

**MINUTES OF 356TH MEETING OF REGISTRATION BOARD
TO BE HELD ON 07TH APRIL, 2026**

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

356th meeting of Registration Board was held on 07th April, 2026 in the Committee Room, Drug Regulatory Authority of Pakistan, Prime Minister's National Health Complex Park Road, Chak Shehzad, Islamabad.

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

The meeting was attended by the following:

1.	Malik Muhammad Saleem, Ex Deputy Manager Production. Rhone Poulenc Rorer Pakistan, Rawalpindi.	Member (Virtual)
2.	Dr. Syed Asad Ali Shah, Principal Animal Husbandry In-Service Training Institute, Peshawar.	Member (Virtual)
3.	Dr. Tehseen Fatima, Dow College of Biotechnology, Dow University of Health Sciences, Karachi.	Member (Virtual)
4.	Dr. Ali Jan, Director, Drugs Testing Laboratory, Govt. of Baluchistan Quetta.	Member (Virtual)
5.	Mr. Imranullah Khan, Director Drugs Testing Laboratory, Govt. of Khyber Pakhtunkhuwa, Peshawar.	Member (Virtual)
6.	Syed Adnan Rizvi, Director Drugs Testing Laboratory, Govt. of Sindh, Karachi.	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

Mr. Nadeem Alamgir (Pharma Bureau), Mr. Umer Farooq (PPMA) and Dr. Shahnawaz (PCDA) attended the meeting as observers.

Item No. I Confirmation of Minutes of Registration Board meetings.

a. Minutes 354th meeting of Registration Board

354th meetings of Registration Board were held on 04th – 05th March, 2026. Accordingly, draft minutes of the 354th meeting of Registration Board were prepared and circulated among the members through email for their perusal / approval / comments (if any). All members agreed to the draft minutes. Accordingly, fair minutes of 354th meeting were processed to Chairman, Registration Board for perusal/approval. After approval from Chairman Registration Board, fair minutes of 354th meeting of Registration Board were circulated among concerned divisions/sections for implementation.

b. Minutes 355th meeting of Registration Board

355th meetings of Registration Board were held on 25th March, 2026. Accordingly, draft minutes of the 355th meeting of Registration Board were prepared and circulated among the members through email for their perusal / approval / comments (if any). All members agreed to the draft minutes. Accordingly, fair minutes of 355th meeting were processed to Chairman, Registration Board for perusal/approval. After approval from Chairman Registration Board, fair minutes of 355th meeting of Registration Board were circulated among concerned divisions/sections for implementation.

Decision: Registration Board confirmed the minutes of 354th and 355th meeting.

S. No.	CASE TITLE
1.	Substandard Imcomox For Oral Suspension 60ml, Reg. No. 013756 Batch No # 029 And Imcodal Oral Suspension Reg. No. 013363 Batch No # 013 Manufactured By M/S Imco Pharmaceutical Labs, Industrial Estate Hayatabad, Peshawar
2.	Substandard Zolint Suspension, Reg. No. 016494 Batch No # 25024 Manufactured By M/s Libra (Private) Limited
3.	Manufacture & Sale Of Sub-Standard Pedolil Suspension Batch No. 167 Manufactured By M/s JASM Pharmaceuticals (Pvt) Ltd., Risalpur
4.	Manufacture & Sale Of Sub-Standard CB-Get Powder For Suspension Batch No. D-346 Manufactured By M/S Iceberg Pharmaceuticals (Pvt.) Ltd., Risalpur, KPK-Pakistan
5.	Manufacture & Sale Of Sub-Standard Awahaem Tablets Batch No. 2781 Manufactured By M/S Usawa Pharmaceuticals (Pvt) Ltd., Risalpur
6.	Manufacture & Sale Of Sub-Standard Fenbar Tablets Batch No. 2752 Manufactured By M/S Usawa Pharmaceuticals (Pvt) Ltd., Risalpur
7.	Substandard Zayzine Syrup Batch No. 25289, Reg No. 096969 Manufactured By M/S Zaynoon Pharmaceuticals (Pvt) Limited, Peshawar.
8.	Manufacture & Sale Of Sub-Standard /Misbranded /Counterfeit Drug Samples Manufactured By M/S Swat Pharmaceutical, Swat
9.	Availability Of Counterfeit Cephadrine Capsules Against Brand Velosef Capsule Manufactured By GSK Pakistan Limited, Registration No. 001863
10.	OOS Investigation Of Substandard Melovetz 10 Injection, Reg. No. 102021 Batch No # 2599063 Manufactured By M/S. Vetz Pharmaceuticals (Pvt.) Ltd., Plot # Q-1, S.I.T.E Kotri, Sindh
11.	Manufacture And Sale Of Sub-Standard Glitric Tablet 2.6mg Batch No. 25h261, Glitric Tablet 6.4mg Batch No 25h262 And Betahist Tablet 16mg Batch No. 25h249 Manufactured By M/S. Linta Pharmaceuticals Plot No. 3 Street No. S-5 National Industrial Zone (RCCI) Rawat, Islamabad DML No. 000810)

CASE NO.1: SUBSTANDARD IMCOMOX FOR ORAL SUSPENSION 60ML, REG. NO. 013756 BATCH NO # 029 AND IMCODAL ORAL SUSPENSION REG. NO. 013363 BATCH NO # 013 MANUFACTURED BY M/S IMCO PHARMACEUTICAL LABS, INDUSTRIAL ESTATE HAYATABAD, PESHAWAR

The Federal Inspector of Drugs, DRAP, Peshawar visited the premises of M/s Imco Pharmaceuticals, Plot No, 73, Industrial Estate, Hayatabad, Peshawar on 07-05-2025 and took samples of the Imcomox for Oral suspension 60ml and Imcodal Oral Suspension 60ml on Form-3 and sent to the Federal Government Analyst, CDL Karachi for test/analysis on Form-4.

