 200mg
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	10's-As per SRO, 120's-As per SRO
	Shelf Life (Unit)	24 Month Below 30°C
	For generic drugs (me-too Status)	TASIGNA 200mg Capsule
	Pharmaceutical Group of (API)	M/s Dr.Reddy's Laboratories Limited
	Name, address of Manufacturing site:	M/s Dr.Reddy's Laboratories Limited- Formulation Technical Operations - Unit-VII P1 to P9 & Q1 to Q5, Phase - III, VSEZ, Duvvada, Visakhapatnam, Andhra Pradesh 530 046, India-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Name, address of Marketing Authorization Holder:	A.J. Mirza Pharma (Pvt.) Ltd., 1st Floor, Shafi Court, Merewether Road, Civil Lines. Karachi–Pakistan., Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	GMP Certified
	Details of Authorization Letter :	COA Enclosed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 18 months long term data available
	The status in reference regulatory authorities	US-FDA
	Evaluation Remarks	
	In light of decision of the 220 meeting of the Authority. Legalized CoPP shall be submitted. Legalized letter of Authorization	
	Decision	
	Approved	
	Approved subject to submission of legalized CoPP, letter of Authorization and as per current import policy.	
12	Case Category	Any Other (Abdul Mughees)
	Name, address of Applicant.	GENOME PHARMA RCCI Industrial Estate, Plot No. C-19, Access Road, Rawat, Islamabad. (DHO-ISB-2257)
	Application Form Dy. No / Tracking ID & date of submission	(LP8-PLX-NE4H, 2024-11-27)

	Detail of Fee Submitted	300000.0, 2024-10-29,
	The proposed proprietary name / brand name	Myrofol Injection
	Label Claim	Each ml contains 10mg of Propofol
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 x 1-As per SRO
	Shelf Life (Unit)	24 Year(s)Below 30°C
	For generic drugs (me-too Status)	POFOL 200mg/20ml
	Pharmacotherapeutic Group of (API)	N01AX10: general anesthetics
	Name, address of Manufacturing site:	MAYA BIOTECH PRIVATE LIMITED-Office: Plot No. 46, Industrial Area Phase II, Chandigarh, 160002, INDIA. -India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference product
	Name, address of Marketing Authorization Holder:	Genome Pharma, RCCI Industrial Estate, Plot No. C-19, Access Road, Rawat, Islamabad, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Finished Product Manufacturer: Maya Biotech Pvt. Ltd., illage- Kondi, PO-Thana, Baddi Dist.: Solan, 173205 (H.P), India; GMP Certificate issued by Health and Family Welfare Department, Assistant Drug Controller cum Licensing Authority and valid till 21.0
	Details of Authorization Letter :	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Batches PRF30001, PRF30002, and PRF30003 on long term and accelerated conditions
	The status in reference regulatory authorities	Propofol 10 mg/ml Emulsion for injection/infusion
Evaluation Remarks		
In light of decision of the 220 meeting of the Authority.		
Decision		
Approved		
As per current import policy.		
13	Case Category	Any Other (Abdul Mughees)
	Name, address of Applicant.	XenoBiotech Pharma and Devices House No.43-A, Stree # 5-F, Tulsa Road, Rawalpindi (01-374-0176-112407D)
	Application Form Dy. No / Tracking ID & date of submission	(GN1-MZ1-HV6X, 2026-03-19)
	Detail of Fee Submitted	300000.0, 2025-06-14,
	The proposed proprietary name / brand name	Hyprofol MCT 1% Injection
	Label Claim	Each ml contains: Propofol10mg
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	20ml-As per SRO
	Shelf Life (Unit)	24 MonthBelow 30°C/ 65% RH ± 5% RH, Don't Freeze
	For generic drugs (me-too Status)	Propofol Lipuro B.Braun
	Pharmacotherapeutic Group of (API)	Anesthetic
	Name, address of Manufacturing site:	Shijiazhuang No.4 Pharmaceutical Co., Ltd. - No.333 Lijiang Road, Hi-tech Industrial

		Development Zone, Shijiazhuang -China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached
	Name, address of Marketing Authorization Holder:	Shijiazhuang No.4 Pharmaceutical Co., Ltd. , No.333 Lijiang Road, Hi-tech Industrial Development Zone, Shijiazhuang , China
	Details of Certificates (CoPP/FSC/cGMP):	China FDA
	Details of Authorization Letter :	Attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached (Module -2 & 3)
	The status in reference regulatory authorities	USFDA / MHRA
	Evaluation Remarks	
	In light of the decision of the 220 meeting of the Authority. 1. Legalized CoPP and Letter of Authorization	
	Decision	
	Approved	
	Approved subject to submission of legalized CoPP, letter of Authorization and as per current import policy.	
14	Case Category	Any Other (Abdul Mughees)
	Name, address of Applicant.	AJ Mirza Pharma Pvt Ltd 1st Floor, Shafi Court, Merewether Road, Civil Lines. Karachi–Pakistan. (235)
	Application Form Dy. No / Tracking ID & date of submission	(2SS-PSA-X96W, 2025-10-31)
	Detail of Fee Submitted	300000.0, 13500 2025-08-06, 2025-08-15
	The proposed proprietary name / brand name	LENALIDOMIDE-QILU
	Label Claim	Each Capsule contains: Lenalidomide 5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	7*3's blister-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C.
	For generic drugs (me-too Status)	RELIDOMIDE 5mg Capsule
	Pharmacotherapeutic Group of (API)	Other immunosuppressants
	Name, address of Manufacturing site:	Qilu Pharmaceutical Co., Ltd.-8888 Lvyou Road, High-tech Zone, Jinan, Shandong 250104, China-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Available
	Name, address of Marketing Authorization Holder:	A.J. Mirza Pharma (Pvt.) Ltd., PLOT NO. 44, SECTOR NO. 27, KORANGI INDUSTRIAL AREA, KARACHI, Korangi Korangi Town, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	GMP2025120 stamped by Medical Products Administration of Shandong Province
	Details of Authorization Letter :	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated stability study ($40 \pm 2^{\circ}\text{C}$ / 75%RH $\pm 5\%$) of 6 months & Long-term stability study ($30 \pm 2^{\circ}\text{C}$ / 75%RH $\pm 5\%$) of 24 months
	The status in reference regulatory authorities	USFDA
	Evaluation Remarks	
	In light of the decision of the 220 meeting of the Auhthority. 1. Legalized letter of Authorization	

	Decision	
	Approved	
	Approved subject to submission of legalized letter of Authorization and as per current import policy.	
15	Case Category	Any Other (Abdul Mughees)
	Name, address of Applicant.	AJ Mirza Pharma Pvt Ltd 1st Floor, Shafi Court, Merewether Road, Civil Lines. Karachi–Pakistan. (235)
	Application Form Dy. No / Tracking ID & date of submission	(EGA-TYX-NYMX, 2025-10-31)
	Detail of Fee Submitted	300000.0, 13500 2025-08-06, 2025-08-15
	The proposed proprietary name / brand name	LENALIDOMIDE-QILU
	Label Claim	Each Capsule contains: Lenalidomide 10mg
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	7*3's-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30°C.
	For generic drugs (me-too Status)	RELIDOMIDE 10mg Capsule
	Pharmacotherapeutic Group of (API)	Other immunosuppressants
	Name, address of Manufacturing site:	Qilu Pharmaceutical Co., Ltd.-8888 Lvyou Road, High-tech Zone, Jinan, Shandong 250104, China-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Available
	Name, address of Marketing Authorization Holder:	A.J. Mirza Pharma (Pvt.) Ltd., PLOT NO. 44, SECTOR NO. 27, KORANGI INDUSTRIAL AREA, KARACHI, Korangi Korangi Town, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	GMP Available
	Details of Authorization Letter :	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated stability study (40 ± 2°C / 75%RH ± 5 %) of 6 months & Long-term stability study (30 ± 2°C / 75%RH ± 5 %) of 24 months
	The status in reference regulatory authorities	USFDA
	Evaluation Remarks	
	In light of the decision of the 220 meeting of the Auhthority. 1. Legalized letter of Authorization	
	Decision	
	Approved	
	Approved subject to submission of legalized letter of Authorization and as per current import policy.	
16	Case Category	Any Other (Abdul Mughees)
	Name, address of Applicant.	REVIVE HEALTH CARE 503, 5TH FLOOR EDEN HEIGHTS 6 MAIN GULBERG JAIL ROAD (05-352-0065-031159D)
	Application Form Dy. No / Tracking ID & date of submission	(DZ5-N26-69PH, 2026-03-16)
	Detail of Fee Submitted	313500, 2026-03-12,
	The proposed proprietary name / brand name	TAZINIB Capsule 200mg

	Label Claim	Each capsule contains: Nilotinib hydrochloride dihydrate equivalent to Nilotinib 200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	40's Bottle Pack-As per SRO
	Shelf Life (Unit)	36 MonthStore below 30 degree centigrade
	For generic drugs (me-too Status)	Tasigna 200mg Capsules, Registration No: 052256
	Pharmacotherapeutic Group of (API)	Antineoplastic agent, ATC Code: L01EA03
	Name, address of Manufacturing site:	Qilu Pharmaceutical Co., Ltd.-8888 Lvyou Road, High-tech Zone, Jinan, Shandong 250104, China-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence study & CDP performed by Comparison of applied product vs RLD (Tasigna Capsule 200mg)
	Name, address of Marketing Authorization Holder:	Qilu Pharmaceutical Co., Ltd., 8888 Lvyou Road, High-tech Zone, Jinan, Shandong 250104, China, China
	Details of Certificates (CoPP/FSC/cGMP):	Valid FDA Establishment Identifier (FEI) # 3014576629
	Details of Authorization Letter :	Imported product- Not applicable
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study of API by drug substance manufacturer for three batches (0001L51F, 0002L51F & 0003L51F) based on 6 months of accelerated stability data (25± 2°C / 60% ± 5% RH) and 24 months of long- term stability data (05 ± 3°C). Stability data provided in 3.2.S.7.3
	The status in reference regulatory authorities	TASIGNA Capsule 200mg, MHRA Approved
	Evaluation Remarks	
17	In light of the decision of the 220 meeting of the Auhthority. 1. Legalized/ Appostile letter of Authorization 2. Legalized/ Appostile CoPP	
	Decision	
	Approved	
	Approved subject to submission of legalized CoPP, letter of Authorization and as per current import policy.	
	Case Category	Any Other (Abdul Mughees)
	Name, address of Applicant.	Lucky Core Industries Limited 5 West Wharf Road Karachi (013)
	Application Form Dy. No / Tracking ID & date of submission	(AGR-NZJ-XZM5, 2026-03-16)
	Detail of Fee Submitted	313500, 2025-08-18,
	The proposed proprietary name / brand name	Abiraterone acetate Tablet 250mg
	Label Claim	Each film coated tablet contains: Abiraterone acetate USP..... 250 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	18 MonthStore Below 30 °C.
	For generic drugs (me-too Status)	Abytiga by Oncogen Pharma
	Pharmacotherapeutic Group of (API)	cardiovascular death, myocardial infarction, and stroke in patients with acute coronary syndrome or a history of myocardial infarction

	Name, address of Manufacturing site:	Pinnacle Life Science Pvt. Ltd-O-Block, Kh. No. 1331, 1332 & 1335, Village Manpura, Tehsil Baddi, District Solan, H.P.-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
	Name, address of Marketing Authorization Holder:	Pinnacle Life Science Pvt. Ltd, O-Block, Kh. No. 1331, 1332 & 1335, Village Manpura, Tehsil Baddi, District Solan, H.P., India
	Details of Certificates (CoPP/FSC/cGMP):	15.05.2027
	Details of Authorization Letter :	Imported product
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	imported product stability data provided
	The status in reference regulatory authorities	https://www.accessdata.fda.gov/scripts/cder/daf/in-event=overview.process&ApplNo=2 02379
	Evaluation Remarks	
	In light of the decision of the 220 meeting of the Authority. The firm has submitted BE as the molecule falls under BE notification dated 17th July 2025. However, the DRAP guidelines for interchangeability mention that " All Studies including comparative pharmacokinetic studies & comparative clinical trials or any other studies involving human subjects shall only be conducted after approval from the Clinical Studies Committee (CSC) as per the Bio-Study Rules, 2017. " The firm has not yet provided evidence of approval of the studies as the studies were performed outside Pakistan.	
	Decision	
18	Deferred	
	Registration Board deferred the instant case and decided that for such cases where Bio-equivalence/ Bio-availability studies are mandatory as per notification No-F-348-DRB-Addl-Dir (PER-I)/2025 dated 17th, July 2025, the following shall be submitted:	
	1. Approval of Bio-equivalence / Bio-availability studies by the Clinical Studies Committees under Bio-Study Rules 2017 is mandatory for locally conducted BE/BA studies as requirement of application of registration of drugs or 2. Evidence of submission/approval of any BE/BA Studies to any NRA alongwith approval from Independent Bioethical Committee and licensing status of BE/BA centre in the country of origin, In case of studies conducted outside Pakistan.	
	Case Category	Any Other (Abdul Mughees)
	Name, address of Applicant.	Lucky Core Industries Limited 5 West Wharf Road Karachi (013)
	Application Form Dy. No / Tracking ID & date of submission	(Q9S-BHB-QA7S, 2026-03-16)
	Detail of Fee Submitted	313500, 2025-08-18,
	The proposed proprietary name / brand name	Abiraterone acetate Tablet 500mg
	Label Claim	Each film coated tablet contains: Abiraterone acetate USP..... 500 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	36 MonthStore Below 30 °C.
	For generic drugs (me-too Status)	Abytiga by Oncogen Pharma
	Pharmacotherapeutic Group of (API)	cardiovascular death, myocardial infarction, and stroke in patients with acute coronary syndrome or a history of myocardial infarction

	Name, address of Manufacturing site:	Pinnacle Life Science Pvt. Ltd-O-Block, Kh. No. 1331, 1332 & 1335, Village Manpura, Tehsil Baddi, District Solan, H.P.-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
	Name, address of Marketing Authorization Holder:	Pinnacle Life Science Pvt. Ltd, O-Block, Kh. No. 1331, 1332 & 1335, Village Manpura, Tehsil Baddi, District Solan, H.P., India
	Details of Certificates (CoPP/FSC/cGMP):	15.05.2027
	Details of Authorization Letter :	Imported product
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	imported product stability data provided
	The status in reference regulatory authorities	https://www.accessdata.fda.gov/scripts/cder/daf/in-event=overview.process&ApplNo=202379
	Evaluation Remarks	
	In light of the decision of the 220 meeting of the Authority. The firm has submitted BE as the molecule falls under BE notification dated 17th July 2025. However, the DRAP guidelines for interchangeability mention that " All Studies including comparative pharmacokinetic studies & comparative clinical trials or any other studies involving human subjects shall only be conducted after approval from the Clinical Studies Committee (CSC) as per the Bio-Study Rules, 2017. " The firm has not yet provided evidence of approval of the studies as the studies were performed outside Pakistan.	
	Decision	
	Deferred	
	Registration Board deferred the instant case and decided that for such cases where Bio-equivalence/ Bio-availability studies are mandatory as per notification No-F-348-DRB-Addl-Dir (PER-I)/2025 dated 17th, July 2025, the following shall be submitted:	
	1. Approval of Bio-equivalence / Bio-availability studies by the Clinical Studies Committees under Bio-Study Rules 2017 is mandatory for locally conducted BE/BA studies as requirement of application of registration of drugs or 2. Evidence of submission/approval of any BE/BA Studies to any NRA alongwith approval from Independent Bioethical Committee and licensing status of BE/BA centre in the country of origin, In case of studies conducted outside Pakistan.	
19	Case Category	Any Other (Abdul Mughees)
	Name, address of Applicant.	MSA PHARMA 1st floor, 793-D Block C Faisal Town (05-352-0066-112591D)
	Application Form Dy. No / Tracking ID & date of submission	(Q27-6D3-3SZ4, 2026-03-10)
	Detail of Fee Submitted	313500, 2026-01-30,
	The proposed proprietary name / brand name	Abiraxen Tablet 250mg
	Label Claim	Each film coated tablet contains Abiraterone Acetate USP 250 mg.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4 × 7's tablets per box.Alu-Alu Blisters-As per SRO
	Shelf Life (Unit)	24 Year(s)Do not store above 25°C. Store in the original package in order to protect from moisture.
	For generic drugs (me-too Status)	Abiterone 250mg tablet

	Pharmacotherapeutic Group of (API)	Antineoplastic
	Name, address of Manufacturing site:	Everest Pharmaceuticals Limited. -Plot No.: B-45, 46 & 33, BSCIC I/A, Kanchpur, Narayanganj, Bangladesh -Bangladesh
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Enclosed
	Name, address of Marketing Authorization Holder:	Everest Pharmaceuticals Limited. , BSCIC I/A, Kanchpur, Narayanganj, Bangladesh , Bangladesh
	Details of Certificates (CoPP/FSC/cGMP):	GMP certificate dated 18.01.2023
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Enclosed
	The status in reference regulatory authorities	ZYTIGA 250 mg tablets
	Evaluation Remarks	
	In light of the decision of the 220 meeting of the Authority. The firm has submitted BE as the molecule falls under BE notification dated 17th July 2025. However, the DRAP guidelines for interchangeability mention that " All Studies including comparative pharmacokinetic studies & comparative clinical trials or any other studies involving human subjects shall only be conducted after approval from the Clinical Studies Committee (CSC) as per the Bio-Study Rules, 2017. " The firm has not yet provided evidence of approval of the studies as the studies were performed outside Pakistan.	
20	Decision	
	Deferred	
	Registration Board deferred the instant case and decided that for such cases where Bio-equivalence/ Bio-availability studies are mandatory as per notification No-F-348-DRB-Addl-Dir (PER-I)/2025 dated 17th, July 2025, the following shall be submitted:	
	1. Approval of Bio-equivalence / Bio-availability studies by the Clinical Studies Committees under Bio-Study Rules 2017 is mandatory for locally conducted BE/BA studies as requirement of application of registration of drugs or 2. Evidence of submission/approval of any BE/BA Studies to any NRA alongwith approval from Independent Bioethical Committee and licensing status of BE/BA centre in the country of origin, In case of studies conducted outside Pakistan.	
	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	Mehran International 498-C Feroz Shah Street Karachi (0435)
	Application Form Dy. No / Tracking ID & date of submission	(2EH-D8N-T272, 2026-03-05)
	Detail of Fee Submitted	313500, 2025-12-22,
	The proposed proprietary name / brand name	Propoject EDTA Propofol 200mg/20ml LCT 1% Injection
	Label Claim	Assay limit - 90.0%-110.0% results: 103.7%
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	20ml x 5's-As per SRO
	Shelf Life (Unit)	3 YearStore between 2-25°C. Do not freeze. Protect from light. Keep out of reach of children.
	For generic drugs (me-too Status)	Pofol IV Injection 200mg/20 Regn .No. 019479 - Allied Distributors, 103-K Block 2 PECHS-karachi

Pharmacotherapeutic Group of (API)	M/s.Xi'an Libang Pharmaceutical Co., Ltd. Baoji - API Plant West-door outside, Guo Town, Chencang District, Baoji city, China
Name, address of Manufacturing site:	M/s. Xi'An Libang Pharmaceutical Co.,Ltd. - No.22 Keji Yi Road, Xi'an Hi-tech Industrial development Zone, Xi'an City ,China-China
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence From amnufacturer attached in module 3 -5
Name, address of Marketing Authorization Holder:	M/S. MEHRAN INTERNATIONAL, 498-C, FEROS SHAH MEHTA ROAD KARACHI, Pakistan
Details of Certificates (CoPP/FSC/cGMP):	valid GMP Certificate Attached in Module
Details of Authorization Letter :	N.A
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	stability studies conducted on 3 batches - Batch number: 180101, 180102, 180103 Stability Data - Accelerated- Three batches of the drug substance have been placed in a six-month accelerated stability program. These batches were packaged similar as commercial packaging. The samples will then be subjected to 40°±2°C and 75%±5% relative humidity for 6 months.& Stability Data – Long term The packaging of stability samples from production batches that are placed in the long-term stability program are identical to containers as designed and intended for commercial shipments. Stability samples will then be stored at 25°±2°C and 60%±5% relative humidity for 36 months.
The status in reference regulatory authorities	Propofol 10mg/ml liquid emulsion injection - Manufactured by Aspen pharma Trading Limited, 3016 lake Drive, Citywest Business campus, Dublin 24, Ireland . (MHRA Approved)

Evaluation Remarks

Priority as per decision of 220th meeting of Authority.

After evaluation of application, following observations were communicated to the firm;

1. 3.2.P.2 Please submit pharmaceutical equivalence of the applied product with reference product.

2. 3.2.P.8 Long term stability studies data submitted is of studies conducted as per Zone II conditions. Long term stability studies data performed at Zone IVa conditions is required.

Response of observation 1: Only comparison of formulation is submitted. Pharmaceutical equivalence is not submitted. The same observation was raised at time of screening and firm had submitted same comparison of formulation only instead of pharmaceutical equivalence studies.

Response of Observation 2: Firm has resubmitted module 3 wherein only temperature and humidity conditions are changed as per Zone IVa requirements, everything else, including stability chambers models, their equipment IDs and results in summary sheets are same. Firm has edited module 3 to make it look like the stability was conducted at Zone IVa conditions instead of submitting data of real studies.

Decision

Deferred

Deferred for clarification from the firm regarding discrepancies in submitted stability data. Case shall be placed before the board in next meeting for final decision regardless firm submits its response or not.