2. Federal Government Analyst, CDL Karachi vide test report No. IP-5-25-000019 and No. IP-5-25-000021 dated 29th July, 2025 declared the batch 029 of product Imcomox for Oral suspension 60ml and batch 013 of product Imcodal Oral Suspension 60ml manufactured by M/s Imco Pharmaceuticals, Plot No, 73, Industrial Estate, Hayatabad, Peshawar as of “*Substandard Quality*”. Details of CDL test report are as under.

Name of Product	Manufactured by	Reg. No.	Batch No.	Mfg. Date	Expiry Date	CDL Report
Imcomox for Oral suspension 60ml (Amoxicilline trihydrate 125mg/5ml)	M/s Imco Pharmaceutical Labs, Industrial estate Hayatabad, Peshawar	013756	029	03-2025	03-2027	Sample has been declared as “ <i>Substandard</i> ” on the basis of Assay:52.7% Limit;90-120%
Imcodal Oral Suspension 60ml (Metronidazole benzoate 64mg Furazolidone 25mg/5ml)	M/s Imco Pharmaceutical Labs, Industrial estate Hayatabad, Peshawar	013363	013	05-2024	05-2026	Sample has been declared as “ <i>Substandard</i> ” on the basis of Assay of Furazolidone:45% Limit;90-110%

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

3. Federal Inspector of Drugs, DRAP, Peshawar, submitted the company's request of Appellate testing vide letter nil dated nil received on 23rd September, 2025, after receiving letter along with CDL report from FID Peshawar which was sent on 9th September, 2025)

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

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

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

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

5. In the light of above-mentioned decision of the Board, the division of QA< vide letter F. 03-38/2025-DD (QALT) dated 6th October, 2025, requested the Federal Government Analyst CDL Karachi and M/s Imco Pharmaceuticals, Plot No, 73, Industrial Estate, Hayatabad, Peshawar for the submission of Out of specification (OOS) investigation as directed by the Registration Board.

6. Summary of evaluation of Out of specification (OOS) investigation by the division of QA< is given as under:

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

Federal Government Analyst, CDL Karachi has submitted OOS investigation wherein it is informed that the sample of Imcomox for Oral suspension 60ml is tested in accordance with USP 2024 and has ruled out any possibility of error in the method of test/analysis, equipment and/or any operator or analyst related error.

Federal Government Analyst, CDL Karachi has submitted OOS investigation wherein it is informed that the sample of Imcodal Oral Suspension 60ml is tested in accordance in accordance with Innovator specifications and has ruled out any possibility of error in the method of test/analysis, equipment and/or any operator or analyst related error.

Summary of OOS investigation submitted by M/s Imco Pharmaceuticals, Plot No, 73, Industrial Estate, Hayatabad, Peshawar

M/s Imco Pharmaceuticals, Peshawar in their reply has provided OOS investigation of Imcomox for Oral suspension 60ml at laboratory and manufacturing level along with relevant evidences and has also ruled out any chance of error in the manufacturing or testing of the product in question.

M/s Imco Pharmaceuticals, Peshawar in their reply has provided OOS investigation Imcodal Oral Suspension 60ml at laboratory and manufacturing level along with relevant evidences and has also ruled out any chance of error in the manufacturing or testing of the product in question.

7. Proceedings and Decision of 353rd Meeting of Registration Board

The Board after considering the facts of the case, reports of CDL, Karachi showing assay results as 52.7% and 45%, and after thorough deliberations decided:

- i. *Not to accede the firm's request for retesting of samples from Appellate Laboratory under section 22 (5) of the Drugs Act, 1976.*
- ii. *To issue show cause notice to M/s Imco Pharmaceutical Labs, Industrial estate Hayatabad, Peshawar under Section 42 of the Drugs Act, 1976 and*
- iii. *To call the representatives of the firm for personal hearing before Registration Board in its forthcoming meeting.*

8. Division of QA< issued Show Cause Notice No. F.03-02/2026-QALT (353-RB) dated 12th February 2026 under Section 42 of the Drugs Act 1976.

9. In response to said show cause, M/s Imco Pharmaceutical Labs, Industrial estate Hayatabad, Peshawar. vide letter nil dated 20th February 2026 replied as under:

“we have the following points in our support

1) CDL Time barred testing

The samples were taken on 15/05/2025 while CDL Karachi Performed tests on 29/07/2025 which is clear violation of Drug Act 1976 section 22(2) (Copy Attached). They must submit report within 60 days starting from the day of sampling

2) Wrong testing by CDL Karachi

The CDL Karachi has declared the samples substandard while the sample of imcomax 125mg/5ml batch no 029 was declared of standard quality by DTL Multan (Copy attached).

3) Products of standard quality

We tested the same products repeatedly from our Firm the results were of standard quality test reports were attached with OOS investigation so we challenge the reports of CDL Karachi under section 25(5) of the Drug Act 1976

It is requested to send these products to N.I.H Islamabad for re-testing at our own cost or call us for personal hearing to explain our position personally”

10. Division of QA< issued a notice of personal hearing vide letter F.03-17/2026-QALT (356-RB) dated 1st April, 2026 under Section 42 of the Drug Act 1976.

11. Proceedings and Decision of 356th Meeting of Registration Board

Mr. Imtiaz Khan, Owner of the firm M/s Imco Pharmaceutical Labs, Industrial estate Hayatabad, Peshawar appeared before the Board. He informs that the sample of Imcomax 125mg/5ml Batch No 029 was declared of standard quality by DTL, Multan. They have tested the retained sample and the results were of standard quality. On query Mr. Imtiaz stated that last renewal of DML was conducted in 2009.

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

- i. Product-specific inspection, including verification of the Root Cause Analysis (RCA) and Corrective and Preventive Actions (CAPA), to be conducted by a panel of inspectors/experts to be nominated by the Director (QA/LT).*
- ii. Suspension of the Registrations of Imcomox Oral Suspension (60 ml) Reg # 013756 and Imcodal Oral Suspension 60ml Reg. 013363 manufactured by Imco Pharmaceutical Labs, Industrial estate Hayatabad, Peshawar under section 42 of the Drugs Act, 1976 and rules framed thereunder.*
- iii. Destruction of the recalled stock shall be carried out in the presence of the Area FID.*
- iv. Registration of furazolidone containing products shall be finalized in light of decision already taken by the Registration Board and same shall also be the fate of the above product containing furazolidone.*

CASE NO.2: SUBSTANDARD ZOLINT SUSPENSION, REG. NO. 016494 BATCH NO # 25024 MANUFACTURED BY M/S LIBRA (PRIVATE) LIMITED

The Federal Inspector of Drugs, DRAP, Quetta (Mr. Muhammad Yaqoob) visited the premises of M/s Nazir & sons H.No.8-20/33-B Balochi street, Quetta on 24th June 2025 and took samples of the Zolint Suspension on Form-3 and sent to the Federal Government Analyst, CDL Karachi for test/analysis on Form-4.

2. Federal Government Analyst, CDL Karachi vide test report No. KQ-6-25-000077 dated 10th October, 2025 declared the batch 25024 of product Zolint Suspension manufactured by M/s Libra (Private) Limited, Peshawar. as of “*Substandard Quality*”. Details of CDL test report are as under.

Name of Product	Manufactured by	Reg. No.	Batch No.	Mfg. Date	Expiry Date	CDL Report
Zolint Suspension						Sample has been declared as “ <i>Substandard</i> ” on the basis of Assay
Furazolidone 25mg/5ml	M/s Libra (Private) Limited, Peshawar.	016494	25024	05-2025	04-2027	Furazolidone: 79% Does not comply Limit: 90 to 110%
Metronidazole 75mg/5ml						Metronidazole: 81% Does not comply Limit: 90 to 110%

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

4. Federal Inspector of Drugs, DRAP, Quetta, submitted the company's request of Appellate testing vide letter nil dated 25th October, 2025, after receiving letter along with CDL report from FID Quetta which was sent on 20th October, 2025)

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

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

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

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

6. In the light of above-mentioned decision of the Board, the division of QA< vide letter F. 03-56/2025-DD (QALT) dated 19th November, 2025, requested the Federal Government Analyst CDL Karachi and M/s Libra (Private) Limited, 77-Industrial Estate, Hayatabad Peshawar

for the submission of Out of specification (OOS) investigation as directed by the Registration Board.

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

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

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

Summary of OOS investigation submitted by M/s Libra (Private) Limited, 77-Industrial Estate, Hayatabad Peshawar.

M/s Libra (Private) Limited Peshawar in their reply has provided OOS investigation at laboratory and manufacturing level along with relevant evidences and has also ruled out any chance of error in the manufacturing or testing of the product in question.

8. Proceedings and Decision of 353rd Meeting of Registration Board

The Board after considering the facts of the case, reports of CDL, Karachi showing assay results of Furazolidone: 79%, Metronidazole: 81%, and after thorough deliberations decided:

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

9. Division of QA< issued Show Cause Notice No. F.03-02/2026-QALT (353-RB) dated 12th February 2026 under Section 42 of the Drugs Act 1976.

10. In response to said show cause, M/s Libra (Private) Limited, Peshawar vide letter nil dated 20th February 2026 replied as under:

“Respected Madam,

With reference to letter No. F03-02/2026-QALT(353-RB), regarding Zolint suspension batch #25024 declared sub-standard by CDL Karachi based on their assay report No. KQ-6-25-000077. Upon receipt of intimation regarding the CDL report declaring the sample "Substandard," an immediate investigation was initiated as per our OOS procedure. The retained sample of Batch No. 25024 was re-tested using the validated analytical method. The repeat analysis confirmed assay results within the specified limits.

All analytical instruments were calibrated, system suitability criteria were met, and no analytical anomaly was observed during re-analysis.

The subject batch was manufactured in May 2025 strictly in accordance with the approved Master Formula Record and current Good Manufacturing Practices (cGMP). All in-process controls, including mixing time, homogenization parameters, and bulk assay verification, were found satisfactory and within predefined limits.

Prior to release, the finished product was analyzed in our Quality Control laboratory as per the registered specification. The assay results for both active pharmaceutical ingredients were within

the approved limits of 90%-110%, and the batch was released only after full compliance with quality specifications.

No manufacturing, analytical, or documentation deviation was identified that could justify an assay result of 79% and 81%.

In compliance with DRAP's directives and as part of our internal quality assurance policy, we have been recalled all available stocks from the distribution chain and quarantined for further directives of the DRAP authority.

We fully respect the authority of DRAP and assure complete cooperation. We are prepared to present complete documentary evidence, analytical data, and stability reports during the personal hearing before the Registration Board.

We humbly request reconsideration of the decision regarding retesting and seek an opportunity for independent verification before any adverse regulatory action is finalized.”

11. Division of QA< issued a notice of personal hearing vide letter F.03-17/2026-QALT (356-RB) dated 1st April, 2026 under Section 42 of the Drug Act 1976.

12. Proceedings and Decision of 356th Meeting of Registration Board

Mr. Mahabat Khan Quality Control Manager of M/s Libra (Private) Limited, Peshawar appeared before Board. He said that The retained sample of Batch No. 25024 was re-tested using the validated analytical method. The repeat analysis confirmed assay results within the specified limits also stability batches comply the specified limits. In compliance with DRAP's directives and as part of our internal quality assurance policy, we have been recalled all available stocks from the distribution chain

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

- i. Product-specific inspection, including verification of the Root Cause Analysis (RCA) and Corrective and Preventive Actions (CAPA), to be conducted by a panel of inspectors/experts to be nominated by the Director (QA/LT).*
- ii. Suspension of the Registrations of Zolint Suspension Reg.NO. 016494 manufactured by M/s Libra (Private) Limited, Peshawar under section 42 of the Drugs Act, 1976 and rules framed thereunder.*
- iii. Destruction of the recalled stock shall be carried out in the presence of the Area FID.*
- iv. Registration of furazolidone containing products shall be finalized in light of decision already taken by the Registration Board and same shall also be the fate of the above product containing furazolidone.*

CASE NO.3: MANUFACTURE & SALE OF SUB-STANDARD PEDOLIL SUSPENSION BATCH NO. 167 MANUFACTURED BY M/S JASM PHARMACEUTICALS (PVT) LTD., RISALPUR

The then Federal Inspector of Drugs, DRAP, Peshawar visited the premises of M/s. JASM Pharmaceuticals (Pvt) Ltd., Peshawar on 24th June 2023 and took samples of the Pedolil suspension on Form-3 and sent to the Federal Government Analyst, CDL Karachi for test/analysis on Form-4.