21	Case Category	Any Other (Adil Saeed)
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	Name, address of Applicant.	Biocare Pharmaceutica 807, shadman 1 lahore (05-353-0063-032069D)
	Application Form Dy. No / Tracking ID & date of submission	(639-M34-GPWR, 2025-08-20)
	Detail of Fee Submitted	300000.0, 2025-04-11,
	The proposed proprietary name / brand name	Sofar
	Label Claim	Each bottle contain 250 ml Sevoflurane (100%) for Inhalation Anesthesia
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	Box, 1 bottle @250 m-Controlled
	Shelf Life (Unit)	2 Year(s)below 30 degree Centigrade
	For generic drugs (me-too Status)	Sevorane (Sevoflurane) 250 ml (Getz Pharma (PVT)., Ltd) Reg. No. 027374
	Pharmacotherapeutic Group of (API)	Anesthetic Drug (General Anaesthesia) ATC Code: N01AB08 (WHO)
	Name, address of Manufacturing site:	PT Pratapa Nirmala (Fahrenheit)-JI. Industri VI, Tangerang 15135, Indonesia-Indonesia
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached on CTD Module 3 Page no. 496-524 Pharmaceutical Equivalence (Pg# 498-517) Product/formulation development development, dosage form description (Page #: 496-524)
	Name, address of Marketing Authorization Holder:	PT. Yarindo Farmatama, JI. Raden Saleh Raya No. 4 Dinar Building 3rd Fl Jakarta Pusat-10430 Indonesia, Indonesia
	Details of Certificates (CoPP/FSC/cGMP):	Notarized/Verified GMP is attached on Page 36- 40 CTD Dossier Module 1, GMP Validity: 10, June, 2026
	Details of Authorization Letter :	Details given on Page no. 16 Form 5F (Module#1) Documents attached on Page No. 363-366
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batched 6 months Accelerated & 36 months Long term stability studies is attached in Module 3 on Page 483-489
	The status in reference regulatory authorities	US FDA [Ultane (Sevoflurane) 250 ml Liquid Inhalation -Abbott Laboratories, Approval no. 020478s007, Approval Date: 12/11/2002]
	Evaluation Remarks	
	Priority as per decision of 220th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
	As per policy for inspection abroad.	
22	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	My Body Healer (Private) Limited Office No. 104 & 105, 1st Floor, Plot No. 54-C, Al Murtaza Commercial Lane-2, Phase VIII, DHA, Karachi (670)
	Application Form Dy. No / Tracking ID & date of submission	(MPP-9BT-7HLH, 2026-03-10)
	Detail of Fee Submitted	313500, 2025-12-10,

	The proposed proprietary name / brand name	Captabine 500mg Tablets
	Label Claim	Each film coated tablet contains: Capecitabine ... 500mg
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	10's, 20's, 30's & 120's-Controlled
	Shelf Life (Unit)	2 Year(s)Do not store above 30°C
	For generic drugs (me-too Status)	Zenatibin 500mg Tablets by Hoechst Pakistan Limited
	Pharmacotherapeutic Group of (API)	Nucleoside metabolic inhibitor ATC Code: L01BC06
	Name, address of Manufacturing site:	Pharmacare Premium Ltd.-HHF003. Hal Far Industrial Estate, Birzebbugia, BBG3000, Malta-Malta
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Xeloda 500mg tablet B. No. B1088
	Name, address of Marketing Authorization Holder:	My Body Healer (Private) Limited, Office No. 104 & 105, 1 Floor, Plot No. 54-C, Al Murtaza Commercial Lane-2, Phase VIII, DHA, Karachi., Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Eudra GMP
	Details of Authorization Letter :	COPP and agency agreement is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone II, upto 36 months. Intermediate (Zone IVa conditions) upto 12 months time point.
	The status in reference regulatory authorities	Xeloda 500mg Tablets by Roche - USFDA
	Evaluation Remarks	
	Priority as per decision of 220th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
	As per policy for inspection abroad.	
23	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	Bristol Mayer Biotech Pakistan 73 B Guldasht Town Zarrar Shaheed Lahore (05-352-0068-109282D)
	Application Form Dy. No / Tracking ID & date of submission	(73V-LD8-S3QS, 2025-01-23)
	Detail of Fee Submitted	300000.0, 2024-12-16,
	The proposed proprietary name / brand name	Evona Miso 200
	Label Claim	Each uncoated Tablet Contains: Misoprostol USP.....200 mcg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's (4 tablets)-As per SRO
	Shelf Life (Unit)	24 Month(s)Store below 30°C
	For generic drugs (me-too Status)	S.T.MOM Tablet 200mcg
	Pharmacotherapeutic Group of (API)	G02AD06 misoprostol
	Name, address of Manufacturing site:	ACCENT PHARMACEUTICALS & DIAGNOSTICS-Vill. Bhalon (Seri), Forest Road, Solan-173212 Himachal Pradesh, India-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	-----

	Name, address of Marketing Authorization Holder:	ACCENT PHARMACEUTICALS & DIAGNOSTICS, Vill. Bhalon(Seri), P.O. Galanag Forest Road, Solan-173212, Himachal Pradesh, India, India
	Details of Certificates (CoPP/FSC/cGMP):	GMP certificate is submitted
	Details of Authorization Letter :	---
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Refrigerated conditions upto 60 months.
	The status in reference regulatory authorities	MHRA Approved (Cytotec 200 mcg Tablet)
	Evaluation Remarks	
	Priority as per decision of 220th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
	As per policy for inspection abroad.	
24	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan (01-374-0006-118530D)
	Application Form Dy. No / Tracking ID & date of submission	(9RN-VLB-BRR4, 2025-10-01)
	Detail of Fee Submitted	300000.0, 2025-06-25,
	The proposed proprietary name / brand name	DAPTOLIN 350mg/Vial
	Label Claim	Each lyophilized vial contains: Daptomycin..... 350mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	24 Year(s)Daptomycin for Injection vials containing lyophilized powder should be stored at 2°C to 8°C
	For generic drugs (me-too Status)	Cubicin® (Daptomycin, 350–500 mg) Merck & Co., Inc. Pakistan
	Pharmacotherapeutic Group of (API)	Antibiotics, Lipopeptide antibiotics
	Name, address of Manufacturing site:	Nanjing King-Friend Biochemical Pharmaceutical Co.-No. 16 Xuefu Road , Nanjing High & New Technology Development Zone, Nanjing, Jiangsu 210061 CHINA-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The comparative analysis between the reference product (manufactured by Sagent Pharmaceuticals Inc., Batch No. ADE901) and our product (manufactured by Nanjing King-Friend Biochemical Pharmaceutical Co., Ltd., Batch No. F7190604C) of Daptomycin for Injection shows that both products appear as pale yellow lyophilized powder or cake, aligning with the described appearance. The assay results for the reference and our product fall within the acceptable range of 95.0%–110.0% of the label claim, with values of 106.9% and 102.1%, respectively. Identification testing for our product confirmed compliance via both IR spectroscopy

		and HPLC, matching the reference standard, although IR and HPLC data for the reference product were not available.
	Name, address of Marketing Authorization Holder:	Meitheal Pharmaceuticals Inc., , 8700 West Bryn Mawr Avenue, Suite 600S, Chicago, IL 60631 United States of America, United States of America
	Details of Certificates (CoPP/FSC/cGMP):	Valid
	Details of Authorization Letter :	COPP issued by USFDA for Singapore is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies of Daptomycin drug substance are carried out by drug substance manufacturer, Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd. under long term condition (-20 °C ± 5 °C for 36 months) and accelerated condition (5 °C ± 3 °C for 6 months) as per ICH.
	The status in reference regulatory authorities	Cubicin® (Daptomycin, 350–500 mg) Merck & Co., Inc. (formerly Cubist Pharmaceuticals) USFDA APPROVED
	Evaluation Remarks	
	Priority as per decision of 220th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of Board.	
	Decision	
	Approved	
	As per policy for inspection abroad.	
25	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan (01-374-0006-118530D)
	Application Form Dy. No / Tracking ID & date of submission	(MGT-WWH-UW9N, 2025-08-29)
	Detail of Fee Submitted	300000.0, 2025-05-29,
	The proposed proprietary name / brand name	ISORIN 100ml
	Label Claim	Each 100ml bottle contains: Isoflurane..... 100ml
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	24 Month(s)Store in a tightly closed container not exceeding 30°C
	For generic drugs (me-too Status)	Registration Number: 044867 Brand Name: Restane Liquid for inhalation Composition: ISOFLURANE, USP 100%, Per 100ml Isoflurane USP 100%w/v MAH: Allied Distributors, Akhai Arcade, 1st Floor ,103-K, B
	Pharmacotherapeutic Group of (API)	N01AB06 Volatile Anesthetics
	Name, address of Manufacturing site:	Lunan Better Pharmaceutical Co., Ltd-No 243, Yinqueshan Road, Linyi City, Shandong Province, China-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Forane Batch No. NO50G916
	Name, address of Marketing Authorization Holder:	Lunan Better Pharmaceutical Co., Ltd., No 243, Yinqueshan Road, Linyi City, Shandong

		Province, China, China
	Details of Certificates (CoPP/FSC/cGMP):	COPP and DMLis submitted.
	Details of Authorization Letter :	Letter of authorization and COPP is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVb upto 36 months.
	The status in reference regulatory authorities	Brand Name: FORANE (Isoflurane USP) Dosage Form: Liquid for Inhalation , 100ml and 250ml. Manufactured by: Baxter Healthcare Corporation Deerfield, IL 60015 USA USFDA Approved
	Evaluation Remarks	
	Priority as per decision of 220th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
	As per policy for inspection abroad.	
26	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	AMB HK ENTERPRISES (PVT) LTD, LAHORE 2nd floor plaza 60, Commercial Block K, Phase-1 DHA, Lahore. (05-352-0058-104514D)
	Application Form Dy. No / Tracking ID & date of submission	(BWZ-GXA-62EL, 2026-02-09)
	Detail of Fee Submitted	,
	The proposed proprietary name / brand name	Merogon 1g
	Label Claim	Each vial contain Meropenem1g Blended with Sodium carbonate
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	24 Month(s) Preserve at or below 30 degrees Centigrade
	For generic drugs (me-too Status)	Generic
	Pharmacotherapeutic Group of (API)	J01DH02 Carbapenems
	Name, address of Manufacturing site:	Haikou Pharmaceutical Factory Co., Ltd.-No192, Nanhai Road, Xiuying District, Haikou City, Hainan Province, P.R.China 570311-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed against Meronem Pfizer.
	Name, address of Marketing Authorization Holder:	AMB HK ENTERPRISES (PVT) LTD., 130 D, Commercial Broadway, Phase 8 DHA, Lahore, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	COPP is submitted.
	Details of Authorization Letter :	COPP and agency agreement is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone II, upto 36 months time point.
	The status in reference regulatory authorities	FDA approved
	Evaluation Remarks	
	Priority as per decision of 220th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	

	Approved	
	As per policy for inspection abroad.	
27	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	AMB HK ENTERPRISES (PVT) LTD, LAHORE 2nd floor plaza 60, Commercial Block K, Phase-1 DHA, Lahore. (05-352-0058-104514D)
	Application Form Dy. No / Tracking ID & date of submission	(B49-MDP-HBQ2, 2026-02-13)
	Detail of Fee Submitted	, 313500 , 2026-01-28
	The proposed proprietary name / brand name	Merogon 500mg
	Label Claim	Each vial contains Meropenem.....500mg Blended with Sodium carbonate
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	24 Month(s) Preserve at or below 30 degrees Centigrade
	For generic drugs (me-too Status)	Generic
	Pharmacotherapeutic Group of (API)	J01DH02 Carbapenems
	Name, address of Manufacturing site:	Haikou Pharmaceutical Factory Co., Ltd.-No192, Nanhai Road, Xiuying District, Haikou City, Hainan Province, P.R.China 570311-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed against Meronem Pfizer.
	Name, address of Marketing Authorization Holder:	AMB HK ENTERPRISES (PVT) LTD., 130 D, Commercial Broadway, Phase 8 DHA, Lahore, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	COPP is submitted.
	Details of Authorization Letter :	COPP and agency agreement is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone II, upto 36 months time point.
	The status in reference regulatory authorities	FDA approved
	Evaluation Remarks	
	Priority as per decision of 220th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
	As per policy for inspection abroad.	
28	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	Al Habib Pharmaceuticals. Plot 81 SMCHS BLOCK B (0414)
	Application Form Dy. No / Tracking ID & date of submission	(9AP-P2L-NPQQ, 2026-02-04)
	Detail of Fee Submitted	313500, 2025-10-30,
	The proposed proprietary name / brand name	IMEVEC 400mg Film Coated Tablets
	Label Claim	Each film coated tablet contains: Imatinib mesilate equivalent to Imatinib.....400mg

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 30's, 60's, 90's, 120's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 c
	For generic drugs (me-too Status)	IMANIX 400mg (Imatinib mesilate) Tablets , Registration number : 125542 HIMMEL Pharmaceuticals
	Pharmacotherapeutic Group of (API)	L01EA01 Mac Chem Products (India) Pvt. Ltd.
	Name, address of Manufacturing site:	NAPROD Life Sciences Pvt Ltd-G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Palghar-401 506, Maharashtra State.-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	glivex 400mg film coated Tablet Mfg M/s Novartis. B. No JZ9662
	Name, address of Marketing Authorization Holder:	Al Habib Pharmaceuticals, Plot 81, Block B, SMCHS, Karachi , Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	GMP certificate issued by FDA Maharashtra is Submitted.
	Details of Authorization Letter :	Letter of Authorization and COPP is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	upto 60 months, Zone IVa
	The status in reference regulatory authorities	GLEEVEC (Imatinib Mesylate) 400mg Tablet (US-FDA Approved) New Drug Application (NDA): 021588 , Company: NOVARTIS
	Evaluation Remarks	
	Priority as per decision of 220th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
	As per policy for inspection abroad.	
29	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	IBL Health Care Ltd One IBL Centre, 2nd Floor, Plot No 01, Block 7 & 8 Dehli Merchantile Cooperative Housing Society (DMCHS Tipu Sultan Road, Off Shahrah-e-Faisal, Karachi. (0424)
	Application Form Dy. No / Tracking ID & date of submission	(UXZ-78A-6E9M, 2025-05-15)
	Detail of Fee Submitted	300000.0, 2025-03-25,
	The proposed proprietary name / brand name	Isolife 100ml Liquid for Inhalation
	Label Claim	Each 100ml contains: Isoflurane.....100% v/v
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO 228-As per SRO
	Shelf Life (Unit)	24 Month(s)15°C-30°C
	For generic drugs (me-too Status)	Restane 100ml liquid for inhalation by M/s Allied Ditributor
	Pharmacotherapeutic Group of (API)	Anesthetic
	Name, address of Manufacturing site:	Shandong New Time Pharmaceutical Co., Ltd.- No.1 North Outer Ring Road, Feixian County, Shandong 273499, China.-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Forane B. No. N050G916

	Name, address of Marketing Authorization Holder:	Shandong New Time Pharmaceutical Co., Ltd., No.1 North Outer Ring Road, Feixian County, Shandong, China, China
	Details of Certificates (CoPP/FSC/cGMP):	Copy of DML and COPP is submitted
	Details of Authorization Letter :	COPP and agency agreement is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Isoflurane 100ml liquid for inhalation UK (MHRA)
	Evaluation Remarks	
	Priority as per decision of 220th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
	As per policy for inspection abroad.	
30	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	REVIVE HEALTH CARE 503, 5TH FLOOR EDEN HEIGHTS 6 MAIN GULBERG JAIL ROAD (05-352-0065-031159D)
	Application Form Dy. No / Tracking ID & date of submission	(TV4-HXG-3LW3, 2026-02-26)
	Detail of Fee Submitted	313500, 2026-02-26,
	The proposed proprietary name / brand name	REXULIP INJECTION 20 MG/10ML
	Label Claim	Each mL Contains: Doxorubicin Hydrochloride as pegylated liposomal 2 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's Vial-As per SRO
	Shelf Life (Unit)	24 Month(s)Store in a refrigerator (2 – 8 degree centigrade). Do not freeze.
	For generic drugs (me-too Status)	Registration No. 090741 by Revive Healthcare
	Pharmacotherapeutic Group of (API)	Antineoplastic agent. ATC: L01DB01
	Name, address of Manufacturing site:	Qilu Pharmaceutical (Hainan) Co., Ltd.-No.273-A, Nanhai Avenue, National High-Tech Zone, Haikou, Hainan, 570314, China-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence Study of applied product VS RLD By QC Comparison & Bioequivalence Study provided in section 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, China
	Details of Certificates (CoPP/FSC/cGMP):	FDA Establishment Identifier (FEI) No. 3008250362, Valid 31.12.2026
	Details of Authorization Letter :	Not applicable for imported product
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Complete stability provided in section 3.2.S.7.3
	The status in reference regulatory authorities	USFDA: DOXORUBICIN HYDROCHLORIDE LIPOSOME INJECTION 20MG/10ML, ANDA 219881 BY QILU PHARMACEUTICAL HAINAN CO LTD

	Evaluation Remarks	
	Priority as per decision of 220th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
	As per policy for inspection abroad.	
31	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	MAFHH ENTERPRISES A-71 Rabia Palace, Rashid Minhas Road, Block-10A Gulshan e Iqbal Karachi (0302)
	Application Form Dy. No / Tracking ID & date of submission	(T26-2B4-J3YR, 2025-05-02)
	Detail of Fee Submitted	300000.0, 2025-03-11,
	The proposed proprietary name / brand name	Mafreotide Injection 0.1mg/1ml
	Label Claim	Each 1ml vial contains: Octreotide Acetate 0.1 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5's-As per SRO
	Shelf Life (Unit)	2 Year(s)2-8°C
	For generic drugs (me-too Status)	Sandostatin Injection by Novartis
	Pharmacotherapeutic Group of (API)	H01CB02 Somatostatin and analogues
	Name, address of Manufacturing site:	Hainan Zhonghe Pharmaceutical Co., Ltd. - Haikou Free Trade Zone, No.168 Nanhai Avenue, Haikou City - 570216, Hainan Province, P. R. China -China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed against 3 different batches of Reference product.
	Name, address of Marketing Authorization Holder:	MAFHH ENTERPRISES, Address: Suit#. A-71, Rabia Place,Gulshan-e-Iqbal, Block-10/A, Main Rashid Minhas Road, Karachi. , Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	COPP and DML is submitted
	Details of Authorization Letter :	COPP and agency agreement is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Refrigerated conditions.
	The status in reference regulatory authorities	MHRA Approved
	Evaluation Remarks	
	Priority as per decision of 220th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
	As per policy for inspection abroad.	
32	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	AMB HK ENTERPRISES (PVT) LTD, LAHORE 2nd floor plaza 60, Commercial Block K, Phase-1 DHA, Lahore. (05-352-0058-104514D)
	Application Form Dy. No / Tracking ID & date of submission	(R71-PDA-3R68, 2025-03-29)

	Detail of Fee Submitted	300000.0, 2025-01-10,
	The proposed proprietary name / brand name	Meronex Injection 1G
	Label Claim	Each Vial Contains : Meropenem..... 1g Blended with Sodium Carbonate.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 Vial + 2*10mL Steri-Controlled
	Shelf Life (Unit)	24 Month(s)Store below 30°C
	For generic drugs (me-too Status)	Generic
	Pharmacotherapeutic Group of (API)	J01DH02
	Name, address of Manufacturing site:	CSPC Ouyi Pharmaceutical Co., Ltd-No.88 Yangzi Road, Economic and Technological Development Zone, Shijiazhuang, Hebei, China.- China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Meropenem manufactured by M/s Pfizer
	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):	DML and COPP is submitted.
	Details of Authorization Letter :	COPP and agency agreement is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone II, upto 24 months.
	The status in reference regulatory authorities	MHRA
	Evaluation Remarks	
	Priority as per decision of 220th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of Registration board.	
	Decision	
	Approved	
	As per policy for inspection abroad.	
33	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	AMB HK ENTERPRISES (PVT) LTD, LAHORE 2nd floor plaza 60, Commercial Block K, Phase-1 DHA, Lahore. (05-352-0058- 104514D)
	Application Form Dy. No / Tracking ID & date of submission	(S62-25G-9593, 2025-03-29)
	Detail of Fee Submitted	300000.0, 2025-01-10,
	The proposed proprietary name / brand name	Meronex Injection 500mg
	Label Claim	Each Vial Contains : Meropenem..... 500mg Blended with sodium carbonate.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 vial+ 10ml sterile-Controlled
	Shelf Life (Unit)	24 Month(s)Store below 30°C.
	For generic drugs (me-too Status)	Generic
	Pharmacotherapeutic Group of (API)	J01DH02
	Name, address of Manufacturing site:	CSPC Ouyi Pharmaceutical Co., Ltd-No.88 Yangzi Road, Economic and Technological Development Zone, Shijiazhuang, Hebei, China.- China

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Meronem Injection Manufactured by M/s Pfizer
	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):	DML and COPP is submitted.
	Details of Authorization Letter :	COPP and agency agreement is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone II, upto 24 months.
	The status in reference regulatory authorities	MHRA
	Evaluation Remarks	
	Priority as per decision of 220th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of Registration board.	
	Decision	
	Approved	
	As per policy for inspection abroad.	
34	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	Bristol Mayer Biotech Pakistan 73 B Guldasht Town Zarrar Shaheed Lahore (05-352-0068-109282D)
	Application Form Dy. No / Tracking ID & date of submission	(7Q3-WMW-H8MJ, 2025-01-23)
	Detail of Fee Submitted	300000.0, 2024-12-19,
	The proposed proprietary name / brand name	SMART PILL 72
	Label Claim	Each Film coated tablets contains: Levonorgestrel1.5 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	36 Year(s) Store at a temperature not exceeding 30°C
	For generic drugs (me-too Status)	Femnor 1.5mg Tablets (Pacific Pharmaceutical Ltd)
	Pharmacotherapeutic Group of (API)	G03AD01 Emergency contraceptives
	Name, address of Manufacturing site:	ACCENT PHARMACEUTICALS & DIAGNOSTICS-Vill. Bhalon (Seri), Forest Road, Solan-173212 Himachal Pradesh, India-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Norlevo Tablets B. No. LX098G Mfg HRA Pharma UK.
	Name, address of Marketing Authorization Holder:	ACCENT PHARMACEUTICALS & DIAGNOSTICS, Vill. Bhalon(Seri), P.O. Galanag Forest Road, Solan-173212, Himachal Pradesh, India, India
	Details of Certificates (CoPP/FSC/cGMP):	GMP certificate issued on basis of inspection dated 03.02..2022 is submitted.
	Details of Authorization Letter :	COPP & Agency agreement is submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	upto 24 months. Zone II conditions.
	The status in reference regulatory authorities	MHRA APPROVED (LEVONORGESTREL 1.5 mg TABLET)
	Evaluation Remarks	

	Priority as per decision of 220th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
	As per policy for inspection abroad.	
35	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	Bristol Mayer Biotech Pakistan 73 B Guldasht Town Zarrar Shaheed Lahore (05-352-0068-109282D)
	Application Form Dy. No / Tracking ID & date of submission	(DQ1-VZL-A8WX, 2025-01-23)
	Detail of Fee Submitted	300000.0, 2024-12-10,
	The proposed proprietary name / brand name	Iohexol Injection USP 350mg /ml
	Label Claim	Each ml of 50ml vial contains: Iohexol 755 mg (Equivalent to 350mg iodine)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 vial-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at or below 30 ° C
	For generic drugs (me-too Status)	OMNIPAQUE® LOCAL REGISTRATION (IMPORT)
	Pharmacotherapeutic Group of (API)	Contrast media
	Name, address of Manufacturing site:	SAI PARENTERALS LIMITED-D1 & D4, Survey No. 280, Phase - V, IDA Jeedimetla (V), Quthbullapur(M), Medchal - Malkajgiri, Hyderabad - 500 055 Telangana, India-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Omnipaque GE healthCare
	Name, address of Marketing Authorization Holder:	M/s. SAI PARENTERALS LIMITED, D1 & D4, Survey No. 280, Phase - V, IDA Jeedimetla (V), Quthbullapur(M), Medchal - Malkajgiri, Hyderabad - 500 055 Telangana, India., India
	Details of Certificates (CoPP/FSC/cGMP):	GMP certificate is submitted.
	Details of Authorization Letter :	Agency agreement is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVb, upto 3 years
	The status in reference regulatory authorities	OMNIPAQUE® USFDA APPROVED FORMULATION
	Evaluation Remarks	
	Priority as per decision of 220th meeting of authority . Application fulfills codal formalities. recommended for consideration of board.	
	Decision	
	Approved	
	As per policy for inspection abroad.	
36	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	Bristol Mayer Biotech Pakistan 73 B Guldasht Town Zarrar Shaheed Lahore (05-352-0068-109282D)

Application Form Dy. No / Tracking ID & date of submission	(GGY-993-S1T3, 2025-02-11)
Detail of Fee Submitted	300000.0, 2024-07-05,
The proposed proprietary name / brand name	Medroxyprogesterone Acetate Injectable Suspension USP 150MG/ML,1ML Vial
Label Claim	Each 1ml vial Contains: Medroxyprogesterone Acetate.....150 mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	1's & 25's-As per SRO
Shelf Life (Unit)	24 Month(s)Store below 30°C
For generic drugs (me-too Status)	Depo-Provera 150mg/ml
Pharmacotherapeutic Group of (API)	G03AC06 Progestogens
Name, address of Manufacturing site:	Montage Laboratories Pvt. Ltd.)-Survey No: 35. At. Dhandha, Idar road, Himatnagar, 383001, Gujarat (India)-India
Pharmaceutical Equivalence and Comparative Dissolution Profile	Depo-Provera B. No. GN2817 Mfg Pfizer
Name, address of Marketing Authorization Holder:	Sanzyme (P) Ltd, Survey No:35, Dhandha, Idar road, Himatnagar- 383 001, Gujarat, India, India
Details of Certificates (CoPP/FSC/cGMP):	GMP issued by FDA Gujrat India is Submitted.
Details of Authorization Letter :	COPP is submitted. MA holder and manufacturer is M/s Montage Laboratories Pvt. Ltd. India. Agency agreement is also submitted.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone II upto 48 months.
The status in reference regulatory authorities	MHRA Approved(Depo-Provera)
Evaluation Remarks	
Priority as per decision of 220th meeting of Authority.	
In initial Submission form had submitted a License Form 28 bearing No. G/28/1709 wherein it is mentioned that its FOR EXPORT ONLY. COPP issued on basis of this license mentions that product is actually on the market in the exporting country.	
Due to this discrepancy, firm was asked to clarify free sale status of applied product in country of origin. In response to which firm submitted another Form No 28 having Number G/28/1709, but only its first page was submitted and it was mentioned that it had 6 pages in total (1/6).	
Firm was again asked to submit complete license document having all 6 pages. In response firm submitted another form 28 having same number instead of submitting complete document that was asked from the firm.	
As per initial Form 28 issued Vide No. G/28/1709 it appears that product was registered for export purpose and firm has not submitted any subsequent evidence that product was also registered for domestic use in India.	
The submitted evidence is not sufficient to establish free sale status of the product in exporting country.	
Decision	
Rejected	
The board rejected the instant application due to the reason that firm is unable to give sufficient evidence to establish free sale status of the applied product in country of origin.	
Case Category	Any Other (Adil Saeed)
Name, address of Applicant.	Bristol Mayer Biotech Pakistan 73 B Guldasht Town Zarrar Shaheed Lahore (05-352-0068-109282D)

Application Form Dy. No / Tracking ID & date of submission	(GTG-SMW-DLM3, 2025-01-23)
Detail of Fee Submitted	300000.0, 2024-12-16,
The proposed proprietary name / brand name	Evona MT Kit
Label Claim	Each combo pack contains: One Mifepristone Oral Tablet Each Uncoated Tablet Contains: Mifepristone..... 200 mg Four Misoprostol vaginal Tablets Each Uncoated Tablet Contains: Misoprostol USP.....200 mcg (as Misoprostol 1% Dispersion in HPMC)
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	1's-As per SRO
Shelf Life (Unit)	36 Year(s)Store at a room temperature
For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	Medabon is indicated for medical termination of developing intra-uterine pregnancy of up to 63 days of amenorrhoea
Name, address of Manufacturing site:	ACCENT PHARMACEUTICALS & DIAGNOSTICS-Vill. Bhalon (Seri), Forest Road, Solan-173212 Himachal Pradesh, India-India
Pharmaceutical Equivalence and Comparative Dissolution Profile	--
Name, address of Marketing Authorization Holder:	ACCENT PHARMACEUTICALS & DIAGNOSTICS, Vill. Bhalon(Seri), P.O. Galanag Forest Road, Solan-173212, Himachal Pradesh, India, India
Details of Certificates (CoPP/FSC/cGMP):	GMP certificate valid till 09.02.2025 is submitted.
Details of Authorization Letter :	---
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Misoprostol Long term refrigerated upto 60 months.
The status in reference regulatory authorities	MHRA Approved(MEDABON: COMBIPACK OF MIFEPRISTONE 200 MG TABLET AND MISOPROSTOL 4 X 0.2 MG VAGINAL TABLETS)
Evaluation Remarks	
Priority as per decision of 220th meeting of authority.	
Applied product is a combination pack. It contains 1 tablet of Mifepristone and 4 tablets of Misoprostol. All 5 tablets are co-blistered in one single blister.	
The firm was asked to submit separate dossiers with separate fee for both tablets, but firm has requested to process it in one single dossier.	
Further firm has submitted Free Sale Certificate instead of COPP.	
Decision	
Deferred	
The board deferred the case for further deliberation and consideration of decision of Authority as the indication of applied product is abortifacient.	
38	Case Category Any Other (Adil Saeed)

	Name, address of Applicant.	Mehran International 498-C Feroz Shah Street Karachi (0435)
	Application Form Dy. No / Tracking ID & date of submission	(QBP-1RR-MHB7, 2025-04-21)
	Detail of Fee Submitted	300000.0, 2025-02-06,
	The proposed proprietary name / brand name	IOHEXOL INJECTION 35G/100ML
	Label Claim	ASSAY ACCEPTANCE CRITERIA 95%-105% RESULTS 98.0%-102.0%
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100ML-As per SRO
	Shelf Life (Unit)	2 Year(s)DO NOT STORE ABOVE 30 °C
	For generic drugs (me-too Status)	OMNIPAQUE - IOHEXOL 350MG/100ML MFG BY MEXIMP TECHNOLOGIES
	Pharmacotherapeutic Group of (API)	Contrast media
	Name, address of Manufacturing site:	M/S.Cisen Pharmaceutical Co., Ltd.-Hai chuan Road, Jining High&New Technology Industries Development Zone, Shandong Province, P.R.China.-China
	Name & address of API manufacturer	M/S. Zhejiang Starry Pharmaceutical Co., Ltd. (Starry) Address: No.1 Starry Road of Xianju Modern Industrial Centralization Zone, Xianju, Zhejiang, 317300, China
	Detail of stability batches of drug product	Zone IVb upto 36 months.
	Documents for the procurement of API with approval from DRAP (in case of Import)	COPP and agency agreement is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Glenkark's Ohexol 35mg/1ml B. No. 123456
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	IOHEXOL 350MG/100ML SOLUTION FOR INJECTION MFG BY GLENMARK PHARMACEUTICALS EUROPE LTD. U.K.
	GMP status of the firm	COPP and DML is submitted
	Evidence of approval of manufacturing facility	DML is submitted
	Evaluation Remarks	
	Priority as per decision of 220th meeting of authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
	As per policy for inspection abroad.	
39	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	Hakimsons (Pvt)., Ltd. A-58/B , SITE Karachi (055)
	Application Form Dy. No / Tracking ID & date of submission	(QBA-9WU-6VYB, 2024-03-13)
	Detail of Fee Submitted	300000.0, 2024-01-05,
	The proposed proprietary name / brand name	BENDOKEY 25 Injection (2.5mg/mL)

Label Claim	Each Vial Contains : Bendamustine Hydrochloride25 mg (2.5mg/mL)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's or As per SRO-As per SRO
Shelf Life (Unit)	24 Month(s)Store below 30C
For generic drugs (me-too Status)	Not Available
Pharmacotherapeutic Group of (API)	L01AA09 ALKYLATING AGENTS
Name, address of Manufacturing site:	M/s Eugia Pharma Specialities Limited,-Survey No. 550, 551 & 552, Kolthur Village, Shameerpet Mandal, Medchal-Malkajgiri District, Telangana, India, Pin- 500078 -India
Pharmaceutical Equivalence and Comparative Dissolution Profile	Levact 2.5mg/ml Lyophilized batch No. D059
Name, address of Marketing Authorization Holder:	M/s Hakimsons (Private)., Limited., A-58/B, S.I.T.E., Manghopir Road - Karachi., Pakistan
Details of Certificates (CoPP/FSC/cGMP):	Copy of License retention cert is submitted
Details of Authorization Letter :	NA
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
The status in reference regulatory authorities	Treanda Injection by Cephalon, Inc. approved by USFDA

Evaluation Remarks

During evaluation it was observed that COPP submitted is expired and a Free Sale Certificate No. 61638/TS/2021 dated 28.05.2021 valid till 28.05.2022 is also submitted wherein product market is mentioned as Export (Not Local).

The case was deferred in 345th meeting with decision "Deferred for clarification regarding free sale status of the product in country of origin and submission of valid legalized COPP."

The firm responded with following comment and no attachment was submitted. "With reference to your query, please find enclosed herewith the below documents for your further evaluation and inclusion in upcoming DRB meeting agenda ;
1) Product Valid CoPP
2) Explanatory letter for non-availability in country of origin "

The firm has been asked 2 more time to submit clarification but is not responding.

Decision

Rejected

The board deliberated on the matter that firm is not able to give evidence to clarify free sale status of the applied product in country of origin and is not submitting their response despite being asked multiple times. Due to these reasons, the board Rejected the instant application.

40	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	Hakimsons (Pvt)., Ltd. A-58/B , SITE Karachi (055)
	Application Form Dy. No / Tracking ID & date of submission	(EMX-SNV-EDV9, 2024-03-13)
	Detail of Fee Submitted	300000.0, 2024-01-05,
	The proposed proprietary name / brand name	BENDOKEY 100 Injection (2.5mg/mL)
	Label Claim	Each Vial Contains : Bendamustine Hydrochloride100 mg (2.5mg/mL)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's or As per SRO-As per SRO
	Shelf Life (Unit)	24 Month(s)Store below 30C

For generic drugs (me-too Status)	Not Available
Pharmacotherapeutic Group of (API)	L01AA09 ALKYLATING AGENTS
Name, address of Manufacturing site:	M/s Eugia Pharma Specialities Limited,-Survey No. 550, 551 & 552, Kolthur Village, Shameerpet Mandal, Medchal-Malkajgiri District, Telangana, India, Pin- 500078 -India
Pharmaceutical Equivalence and Comparative Dissolution Profile	Astellas Pharma GmbH Lyophilized product batch No. C900
Name, address of Marketing Authorization Holder:	M/s Hakimsons (Private)., Limited., A-58/B, S.I.T.E., Manghopir Road - Karachi., Pakistan
Details of Certificates (CoPP/FSC/cGMP):	Copy of License retention cert is submitted
Details of Authorization Letter :	NA
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
The status in reference regulatory authorities	Treanda Injection by Cephalon, Inc. approved by USFDA

Evaluation Remarks

During evaluation it was observed that COPP submitted is expired and a Free Sale Certificate No. 61638/TS/2021 dated 28.05.2021 valid till 28.05.2022 is also submitted wherein product market is mentioned as Export (Not Local).

The case was deferred in 345th meeting with decision "Deferred for clarification regarding free sale status of the product in country of origin and submission of valid legalized COPP."

The firm responded with following comment and no attachment was submitted. "With reference to your query, please find enclosed herewith the below documents for your further evaluation and inclusion in upcoming DRB meeting agenda ;
1) Product Valid CoPP
2) Explanatory letter for non-availability in country of origin "

The firm has been asked 2 more time to submit clarification but is not responding.

Decision

Rejected

The board deliberated on the matter that firm is not able to give evidence to clarify free sale status of the applied product in country of origin and is not submitting their response despite being asked multiple times. Due to these reasons, the board Rejected the instant application.

41	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	Bristol Mayer Biotech Pakistan 73 B Guldasht Town Zarrar Shaheed Lahore (05-352-0068-109282D)
	Application Form Dy. No / Tracking ID & date of submission	(ZLM-U9V-EQQ2, 2025-03-26)
	Detail of Fee Submitted	150000.0, 2025-02-11,
	The proposed proprietary name / brand name	Shincort Injection 40mg/ml
	Label Claim	Each ampoule Contains: Triamcinolone Acetonide40 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's(100amp)-As per SRO
	Shelf Life (Unit)	24 Month(s)Store at room temperature 30°C
	For generic drugs (me-too Status)	Kenatex 40mg Injection by M/s Rotex Pharma (Reg # 097783)
	Pharmacotherapeutic Group of (API)	H02AB08 Glucocorticoids

	Name, address of Manufacturing site:	Yung Shin Pharm. Ind. Co; Ltd-No.27, Kung Chiu Rd, Tachia, Taichung, 43744, Taiwan, Republic of China-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	With Kenacort-A 40.
	Name, address of Marketing Authorization Holder:	Yung Shin Pharm. Ind. Co; Ltd, No.27, Kung Chiu Rd, Tachia, Taichung, 43744, Taiwan, Republic of China, China
	Details of Certificates (CoPP/FSC/cGMP):	COPP is submitted
	Details of Authorization Letter :	COPP and Agency agreement is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	MHRA approved : Kenalog Intra-articular /Intramuscular Injection 40mg/ml (suspension)
	Evaluation Remarks	
	Priority as per decision of 220th meeting of Authority.	
	Application fulfills codal formalities, but following point needs to be considered;	
	The origin of product is from Republic of China (Taiwan) but documents are legalized from Malaysia.	
	The firm was asked for clarification and they have submitted following;	
	It is because in taiwan there is no Pakistani mission. means no embassy or consulate of pakistan in taiwan. But there is is malaysian embassy in taiwan. Justification for Legalization of Documents via Malaysia The documents have been legalized through Malaysia due to the absence of a Pakistani diplomatic mission (Embassy/Consulate) in Taiwan (Republic of China). As a result, direct attestation of documents from Taiwan by Pakistani authorities is not feasible. Malaysia has an established diplomatic presence in Taiwan, which facilitates the legalization and authentication of documents originating from Taiwan. Therefore, the Malaysian Embassy has been utilized as an intermediary for document legalization.	
	Decision	
	Deferred	
	Deferred for further deliberations in the next meeting.	
42	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	HealthBee Projects Private Limited Ground Floor, Momi Plaza, Plot No 43, Business Square, Phase 7, Bahria Town (01-374-0176-065437D)
	Application Form Dy. No / Tracking ID & date of submission	(DXB-RV2-HD4Z, 2026-03-16)
	Detail of Fee Submitted	75000, 238500 2025-09-15, 2025-10-31
	The proposed proprietary name / brand name	TLD 50mg/300mg/300mg
	Label Claim	Each film coated bilayer tablet contains; Dolutegravir sodium eq. to Dolutegravir.....50mg Lamivudine.....300mg Tenofovir Disoproxil Fumarate..... 300 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	30 tablets per bottle, 90 tablets per bottle-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30C
	For generic drugs (me-too Status)	Yes
	Pharmacotherapeutic Group of (API)	Antiretroviral combination

	Name, address of Manufacturing site:	Shanghai Desano Bio-pharmaceutical Co., Ltd.-1479 Zhangheng Road, China (Shanghai) Pilot Free Trade Zone, Shanghai 201203, China.- China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Product of M/s Aizant Drug Research Solutions Pvt Ltd. B. No. DLTTA1802A CDP at only 6.8pH, BE studies are submitted.
	Name, address of Marketing Authorization Holder:	HealthBee Projects Private Limited, Ground Floor, Momi Plaza, Plot no 43, Business Square Phase 7, Bahria Town, District Rawalpindi, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Facility is inspected USFDA.
	Details of Authorization Letter :	COPP and agency agreement is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	FDA approval attached
	Evaluation Remarks	
	Priority as per decision of 220th meeting of Authority.	
	As per COPP submitted the product is not on free sale in country of origin i.e, China. But this product is WHO pre-qualified. Further product application is submitted and processed by USFDA for tentative approval and as per submitted evidence it will be allowed to be marketed once patent expires.	
	the scientific assessment and knowledge about this product at the time of prequalification is available on WHO website. Name of FPP mentioned is HA746, Manufacturer: Shanghai Desano Bio-Pharmaceutical Co., Ltd., 1479, Zhangheng Road, China (Shanghai) Pilot Free Trade Zone, Shanghai, 201203, P.R. China, The conclusion of quality part is given as "The quality part of the dossier is accepted" The final Benefit Risk Assessment is given as "Based on WHO's assessment of data on quality, bioequivalence, safety and efficacy the team of assessors considered that the benefit-risk profile of [HA746 trade name] was acceptable for the following indication: ' treatment of human immunodeficiency virus (HIV) infection in adults and adolescents weighing at least 30 kg ', and would allow inclusion of [HA746 trade name], manufactured at Shanghai Desano Bio-Pharmaceutical Co., Ltd., 1479, Zhangheng Road, China (Shanghai) Pilot Free Trade Zone, Shanghai, 201203, P.R. China in the list of prequalified medicinal products"	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved As per current import policy.	
43	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	Himmel Pharmaceuticals Private Limited Ground Floor, 6- Judicial Colony phase-1 (Ext.) Shahrah Nazaria e Pakistan, (05-352-0065-016174D)
	Application Form Dy. No / Tracking ID & date of submission	(2SL-84U-W6WZ, 2025-03-29)
	Detail of Fee Submitted	300000.0, 2024-12-11,
	The proposed proprietary name / brand name	Promester 50mg/ml I.M. Solution For Injection
	Label Claim	Each 1ml vial contains progesterone..... 50 mg.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5's-As per SRO
	Shelf Life (Unit)	24 Year(s)Store at temperatures below 30°C.
	For generic drugs (me-too Status)	Not Applicable

	Pharmacotherapeutic Group of (API)	Progesterone
	Name, address of Manufacturing site:	VEM İlaç San. ve Tic. A.Ş.-Cerkezkoy Organize Sanayi Bolgesi Karaagac Mahallesi Fatih Bulvari No: 38 Kapakli/TEKIRDAG-Turkey
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PROGESTAN 50 mg/ml IM enjeksiyonluk çözelti B. No. 3368008
	Name, address of Marketing Authorization Holder:	VEM İlaç San. ve Tic. A.Ş., Maslak Mahallesi AOS 55. Sokak 42 Maslak A Blok Sit. No: 2/134 Sariyer/ISTANBUL, Turkey
	Details of Certificates (CoPP/FSC/cGMP):	GMP certificate is submitted
	Details of Authorization Letter :	COPP and agency agreement is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	PROGESTAN 50 mg/ml I.M. (Turkey)
	Evaluation Remarks	
	Priority as per Decision of 220th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
	As per policy for inspection abroad.	
44	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	Himmel Pharmaceuticals Private Limited Ground Floor, 6- Judicial Colony phase-1 (Ext.) Shahrah Nazaria e Pakistan, (05-352-0065-016174D)
	Application Form Dy. No / Tracking ID & date of submission	(EA2-79B-HN95, 2025-03-27)
	Detail of Fee Submitted	300000.0, 2024-12-06,
	The proposed proprietary name / brand name	Cancas 50mg I.V. Lyophilized Powder For Infusion, Vial
	Label Claim	Each vial contains Caspofungin acetate equivalent to Caspofungin.50 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	24 Year(s)Store between 2-8°C in refrigerator..
	For generic drugs (me-too Status)	Caspo PMS Powder for Solution for Infusion,50mg (Punjab Medical Services)
	Pharmacotherapeutic Group of (API)	J02AX04 Other antimycotics for systemic use
	Name, address of Manufacturing site:	VEM İlaç San. ve Tic. A.Ş.-Cerkezkoy Organize Sanayi Bolgesi Karaagac Mahallesi Faith Bulvari No: 38 Kapakli/TEKIRDAG-Turkey
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Cancidas 50 mg powder for concentrate for solution for infusion - Merck Sharp & Dohme Limited B. No. 2150400
	Name, address of Marketing Authorization Holder:	VEM İlaç San. ve Tic. A.Ş., Maslak Mahallesi AOS 55. Sokak 42 Maslak A Blok Sit. No: 2/134 Sariyer/ISTANBUL, Turkey
	Details of Certificates (CoPP/FSC/cGMP):	GMP certificate is submitted
	Details of Authorization Letter :	COPP and agency agreement is submitted.