2. Federal Government Analyst, CDL Karachi vide test report No. IP-8-23-000058 dated 14th September, 2023 declared the batch 167 of product Pedolil suspension manufactured by Ms. JASM Pharmaceuticals (Pvt.) Ltd., Risalpur as of “*Substandard Quality*”. Details of CDL test report are as under.

Name of Product	Manufactured by	Reg. No.	Batch No.	Mfg. Date	Expiry Date	CDL Report
Pedolil suspension Paracetamol (250mg/5ml)	Ms. JASM Pharmaceuticals (Pvt.) Ltd., Risalpur.	110389	167	05-23	04-25	“Substandard” on the basis of Deliverable volume: Does not comply Limit: Meets the requirement of general Chapter <698>

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

4. Federal Inspector DRAP, Peshawar, has submitted detailed investigation report and concluded that M/s. JASM Pharmaceuticals (Pvt.) Ltd., Risalpur, was involved in violation of Section 23(1)(a) (v) of the Drugs Act, 1976 and rules framed thereunder.

5. In the light of mentioned report, Division of QA< issued Show Cause Notice No. F. No.03-33/2023-QC dated 4th February, 2026 under Section 42 of the Drugs Act 1976.

13. In response to said show cause, M/s. JASM Pharmaceuticals (Pvt.) Ltd., Risalpur vide letter nil dated 10th February 2026 replied as under:

“Respected Madam,

With reference to your Letter No. 103-48/2024-AD (QALT-IV) dated February 4, 2026, regarding the above-mentioned subject, Pedolil Suspension 250 mg/5 ml (Batch No. 167. Pack Size: 90 ml) was declared substandard by the Appellate Laboratory due to issues related to deliverable volume. However, according to Federal Government Analyst CDL Report No. IP-8-23-000058, the product complies Assay, PH accordingly with USP specifications.

JASM Pharmaceutical is a GMP-compliant company and is regularly inspected by FID. An immediate recall was initiated, achieving a 57.20% recovery rate as verified by FID Peshawar. A CAPA was submitted to FID Peshawar, which reviewed and verified our corrective actions satisfactorily. The incident was due to light shortfall unexpectedly occurs. and comprehensive corrective measures have been implemented to prevent recurrence. Further increase the surveillance time during the filling process to prevent such incidents in the future.

Sr.#	Observations	Action	Status
1.	Electrical shortfall during the filling caused deviation of volume.	50 KW Generator installed. 50 KW Hybrid Solar System	Corrected
2.	Electrical shortfall during the filling blockage the pump nozzle and the volume deviation caused.	➤ Pump silicon Seals Replaced. ➤ Pumps Polished.	Corrected

3.	Validation of the Liquid filling Machine.	Validated the Machine.	Corrected
4.	Performance Qualification of the Liquid filling Machine.	Performance Qualification attached.	Corrected

It is prior that the case may be closed by the registration board at this stage. As known. further action is required. Any further direction issued by the Board in the case shall be implemented in letter and spirit.”

6. Division of QA< issued a notice of personal hearing vide letter F.03-17/2026-QALT (356-RB) dated 1st April, 2026 under Section 42 of the Drug Act 1976.

7. Proceedings and Decision of 356th Meeting of Registration Board

No person on behalf of M/s. JASM Pharmaceuticals (Pvt.) Ltd., Risalpur appeared before Board.

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

- i. Product-specific inspection, including verification of the Root Cause Analysis (RCA) and Corrective and Preventive Actions (CAPA), to be conducted by a panel of inspectors/experts to be nominated by the Director (QA/LT).*
- ii. Suspension of the Registration of Pedolil suspension Registration No. 110389 manufactured by M/s. Ms. JASM Pharmaceuticals (Pvt.) Ltd., Risalpur under section 42 of the Drugs Act, 1976 and rules framed thereunder, for a period of six months or till verification of Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) by a panel with satisfactory report; whichever is earlier.*
- iii. Destruction of the recalled stock shall be carried out in the presence of the Area FID.*

CASE NO.4: MANUFACTURE & SALE OF SUB-STANDARD CB-GET POWDER FOR SUSPENSION BATCH NO. D-346 MANUFACTURED BY M/S ICEBERG PHARMACEUTICALS (PVT.) LTD., RISALPUR, KPK-PAKISTAN

The then Federal Inspector of Drugs, DRAP, Peshawar visited the premises of M/s JSK Medica (Pvt) Ltd., (Formerly M/s Iceberg Pharmaceuticals (Pvt.) Ltd.,) Risalpur, Kpk-Pakistan on 8th July, 2021, and took samples of the CB-Get powder for suspension on Form-3 and sent to the Federal Government Analyst, CDL Karachi for test/analysis on Form-4.

2. Federal Government Analyst, CDL Karachi vide test report No. IP.64/2021 dated 27th January, 2023 declared the batch D-346 of product CB-Get powder for suspension manufactured by M/s JSK Medica (Pvt) Ltd., (Formerly M/s Iceberg Pharmaceuticals (Pvt.) Ltd.,) Risalpur, Kpk-Pakistan as of “*Substandard Quality*”. Details of CDL test report are as under.

Name of Product	Manufactured by	Reg. No.	Batch No.	Mfg. Date	Expiry Date	CDL Report
CB-Get powder for suspension. (Cefixime 100mg/5ml)	M/s JSK Medica (Pvt) Ltd., Risalpur (Formerly known as M/s. Iceberg)	085224	D-346	06-2021	06-2023	“ <i>Substandard</i> ” on the basis of Assay Cefixime: 76.1% Limit: 90.0% to 120.0%

	Pharmaceuticals (Pvt.) Ltd. Risalpur)					<i>Does not comply</i>
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3. Federal Inspector of Drugs Peshawar was directed to investigate the matter and submit a comprehensive report in the matter.