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	below -70C upto 36 months.
	The status in reference regulatory authorities	Cancidas 50mg Injection (France)
	Evaluation Remarks	
	Priority as per decision of 220th meeting of Authority Application fulfills codal formalities. Recommended for consideration of Board.	
	Decision	
	Approved	
	As per policy for inspection abroad.	
45	Case Category	Any Other (Dr. Farhad Ullah)
	Name, address of Applicant.	WELLOCITI Healthcare (Pvt) Ltd 209, 2nd Floor, Tahir Plaza, Near City Court, Karachi (809)
	Application Form Dy. No / Tracking ID & date of submission	(VXU-HBQ-J35J, 2025-07-15)
	Detail of Fee Submitted	300000.0, 2025-04-17,
	The proposed proprietary name / brand name	Gembin 1000mg
	Label Claim	Each vail contains: Gemcitabine Powder solution for infusion1000mg/vial
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	2 Year(s)30c
	For generic drugs (me-too Status)	Gemzar 1gm Injection by M/s Eli Lilly Pakistan
	Pharmacotherapeutic Group of (API)	Pyrimidine Analogues WHO ATC code; L01BC05
	Name, address of Manufacturing site:	SP Accure Labs Pvt. Ltd.,-Plot. No.12, Biotech Park, Phase II, Lalgadi Malakpet (V), Shamirpet (M), Medchal - Malkajgiri (Dist.), Telangana (State), 500101, India-India Zydus Healthcare Limited(Marketing authorization)-CTS No. 460/6, I.B. Patel Road, Village Pahadi, Goregaon East, Mumbai-400063-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Gemzar powder for solution for Infusion by M/s Bristol Mayors squibb
	Name, address of Marketing Authorization Holder:	Wellociti Healthcare (Pvt.) Limited, Office no. 209, 2nd Floor, Tahir Plaza, Near City Court, Karachi, Pakistan, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Certificate of Pharmaceutical Product: Firm has submitted notarized copy of Certificate of Pharmaceutical Product 3474589/TS/2022 issued by Drugs Control Administration, Government of Telangana India valid upto 24-08-2025 for Gemcitabin powder for soluti
	Details of Authorization Letter :	Firm has submitted copy of letter of sole distributor/authorized imported from M/s Zydus Healthcare Limited., having its registered office located at "Zydus Corporate Park", Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, SarkhejGandhinagar

		Highway, Ahmedabad- 382 481 India. for applied product dated; September 2022.
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		Gemcitabine 1000mg powder for solution for infusion MHRA Approved
Evaluation Remarks		
Priority as per Decision of 220th meeting of Authority		
Sr. No	Shortcomings	Firm's response
1.	Correct label claim of applied product as per CoPP and RRA along with submission of applicable fee	Label claim mentioned in COPP is: Each vial contains Gemcitabine Hydrochloride Ph.Eur Equivalent Gemcitabine 1000 mg Mannitol Ph. Eur 1000 mg Excipients q.s. Fee for correction of label claim is submitted
2.	Product license holder as per submitted CoPP is different than that mentioned in submitted application and letter of authorization. Clarification is required.	SPAL (SP Accure Pvt. Ltd.) is authorized contract manufacturer of Zydus Healthcare Ltd. 1. Letter from SPAL / SP Accure Pvt. Ltd) authorizing Zydus Healthcare Ltd, as marketing authorization holder is attached herewith as Annexure 1. Same letter is submitted for Zydus Cisplat 50 as well which is already approved by DRAP. As per the submitted CoPP, the product license holder is SPAL Pvt. Ltd., India, while Zydus Healthcare Limited, India is only exporter and details of Zydus Healthcare Limited, India is not given on CoPP.
3.	As you have stated that "SPAL (SP Accure Pvt. Ltd.) is authorized contract manufacturer of Zydus Healthcare Ltd." then submit its approval from concerned regulatory authority in country of origin.	No response submitted
4.	Batch analysis report and stability study data of commercial scale batches shall be submitted since the submitted batch analysis report and stability study is of Pilot Scale/Process validation batches	Batch analysis report is attached herewith Annexure 4. Stability data on commercial batches are available as on date. We will share once product is commercialized after due registration. We ensure regulatory authority that batch size of commercial batch will be same as process validation batches, any change from this will be implemented only after approval from DRAP.
Decision		
Rejected		
The board deliberated on the matter that firm has stated that they have not yet manufactured any commercial batch of the applied product and COPP mentions that product is actually present in the market of country of origin. The response of the firm contradicts with the COPP submitted. As per firm's response it is evident that product is not yet commercialized in country of origin. Due to this reason board decided to reject the instant case.		
46	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	Getz Pharma (Pvt) Limited Plot No. 29-30, Sector-27, Korangi Industrial Area, Karachi, Pakistan (DSL 0655)

	Application Form Dy. No / Tracking ID & date of submission	(WHP-DN8-QS1A, 2024-06-11)
	Detail of Fee Submitted	300000.0, 2024-04-08,
	The proposed proprietary name / brand name	DMF
	Label Claim	Each Delayed release capsule contains: Dimethyl fumarate240mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30's-As per SRO,60's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 15 to 30oC
	For generic drugs (me-too Status)	could not be confirmed
	Pharmacotherapeutic Group of (API)	Antineoplastic & immunomodulating agents.
	Name, address of Manufacturing site:	M/s Amneal Pharmaceutical Private Limited-Plot No. 882/1-871, Near Hotel Kankavati, Sarkhej - Bavla Highway, Village-Rajoda, Taluka-Bavla, Dist: Ahmedabad, Gujrat, India.-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Tecfidera 240mg delayed release capsule.
	Name, address of Marketing Authorization Holder:	M/s Getz Pharma Private Limited, Plot No.: 29-30, Sector - 27, Korangi Industrial Area, Karachi, Pakistan, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	GMP certificate valid till 23-09-2024 is submitted. License validity certificate is submitted. Validity is 24-10-2026.
	Details of Authorization Letter :	CoPP: Copy of legalized CoPP issued on 30-10-2023. The applied product is available in free sale and the operations & facilities conform to WHO-GMP. Distribution agreement: The agreement is for 3 products including Dimethyl Fumarate Capsule. LOA: Product specific LOA is also submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated ($25 \pm 2^{\circ}\text{C}$ & $60 \pm 5\% \text{ RH}$) and 48 months real time ($2-8^{\circ}\text{C}$ ($5^{\circ}\text{C} \pm 3^{\circ}\text{C}$)) stability data of 03 batches is submitted.
	The status in reference regulatory authorities	TECFIDERA (Dimethyl Fumarate) Delayed-Release Capsules 240mg by M/s Biogen Inc. Cambridge, UK (USFDA Approved).
47	Evaluation Remarks	
	The firm has submitted withdrawal request for the instant case.	
	Decision	
	Rejected	
	The Board acceded to the request of the firm for withdrawal of the application.	
47	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	AMB HK ENTERPRISES (PVT) LTD, LAHORE 2nd floor plaza 60, Commercial Block K, Phase-1 DHA, Lahore. (05-352-0058-104514D)
	Application Form Dy. No / Tracking ID & date of submission	(XE6-B54-3N3V, 2025-05-22)
	Detail of Fee Submitted	300000.0, 2025-03-10,

	The proposed proprietary name / brand name	Amtrix 1G
	Label Claim	Each vial contains: Ceftriaxone as sodium.....1g
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1'S ; 50'S AND/OR AS-Controlled
	Shelf Life (Unit)	2 Year(s)store below 30 degree celsius
	For generic drugs (me-too Status)	Oxidil by Sami Pharma
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Name, address of Manufacturing site:	CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., L-No.88, Yangzi Road, Economic and Technological Development Zone, Shijiazhuang City, China-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Report for PE studies against Rocephin by M/s Roche Products Limited (EU) is submitted.
	Name, address of Marketing Authorization Holder:	AMB HK ENTERPRISES(PVT) LTD, 2ND FLOOR PLAZA 60, COMMERCIAL BLOCK K, PHASE 1, DHA, LAHORE, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Copy of DML No. JI20150137 valid till 27-11-20230 is submitted. The manufacturing scope includes Cephalosporins.
	Details of Authorization Letter :	CoPP: Apostille copp no. Hebeu200250364 valid till 07-07-2027 is submitted. Ceftriaxone as sodium 1g is available in free sale in exporting country and, the facilities and operations conform to WHO-GMP as per submitted CoPP. DSL: DSL valid till 08-05-2028 is submitted. LOA: Copy of LOA is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	USFDA approved
Evaluation Remarks		
The application has been processed in compliance to the decision of DRAP Authority on priority. The application is deficient for: 1. Submission of analytical method verification studies for drug substance. 2. Submission of notarised letter of authorization.		
Decision		
48	Deferred	
	for submission of:	
	1. Analytical method verification studies for drug substance.	
	2. Notarized letter of authorization.	
	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	AMB HK ENTERPRISES (PVT) LTD, LAHORE 2nd floor plaza 60, Commercial Block K, Phase-1 DHA, Lahore. (05-352-0058-104514D)
	Application Form Dy. No / Tracking ID & date of submission	(7HJ-7NY-J1TX, 2026-01-27)
	Detail of Fee Submitted	300000.0, 2025-03-19,
	The proposed proprietary name / brand name	Amtrix 500mg
	Label Claim	Each vial contains: Ceftriaxone as Sodium.. 500mg

	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1'S ; 50'S AND/OR AS-Controlled
	Shelf Life (Unit)	3 Year(s)the finished product should be stored in a dry place and not above 30°C
	For generic drugs (me-too Status)	generic
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Name, address of Manufacturing site:	CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., L-No.88, Yangzi Road, Economic and Technological Development Zone, Shijiazhuang City, China.-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Report for PE studies against Rocephin by M/s Roche Products Limited (EU) is submitted.
	Name, address of Marketing Authorization Holder:	AMB HK ENTERPRISES(PVT) LTD, 2ND FLOOR PLAZA 60, COMMERCIAL BLOCK K, PHASE 1, DHA, LAHORE, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Copy of DML No. JI20150137 valid till 27-11-20230 is submitted. The manufacturing scope includes Cephalosporins.
	Details of Authorization Letter :	CoPP: Apostille copp no. Hebeu200250450 valid till 07-07-2027 is submitted. Ceftriaxone as sodium 0.5g is available in free sale in exporting country and, the facilities and operations conform to WHO-GMP as per submitted CoPP. DSL: DSL valid till 08-05-2028 is submitted. LOA: Copy of LOA is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	submitted
	The status in reference regulatory authorities	USFDA approved
	Evaluation Remarks	
	The application has been processed in compliance to the decision of DRAP Authority on priority. The application is deficient for: 1. Submission of analytical method verification studies for drug substance. 2. Submission of notarised letter of authorization.	
	Decision	
	Deferred	
	for submission of:	
	1. Analytical method verification studies for drug substance.	
	2. Notarized letter of authorization.	
49	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	AMB HK ENTERPRISES (PVT) LTD, LAHORE 2nd floor plaza 60, Commercial Block K, Phase-1 DHA, Lahore. (05-352-0058-104514D)
	Application Form Dy. No / Tracking ID & date of submission	(3LL-3XV-Y4E8, 2025-05-22)
	Detail of Fee Submitted	300000.0, 2025-04-08,
	The proposed proprietary name / brand name	Ampitrex
	Label Claim	Each vial contains: Ampicillin as Sodium.....500mg
	Reference to Finished product specifications	United States Pharmacopeia

	Proposed Pack Size	1's;50's-Controlled
	Shelf Life (Unit)	36 Month(s)Store below 30 Degrees Celsius. Protect from Light and Heat
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	Penicillin Antibiotic
	Name, address of Manufacturing site:	CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., L-No.88 Yangzi Road, Economic & Technological Development Zone, Shijiazhuang City, Hebei Province, China.-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence report against Ampicillin Sodium by Ms Sandoz Inc.
	Name, address of Marketing Authorization Holder:	AMB HK ENTERPRISES (PVT) LTD, LAHORE, 2nd floor plaza 60, Commercial Block K, Phase-1 DHA, Lahore., Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Copy of DML No. JI20150137 valid till 27-11-20230 is submitted. The manufacturing scope includes (Cephalosporin/Penicillins)
	Details of Authorization Letter :	CoPP: Apostille CoPP No. Hebei20240273 valid till 14-05-2025 is submitted. The applied product is available in free sale in exporting country and, the facilities and operations conform to WHO-GMP as per submitted CoPP. DSL: DSL valid till 08-05-2028 is submitted. LOA: Copy of letter of authorization is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies of Drug Substance conducted at: a) Long Term Storage Condition($30\pm 2^{\circ}\text{C}/\text{RH}:75\pm 5\%$) and B) Accelerated Storage condition($40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\%\text{RH} \pm 5\%\text{RH}$) for 03 batches.
	The status in reference regulatory authorities	USFDA approved
	Evaluation Remarks	
	The application has been processed in compliance to the decision of DRAP Authority on priority. The application is deficient for: 1. Submission of apostille/legalized and valid CoPP since the submitted CoPP is expired. 2. Submission of notarised letter of authorization.	
	Decision	
	Approved	
	as per policy of import for inspection of manufacturer abroad.	
	Moreover, the firm shall submit:	
	1. Apostille/legalized and valid CoPP.	
	2. Notarized letter of authorization.	
50	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	AMB HK ENTERPRISES (PVT) LTD, LAHORE 2nd floor plaza 60, Commercial Block K, Phase-1 DHA, Lahore. (05-352-0058-104514D)
	Application Form Dy. No / Tracking ID & date of submission	(8ZS-54G-S1R1, 2026-02-04)
	Detail of Fee Submitted	300000.0, 2025-03-10,
	The proposed proprietary name / brand name	Purofen

	Label Claim	Each Tablet Contains: Paracetamol.....500mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per Sro-Controlled
	Shelf Life (Unit)	3 Year(s) Stored below 30°C in cool and dry place. Protect from heat and light. Keep out of reach of children
	For generic drugs (me-too Status)	generic
	Pharmacotherapeutic Group of (API)	NSAID
	Name, address of Manufacturing site:	HEBEI JIHENG PHARMACEUTICAL CO., LTD.-No.2888 Zhenhua street, Hengshui Industrial Park, Hebei-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and cdp studies have been performed against the reference product i.e. Doliprone tablet 500mg by M/s Sanofi Aventis, France.
	Name, address of Marketing Authorization Holder:	AMB HK ENTERPRISES(PVT) LTD, 2ND FLOOR PLAZA 60, COMMERCIAL BLOCK K, PHASE 1, DHA, LAHORE, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	DML No. Ji20150076 valid till 21-05-20230 included the scope of manufacturing of tablets.
	Details of Authorization Letter :	CoPP: Apostille CoPP No. Hebei20250698 valid till 23-11-2027 is submitted. The applied product is available in free sale in exporting country and, the facilities and operations are according WHO-GMP as per submitted CoPP. LOA: Apostille agency agreement contract dated 08-02-2025 is submitted. DSL: DSL valid till is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 48 months real time stability studies of 03 batches according to zone iv-A.
	The status in reference regulatory authorities	FDA approved
	Evaluation Remarks	
	The application has been processed on priority as per the decision of DRAP Authority.	
	Decision	
	Approved	
	as per Policy of import for inspection of manufacturer abroad.	
51	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	Mehran International 498-C Feroz Shah Street Karachi (0435)
	Application Form Dy. No / Tracking ID & date of submission	(DGB-AR4-DY2R, 2026-01-14)
	Detail of Fee Submitted	313500, 2025-10-17,
	The proposed proprietary name / brand name	Normalsaline Injection 0.9% 100ml
	Label Claim	Each 100ml contains: Sodium Chloride.....0.9g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 Bottle/Box PP Bottle -As per SRO
	Shelf Life (Unit)	3 Year(s) Store below 25°C
	For generic drugs (me-too Status)	Macsol NS IV Solution, Manufactured By: Searle Pakistan Pvt Ltd.
	Pharmacotherapeutic Group of (API)	I.V. Solution Additives, Electrolyte Solutions.

	Name, address of Manufacturing site:	M/S. Guizhou Tiandi Pharmaceutical Co. Ltd. - No.6 Baokang Road. Yilong Hongxing Medical Enterprise Area, Xingyi, Buyi & Miao county, Qianxinan, Guizhou.-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence report is submitted against the comparator's product by M/s Shijiazhuang No. 4 Pharmaceutical Co., Ltd., China.
	Name, address of Marketing Authorization Holder:	M/s. Guizhou Tiandi Pharmaceutical Co. Ltd., No.6 Baokang Road. Yilong Hongxing Medical Enterprise Area, Xingyi, Buyi & Miao county, Qianxinan, Guizhou., China
	Details of Certificates (CoPP/FSC/cGMP):	Valid copy of DML No. Qian20160066 is submitted.
	Details of Authorization Letter :	CoPP: Copy of apostille CoPP No. CoPP_20220008 dated 19-01-2022 (validity 5 years) is submitted. The applied product is available in free sale in exporting country and, the operations and facilities conform to WHO-GMP as per submitted CoPP issued by Yilong New District Market Supervision and Administration Bureau. LOA: LOA dated 05-11-2024 is submitted. DSL: Valid copy of DSL is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	accelerated stability study - At temperature 40±2°C , R.H. of 75±5%, For a period of 6 months. long-term stability study - At temperature 30±2°C , R.H. of 65±5% , For a period of 36 months.
	The status in reference regulatory authorities	Sodium chloride IV Infusion 0.9% 100ml, Manufactured by: M/s.Baxter Healthcare ltd. UK.
	Evaluation Remarks	
	The application has been processed on priority in compliance to the decision of DRAP Authority. The firm needs to submit AMV studies for drug substance for specificity and accuracy parameters since data for precision is submitted.	
	Decision	
52	Deferred	
	for submission analytical method verification studies for drug substance.	
	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	Al Habib Pharmaceuticals. Plot 81 SMCHS BLOCK B (0414)
	Application Form Dy. No / Tracking ID & date of submission	(MZR-Z7L-2ASY, 2026-02-12)
	Detail of Fee Submitted	313500, 2025-11-10,
	The proposed proprietary name / brand name	BLENOXANE
	Label Claim	Each Vial Contains: Bleomycin as Sulphate.....15000 IU (Lyophilized)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	24 Month(s)Store below 2°C to 8°C. Protect from light.

	For generic drugs (me-too Status)	Product Name: Bemocin 15 Unit Injection Company Name: Atco Pharma International (Pvt) Ltd Dosage Form: Injection Pack Size(s): 1s vial Registration No: 045752
	Pharmacotherapeutic Group of (API)	Cytotoxic antibiotics and related substances
	Name, address of Manufacturing site:	NAPROD Life Sciences Pvt Ltd-G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Palghar-401 506, Maharashtra State.-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the reference product i.e. Bleomedac for injection by M/s Medac GmbH, Germany.
	Name, address of Marketing Authorization Holder:	Al Habib Pharmaceuticals, Plot 81, Block B, SMCHS, Karachi , Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Apostille GMP certificate is submitted valid till 15-04-2028 which includes Lyophilized/powder injectable (Cytotoxic) in the scope.
	Details of Authorization Letter :	CoPP: Apostille CoPP No. CoPP/CERT/KD/153752/2025/11/57734/275622 valid till 15-04-2028 is submitted. The applied product is available in free sale and, the facilities and operations conform to WHO-GMP as per submitted CoPP. DSL: Valid DSL till 15-05-2029 is submitted. LOA: Authorization letter dated 10-11-2025 is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted.
	The status in reference regulatory authorities	BLEOMYCIN ACCORD Bleomycin (as sulfate) 15,000 IU Powder for injection vial, TGA APPROVED ARTG ID 455446
	Evaluation Remarks	
	The case has been processed on priority as per the decision of DRAP Authority.	
	Decision	
	Approved	
	As per policy of import for inspection of manufacturer abroad.	
53	Case Category	Priority As Per 257-M of RB (Farooq Aslam)
	Name, address of Applicant.	REVIVE HEALTH CARE 503, 5TH FLOOR EDEN HEIGHTS 6 MAIN GULBERG JAIL ROAD (05-352-0065-031159D)
	Application Form Dy. No / Tracking ID & date of submission	(YQV-SPG-4RDG, 2026-01-05)
	Detail of Fee Submitted	313500, 2025-10-27,
	The proposed proprietary name / brand name	REVIBORT Injection 1.0 mg
	Label Claim	Each Vial Contains: Bortezomib 1.0 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's Vial-As per SRO
	Shelf Life (Unit)	24 Month(s)Store below 30 degree centigrade
	For generic drugs (me-too Status)	Registration No: 115738, By Revive Health Care
	Pharmacotherapeutic Group of (API)	Antineoplastic agent (Proteasome inhibitor), ATC Code: L01XG01
	Name, address of Manufacturing site:	Qilu Pharmaceutical Co., Ltd.-8888 Lvyou Road, High-tech Zone, Jinan, Shandong 250104, China-

		China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence provided between QILU's Product (Bortezomib for Injection 1.0mg) VS Innovator's product (VELCADE)
	Name, address of Marketing Authorization Holder:	Qilu Pharmaceutical Co., Ltd., 8888 Lvyou Road, High-tech Zone, Jinan, Shandong 250104, China, China
	Details of Certificates (CoPP/FSC/cGMP):	Valid Eudra GMP Certificate No. ES/046HV/25
	Details of Authorization Letter :	CoPP: CoPP No. 20251248 valid till 11-09-2027 is submitted. The applied product is available in free sale and, the facilities and operations conform to WHO-GMP as per submitted CoPP. DSL: DSL valid till 21-05-2027 is submitted. LOA: LOA dated 19-08-2025 is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 6 months Accelerated and 24 months of long- term performed on four consecutive commercial batches (16D001GF3, 16D002GF3, 16D003GF3 and 3A002GH7). Stability data provided in section 3.2.S.7.3
	The status in reference regulatory authorities	VELCADE 1.0 mg Injection, by Janssen-Cilag, Belgium, EMA Approved
	Evaluation Remarks	
	The case was deferred in 354th meeting For clarification for the following points: 1. As per the innovator's literature, the storage conditions of -20oC is for drug substance while the drug product is stored at room temperature. Therefore, the storage conditions of -20oC for real time stability studies for drug product are not acceptable.(Reply: The stability data of accelerated (6M) and long term (24M) according to Zone IVa of 3 consecutive commercial scale Batches (16F0012B24, 16F0022B24 & 16F0032B24) (Batch size: 10,000 vials)2. Stability data of drug product for commercial batches is required till shelf life. (Reply: The stability data of accelerated (6M) and long term (24M) on Zone IVa of 3 consecutive commercial scale Batches (16F0012B24, 16F0022B24 & 16F0032B24) (Batch size: 10,000 vials)) 3. Submission of Legalized/apostille CoPP.(REply: CoPP No. 20251248 valid till 11-09-2027 is submitted. The applied product is available in free sale and, the facilities and operations conform to WHO-GMP as per submitted CoPP. Remarks:The application is still deficient for submission of legalised/apostille CoPP since copy of CoPP is submitted.	
	Decision	
	Approved	
	As per policy of import for inspection of manufacturer abroad. Moreover, the firm shall submit legalised/apostille and valid CoPP.	
54	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	Inaya traders Flat No. 1, first floor, plot No. A-152, block 8, KAECHS, Karachi-Pakistan (0470)
	Application Form Dy. No / Tracking ID & date of submission	(BUW-T21-21SV, 2025-07-28)
	Detail of Fee Submitted	300000.0, 2025-05-07,
	The proposed proprietary name / brand name	Ampicillin injection (generic name)
	Label Claim	Each vial contain: Ampicillin as sodium.....500 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50 vials-As per SRO
	Shelf Life (Unit)	3 Year(s)Room temperature

	For generic drugs (me-too Status)	Ampiwell injection fynk pharmaceuticals
	Pharmacotherapeutic Group of (API)	Penicillin
	Name, address of Manufacturing site:	SINOPHARM WEIQIDA PHARMACEUTICAL CO., LTD-High-tech Industrial Zone, Economic & Technological Development Zone, Datong City, Shanxi Province, P.R. of China.-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Report for PE studies has been submitted against the comparator's product by M/s Reyoung Pharmaceutical Co. Ltd., China.
	Name, address of Marketing Authorization Holder:	Inaya traders, Flat No. 1, first floor, plot No. A-152, block 8, KAECHS, Karachi-Pakistan, Paklistan
	Details of Certificates (CoPP/FSC/cGMP):	DML No. Jin20160008 valid till 05-11-2030 is submitted. The manufacturing scope includes Powder for Injection (Penicillin).
	Details of Authorization Letter :	CoPP: Apostille CoPP No. Shanxi20220030 valid till 27-08-2025 is submitted. The applied product is available in free sale in exporting country and, the operations and facilities conform to WHO-GMP as per submitted CoPP. DSL: DSL valid till 21-06-2029 is submitted. LOA: Copy of letter of authorization is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 24 months real time (25°C ± 2°C, 60% RH ± 5%RH) stability data of 03 batches is submitted.
	The status in reference regulatory authorities	Available USFDA
	Evaluation Remarks	
	The application has been processed in compliance to the decision of DRAP Authority.	
	Decision	
	Approved	
	As per policy of import for inspection of manufacturer abroad.	
55	Case Category	Import (Haleema Sharif)
	Name, address of Applicant.	Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan (01-374-0006-118530D)
	Application Form Dy. No / Tracking ID & date of submission	(AM8-YAS-2AUB, 2025-03-04)
	Detail of Fee Submitted	300000.0, 2025-01-08,
	The proposed proprietary name / brand name	ZUPANIB-400
	Label Claim	Each film coated tablet contains: Pazopanib Hydrochloride eq. to Pazopanib..... 400mg Excipients.... q.s
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30's-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C. Protect from light.
	For generic drugs (me-too Status)	Registration Number: 084162, Votrient Tablet 400mg, Each film coated tablet contains: Pazopanib (As hydrochloride)... 400mg MAH: Novartis Pharma (Pakistan) Limited
	Pharmacotherapeutic Group of (API)	ANTINEOPLASTIC AGENTS (PROTEIN KINASE INHIBITORS)

	Name, address of Manufacturing site:	Zuvius Lifesciences Pvt. Ltd.-At.Kharuni-Lodhimajra Road, Vill. Nandpur, Baddi, Distt. Solan, (H.P.)-173205 India-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted
	Name, address of Marketing Authorization Holder:	Zuvius Lifesciences Pvt. Ltd., At-Kharuni-Lodhimajra Road, Vill. Nandpur, Baddi, Distt. Solan (H.P.)173205 India, India
	Details of Certificates (CoPP/FSC/cGMP):	Import Product
	Details of Authorization Letter :	Import Product
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	submitted in dossier
	The status in reference regulatory authorities	Votrient Tablets 400mg Novartis Pharmaceuticals UK Ltd Approved in USFDA
	Evaluation Remarks	
	The case was deferred in 352nd meeting for the following: 1. Original legalized CoPP is required. 2. Reference for this limit of dissolution testing Q NLT 75% in 45 minutes. 3. Either original or notarised product specific valid sole agency agreement.Firm has not submitted requisite documents till date.	
	Decision	
	Deferred	
	Registration Board deferred the case for the following:	
	1. Original legalized CoPP is required.	
	2. Reference for this limit of dissolution testing Q NLT 75% in 45 minutes.	
	3. Either original or notarised product specific valid sole agency agreement.	
56	Case Category	Priority As Per 257-M of RB (Haleema Sharif)
	Name, address of Applicant.	Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan (01-374-0006-118530D)
	Application Form Dy. No / Tracking ID & date of submission	(WUX-7VL-A756, 2025-02-17)
	Detail of Fee Submitted	300000.0, 2025-01-06,
	The proposed proprietary name / brand name	BLEOZ 15
	Label Claim	Each vial contains: Bleomycin sulphate USP Eq. to Bleomycin 15 IU
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's Vial -As per SRO
	Shelf Life (Unit)	24 Month(s)Store the vials in original carton at temperature 2-8°C. Protect from light.
	For generic drugs (me-too Status)	Registration Number: 092304, Brand Name: Bleotex 15 Units Powder for Injection, MAH: Rotex Pharma
	Pharmacotherapeutic Group of (API)	ANTINEOPLASTIC AGENTS (CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES)
	Name, address of Manufacturing site:	Zuvius Lifesciences Pvt. Ltd.-At.Kharuni-Lodhimajra Road, Vill. Nandpur, Baddi, Distt. Solan, (H.P.)-173205 India-India

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted in dossier
	Name, address of Marketing Authorization Holder:	Zuvius Lifesciences Pvt. Ltd., At-Kharuni-Lodhimajra Road, Vill. Nandpur, Baddi, Distt. Solan (H.P.)173205 India, India
	Details of Certificates (CoPP/FSC/cGMP):	Import Product
	Details of Authorization Letter :	Import Product
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
	The status in reference regulatory authorities	Blenoxane 15 Units, Approved in USFDA (Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**). Distributed by: Nippon Kayaku Co., Ltd. Tokyo, Japan. MAH: Bristol-Myers Squibb Company
	Evaluation Remarks	
	Registration Board in its 352n meeting deferred the product for submission of following: Original Legalized CoPP of applied product. Analytical method & analytical method validation studies of impurities. Either original or notarized sole agency agreement. Firm still has not submitted original legalized CoPP of applied product till date.	
	Decision	
	Deferred	
	Registration Board deferred the case for the following:	
	1. Original legalized CoPP.	
57	Case Category	Import (Haleema Sharif)
	Name, address of Applicant.	Oncovanz Pharmaceuticals Private Limited C 52 Block 4 Gulshan e Iqbal (0418)
	Application Form Dy. No / Tracking ID & date of submission	(LUV-7SS-B17P, 2025-09-03)
	Detail of Fee Submitted	300000.0, 2025-06-19,
	The proposed proprietary name / brand name	Phosphovanz 0.5g Powder for Injection
	Label Claim	Cyclophosphamide may be used alone or in combination with other chemotherapeutic agents, depending on the indication. Cyclophosphamide is indicated in the treatment of: • Chronic Lymphocytic Leukemia (CLL) • Acute Lymphocytic Leukemia (ALL) • As conditioning for a bone marrow transplantation, in the treatment of Acute Lymphoblastic Leukemia, Chronic Myelogenous Leukemia and Acute Myelogenous Leukemia, in combination with whole body irradiation or busulfan. • Hodgkin's lymphoma, Non-Hodgkin's lymphoma and Multiple Myeloma • Metastatic ovarian, and breast, carcinoma • Adjuvant treatment of breast carcinoma • Ewing's sarcoma • Small cell lung cancer • Advanced or metastatic neuroblastoma, • Life-threatening autoimmune diseases: severe progressive forms of lupus nephritis and Wegener's granulomatosis.
	Reference to Finished product specifications	British Pharmacopeia

	Proposed Pack Size	30 ml Amber Glass Vial -As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C., Protect from light and moisture.
	For generic drugs (me-too Status)	Oncofos 500mg Powder for Injection
	Pharmacotherapeutic Group of (API)	Alkylating agent
	Name, address of Manufacturing site:	Zee Laboratories Limited -Behind 47, Industrial Area, Paonta Sahib-173025 (India)-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not Applicable
	Name, address of Marketing Authorization Holder:	Oncovanz Pharmaceuticals (Pvt.) Ltd, Plot# C-52, Block 4, Gulshan-e-Iqbal, Karachi, Pakistan, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Valid & Legalized issued by regulatory body of India
	Details of Authorization Letter :	Imported Finished Product.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated stability studies: 25 ±2°C / 60% RH 5% and Long-term stability studies 5 ±3°C
	The status in reference regulatory authorities	Cyclophosphamide for Injection
	Evaluation Remarks	
	Shortcomings were conveyed to the firm On November 3rd, 2025, 3:55 pm. A reminder was issued to the firm on March 16th, 2026, 12:59 pm to which firm has not replied yet. Impurity Profiling:Firm is claiming BP specifications however Impurity profiling has not been conducted by either the drug substance manufacturer or the drug product manufacturer as per BP. Certificate of Pharmaceutical Product (COPP) / Free Sale Certificate: The firm has not submitted a COPP. The Free Sale Certificate submitted (dated 07.01.2023) had a 2-year validity and is now expired. GMP Certificate: The GMP certificate of the firm was valid until 10.08.2025. It was not valid at the time of evaluation and is currently invalid. Analytical Method Verification:Analytical method verification studies for the applied product, as performed by the drug product manufacturer, have not been submitted. Stability Studies Documentation:Supporting documents, such as chromatograms, for stability studies have not been provided. Without these, the authenticity and reliability of the submitted stability data cannot be verified. 6. Product Registration:The registration letter for the product in country of origin has not been submitted.	
	Decision	
	Deferred	
	Registration Board deferred the case for the following:	
	1. Original legalized CoPP.	
	2. Analytical Method Verification studies by drug product manufacturer.	
	3. Supporting documents, such as chromatograms, raw data sheets for the authenticity and reliability of the submitted stability studies data.	
	4. The registration letter for the product in country of origin has not been submitted.	
	5.Impurity profiling by drug substance and drug product manufacturer as per BP.	
58	Case Category	Import (Haleema Sharif)
	Name, address of Applicant.	Oncovanz Pharmaceuticals Private Limited C 52 Block 4 Gulshan e Iqbal (0418)
	Application Form Dy. No / Tracking ID & date of submission	(ZPZ-SX2-NEHW, 2025-08-06)

Detail of Fee Submitted	300000.0, 2025-06-24,
The proposed proprietary name / brand name	Phosphovanz 1g Powder for Injection
Label Claim	Cyclophosphamide may be used alone or in combination with other chemotherapeutic agents, depending on the indication. Cyclophosphamide is indicated in the treatment of: • Chronic Lymphocytic Leukemia (CLL) • Acute Lymphocytic Leukemia (ALL) • As conditioning for a bone marrow transplantation, in the treatment of Acute Lymphoblastic Leukemia, Chronic Myelogenous Leukemia and Acute Myelogenous Leukemia, in combination with whole body irradiation or busulfan. • Hodgkin's lymphoma, Non-Hodgkin's lymphoma and Multiple Myeloma • Metastatic ovarian, and breast, carcinoma • Adjuvant treatment of breast carcinoma • Ewing's sarcoma • Small cell lung cancer • Advanced or metastatic neuroblastoma, • Life-threatening autoimmune diseases: severe progressive forms of lupus nephritis and Wegener's granulomatosis.
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	50 ml Amber Glass Vial -As per SRO
Shelf Life (Unit)	24 MonthStore below 30°C., Protect from light and moisture.
For generic drugs (me-too Status)	Oncofos 1g Powder for Injection
Pharmacotherapeutic Group of (API)	Alkylating agent
Name, address of Manufacturing site:	Zee Laboratories Limited -Behind 47, Industrial Area, Paonta Sahib District Sirmour (H.P.) India.- India
Pharmaceutical Equivalence and Comparative Dissolution Profile	Not Applicable
Name, address of Marketing Authorization Holder:	Oncovanz Pharmaceuticals (Pvt.) Ltd, Plot# C-52, Block 4, Gulshan-e-Iqbal, Karachi, Pakistan, Pakistan
Details of Certificates (CoPP/FSC/cGMP):	Valid & Legalized issued by regulatory body of India
Details of Authorization Letter :	Attached
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated stability studies: 25 ±2°C / 60% RH 5% and Long-term stability studies 5 ±3°C
The status in reference regulatory authorities	Cyclophosphamide for Injection
Evaluation Remarks	
Shortcomings were conveyed to the firm On November 3rd, 2025, 3:40 pm. A reminder was issued to the firm on March 16th, 2026, 1:01 pm to which firm has not replied yet. Impurity Profiling: Firm is claiming BP specifications however Impurity profiling has not been conducted by either the drug substance manufacturer or the drug product manufacturer as per BP. Certificate of Pharmaceutical Product (COPP) / Free Sale Certificate: The firm has not submitted a COPP. The Free Sale Certificate submitted. GMP Certificate: The GMP certificate of the firm was valid until 10.08.2025. It was not valid at the time of evaluation and is currently invalid. Analytical Method Verification: Analytical method verification studies for the applied product, as performed by the drug product manufacturer, have not been submitted. Stability Studies Documentation: Supporting documents, such as chromatograms, for stability studies have not been provided. Without these, the authenticity and reliability of the submitted stability data cannot be verified. 6. Product Registration: The registration letter for the product in country of origin has not been submitted.	

	Decision	
	Deferred	
	Registration Board deferred the case for the following:	
	1.Original legalised CoPP.	
	2.Analytical Method Verification studies by drug product manufacturer.	
	3. Supporting documents, such as chromatograms, raw data sheets for the authenticity and reliability of the submitted stability studies data.	
	4. The registration letter for the product in country of origin has not been submitted.	
	5. Impurity profiling by drug substance and drug product manufacturer as per BP.	
59	Case Category	Import (Haleema Sharif)
	Name, address of Applicant.	Hakimsons (Pvt)., Ltd. A-58/B , SITE Karachi (055)
	Application Form Dy. No / Tracking ID & date of submission	(N42-H7S-3YG4, 2025-06-19)
	Detail of Fee Submitted	300000.0, 2025-05-02,
	The proposed proprietary name / brand name	GEFBOOK TABLETS 250mg
	Label Claim	Each Film Coated Tablet Contains : Gefitinib 250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	3x10's OR As per ma-De-Controlled
	Shelf Life (Unit)	24 Year(s)Do not Store above 30C
	For generic drugs (me-too Status)	GEFTICIP Tablets 250mg by A.J. Mirza ; Regn # 088385 ; GEFITEC Tablets 250mg by Revive Pharmakon ; Regn # 090740
	Pharmacotherapeutic Group of (API)	Antineoplastic agent - protein kinase inhibitors.
	Name, address of Manufacturing site:	M/s Eugia Pharma Specialities Limited.-UNIT-1, SY.NO. 550, 551 & 552,KOLTHUR VILLAGE,SHAMIRPET MANDAL,MEDCHAL - MALKAJGIRI DISTRICT,PINCODE 500101 ,TELANGANA STATE,INDIA.-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	As enclosed in Section 2.3.P.2.2 of MODULE-II & Section 3.2.P.2.2 of MODULE-III
	Name, address of Marketing Authorization Holder:	M/s Hakimsons (Pvt)., Ltd., A-58/B , S.I.T.E, Manghopir Road, Karachi., Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	As enclosed in Sub-Section 1.3.5 of MODULE - I
	Details of Authorization Letter :	Not Applicable as Import Finished Product
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	As enclosed in Section - 2.3.S.7 of MODULE-II & Section - 3.2.S.7 of MODULE-III
	The status in reference regulatory authorities	IRESSA® Tablets 250mg as approved by USFDA
	Evaluation Remarks	
	Shortcomings were conveyed to firm on December 31st 2025 and reminder was issued to firm On March 17 2026 and March 19 2026, to which firm has not replied yet, The Product is registered only for Export as per free sale certificate issued for unit I. Firm also has submitted a COPP which is only attested by MEA India and is not attested by High Commission of Pakistan in India. And also unit I	

is not mentioned on it. However firm is importing from unit I facility as per manufacturer information provided by firm with this application Comparative dissolution profile in three media: pH 1.2, pH 4.5, and pH 6.8. Stability studies of three commercial batches of the drug product up to the proposed shelf life under Zone IVa or Zone IVb conditions, along with chromatograms and raw data sheets.

Decision

Deferred

Registration Board deferred the case for submission of following documents/ clarifications.

1. The Product is registered only for Export as per free sale certificate issued for unit I.
2. Firm also has submitted a COPP which is only attested by MEA India and is not attested by High Commission of Pakistan in India. And also unit I is not mentioned on it. However firm is importing from unit I facility as per manufacturer information provided by firm with this application
3. Comparative dissolution profile in three media: pH 1.2, pH 4.5, and pH 6.8.
4. Stability studies of three commercial batches of the drug product up to the proposed shelf life as per Zone IVa or Zone IVb conditions, along with chromatograms and raw data sheets.