4. Federal Inspector DRAP, Peshawar, has submitted detailed investigation report and concluded that M/s JSK Medica (Pvt) Ltd., Risalpur (Formerly known as M/s. Iceberg Pharmaceuticals (Pvt.) Ltd. Risalpur), was involved in violation of Section 23(1)(a) (v) of the Drugs Act, 1976 and rules framed thereunder.

5. In the light of mentioned report, Division of QA< issued Show Cause Notice No. F. No.03-10/2023-QC dated 4th February, 2026 under Section 42 of the Drugs Act 1976.

6. Division of QA< issued a notice of personal hearing vide letter F.03-17/2026-QALT (356-RB) dated 1st April, 2026 under Section 42 of the Drug Act 1976.

7. Proceedings and Decision of 356th Meeting of Registration Board

In compliance to the show cause notice and personal hearing letter issued, Mr. Jamil Ahmed General Manager and Mr. Nisar Ahmed Siddiqui Regulatory consultant of M/s JSK Medica (Pvt) Ltd., Risalpur (Formerly known as M/s. Iceberg Pharmaceuticals (Pvt.) Ltd. Risalpur) appeared before Board. They said that this batch was manufactured in 2021 while they acquired the manufacturing unit in 2023. They further stated that they had changed the title from Iceberg to JSK Medica

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

- i. Product-specific inspection, including verification of the Root Cause Analysis (RCA) and Corrective and Preventive Actions (CAPA), to be conducted by a panel of inspectors/experts to be nominated by the Director (QA/LT).*
- ii. Suspension of the Registration of CB-Get powder for suspension Reg. No. 085224 manufactured by M/s JSK Medica (Pvt) Ltd., Risalpur (Formerly known as M/s. Iceberg Pharmaceuticals (Pvt.) Ltd. Risalpur) under section 42 of the Drugs Act, 1976 and rules framed thereunder, for a period of six months or till verification of Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) by a panel with satisfactory report; whichever is earlier.*
- iii. Destruction of the recalled stock shall be carried out in the presence of the Area FID.*

**CASE NO.5: MANUFACTURE & SALE OF SUB-STANDARD AWAHAEM TABLETS
BATCH NO. 2781 MANUFACTURED BY M/S USAWA
PHARMACEUTICALS (PVT) LTD., RISALPUR**

The then Federal Inspector of Drugs, DRAP, Peshawar visited the premises of M/s. Usawa Pharmaceuticals (Pvt.) Ltd Plot No., 146, (SIZ) Risalpur, on 22nd October, 2022, and took samples

of the Awahaem Tablets on Form-3 and sent to the Federal Government Analyst, CDL Karachi for test/analysis on Form-4.

2. Federal Government Analyst, CDL Karachi vide test report No. IP-11-22-000165 dated 20th January, 2023 declared the batch 2781 of product Awahaem Tablets manufactured by M/s. Usawa Pharmaceuticals (Pvt.) Ltd., Risalpur. as of “*Substandard Quality*”. Details of CDL test report are as under.

Name of Product	Manufactured by	Reg. No.	Batch No.	Mfg. Date	Expiry Date	CDL Report
Awahaem Tablets (Elemental Iron 100mg/Tablet Folic acid 0.35mg/Tablet)	Ms. Usawa Pharmaceuticals (Pvt.) Ltd., Risalpur.	069736	2781	06-2022	06-2024	“ <i>Substandard</i> ” “on the basis of Assay Folic Acid: 83.34% Limit: 90.0% to 110.0% <i>Does not comply</i>

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

4. Federal Inspector DRAP, Peshawar, has submitted detailed investigation report and concluded that Ms. Usawa Pharmaceuticals (Pvt.) Ltd., Risalpur was involved in violation of Section 23(1)(a) (v) of the Drugs Act, 1976 and rules framed thereunder.

5. In the light of mentioned report, Division of QA< issued Show Cause Notice No. F. No.03-08/2023-QC dated 11th February, 2026 and Corrigendum of Showcause Notice dated 18th February, 2025 under Section 42 of the Drugs Act 1976.

6. Division of QA< issued a notice of personal hearing vide letter F.03-17/2026-QALT (356-RB) dated 1st April, 2026 under Section 42 of the Drug Act 1976.

7. Proceedings and Decision of 356th Meeting of Registration Board

Mr. Ibrar Ahmed, Quality Control Manager of M/s. Usawa Pharmaceuticals (Pvt.) Ltd., Risalpur appeared before Board. He said that they had recalled the stock immediately and reported to FID, Peshawar. Out of 3000 Packs 670 packs of Awahaem Tablets were recalled.

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

- i. Product-specific inspection, including verification of the Root Cause Analysis (RCA) and Corrective and Preventive Actions (CAPA), to be conducted by a panel of inspectors/experts to be nominated by the Director (QA/LT).***
- ii. Suspension of the Registration of Awahaem Tablets Reg. No. 069736 manufactured by M/s. Usawa Pharmaceuticals (Pvt.) Ltd., Risalpur under section 42 of the Drugs Act, 1976 and rules framed thereunder, for a period of six months or till verification of Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) by a panel with satisfactory report; whichever is earlier.***
- iii. Destruction of the recalled stock shall be carried out in the presence of the Area FID.***

CASE NO.6: MANUFACTURE & SALE OF SUB-STANDARD FENBAR TABLETS
BATCH NO. 2752 MANUFACTURED BY M/S USAWA
PHARMACEUTICALS (PVT) LTD., RISALPUR

The then Federal Inspector of Drugs, DRAP, Peshawar visited the premises of M/s. Usawa Pharmaceuticals (Pvt.) Ltd Plot No., 146, (SIZ) Risalpur, on 22nd October, 2022, and took samples of the Fenbar Tablets on Form-3 and sent to the Federal Government Analyst, CDL Karachi for test/analysis on Form-4.

2. Federal Government Analyst, CDL Karachi vide test report No. IP-11-22-000168 dated 23rd January, 2023 declared the batch 2752 of product Fenbar Tablets manufactured by M/s. Usawa Pharmaceuticals (Pvt.) Ltd., Risalpur. as of “*Substandard Quality*”. Details of CDL test report are as under.

Name of Product	Manufactured by	Reg. No.	Batch No.	Mfg. Date	Expiry Date	CDL Report
Fenbar Tablets (Diclofenac 50mg/Tablet)	Ms. Usawa Pharmaceuticals (Pvt.) Ltd., Risalpur.	023961	2752	04-2022	04-2025	“ <i>Substandard</i> ” “on the basis of Dissolution Buffer Stage Limit: Not less than 75% (Q) <i>Does not comply</i>

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

4. Federal Inspector DRAP, Peshawar, has submitted detailed investigation report and concluded that Ms. Usawa Pharmaceuticals (Pvt.) Ltd., Risalpur was involved in violation of Section 23(1)(a) (v) of the Drugs Act, 1976 and rules framed thereunder.

5. In the light of mentioned report, Division of QA< issued Show Cause Notice No. F. No.03-09/2023-QC dated 13th February, 2026 and Corrigendum of Showcause Notice dated 18th February, 2025 under Section 42 of the Drugs Act 1976.

6. Division of QA< issued a notice of personal hearing vide letter F.03-17/2026-QALT (356-RB) dated 1st April, 2026 under Section 42 of the Drug Act 1976.

7. Proceedings and Decision of 356th Meeting of Registration Board

In compliance to the show cause notice and personal hearing letter issued, Mr. Ibrar Ahmed Quality Control Manager of M/s. Usawa Pharmaceuticals (Pvt.) Ltd., Risalpur appeared before Board. He said that they had recalled the stock immediately and reported to FID, Peshawar. Out of 3000 Packs 236 packs of Fenbar Tablets were recalled.

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

- i. Product-specific inspection, including verification of the Root Cause Analysis (RCA) and Corrective and Preventive Actions (CAPA), to be conducted by a panel of inspectors/experts to be nominated by the Director (QA/LT).***

- ii. ***Suspension of the Registration of Fenbar Tablets Reg. No. 023961 manufactured by M/s. Usawa Pharmaceuticals (Pvt.) Ltd., Risalpur under section 42 of the Drugs Act, 1976 and rules framed thereunder, for a period of six months or till verification of Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) by a panel with satisfactory report; whichever is earlier.***
- iii. ***Destruction of the recalled stock shall be carried out in the presence of the Area FID.***

CASE NO.7: SUBSTANDARD ZAYZINE SYRUP BATCH NO. 25289, REG NO. 096969 MANUFACTURED BY M/S ZAYNOON PHARMACEUTICALS (PVT) LIMITED, PESHAWAR.

The Federal Inspector of Drugs, DRAP, Peshawar visited the premises of M/s Zaynoon Pharmaceuticals (Pvt) Limited, Peshawar on 9th July, 2025, and took samples of the Zayzine Syrup on Form-3 and sent to the Federal Government Analyst, CDL Karachi for test/analysis on Form-4.

2. Federal Government Analyst, CDL Karachi vide test report No. IP-7-25-000072 dated 29th October, 2025, declared the batch 25289 of product Zayzine Syrup manufactured by M/s Zaynoon Pharmaceuticals (Pvt) Limited, Peshawar as of “*Substandard Quality*”. Details of CDL test report are as under.

Name of Product	Manufactured by	Reg. No.	Batch No.	Mfg. Date	Expiry Date	CDL Report
Zayzine Syrup (60ml) Cetirizine dihydrochloride	M/s Zaynoon Pharmaceuticals (Pvt) Limited, Peshawar	096969	25289	07-2025	06-2027	Sample has been declared as “ <i>Substandard</i> ” on Assay Cetirizine dihydrochloride: 137.9% <i>Does not comply</i> Limit:90.0% to 110.0%

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

4. Federal Inspector DRAP, Peshawar, has submitted detailed investigation report and concluded that M/s Zaynoon Pharmaceuticals (Pvt) Limited, Peshawar was involved in violation of Section 23(1)(a) (v) of the Drugs Act, 1976 and rules framed thereunder.

5. In the light of mentioned report, Division of QA< issued Show Cause Notice No. F.03-59/2025-DD(QALT) dated 16th February, 2026 under Section 42 of the Drugs Act 1976.

6. Division of QA< issued a notice of personal hearing vide letter F.03-17/2026-QALT (356-RB) dated 1st April, 2026 under Section 42 of the Drug Act 1976.

It is to inform that same product has already been declared as of *Adulterated and Sub-Standard (Sub-standard & Falsified)*” quality by CDL, Karachi on the basis of physical appearance

(Containing foreign particles visible to the naked eye). The case was placed before the 353rd meeting of RB, where in board decided as under:

- i. Submission of RCA and CAPA by the firm.
- ii. Product Specific Inspection including verification of RCA and CAPA by panel of inspectors/experts to be nominated by Director QA/LT.
- iii. Suspension of the Registration of Zayzine Syrup (60ml), Registration No. 096969 manufactured by M/s Zaynoon Pharmaceuticals (Pvt) Limited, Peshawar under section 42 of the Drugs Act, 1976 and rules framed thereunder, till verification of Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) by a panel constituted by the Director (QA<) with satisfactory report.
- iv. Firm shall submit complete recall status of aforementioned batch of product “Zayzine” as per Recall Guidelines Doc No. QALT/GL/RA/001 to the QALT Division, DRAP, Islamabad.

7. Proceedings and Decision of 356th Meeting of Registration Board

Mr. Shaukat Ayaz, Quality Control Manager of M/s Zaynoon Pharmaceuticals (Pvt) Limited, appeared before Board. He said that the Zayzine syrup batch was manufactured as R&D trial for the purpose of change in colour and flavors as per market demand. It was 100 Liter Trial Batch and never been marketed, supplied or released for commercial distribution in the market. The entire trial batch remain fully retained in our warehouse.