60	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. (05-352-0058-104514D)
	Application Form Dy. No / Tracking ID & date of submission	(13X-5SG-LEL6, 2024-07-09)
	Detail of Fee Submitted	300000.0, 2024-05-21,
	The proposed proprietary name / brand name	Tranquiloze injection
	Label Claim	Used for induction and maintenance of anesthesia.
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	5's vial/box-As per SRO
	Shelf Life (Unit)	24 MonthStore below 25°C and not frozen.
	For generic drugs (me-too Status)	Generic
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Jiangsu Yingke Biopharmaceuticals Co., Ltd- building 41 no. 801 Jiankang Avenue, Taizhou, Jiagnsu, China-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	M/s ABM HK ENTERPRISES (PVT) LTD, 2nd Floor, Plaza 60, Commercial Block-K, Phase-1,DHA, Lahore, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	FDA
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board	

	Decision	
	Approved	
	Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy.	
61	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. (05-352-0058-104514D)
	Application Form Dy. No / Tracking ID & date of submission	(P4Y-3DZ-W9YY, 2024-08-26)
	Detail of Fee Submitted	300000.0, 2024-08-22,
	The proposed proprietary name / brand name	Amocillin Capsules
	Label Claim	used against bacterial infections.
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10 capsules per blis-Controlled
	Shelf Life (Unit)	36 MonthDo not store above 30°C.
	For generic drugs (me-too Status)	Generic
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	CSPC Zhongnuo Pharmaceutical(Shijiazhuang) Co., Lt-No.88 Yangzi Road, Economic and Technological Development Zone, Shijiazhuang, Hebei, China-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	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):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	FDA
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
	Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy.	
62	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. (05-352-0058-104514D)
	Application Form Dy. No / Tracking ID & date of submission	(6YW-633-E2S9, 2024-09-30)
	Detail of Fee Submitted	300000.0, 2024-09-19,

	The proposed proprietary name / brand name	Ertanex Injection
	Label Claim	Used as Antibiotic to treat certain serious infections, including pneumonia and urinary tract, skin, diabetic foot, gynecological, pelvic, and abdominal (stomach area) infections, that are caused by bacteria
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	As per SRO-Controlled
	Shelf Life (Unit)	24 MonthStore below25 °C. Keep the vial in the outer container
	For generic drugs (me-too Status)	Generic
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	CSPC Ouyi Pharmaceutical Co., Ltd-No.88 Yangzi Road, Economic and Technological Development Zone, Shijiazhuang, Hebei, China - China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	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):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	FDA
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
	Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy.	
63	Case Category	Routine (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan (01-374-0006-118530D)
	Application Form Dy. No / Tracking ID & date of submission	(18U-VDE-WQ8H, 2024-04-19)
	Detail of Fee Submitted	300000.0, 2024-02-02,
	The proposed proprietary name / brand name	Zaxol-30
	Label Claim	Zaxol-30 (Paclitaxel Injection USP 30mg/5ml) Each ml contains: Paclitaxel USP.....6mg Polyoxyl 35 Castor Oil USNF 527mg Dehydrated alcohol BP..... 49.7%5v/v
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's vial packing-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C,Protect from light
	For generic drugs (me-too Status)	MAH: Novartis Pharma (Pakistan) Limited Brand Name: Paclitaxel Ebewe 30Mg/5Ml Concentrate for Solution for Infusion. Composition: Each 5ml

		vial contains:-Paclitaxel_ 30 mg Registration Number: 084814
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Zuvius Lifesciences Pvt. Ltd.-At.Kharuni-Lodhimajra Road,Vill.Nandpur, Baddi,Distt Solan, Himachal Pradesh-173205-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	Lab Diagnostic Systems (SMC) Pvt. Ltd., 36-A,PSIC,SIE, Taxila, Rawalpindi, Pakistan, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Taxol by Bristol-Myers Squibb CompanyPrinceton, NJ 08543 USA--FDA Approved.
	Evaluation Remarks	
	M/s Zuvius Lifesciences (Pvt.) Limited has a loan license in India	
	Decision	
	Not Applicable	
	As product has already been approved in 336th meeting of Registration Board.	
64	Case Category	Routine (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Merixil Pharma Office 28, 2nd Floor, Rose Plaza , I-8 Markaz (DHO-ISB-1745)
	Application Form Dy. No / Tracking ID & date of submission	(9XZ-5YZ-HW3G, 2026-02-10)
	Detail of Fee Submitted	313500, 2025-12-02,
	The proposed proprietary name / brand name	APACROSS 5MG/ML
	Label Claim	Each Vial Contain Paclitaxel Albumin 100 mg/20ml, 5MG/ML POWDER FOR DISPERSION FOR INFUSION (formulated as albumin bound nanoparticles)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1`s-Controlled
	Shelf Life (Unit)	30 MonthBELOW 30 C
	For generic drugs (me-too Status)	PACLINAB 100MG
	Pharmacotherapeutic Group of (API)	ATC code : L01CD01, (ANTINEOPLASTIC AGENTS)
	Name, address of Manufacturing site:	Sichuan Huiyu Pharmaceutical Co., Ltd-Building 3, No333 Hanyang Road, Shizhang District, Neijiang, Sichuan,-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached
	Name, address of Marketing Authorization Holder:	SEACROSS PHARMACEUTICALS LIMITED, BEAUMONT BUSINESS CENTRES, 6 SNOW HILL, LONDON, EC1A 2AY,, United Kingdom
	Details of Certificates (CoPP/FSC/cGMP):	Complined
	Details of Authorization Letter :	N/A

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached
	The status in reference regulatory authorities	US FDA/MHRA/EMA-ABRAXANE Injection
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
	Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy.	
65	Case Category	Import (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan (01-374-0006-118530D)
	Application Form Dy. No / Tracking ID & date of submission	(R7W-NU4-X3TA, 2024-04-19)
	Detail of Fee Submitted	300000.0, 2024-02-02,
	The proposed proprietary name / brand name	Zaxol-100
	Label Claim	Zaxol-100 (Paclitaxel Injection USP 100mg/16.7ml) Each ml contains: Paclitaxel USP... 6mg Polyoxyl 35 castor oil USNF.... 527mg Dehydrated Alcohol BP....49.7%v/v
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's vial packing-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 30°C. Keep the vial in the outer carton, in order to protect from light.
	For generic drugs (me-too Status)	MAH: Novartis Pharma (Pakistan) Limited Brand Name: Paclitaxel Ebewe 100mg/16.7ml Concentrate for Solution for Infusion. Composition: Each 16.7ml vial contains: Paclitaxel 100mg Registration Number: 0
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Zuvius Lifesciences Pvt. Ltd.-At-Kharuni - Lodhimajra Road, Vill. Nandpur , Disst. Solan(H.P)-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	Lab Diagnostic Systems (SMC) Pvt. Ltd., 36-A,PSIC,SIE, Taxila, Rawalpind, Pakistan, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Taxol by Bristol-Myers Squibb CompanyPrinceton, NJ 08543 USA--FDA Approved.
	Evaluation Remarks	
	M/s Zuvius Lifesciences (Pvt.) Limited has a loan license in India	
	Decision	

	Not Applicable	
	As product has already been approved in 336th meeting of Registration Board.	
66	Case Category	Routine (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan (01-374-0006-118530D)
	Application Form Dy. No / Tracking ID & date of submission	(Z23-245-8R24, 2024-04-19)
	Detail of Fee Submitted	300000.0, 2024-02-02,
	The proposed proprietary name / brand name	Zaxol-300
	Label Claim	Zaxol-300 (Paclitaxel Injection USP 300mg/50ml) Each ml contains: Paclitaxel USP.....6mg Polyoxyl 35 Castor oil USNF.....527mg Dehydrated alcohol BP..... 49.7%v/v
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's vial packing-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 30°C. Keep the vial in the outer carton, in order to protect from light.
	For generic drugs (me-too Status)	MAH: Novartis Pharma (Pakistan) Limited Brand Name: Paclitaxel Ebewe 300Mg/5Ml Concentrate for Solution for Infusion. Composition: Each 50ml vial contains: - Paclitaxel_ 300 mg Registration Number: 07
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Zuvius Lifesciences Pvt. Ltd.-At.Kharuni-Lodhimajra Road,Vill.Nandpur, Baddi, Distt Solan, Himachal Pradesh-173205-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	Lab Diagnostic Systems (SMC) Pvt. Ltd., 36-A,PSIC,SIE, Taxila, Rawalpind, Pakistan, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	. Taxol by Bristol-Myers Squibb Company Princeton, NJ 08543 USA -- FDA Approved
	Evaluation Remarks	
	M/s Zuvius Lifesciences (Pvt.) Limited has a loan license in India	
	Decision	
	Not Applicable	
	Already approved in 336th meeting of Registration Board.	
67	Case Category	Priority As Per 257-M of RB (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	AJ Mirza Pharma Pvt Ltd 1st Floor, Shafi Court, Merewether Road, Civil Lines. Karachi–Pakistan. (235)

	Application Form Dy. No / Tracking ID & date of submission	(PYM-3A6-611X, 2025-09-12)
	Detail of Fee Submitted	313500.0, 2025-08-15,
	The proposed proprietary name / brand name	PALBOCICLIB-QILU
	Label Claim	Each Capsule contains: Palbociclib 125mg
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	21's Bottle -As per SRO
	Shelf Life (Unit)	24 MonthStore below 30°C.
	For generic drugs (me-too Status)	Ibrance 125mg Capsule
	Pharmacotherapeutic Group of (API)	A Kinase Inhibitors
	Name, address of Manufacturing site:	Qilu Pharmaceutical Co., Ltd.-8888 Lvyou Road, High-tech Zone, Jinan, Shandong 250104-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Available
	Name, address of Marketing Authorization Holder:	A.J. Mirza Pharma (Pvt.) Ltd., PLOT NO. 44, SECTOR NO. 27, KORANGI INDUSTRIAL AREA, KARACHI, Korangi Korangi Town, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	GMP Inspection complaince
	Details of Authorization Letter :	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated stability study ($40 \pm 2^{\circ}\text{C}$ / $75\%\text{RH} \pm 5\%$) of 6 months & Long-term stability study ($30 \pm 2^{\circ}\text{C}$ / $65\%\text{RH} \pm 5\%$) of 36 months
	The status in reference regulatory authorities	USFDA
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
	Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy.	
68	Case Category	Priority As Per 257-M of RB (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	AJ Mirza Pharma Pvt Ltd 1st Floor, Shafi Court, Merewether Road, Civil Lines. Karachi–Pakistan. (235)
	Application Form Dy. No / Tracking ID & date of submission	(SLX-UDT-EV2L, 2025-09-12)
	Detail of Fee Submitted	313500.0, 2025-08-15,
	The proposed proprietary name / brand name	PALBOCICLIB-QILU
	Label Claim	Each Capsule contains: Palbociclib 100mg
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	21's Bottle-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30°C.
	For generic drugs (me-too Status)	Ibrance 100mg Capsule
	Pharmacotherapeutic Group of (API)	A Kinase Inhibitors
	Name, address of Manufacturing site:	Qilu Pharmaceutical Co., Ltd.-8888 Lvyou Road, High-tech Zone, Jinan, Shandong 250104, China-China

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Available
	Name, address of Marketing Authorization Holder:	A.J. Mirza Pharma (Pvt.) Ltd., PLOT NO. 44, SECTOR NO. 27, KORANGI INDUSTRIAL AREA, KARACHI, Korangi Korangi Town, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	GMP Inspection complaince
	Details of Authorization Letter :	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated stability study ($40 \pm 2^{\circ}\text{C}$ / $75\%\text{RH} \pm 5\%$) of 6 months & Long-term stability study ($30 \pm 2^{\circ}\text{C}$ / $65\%\text{RH} \pm 5\%$) of 24 months
	The status in reference regulatory authorities	USFDA
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
	Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy.	
69	Case Category	Priority As Per 257-M of RB (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Al Habib Pharmaceuticals. Plot 81 SMCHS BLOCK B (0414)
	Application Form Dy. No / Tracking ID & date of submission	(7QB-PLT-28TP, 2026-02-04)
	Detail of Fee Submitted	300000.0, 2025-07-23,
	The proposed proprietary name / brand name	IPALXANE
	Label Claim	Each capsule contains: Palbociclib.....125mg
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	7s, 21s, 7x3-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30
	For generic drugs (me-too Status)	Product Name: Palbonix 125mg Capsule Company Name: Beacon Pharmaceuticals, Bangladesh (Imported by: HIMMEL PHARMACEUTICALS (PVT.) LTD) Dosage Form: Capsule Label Claim: Each capsule contains: Palbocic
	Pharmacotherapeutic Group of (API)	Cdymax (India) Pharma Private Limited, ADDRESS: No. 116/117, KIADB Industrial Area, Jigani, Bangalore - 560 105. Karnataka, India. DUNS number: 91-651-2426 FEI Number: 3009882550
	Name, address of Manufacturing site:	Eczane Pharma S.A.- Laprida 43 – Avellaneda – Buenos Aires – Argentina (CP1870), GMP Certificate in Argentina 9084/2022-Argentina
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached
	Name, address of Marketing Authorization Holder:	Al Habib Pharmaceuticals , Address Plot # 81, Block B, SMCHS, Karachi,74400 – PAKISTAN, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Attached
	Details of Authorization Letter :	Attached

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached
	The status in reference regulatory authorities	IBRANCE (Palbociclib) 125mg Capsule , (NDA): 207103 Company: PFIZER
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
	Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy.	
70	Case Category	Import (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Bristol Mayer Biotech Pakistan 73 B Guldasht Town Zarrar Shaheed Lahore (05-352-0068-109282D)
	Application Form Dy. No / Tracking ID & date of submission	(8AT-XZ9-WW3H, 2024-09-24)
	Detail of Fee Submitted	300000.0, 2024-09-18,
	The proposed proprietary name / brand name	Evrongest
	Label Claim	Each film coated tablet contains: Progesterone USP.....200 mg (Natural Micronized)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's containing 10 ta-As per SRO
	Shelf Life (Unit)	24 MonthStore at a temp below 30°C, protect from light
	For generic drugs (me-too Status)	Luteina 200mg Tablet
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	ACCENT PHARMACEUTICALS & DIAGNOSTICS-Vill. Bhalon (Seri), Forest Road, Solan-173212 Himachal Pradesh, India-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	ACCENT PHARMACEUTICALS & DIAGNOSTICS, Vill. Bhalon (Seri), Forest Road, Solan-173212 Himachal Pradesh, 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	Finnish Medicine Agency (Finland) Approved Lutinus by Ferring
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
	Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy.	

71	Case Category	Import (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Bristol Mayer Biotech Pakistan 73 B Guldasht Town Zarrar Shaheed Lahore (05-352-0068-109282D)
	Application Form Dy. No / Tracking ID & date of submission	(ZTW-WZ2-WW5V, 2024-12-24)
	Detail of Fee Submitted	300000.0, 2024-12-19,
	The proposed proprietary name / brand name	FCOZ 150
	Label Claim	Each Uncoated tablet contains: Fluconazole USP 150 mg Excipients q.s.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's (1 Tablet)-As per SRO
	Shelf Life (Unit)	36 MonthStore below 30°C
	For generic drugs (me-too Status)	Fonaz 150mg Tablet
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	ACCENT PHARMACEUTICALS & DIAGNOSTICS-Vill. Bhalon(Seri), P.O. Galanag Forest Road, Solan-173212, Himachal Pradesh, India-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	ACCENT PHARMACEUTICALS & DIAGNOSTICS, Vill. Bhalon(Seri), P.O. Galanag Forest Road, Solan-173212, Himachal Pradesh, India, India
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	FDA Approved (DIFLUCAN 150 mg Tablet)
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board	
72	Decision	
	Approved	
	Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy.	
	Case Category	Import (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Bristol Mayer Biotech Pakistan 73 B Guldasht Town Zarrar Shaheed Lahore (05-352-0068-109282D)
	Application Form Dy. No / Tracking ID & date of submission	(UQ3-XXJ-GU4S, 2024-11-13)
	Detail of Fee Submitted	300000.0, 2024-08-29,
	The proposed proprietary name / brand name	ACCECABO
	Label Claim	Each Uncoated Tablet contains: Cabergoline USP.....0.5 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's containing 4 Tab-As per SRO

	Shelf Life (Unit)	24 MonthStore at a temperature not exceeding 30°C
	For generic drugs (me-too Status)	N/A
	Pharmaceutical Group of (API)	
	Name, address of Manufacturing site:	ACCENT PHARMACEUTICALS & DIAGNOSTICS- Vill. Bhalon(Seri), P.O. Galanag Forest Road, Solan-173212, Himachal Pradesh, India-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	ACCENT PHARMACEUTICALS & DIAGNOSTICS, Vill. Bhalon(Seri), P.O. Galanag Forest Road, Solan-173212, Himachal Pradesh, India, India
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Dostinex 0.5 mg tablets (Pfizer Limited)
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
	Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy.	
73	Case Category	Import (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Bristol Mayer Biotech Pakistan 73 B Guldasht Town Zarrar Shaheed Lahore (05-352-0068-109282D)
	Application Form Dy. No / Tracking ID & date of submission	(TVB-2MG-1AL8, 2024-09-30)
	Detail of Fee Submitted	300000.0, 2024-09-18,
	The proposed proprietary name / brand name	Evona L
	Label Claim	Each Uncoated Tablet contains: Levonorgestrel BP 0.15mg Ethinylestradiol BP..... 0.03mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1x21's -As per SRO
	Shelf Life (Unit)	36 MonthStore below 30°C
	For generic drugs (me-too Status)	FAMILA 28
	Pharmaceutical Group of (API)	
	Name, address of Manufacturing site:	ACCENT PHARMACEUTICALS & DIAGNOSTICS-Vill. Bhalon (Seri), Forest Road, Solan-173212 Himachal Pradesh, India-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	ACCENT PHARMACEUTICALS & DIAGNOSTICS, Vill. Bhalon(Seri), P.O. Galanag Forest Road, Solan-173212, Himachal Pradesh, India, India

	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	famhp (Belgium) Approved Asterluna Continu 30 by Exeltis Germany GmbH
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
	Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy.	
74	Case Category	Import (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Inaya International Plot # 08 Kahyaban e Rizwan Phase 7 DHA Karachi (331)
	Application Form Dy. No / Tracking ID & date of submission	(Z1N-8ZX-LVRD, 2024-08-21)
	Detail of Fee Submitted	300000.0, 2024-05-31,
	The proposed proprietary name / brand name	Gentamicin injection (generic name)
	Label Claim	Each 2ml contains: Gentamicin(as sulfate).....80mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100× 2ml ampoules-As per SRO
	Shelf Life (Unit)	3 YearRoom temperature
	For generic drugs (me-too Status)	Gentic 80 mg bosch pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Shandong Yikang Pharmaceutical Co., Ltd.-No. 3288, Yikang Avenue, Tengzhou City, Shandong Province, China -China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	Shandong Yikang Pharmaceutical Co., Ltd. , No. 3288, Yikang Avenue, Tengzhou City, Shandong Province, China , China
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Available MHRA UK
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
	Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy.	
75	Case Category	Import (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Inaya traders Flat No. 1, first floor, plot No. A-152, block 8, KAECHS, Karachi-Pakistan (0470)

	Application Form Dy. No / Tracking ID & date of submission	(5AV-YZE-GZBG, 2024-08-21)
	Detail of Fee Submitted	300000.0, 2024-07-04,
	The proposed proprietary name / brand name	Water for injection 5ml (generic name)
	Label Claim	Each ampoule contains: Water For Injection.....5 ml
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100× 5ml ampoules-As per SRO
	Shelf Life (Unit)	3 YearRoom temperature
	For generic drugs (me-too Status)	Water for injection (bosch pharma)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Xinxiang Changle Pharmaceutical Co., Ltd.-The Eastern Suburb of Huixian City, Henan Province-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	Xinxiang Changle Pharmaceutical Co., Ltd, The Eastern Suburb of Huixian City, Henan Province, China
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Available MHRA UK
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
	Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy.	
76	Case Category	Import (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Inaya traders Flat No. 1, first floor, plot No. A-152, block 8, KAECHS, Karachi-Pakistan (0470)
	Application Form Dy. No / Tracking ID & date of submission	(5DH-DRB-MWNP, 2024-09-18)
	Detail of Fee Submitted	300000.0, 2024-07-02,
	The proposed proprietary name / brand name	Dexamethasone injection(generic name)
	Label Claim	Each ml contains: Dexamethasone Sodium Phosphate U.S.P equivalent to Dexamethasone Phosphate..... 4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	25 ampoules-As per SRO
	Shelf Life (Unit)	3 YearRoom temperature
	For generic drugs (me-too Status)	Dexamethasone injection (venus pharma)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Xinxiang Changle Pharmaceutical Co., Ltd.-The Eastern Suburb of Huixian City, Henan Province-China

	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	Xinxiang Changle Pharmaceutical Co., Ltd, The Eastern Suburb of Huixian City, Henan Province, China
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Available MHRA UK
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
	Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy.	
77	Case Category	Import (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	AMB HK ENTERPRISES (PVT) LTD, LAHORE 2nd floor plaza 60, Commercial Block K, Phase-1 DHA, Lahore. (05-352-0058-104514D)
	Application Form Dy. No / Tracking ID & date of submission	(95Y-4LW-SLUQ, 2024-10-17)
	Detail of Fee Submitted	300000.0, 2024-10-15,
	The proposed proprietary name / brand name	SEVOCARE
	Label Claim	USED TO INDUCE AND MAINTAIN GENERAL ANESTHESIA
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	AS PER SRO -Controlled
	Shelf Life (Unit)	36 MonthSevoflurane should be stored in a tightly closed container NOT above 25°C.
	For generic drugs (me-too Status)	GENERIC
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Hebei Yipin Pharmaceutical Co., Ltd.-Sanxia road, Economy Technology Area of Shijiazhuang, Hebei, China-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	AMB HK ENTERPRISES(PVT)LTD, 2nd FLOOR PLAZA 60, COMMERCIAL BLOCK-K, PHASE-1 , DHA , LAHORE, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	FDA APPROVED
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board	
	Decision	

	Approved	
	Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy.	
78	Case Category	Import (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Himmel Pharmaceuticals Private Limited Ground Floor, 6- Judicial Colony phase-1 (Ext.) Shahrah Nazaria e Pakistan, (05-352-0065-016174D)
	Application Form Dy. No / Tracking ID & date of submission	(689-99S-AAN9, 2024-08-07)
	Detail of Fee Submitted	300000.0, 2024-07-15,
	The proposed proprietary name / brand name	Adozin 10 mg/2ml I.V. Solution for Injection and Infusion, Ampoule
	Label Claim	Each ml contains..... Adenosine 5mg (5mg/mL)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	36 MonthIt should be stored at room temperature below 25°C.
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	VEM İlaç San. ve Tic. A.Ş.-Çerkezköy Organize Sanayi Bölgesi Karaağaç Mahallesi Fatih Bulvarı No:38 Kapaklı/TEKİRDAĞ/TURKEY -Turkey
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	VEM İLAÇ San. ve Tic. A.Ş., Maslak Mahallesi AOS 55. Sokak 42 Maslak A Blok Sit. No: 2/134 Sarıyer/İSTANBUL/TÜRKİYE, Turkey
	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	Adenosin Life Medical 5mg/ml, Solution for Injection(Sweden)
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
	Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy.	
79	Case Category	Import (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Himmel Pharmaceuticals Private Limited Ground Floor, 6- Judicial Colony phase-1 (Ext.) Shahrah Nazaria e Pakistan, (05-352-0065-016174D)
	Application Form Dy. No / Tracking ID & date of submission	(EYN-6LD-Y156, 2024-08-22)

	Detail of Fee Submitted	300000.0, 2024-07-15,
	The proposed proprietary name / brand name	Adozin 3mg/ml I.V. Solution for Injection, Ampoule
	Label Claim	Each ml contains..... Adenosine 3mg (3mg/mL)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	36 MonthIt should be stored at room temperature below 25°C.
	For generic drugs (me-too Status)	Caden Injection 6mg/2ml (Adenosine)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	VEM İlaç San. ve Tic. A.Ş.-Çerkezköy Organize Sanayi Bölgesi Karaağaç Mahallesi Fatih Bulvarı No: 38 Kapaklı/TEKİRDAĞ/TURKEY-Turkey
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	Himmel Pharmaceuticals (Pvt.) Ltd, Ground Floor, 6-Judicial Colony, Phase 1 (Ext.), Shahrah Nazaria e Pakistan, Lahore, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Adrekar 3mg/mL Solution for Injection(Adenosine),(France)
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
	Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy.	
80	Case Category	Import (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Himmel Pharmaceuticals Private Limited Ground Floor, 6- Judicial Colony phase-1 (Ext.) Shahrah Nazaria e Pakistan, (05-352-0065-016174D)
	Application Form Dy. No / Tracking ID & date of submission	(ERU-7YQ-AHVS, 2024-09-05)
	Detail of Fee Submitted	300000.0, 2024-08-16,
	The proposed proprietary name / brand name	GRANSET 3mg/3 ml I.V. Solution for Infusion
	Label Claim	Each ml contains: 3mg of Granisetron
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5's-As per SRO
	Shelf Life (Unit)	24 MonthStore at room temperature below 25°C.
	For generic drugs (me-too Status)	Kytril 3mg/3ml I.V. Solution for Infusion(Granisetron Hydrochloride), (Martin Dow)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	VEM İlaç San. ve Tic. A.Ş.-Cercezkoy Organize Sanayi Bolgesi Karaagac Mahallesi Faith Bulvari

		No: 38 Kapakli/TEKIRDAG/TURKIYE-Turkey
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	VEM İlaç San. ve Tic. A.Ş., Maslak Mahallesi AOS 55. Sokak 42 Maslak A Blok Sit. No: 2/134 Sariyer/ISTANBUL/TURKIYE, Turkey
	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	Kytril 3mg/3ml I.V. Solution for Infusion(Granisetron Hydrochloride),(Roche Switzerland)
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
	Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy.	
81	Case Category	Import (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Getz Pharma (Pvt) Limited Plot No. 29-30, Sector-27, Korangi Industrial Area, Karachi, Pakistan (DSL 0655)
	Application Form Dy. No / Tracking ID & date of submission	(56W-MSB-5YXZ, 2024-10-02)
	Detail of Fee Submitted	300000.0, 2024-09-19,
	The proposed proprietary name / brand name	DMF
	Label Claim	Each Delayed release capsule contains: Dimethyl fumarate120mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-As per SRO,30's-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 30°C. Protect from sunlight and moisture.
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Amneal Pharmaceutical Private Limited-Plot No.: 882/1-871, Near Hotel Kankavati , Sarkhej - Bavla Highway, Village-Rajoda, Taluka – Bavla Dist. Ahmedabad, Gujrat. -India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	M/s Getz Pharma Private Limited, Plot No.: 29-30, Sector - 27, Korangi Industrial Area, Karachi, Pakistan, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	TECFIDERA (Dimethyl Fumarate) Delayed-Release Capsules 120mg by M/s Biogen Inc.