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

- i. *Suspension of the Registration of Zayzine Syrup (60ml), Registration No. 096969 manufactured by M/s Zaynoon Pharmaceuticals (Pvt) Limited, Peshawar under section 42 of the Drugs Act, 1976 and rules framed thereunder, shall remained suspended till satisfactory report received from the nominated panel.*
- i. *Directed to the M/s Zaynoon Pharmaceuticals (Pvt) Limited, Peshawar to manufacture a new trial batch, after which FID shall perform sampling, and the report from CDL shall be presented in the Registration Board meeting.*
- ii. *Destruction of the R&D stock shall be carried out in the presence of the Area FID.*

CASE NO.8: MANUFACTURE & SALE OF SUB-STANDARD /MISBRANDED /COUNTERFEIT DRUG SAMPLES MANUFACTURED BY M/S SWAT PHARMACEUTICAL, SWAT

The then Federal Inspector of DRAP, Peshawar inspected Premises of M/s. Swat Pharmaceutical, Swat, on 14th July, 2023, wherein following samples were taken for the purpose of test/analysis on prescribed Form-3. Federal Government Analyst, Central Drugs Laboratories, Karachi declared the below mentioned Samples as mentioned against each case. Details of CDL test reports are as under:

Name of Product	Manufactured by	Reg. No.	Batch No.	Mfg. Date	Expiry Date	CDL Report	CDL Test Report No and Date
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Albex Tablet Albendazole (200mg)	M/s. Swat Pharmaceuti cal, Swat.	020921	112	04- 23	03- 25	“Substandard “on the basis of Dissolution: does not comply Limit: Meet the requirements of USP general chapter <711> Tolerance: NLT 80% (Q)	IP-8-23-000053 dated 20 th September, 2023
Zolan Suspension Metronidazol e (200mg/5ml)	M/s. Swat Pharmaceuti cals, Swat.	027683	L083	05- 23	04- 25	“Substandard “on the basis of pH: 4.71 does not comply Limit: 5.0 to 6.5	IP-8-23-000054 dated 28 th September, 2023
Piperazine Elixir 30ml Piperazine Citrate Eq to n Piperazine Hydrate 750mg/5ml	M/s. Swat Pharmaceuti cals, Swat	002235	L085	06- 23	05- 25	“Substandard “on the basis of weight per ml: 1.02g <i>Does not comply</i> Limit: 1.20g to 1.30g Assay: 11.520%W/V- <i>Does not comply</i> Limit: 15.3% w/v to 17.7% w/v	IP-8-23-000056, dated 16 th November, 2023
Weena Syrup 250ml Ferrous sulphate 400 mg/ 10ml Ascorbic Acid 25mg/1 0ml	M/s. Swat Pharmaceuti cals, Swat	003049	L090	07- 23	06- 25	“Substandard “on the basis of Assay, Ferrous sulphate: 43.97% Limit: 90% to 110% Ascorbic Acid: 27.31% Limit: 90% to 110%	IP-8-23-000055, dated 31 st Octobert,2023

Panasetol tablet	M/s. Swat Pharmaceuticals, Swat	073328	074	09-2022	08-2024	Counterfeit (Falsified). Under Section 3(f) of the Drugs act 1976. The Color Scheme, name, text and presentation of inner most label (blister) of the sample “Panasetol Tablets” nearly resemble as to be calculated to deceive the inner most label of brand leader drug Product “Panadol Tablets” Registration No. 101138 manufactured by “Pharmatec Pakistan (Pvt) Ltd, Karachi.	IP-8-23-000049, dated 14 th September, 2023
Panasetol tablet	M/s. Swat Pharmaceuticals, Swat	073328	113	05-2023	04-2025	The sample is provided in strip packing, and blister packing also. The same product with the same registration number, is sent to Central drugs laboratory in strip packing also, necessary action in this matter may kindly be taken as per guidance of PE&R division	IP-8-23-000050, dated 14 th September, 2023

Panasetol CF tablet	M/s. Swat Pharmaceuticals, Swat	076834	082	11-22	10-24	The sample is provided in strip packing, and blister packing also. The same product with the same registration number, is sent to Central drugs laboratory in strip packing also, necessary action in this matter may kindly be taken as per guidance of PE&R division	IP-8-23-000051, dated 24 th October, 2023,
Panasetol CF Tablet	M/s. Swat Pharmaceuticals, Saidu Sharif Swat.	076834	A029	02-22	02-25	Sample has been declared as “Misbranded” on the basis of <i>The information regarding Name of Sample, Name of Manufacturer, Registration Number, Principal place of business of the manufacturer, dosage and instruction on the inner most label (Blister) is not clearly visible in a conspicuous manner as required under rule 3 of the Drugs (Labeling& Packing) Rules 1986. Hence, sample is declared “Misbranded” under section 3(s)(i) of the Drug Act, 1976.</i>	IP-8-23-000052 dated 24 th October, 2023,

2. Federal Inspector of Drugs Peshawar was directed to investigate the matter and submit a comprehensive report in the matter.
3. Federal Inspector DRAP, Peshawar, submitted investigation report and concluded that M/s. Swat Pharmaceuticals, Saidu Sharif Swat, was involved in violation of Section 23(1)(a)(ii)(v) of the Drugs Act, 1976 and rules framed thereunder.
4. In the light of mentioned report, Division of QA< issued Show Cause Notice No. F. No.03-34/2023-QC dated 3rd March, 2026 under Section 42 of the Drugs Act 1976 for violation section 23(1)(a)(ii)(iii)(v) of the Drug Act 1976.
5. Division of QA< issued a notice of personal hearing vide letter F.03-17/2026-QALT (356-RB) dated 1st April, 2026 under Section 42 of the Drug Act 1976.

6. Proceedings and Decision of 356th Meeting of Registration Board

Mr. Wali Ullah Quality Control Manager and Mr. Qazi Jabran **Ahmed** of M/s. Swat Pharmaceutical, Swat. appeared before Board. They said renewal of DML was granted in November, 2025 and new management takeover the firm in December, 2025. They further stated that stability studies for trial batches of the products in question have been started. Furthermore, we have redesigned the labels and cartons of counterfeit product.