		Cambridge, UK (USFDA Approved).
	Evaluation Remarks	
	Firm has requested for withdrawal of applied product.	
	Decision	
	Rejected	
	Registration Board approved the firm requested for withdrawal of applied product.	
82	Case Category	Import (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Skymed Healthcare Private Limited House No:2, Gor-1 near Chamba House Lahore, Pakistan. (05-352-0063-038947D)
	Application Form Dy. No / Tracking ID & date of submission	(NSG-LXY-L7W5, 2024-08-21)
	Detail of Fee Submitted	75000.0, 225000.0 2023-11-03, 2024-02-16
	The proposed proprietary name / brand name	Ultan 2mg Injection
	Label Claim	Ultan 2mg Injection (Remifentanil Hydrochloride)
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	pack of 5 vials-As per SRO
	Shelf Life (Unit)	24 MonthStore at room temperature below 25 degrees.
	For generic drugs (me-too Status)	-
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Centurion Ilac San. Ve. Tic. AS.-Malikoy Baskent Organize Sanayi Bolgesi Mah. 19. Cad. No: 70/A Sincan/Ankara.-Turkey
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	Skymed Healthcare Private Limited, House no. 02, GOR-1 near Chamba House, Lahore, Pakistan., Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Turkish Medicine and Medical Devices Agency
	Evaluation Remarks	
	.	
	Decision	
	Approved	
	Approved subject to submission of the original legalized CoPP/GMP & FSC and ground clearance NOC from Ministry of Interior and Narcotics Control, and in accordance with the current import policy.	
83	Case Category	Import (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Skymed Healthcare Private Limited House No:2, Gor-1 near Chamba House Lahore, Pakistan. (05-352-0063-038947D)
	Application Form Dy. No / Tracking ID & date of submission	(SBP-RHY-R89D, 2024-07-05)

	Detail of Fee Submitted	150000.0, 150000.0 2023-11-16, 2024-02-16
	The proposed proprietary name / brand name	Skyfol Injection
	Label Claim	Propofol Injectable Emulsion 200mg/20ml.
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	pack of 5-As per SRO
	Shelf Life (Unit)	2 Year2 to 25 degree celsius
	For generic drugs (me-too Status)	Generic (Diprivan)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Guangdong Jiabo Pharmaceutical Co., Ltd.-Bio-Pharmaceutical Park, High & New Technology Development Zone, Qingyuan City, Guangdong Province, China.-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	Skymed Healthcare Private Limited, House no. 02, GOR-1 near Chamba House, Lahore, Pakistan., Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	NMPA
	Evaluation Remarks	
	.	
	Decision	
	Approved	
	Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy.	
84	Case Category	Priority As Per 257-M of RB (Saima Hussain)
	Name, address of Applicant.	Oncovanz Pharmaceuticals Private Limited C 52 Block 4 Gulshan e Iqbal (0418)
	Application Form Dy. No / Tracking ID & date of submission	(MD5-H5E-L63S, 2025-08-06)
	Detail of Fee Submitted	300000.0, 2025-05-30,
	The proposed proprietary name / brand name	Osivanz 80 Tablet
	Label Claim	•The adjuvant treatment after complete tumour resection in adult patients with stage IB-IIIa non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations. •The first-line treatment of adult patients with locally advanced or metastatic NSCLC with activating EGFR mutations. •The treatment of adult patients with locally advanced or metastatic EGFR T790M mutation-positive NSCLC.
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	30 Tablets is packed-As per SRO
	Shelf Life (Unit)	24 MonthStored at temperature below 30°C.

For generic drugs (me-too Status)	Tagrix Tablet 80mg
Pharmacotherapeutic Group of (API)	Antineoplastic agent-Protein Kinase Inhibitor
Name, address of Manufacturing site:	Ziska Pharmaceuticals Ltd.-Karolsurichala, Shafipur, Kaliakoir, Gazipur,Bangladesh - Bangladesh
Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached
Name, address of Marketing Authorization Holder:	Oncovanz Pharmaceuticals (Pvt.) Ltd, P Plot# C-52, Block 4,Gulshan-e-Iqbal, Karachi, Pakistan, Pakistan
Details of Certificates (CoPP/FSC/cGMP):	Valid & Legalized issued by regulatory body of Bangladesh
Details of Authorization Letter :	Attached
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated stability studies: 40°C±2°C/&75% ±5% and Long-term stability studies 25°C±2°C& 60%±5%.
The status in reference regulatory authorities	TAGRISSO Health Canada

Evaluation Remarks

Sr.no.	observations	Response of the Firm
1.	The applied product is in L01 group i.e. cytotoxic drug and as per decision of Registration Board in its 282nd meeting, “The manufacturing of cytotoxic drug shall be carried out in a dedicated or self-contained facilities and manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drug” Accordingly evidence of self-contained or dedicated facility of manufacturer abroad shall be submitted.	Firm in their reply stated that,Please be informed that Ziska Pharmaceuticals Ltd. operates in full compliance with GMP requirements and holds a valid GMP certificate issued by the relevant regulatory authority. The manufacturing site has established comprehensive Quality Management Systems and well-defined SOPs covering all critical operations, including production, cleaning, validation, personnel training, environmental monitoring, and cross-contamination control. Oncology products are manufactured within the general manufacturing facility; however, stringent GMP controls are implemented to ensure product quality and patient safety. Based on the above, although a physically separate oncology manufacturing block is not available, Ziska Pharmaceuticals Ltd. ensures safe and compliant manufacture of oncology products through validated processes and strict adherence to GMP and quality SOPs.

2.	Provide a scientifically justified rationale for including the overage of active ingredient in the applied formulation, supported by references to relevant international standards and guidelines, since the submitted reference along with reply is relevant to the setting of acceptance limit for assay test.	Firm in their reply refer section 3.2.P.2.2 in which it is mentioned that, “In our formulation of Osivanz 80 Tablet, we have included 2% overage of the active ingredient Osimertinib Mesylate. This decision is based on the need to maintain product efficacy throughout its shelf life. The overage compensates for the natural degradation or loss of potency of the active ingredient over time, ensuring that even at the end of its shelf life, the product still meets its required specifications”. The reply was submitted without any reference document which evident that the product undergoes the natural degradation or loss of potency of the active ingredient over time.
3.	Submit documentary evidence and appropriate references from applicable international guidelines in support of your declaration letter of using working standard procured from a supplier other than the API manufacturer for quality control testing of the drug product.	Firm in their reply stated that The working standard used for drug product testing was procured from a qualified supplier, Shandong Sihuan Pharmaceutical Co., Ltd., China (Batch No.: 2024080601), as attached. It was qualified against a reference standard from Shaoxing Hantai Pharmaceutical Co., Ltd., China (Batch No.: 230601), as attached, through appropriate characterization studies, thereby ensuring its suitability for the intended analytical use.
4.	Revise the acceptance criteria for the dissolution test to align with the innovator product. Additionally, submit the dissolution performance report evaluated against the revised acceptance criteria, including complete analytical data.	In their response firm submitted the Comparative dissolution profile report along with pharmaceutical equivalence report and analytical parameter with validation report of finished product in which the dissolution limit are NLT 70% (Q) in 45 minutes of labelled amount, which is different from acceptance limit of innovator product i.e. Q % at 30 minutes.

Decision

Rejected

The Registration Board has decided to reject the instant application for the following reasons:

1. The applied product belongs to the L01 group (L01EB04) as per the WHO Anatomical Therapeutic Chemical (ATC) classification system. As it is classified under cytotoxic/antineoplastic agents, its manufacturing shall be carried out in dedicated or self-contained facility. However, the Manufacturer Abroad does not possess a dedicated or self-contained facility for the production of the applied antineoplastic drug.
2. The manufacturer has included a 2% overage of the active ingredient in the formulation but has failed to provide a scientific justification for this addition. No supporting literature or evidence has been submitted to substantiate their claim that the active ingredient undergoes natural degradation or loss of potency over time, warranting such overage.
3. The Manufacturer has not adopted the dissolution acceptance criteria recommended by the innovator product (i.e., Q in 30 minutes). Instead, the manufacturer has set a dissolution limit of not less than (NLT) 70% (Q) in 45 minutes, without providing adequate scientific justification for this deviation.

85	Case Category	Priority As Per 257-M of RB (Saima Hussain)
	Name, address of Applicant.	ATCO LIFE SCIENCES (PRIVATE) LIMITED B-18 S.I.T.E. Karachi (051)

	Application Form Dy. No / Tracking ID & date of submission	(QQG-YMP-X68G, 2025-09-16)
	Detail of Fee Submitted	300000.0, 2025-07-07,
	The proposed proprietary name / brand name	DASATAB 100 Tablet
	Label Claim	Each film Coated Tablet Contains: Dasatinib 100 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3×10's -Controlled
	Shelf Life (Unit)	24 MonthNot Store and Transport above 30 degree centigrade.
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Antineoplastic agents, protein kinase inhibitors
	Name, address of Manufacturing site:	Eskayef Pharmaceuticals Limited-Murapara, Rupganj, Narayanganj 1464, Bangladesh.- Bangladesh
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence Study Report and Comparative Dissolution Profile performed against Sprycel (dasatinib) 100 mg film-coated tablets by Bristol-Myers Squibb Company
	Name, address of Marketing Authorization Holder:	Eskayef Pharmaceuticals Limited, Murapara, Rupganj, Narayanganj 1464, Bangladesh., Bangladesh
	Details of Certificates (CoPP/FSC/cGMP):	GMP attached
	Details of Authorization Letter :	Provided
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 Months Data of Accelerated Stability and 24 Months Data of Long-Term Stability attached in Module 03.
	The status in reference regulatory authorities	Sprycel (dasatinib) 100 mg film-coated tablets by Bristol-Myers Squibb Company US
	Evaluation Remarks	
	Firm submitted the CoPP certificate no. DGDA/ 6-214/15322 dated 28-08-2024 issued by Directorate General of Drug Administration Mohakhali,Dhaka,Bangladesh. Letter of Authorization submitted dated September 17, 2024, certify that M/s. ATCO Life Sciences (Private) Limited having registered office at B-18, S.I.T.E., Karachi-75700, Pakistan is the authorized agent of Eskayef Pharmaceuticals Limited situated at plot: 82, Road: 14, Block: B, Banani, Dhaka-I213, Bangladesh to register and sell the DASATAB 100 Film Coated Tablet products in the territory of Pakistan.	
	Decision	
	Approved	
	Approved as per policy of import for inspection of manufacturer abroad.	
86	Case Category	Import (Shahrukh Ali)
	Name, address of Applicant.	TJL Distribution No.2, SS Club Road, Peshawar KPK (8c-4v62c602)
	Application Form Dy. No / Tracking ID & date of submission	(53Y-EQG-J9QV, 2025-04-09)
	Detail of Fee Submitted	300000.0, 2025-02-06,
	The proposed proprietary name / brand name	Lifesol-RL
	Label Claim	Each 100ml contains : sodium chloride0.6g calcium chloride 2H2O.....0.027g. potassium chloride.....0.04 g. sodium lactate0.32g

	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	500mL-As per SRO
	Shelf Life (Unit)	3 Yearstore below 30 degree centigrade
	For generic drugs (me-too Status)	ringer lactate infusion
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	TJL pharmaceutical -parak sanati pul-e- charkhi-sarak-e-dispachary, street No-1 kabul city - Afghanistan
	Name & address of API manufacturer	source of finished product TJL pharmaceutical
	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/MHRA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Submitted for consideration by board as firm is importing the drug from Afghanistan, GMP and other certificates are issued by DGCS India. Stability chromatograms or other key parameters as required by CTD are not submitted.	
	Decision	
	Rejected	
	The board rejected the application as necessary documents submitted are not from the country of origin.	
87	Case Category	Import (Shahrukh Ali)
	Name, address of Applicant.	TJL Distribution No.2, SS Club Road, Peshawar KPK (8c-4v62c602)
	Application Form Dy. No / Tracking ID & date of submission	(5TN-174-P4B8, 2025-04-09)
	Detail of Fee Submitted	300000.0, 2025-02-06,
	The proposed proprietary name / brand name	Lifesol-para
	Label Claim	each 100ml contain : paracetamol1000mg/100ml
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	100mL-As per SRO
	Shelf Life (Unit)	2 Yearstore below 30 degree centigrade
	For generic drugs (me-too Status)	provas
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	TJL pharmaceutical -parak sanati pul-e- charkhi-sarak-e-dispachary, street No-1 kabul city - Afghanistan
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	TJL distributor , street SS club Arbab Road university Road peshawar, Pakistan

	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	USFDA
	Evaluation Remarks	
	Submitted for consideration by board as firm is importing the drug from Afghanistan, GMP and other certificates are issued by DGCS India. Stability chromatograms or other key parameters as required by CTD are not submitted.	
	Decision	
	Rejected	
	The board rejected the application as necessary documents submitted are not from the country of origin.	
88	Case Category	Import (Shahrukh Ali)
	Name, address of Applicant.	TJL Distribution No.2, SS Club Road, Peshawar KPK (8c-4v62c602)
	Application Form Dy. No / Tracking ID & date of submission	(122-VT3-4D4V, 2025-04-09)
	Detail of Fee Submitted	300000.0, 2025-02-04,
	The proposed proprietary name / brand name	Lifesol-G5
	Label Claim	Each 100ml contain: dextrose anhydrous5.0 g
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	500mL-As per SRO
	Shelf Life (Unit)	3 Yearstore below 30 degree centigrade
	For generic drugs (me-too Status)	5% glucose infusion
	Pharmaceutical Group of (API)	
	Name, address of Manufacturing site:	TJL pharmaceutical -parak sanati pul-e- charkhi-sarak-e-dispachary, street No-1 kabul city - Afghanistan
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	TJL distributor , street SS club Arbab Road university Road peshawar, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	USFDA/MHRA
	Evaluation Remarks	
	Submitted for consideration by board as firm is importing the drug from Afghanistan, GMP and other certificates are issued by DGCS India. Stability chromatograms or other key parameters as required by CTD are not submitted.	
	Decision	
	Rejected	
	registration board rejected the case as the exporting country is unable to provide GMP/ COPP and other key certifications to ensure safety and efficacy of manufacturing facility and submitted by third party DGCS India. Stability data submitted lacks key parameters as mentioned in CTD.	

89	Case Category	Import (Shahrukh Ali)
	Name, address of Applicant.	PUNJAB MEDICAL SERVICES 1st Floor, 6 - Judicial Colony (Extension) Shahrah Nzaria e Pakistan (05-352-0063-041061D)
	Application Form Dy. No / Tracking ID & date of submission	(5S5-94G-QS88, 2025-03-27)
	Detail of Fee Submitted	300000.0, 2024-12-18,
	The proposed proprietary name / brand name	Mazenil 0.5mg/5ml I.V. Solution for Injection, Ampoule
	Label Claim	Each Ampoule contains 0.5mg Flumazenil
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5's-As per SRO
	Shelf Life (Unit)	36 Year(s)Store below 30°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Benzodiazepine antagonist
	Name, address of Manufacturing site:	Vem Ilac San. ve Tic. A.S. -Cerkezko y Organize Sanayi Bolgesi Karaagac Mahallesi Fatih Bulvari No: 38 Kapakli/Tekirdag-Turkey
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Flumazenil Kabi 0.1 mg/ml Injektionlösung und Konzentrat zur Herstellung einer Infusionlösung, marketed by Fresenius Kabi Pharmaceutical,
	Name, address of Marketing Authorization Holder:	Vem Ilac San. ve Tic. A.S. , Maslak Mahallesi AOS 55. Sokak 42 Maslak A Blok Sit No: 2/134 Sariyer/Istanbul, Turkey
	Details of Certificates (CoPP/FSC/cGMP):	gmp valid till 7.11.25 copp valid till 27.5.26
	Details of Authorization Letter :	-
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-B
	The status in reference regulatory authorities	Flumazenil Kabi 0.5mg/5ml solution for injection, (0.1mg/ml), Austria
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
90	Decision	
	Approved	
	As per policy for inspection abroad.	
	Case Category	Import (Shahrukh Ali)
	Name, address of Applicant.	PUNJAB MEDICAL SERVICES 1st Floor, 6 - Judicial Colony (Extension) Shahrah Nzaria e Pakistan (05-352-0063-041061D)
	Application Form Dy. No / Tracking ID & date of submission	(Q3P-ZL2-8DYR, 2025-03-23)
	Detail of Fee Submitted	300000.0, 2024-12-18,
	The proposed proprietary name / brand name	Mazenil 1mg/10ml I.V. Solution for Injection, Ampoule
	Label Claim	Each ampoule contains....1mg of Flumazenil
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5's-As per SRO
	Shelf Life (Unit)	36 Year(s)Store below 30°C.

For generic drugs (me-too Status)	Anexate 1mg/10ml I.V. Solution for Injection (Flumazenil), Martin Dow
Pharmacotherapeutic Group of (API)	Benzodiazepine antagonist
Name, address of Manufacturing site:	VEM İlaç San. ve Tic. A.Ş.-Cerkezkoy Organize Sanayi Bolgesi Karaagac Mahallesi Fatih Bulvari No: 38 Kapakli/TEKIRDAG-Turkey
Pharmaceutical Equivalence and Comparative Dissolution Profile	Flumazenil Kabi 0.1 mg/ml Injektionlösung und Konzentrat zur Herstellung einer Infusionlösung, marketed by Fresenius Kabi Pharmaceutical,
Name, address of Marketing Authorization Holder:	VEM İlaç San. ve Tic. A.Ş., Maslak Mahallesi AOS 55. Sokak 42 Maslak A Blok Sit. No: 2/134 Sariyer/ISTANBUL, Turkey
Details of Certificates (CoPP/FSC/cGMP):	gmp valid till 7.11.25 copp valid till 27.5.26
Details of Authorization Letter :	-
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-B
The status in reference regulatory authorities	Flumazenil Kabi 1mg/10ml Solution for Injection, (0.1mg/ml), Austria
Evaluation Remarks	
"The application is complete as per codal formalities for consideration by the Registration Board"	
Decision	
Approved	
As per policy for inspection abroad.	



Drug Regulatory Authority of Pakistan

(Biological Evaluation & Research Division)



Item No. II Division of Biological Evaluation & Research

Sr. No	Title	Description
1	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	PUNJAB MEDICAL SERVICES 1st Floor, 6 - Judicial Colony (Extension) Shahrah Nzaria e Pakistan (05-352-0063-041061D)
	Application Form Dy. No / Tracking ID & date of submission	(35V-WH1-NA25, 2025-07-04)
	Detail of Fee Submitted	300000.0, 2025-06-26,
	The proposed proprietary name / brand name	Diparin
	Label Claim	Each 5ml vial contains: Heparin Sodium BP ...25000 IU
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1s-Free of Cost
	Shelf Life (Unit)	3 Year(s)Do not store above 25° C
	For generic drugs (me-too Status)	Vaxcel Heparin Sodium Injection of M/s Ghazali Brothers (Reg. No. 088528).
	Pharmacotherapeutic Group of (API)	anticoagulants ATC code: B01AB01
	Name, address of Manufacturing site:	Drug International Limited-31/1 Satrong Road, Gopalpur ,Tongi I/A, Ghazipur Bangladesh-Bangladesh
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Name, address of Marketing Authorization Holder:	Drug International Limited, 31/1 Satrong Road, Gopalpur ,Tongi I/A, Ghazipur Bangladesh, Bangladesh
	Details of Certificates (CoPP/FSC/cGMP):	The firm has submitted original, legalized CoPP (Certificate No. DGDA/6-235/2019/2159) dated 23/02/2025 issued by Ministry of Health and Family Welfare, Directorate General of Drug Administration, Bangladesh. The certificate confirms that the product is a
	Details of Authorization Letter :	Letter of Authorization is submitted by the firm issued on 19-05-2025.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated and real time conditions. The real time stability data is 30±2°C and relative humidity (RH) at 75±5%, the frequency of testing is every 3 months over the first year, every 6 months over the second year and then annually. The long term stability testing will last for 3 years. Accelerated is conducted at temperature at 40±2°C and relative humidity at 75±5% for accelerated testing, the time points are

		0, 1, 2, 3, and 6 months on 3 batches BHS200301, BHS200401, and BHS200402.
	The status in reference regulatory authorities	Heparin Rovi 25000IU/5ml MHRA approved
	Evaluation Remarks	
	The firm has submitted the required data. Case may be approved.	
	Decision	
	Approved	
	Registration Board approved the product subject to compliance of current import policy for finished products.	
2	Case Category	Import (M. Zubair Masood)
	Name, address of Applicant.	Getz Pharma (Pvt) Limited Plot No. 29-30, Sector-27, Korangi Industrial Area, Karachi, Pakistan (DSL 0655)
	Application Form Dy. No / Tracking ID & date of submission	(D5R-62X-RDBY, 2026-03-24)
	Detail of Fee Submitted	313500, 9400 2025-08-27, 2026-03-19
	The proposed proprietary name / brand name	GetRapid Solution for Injection 100 Units/ml in Prefilled Cartridge
	Label Claim	Each 3mL Cartridge contains: Insulin Aspart.....300Units
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	3ml x 1's cartridge-Controlled, 3ml x 5's cartridges-Controlled
	Shelf Life (Unit)	30 Year(s) Store in refrigerator at 2°C to 8°C. Do not freeze. Protect from direct light and heat.
	For generic drugs (me-too Status)	NovoRapid FlexPen (Insulin Aspart) Solution for Injection 100U/mL in Pre-filled Pen by M/s Novo Nordisk Pharma (Private) Limited, Pakistan.
	Pharmacotherapeutic Group of (API)	Insulins
	Name, address of Manufacturing site:	M/s Gan & Lee Pharmaceuticals-No. 8 Nanfeng West 1st Street, Huoxian, Tongzhou District, Beijing, China.-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Biosimilarity data is submitted.
	Name, address of Marketing Authorization Holder:	M/s Gan & Lee Pharmaceuticals, No. 8 Nanfeng West 1st Street, Huoxian, Tongzhou District, Beijing,, China
	Details of Certificates (CoPP/FSC/cGMP):	Scanned CoPP No. Beijing20250578 dated 18-11-2025.
	Details of Authorization Letter :	Scanned LOA dated 20-10-2025.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 Batches: GAPA20017, GAPA20018, GAPA20019 Realtime: 48 months at -25 to -18. Accelerated: 06 months at 2-8C.
	The status in reference regulatory authorities	NovoLog (Insulin Aspart) FlexPen 100 Units/ml Solution for Injection in Cartridge by M/s Novo Nordisk Inc, USA.
	Evaluation Remarks	
	.	
	Decision	

3	Approved	
	Keeping in view the legalized CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
3	Case Category	Import (M. Zubair Masood)
	Name, address of Applicant.	Getz Pharma (Pvt) Limited Plot No. 29-30, Sector-27, Korangi Industrial Area, Karachi, Pakistan (DSL 0655)
	Application Form Dy. No / Tracking ID & date of submission	(GQG-688-GEJB, 2026-03-24)
	Detail of Fee Submitted	313500, 2025-08-27,
	The proposed proprietary name / brand name	RapiMix 30 Suspension for Injection 100 Units/ml in Prefilled Cartridge
	Label Claim	Each 3mL Cartridge contains: Insulin Aspart (30%) + Insulin Aspart Protamine (70%).....300U nits
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3ml x 1's cartridge-Controlled, 3ml x 5's cartridges-Controlled
	Shelf Life (Unit)	24 Year(s) Store in refrigerator at 2°C to 8°C. Do not freeze. Protect from direct light and heat.
	For generic drugs (me-too Status)	NovoMix 30 FlexPen (Soluble Insulin Aspart 30% + Insulin Aspart crystallized with Protamine 70%) Suspension for Injection 100U/mL in Pre-filled Pen by M/s Novo Nordisk Pharma (Private) Limited, Pakistan
	Pharmacotherapeutic Group of (API)	Insulins
	Name, address of Manufacturing site:	M/s Gan & Lee Pharmaceuticals-No. 8 Nanfeng West 1st Street, Huoxian, Tongzhou District, Beijing, China.-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Biosimilarity data is submitted.
	Name, address of Marketing Authorization Holder:	M/s Gan & Lee Pharmaceuticals, No. 8 Nanfeng West 1st Street, Huoxian, Tongzhou District, Beijing,, China
	Details of Certificates (CoPP/FSC/cGMP):	Scanned CoPP No. Beijing20250577 dated 18-11-2025.
	Details of Authorization Letter :	Scanned LOA dated 20-10-2025.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 Batches: GAPA20017, GAPA20018, GAPA20019 Realtime: 48 months at -25 to -18. Accelerated: 06 months at 2-8C.
	The status in reference regulatory authorities	NovoLog Mix 70/30 (Insulin Aspart 30% + Insulin Aspart Protamine 70%) FlexPen 100 units/ml Suspension for Injection in Cartridge by M/s Novo Nordisk Inc, USA.
Evaluation Remarks		
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Decision		
Approved		

Keeping in view the legalized CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
4	Case Category
	New Molecule/Formulation (Muneeb Ahmed Cheema)
	Name, address of Applicant.
	Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan (01-374-0006-118530D)
	Application Form Dy. No / Tracking ID & date of submission
	(P93-TJE-3EH5, 2026-01-09)
	Detail of Fee Submitted
	313500, 2025-11-17,
	The proposed proprietary name / brand name
	CECOLIN 9®
	Label Claim
	Each dose (0.5 mL) contains: Recombinant Human Papillomavirus Type 6 L1 protein 30 µg Recombinant Human Papillomavirus Type 11 L1 protein 40 µg Recombinant Human Papillomavirus Type 16 L1 protein 60 µg Recombinant Human Papillomavirus Type 18 L1 protein 40 µg Recombinant Human Papillomavirus Type 31 L1 protein 20 µg Recombinant Human Papillomavirus Type 33 L1 protein 20 µg Recombinant Human Papillomavirus Type 45 L1 protein 20 µg Recombinant Human Papillomavirus Type 52 L1 protein 20 µg Recombinant Human Papillomavirus Type 58 L1 protein 20 µg
	Reference to Finished product specifications
	Any Other
	Proposed Pack Size
	10's-As per SRO
	Shelf Life (Unit)
	18 Year(s)Store at 2-8°C, protecting from light.
	For generic drugs (me-too Status)
	Not Applicable
	Pharmacotherapeutic Group of (API)
	Recombinant Human Papillomavirus 9-Valent (Types 6, 11, 16, 18, 31, 33, 45, 52, 58) Vaccine
	Name, address of Manufacturing site:
	Xiamen Innovax Biotech Co., Ltd.-No. 60, Shanbianhong East Road, Haicang District, Xiamen City, Fujian Province, China-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile
	NA
	Name, address of Marketing Authorization Holder:
	Xiamen Innovax Biotech Co., Ltd., No. 60, Shanbianhong East Road, Haicang District, Xiamen City, Fujian Province, China, China
	Details of Certificates (CoPP/FSC/cGMP):
	Details of Authorization Letter :
	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)
	Stability data of all 9 monovalent antigen bulks at accelerated and real time are provided.
	The status in reference regulatory authorities
	Gardasil 9 (9-valent HPV vaccine) Merck & Co. USFDA Approved
Evaluation Remarks	
Registration Board in its 353rd meeting deferred the case for comments of Federal Directorate of Immunization (FDI) regarding need of product for Pakistan. The FDI has forwarded their views which are reproduced as under: Public Health Burden in Pakistan Cervical cancer remains a significant public health concern in Pakistan. According to global cancer estimates (e.g., GLOBOCAN), cervical cancer ranks among the leading cancers affecting women in Pakistan, with a substantial number of new cases and deaths reported annually. Persistent infection with high-risk Human Papillomavirus (HPV) types, particularly types 16 and 18 is responsible for the majority of	

cervical cancer cases. In addition, other oncogenic HPV types (31, 33, 45, 52 and 58) also contribute to cervical cancer and other cancers, while types 6 and 11 are associated with genital warts. Current Immunization Landscape At present, HPV vaccination is not yet fully integrated into the Expanded Programme on Immunization (EPI) nationwide, although provincial initiatives and phasic introductions have been done in 2 provinces and 2 federating areas for the girls aged 9-14 years. The availability of additional HPV vaccine options in private sector could support to cover the additional age cohort. Added Value of 9-Valent Vaccine A 9-valent HPV vaccine provides broader protection against additional oncogenic HPV types compared to bivalent or quadrivalent vaccines. In the Pakistani context, where cervical cancer screening coverage remains limited and awareness is relatively low, broader strain coverage may offer enhanced preventive benefit. The inclusion of HPV types 31, 33, 45, 52, and 58 potentially increases protection against a greater proportion of cervical cancer cases, which may be particularly relevant in settings where genotyping data suggests circulation of multiple high-risk strains Conclusion Considering the burden of cervical cancer in Pakistan and the preventive potential of HPV vaccination, the availability of a 9-valent HPV vaccine in private sector may provide added public health benefit. Accordingly, from a public health standpoint, the vaccine may be considered beneficial for Pakistan, subject to regulatory evaluation of quality, safety and efficacy. Furthermore, the Federal Directorate of Immunization has introduced the Human Papillomavirus (HPV) Bivalent Vaccine (Cecolin), manufactured by Xiamen Innovax Biotech Co., Ltd., into the EPI schedule under a single-dose regimen, with the support of Gavi, the Vaccine Alliance. It is further submitted that, for vaccines eligible under Gavi support, it is mandatory that the product be prequalified by the World Health Organization. In this context, the case for registration of Cecolin 9 (Recombinant Human Papillomavirus 9-Valent [Types 6, 11, 16, 18, 31, 33, 45, 52, 58] Vaccine) may kindly be processed in accordance with the applicable rules and regulations of the Drug Regulatory Authority of Pakistan. The case was included in agenda of 354th meeting of Registration Board and deferred for deliberation in forthcoming meeting

Decision

Deferred

Registration Board deferred the case for following:

1. Number of doses manufactured since registration.
2. AEFIs reported to NRA/ Uppsala Monitoring Centre of WHO.
3. Status of application for WHO prequalification (if any).



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



Sr. No	Title	Description
5	Case Category	Import (M. Zubair Masood)
	Name, address of Applicant.	Getz Pharma (Pvt) Limited Plot No. 29-30, Sector-27, Korangi Industrial Area, Karachi, Pakistan (DSL 0655)
	Application Form Dy. No / Tracking ID & date of submission	(BGE-E39-Q3Q3, 2025-06-17)
	Detail of Fee Submitted	300000.0, 2025-04-17,
	The proposed proprietary name / brand name	Teniplas Injection 40mg Powder and Solvent for Injection
	Label Claim	(Lyophilized Powder Each vial contains: Tenecteplase.....40mg Solvent Each vial contains: Sterile Water for Injection.....10ml
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's vial + 10mL Ster-As per SRO
	Shelf Life (Unit)	24 Year(s)Do not store above 30°C. Protect from light
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Thrombolytic agent and a tissue plasminogen activator
	Name, address of Manufacturing site:	M/S. Hetero Biopharma Limited-Y.No.458 (Part), TSIIC Formulation Sez, Polepalle (Village), Jadcherla (Mandal), Mahabubnagar (Dist.), Telangana, India-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Biosimilarity data submitted.
	Name, address of Marketing Authorization Holder:	Getz Pharma (Pvt.) Limited , Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi – 74900, Pakistan , Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Scanned legalized CoPP dated 01-11-2021.
	Details of Authorization Letter :	Scanned LOA dated 22-11-2024.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: P8CRD2301, P8CRD2302 & P8CRD2303 Realtime at -20 for 24 months Accelerated at 2-8 for 06 months
	The status in reference regulatory authorities	Metylase (Tenecteplase) Injection 40mg by M/s Boehringer Ingelheim International GmbH,Germany
Evaluation Remarks		

1. As per submitted license of manufacturer & CoPP, the expiry of applied product is 12 months while firm has proposed 24 months shelf life. The firm has submitted a letter of extension in shelf life from regulatory authority of country of origin, the letter is not legalized.

Decision

Approved

Keeping in view the legalized CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs and submission of valid legalized approval of 24 months shelf life from country of origin.

Post Registration Variation Cases:

Case#01: Change of Source of API (Human Insulin Recombinant) for Ferulin-R Injection (Reg# 060432) applied by M/s BF Biosciences Limited, 5-KM Sundar Raiwind Road, Raiwind, Lahore.

The firm M/s BF Biosciences Limited has applied for change of source of API from M/s MJ Biopharm Private Limited INDIA to M/s Tonghua Dongbao Pharmaceutical Co., Ltd.---Dongbao New Village, Tonghua County, Tonghua, Jilin, China for their following product in PRV on e-app vide tracking ID: 9MG-X1U-W79P.

Reg. No.	Brand Name & Composition	Pack Size	Approved shelf life
060432	Ferulin-R Injection Each ml contains: Insulin Human.....100IU (BP Specifications)	10ml	2 years

As Insulin is rDNA protein, so complete data as per following WHO guidelines is required;

“Guidelines on the quality, safety and efficacy of biotherapeutic protein products prepared by recombinant DNA technology”.

The case was deferred in 354th meeting for biosimilarity data.

Remarks by DBE&R:

Firm has submitted following data;

1. Physicochemical characterization against Innovator's Reference product, Humulin R was conducted by the drug substance manufacturer. The conclusion was as under;
“The Regular Human Insulin manufactured by Tonghua Dongbao Pharmaceutical Co. Ltd. (TF0102, TF0103, TF0104) is consistent and comparable to the Innovator's Reference Product, Humulin R Regular batch (C959486P) from Eli Lilly in terms of physical, chemical purity and structural similarity”
2. Process related impurities and product related impurities (including High molecular weight proteins (HMWP) with molecular masses greater than that of insulin) performed by proposed drug substance manufacturer on the drug substance.
3. VERIFICATION OF THE BIOLOGICAL EFFECTS OF RECHON INSULIN HUMAN SOLUBLE AND HUMULIN® REGULAR.
4. Ferulin® R Bioassay Report by LUMS.
5. Clinical Verification Report on Effectiveness and Safety of Short-acting Gansulin Injection in the Treatment of Diabetes Mellitus. The test drug was Gene Recombinant short-acting Human Insulin Injection (Gansulin R) and the control drug was Humulin R.

Decision:

Registration Board approved source of the drug substance M/s Tonghua Dongbao Pharmaceutical Co., Ltd., Dongbao New Village, Tonghua County, Tonghua, Jilin, China, for already registered product Ferulin-R Reg.No.060432.

The Board also approved the following requirements for drug substance import, local manufacturing of rDNA products:

- **Comprehensive comparative characterization of the drug substance against the innovator product.**
- **Complete quality comparison of the product manufactured using the proposed drug substance with the innovator product, to be conducted by the drug substance manufacturer.**
- **Complete quality comparison of the product manufactured by the local manufacturer using the proposed drug substance with the innovator product.**
- **Submission of clinical trial data and/or PK/PD studies performed in the country of origin using the same drug substance, demonstrating comparability of the product with the innovator.**

Case#02: Change of Source of API (Human Insulin Recombinant) for Ferulin-N Injection (Reg# 060433) applied by M/s BF Biosciences Limited, 5-KM Sundar Raiwind Road, Raiwind, Lahore.

The firm M/s BF Biosciences Limited has applied for change of source of API from M/s MJ Biopharm Private Limited INDIA to M/s Tonghua Dongbao Pharmaceutical Co., Ltd.---Dongbao New Village, Tonghua County, Tonghua, Jilin, China for their following product in PRV on e-app vide tracking ID: 93U-H5N-HE8J.

Reg. No.	Brand Name & Composition	Pack Size	Approved shelf life
060433	Ferulin-N Injection Each ml contains: Insulin Human.....100IU (BP Specifications)	10ml	2 years

As Insulin is rDNA protein, so complete data as per following WHO guidelines is required;

“Guidelines on the quality, safety and efficacy of biotherapeutic protein products prepared by recombinant DNA technology”.

The case was deferred in 354th meeting for biosimilarity data.

Remarks by DBE&R:

Firm has submitted following data;

1. Physicochemical characterization against Innovator’s Reference product, Humulin N- Isophane suspension was conducted by the drug substance manufacturer. The conclusion was as under;
“The Regular Human Insulin manufactured by Tonghua Dongbau Pharmaceutical Co. Ltd. (TF0102, TF0103, TF0104) is consistent and comparable to the Innovator’s Reference Product, Humulin R Regular batch (C959486P) from Eli Lilly in terms of physical, chemical purity and structural similarity”
2. Process related impurities and product related impurities (including High molecular weight proteins (HMWP) with molecular masses greater than that of insulin) performed by proposed drug substance manufacturer on the drug substance.
3. VERIFICATION OF THE BIOLOGICAL EFFECTS OF GANSULIN N AND HUMULIN® N
4. Ferulin® N Bioassay Report by LUMS.
5. Clinical Verification Report on Effectiveness and Safety of Gansulin N in the Treatment of Diabetes Mellitus. The test drug was Gene Recombinant short-acting Human Insulin Injection (Gansulin N) and the control drug was Humulin N.

Decision:

Registration Board approved the change of source of the drug substance from MJ Biopharm Private Limited, India, to M/s Tonghua Dongbao Pharmaceutical Co., Ltd., Dongbao New Village, Tonghua County, Tonghua, Jilin, China, for already registered product Ferulin-N Reg.No.060433. The Board also approved the following requirements for drug substance import, local manufacturing of rDNA products:

- Comprehensive comparative characterization of the drug substance against the innovator product.
- Complete quality comparison of the product manufactured using the proposed drug substance with the innovator product, to be conducted by the drug substance manufacturer.
- Complete quality comparison of the product manufactured by the local manufacturer using the proposed drug substance with the innovator product.
- Submission of clinical trial data and/or PK/PD studies performed in the country of origin using the same drug substance, demonstrating comparability of the product with the innovator.

Case#03: Change of Source of API (Human Insulin Recombinant) for Ferulin 70/30 Injection (Reg# 060434) applied by M/s BF Biosciences Limited, 5-KM Sundar Raiwind Road, Raiwind, Lahore.

The firm M/s BF Biosciences Limited has applied for change of source of API from M/s MJ Biopharm Private Limited INDIA to M/s Tonghua Dongbao Pharmaceutical Co., Ltd.---Dongbao New Village, Tonghua County, Tonghua, Jilin, China for their following product in PRV on e-app vide tracking ID: ZH6-ZSH-63JJ.

Reg. No.	Brand Name & Composition	Pack Size	Approved shelf life
060434	Ferulin 70/30 Injection Each ml contains: Insulin (Biphasic Isophane 70/30).....100IU (BP Specifications)	10ml	2 years

As Insulin is rDNA protein, so complete data as per following WHO guidelines is required;

“Guidelines on the quality, safety and efficacy of biotherapeutic protein products prepared by recombinant DNA technology”.

The case was deferred in 354th meeting for biosimilarity data.

Remarks by DBE&R:

Firm has submitted following data;

1. Physicochemical characterization against Innovator’s Reference product, Humulin 70/30- Biphasic Suspension was conducted by the drug substance manufacturer. The conclusion was as under;
“The Biphasic Human Insulin 70/30 (Suspension) manufactured by Tonghua Dongbau Pharmaceutical Co. Ltd. (TF0108, TF0109, TF0110) is consistent and comparable to the Innovator’s Reference Product, Humulin 70/30- Biphasic Suspension batch (C107637L) from Eli Lilly in terms of physical, chemical purity and structural similarity.”
2. Process related impurities and product related impurities (including High molecular weight proteins (HMWP) with molecular masses greater than that of insulin) performed by proposed drug substance manufacturer on the drug substance.
3. VERIFICATION OF THE BIOLOGICAL EFFECTS OF GANSULIN 30 AND HUMULIN® 70/30.
4. Ferulin® 70/30 Bioassay Report by LUMS.
5. A multi-center, randomized, open-label and controlled clinical study to compare the efficacy and safety between Ganshulin 30R and Novolin 30R in the treatment of diabetes mellitus.

Decision:

Registration Board approved the change of source of the drug substance from MJ Biopharm Private Limited, India, to M/s Tonghua Dongbao Pharmaceutical Co., Ltd., Dongbao New Village, Tonghua County, Tonghua, Jilin, China, for already registered product Ferulin-70/30 Injection Reg.No.060434.

The Board also approved the following requirements for drug substance import, local manufacturing of rDNA products:

- **Comprehensive comparative characterization of the drug substance against the innovator product.**
- **Complete quality comparison of the product manufactured using the proposed drug substance with the innovator product, to be conducted by the drug substance manufacturer.**
- **Complete quality comparison of the product manufactured by the local manufacturer using the proposed drug substance with the innovator product.**
- **Submission of clinical trial data and/or PK/PD studies performed in the country of origin using the same drug substance, demonstrating comparability of the product with the innovator.**

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

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