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

- i. Suspension of the Registration of following products of M/s. Swat Pharmaceutical, Swat under section 42 of the Drugs Act, 1976 and rules framed thereunder, till completion of stability studies and submission of stability reports. The Director (QA<) will constitute a panel for verification of stability data of the products.*

S. No	Product	Reg. No	S. No	Product	Reg. No
i.	Albex Tablet	020921	iv.	Weena Syrup 250ml	003049
ii.	Zolan Suspension	027683	v.	Panasetol tablet	073328
iii.	Piperazine Elixir 30ml	002235			

- ii. The Board directed the firm M/s. Swat Pharmaceutical, Swat to apply for RPV for change in color scheme of label and blister of Panasetol tablet and Panasetol-CF tablet. The Board further advises the firm to retain the product in question either in blister or strip packing and get PRV from PE&R Division of DRAP accordingly.*
- iii. Destruction of the recalled stock shall be carried out in the presence of the Area FID.*

CASE NO.9: AVAILABILITY OF COUNTERFEIT CEPHRADINE CAPSULES AGAINST BRAND VELOSEF CAPSULE MANUFACTURED BY GSK PAKISTAN LIMITED, REGISTRATION NO. 001863

1. M/s Glaxo SmithKline (GSK) Pakistan Limited submitted an application dated 12-12-2025, wherein they stated that their product 'Velosef Capsule' has been duly registered under Registration No. 001863, with DRAP, and is also registered with the Trademarks Registry and the Intellectual Property of Pakistan. However, several Pharmaceutical

Companies have been manufacturing and marketing products with packaging, design, artistic work, and color schemes that visually identical and deceptively similar to their product. the name of the companies and their respective products is given below:

- a. Farmaceutics International; Haradene
 - b. Mediate Pharmaceuticals Pvt Ltd; Quin-safe
 - c. Shawan Pharmaceuticals; Wadin
 - d. Medircraft Pharmaceuticals Pvt Ltd; Velomed
2. The firm has attached scanned copies of IPO Tribunal Orders and infringing Products
 3. The firm was asked to provide, commercial packs of above stated products as well as Velosef for comparison purposes; however, the firm was able to provide packs of Velomed Manufactured by Medircraft Pharmaceuticals Pvt Ltd and Velosef manufactured by GSK only.
 4. The firm has requested to restrain the aforementioned companies from manufacturing, packaging, distributing, selling or offering for sale the said products. The firm has further requested assistance in recalling the infringing products from the market.







5. Proceedings and Decision of 356th Meeting of Registration Board

The Division of QA & LT presented the subject case before the Registration Board. After examining the commercial packs of both Velomed and Velosef, the Board decided as under:

1. *“The Board after due consideration and deliberations of the case, observed resemblance in the design pattern, artistic work and color scheme of the primary and secondary labels and packaging of Velosef Capsules 500mg (Reg. No. 001863), Velosef Capsules 250mg (Reg. No. 001871) manufactured by M/s GlaxoSmithKline Pakistan Limited, and Velomed Capsule 500mg (Reg. No. 0022511), Velomed Capsule 250mg (Reg. No. 0022510) manufactured by M/s Medcraft Pharmaceuticals Pvt Ltd, Peshawar. The Board decided to direct the firm M/s Medcraft Pharmaceuticals Pvt Ltd, Peshawar to change the packaging, design, artwork, and color scheme of their product’s Velomed Capsule 500mg (Reg. No. 0022511), Velomed Capsule 250mg (Reg. No. 0022510) to ensure clear differentiation and submit their request for PRV in PE&R Division of DRAP.*
2. *Additionally, in case M/s. Medcraft Pharmaceuticals Pvt Ltd, Peshawar, wish to be heard in person, the firm is directed to intimate the Division of QA & LT in writing prior to the forthcoming meeting of the Registration Board.*
3. *The Board further decided to ask GlaxoSmithKline Pakistan to provide the commercial packs of other products whose packaging, design, artwork, and color schemes reportedly resemble that of Velosef, as referred to in their letter, namely:*
 - i. *Farmaceutics International – Haradene*
 - ii. *Mediate Pharmaceuticals Pvt Ltd – Quin-Safe*
 - iii. *Shawan Pharmaceuticals – Wadin”*

CASE NO.10: OOS INVESTIGATION OF SUBSTANDARD MELOVETZ 10 INJECTION, REG. NO. 102021 BATCH NO # 2599063 MANUFACTURED BY M/S. VETZ PHARMACEUTICALS (PVT.) LTD., PLOT # Q-1, S.I.T.E KOTRI, SINDH

Federal Inspector of Drugs, Karachi during routine GMP inspection on 31-05-2021 took sample of following drug from premises of M/s Vetz Pharmaceuticals (Pvt.) Ltd., Kotri and sent to CDL for test and analysis. Details of CDL test and analysis report were as following

Product	Batch No.	Mfg. Date	Exp. Date	CDL Report
Melovetz 10 Injection 10mg /ml (Meloxicam) (Reg. # 102021)	2199017	05-2021	04-2023	Report No. KQ.161/2021 dated 27-07-2021 pH does not comply Results: 13.45 Ref. Range: 7.5-9.1

3. A notice of personal hearing was issued vide letter No. 03-18/2023-QC (326-RB) dated 08-03-2023. The firm replied vide their letter No. V/23004 dated 13-03-2024 stating that their product Melovetz Inj was in-house specification as per registration letter however CDL did not ask the manufacturer to provide the testing method as their method was developed as per in house specification. The firm further stated that they had revised our finished product specification as per pharmacopeia.
4. Case was placed before 326th Meeting of the Registration Board held on 14th 16th March 2023. The Board after considering the facts of the case and after thorough deliberations decided:
 - a. *Suspension of the Registration of Melovetz Injection, Registration No. 102021 under section 42 of the Drugs Act, 1976 and rules framed thereunder, for six months or till*

verification of Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) by a panel with satisfactory report; whichever is later.

- b. The firm was advised to follow the Pharmacopoeial specifications in compliance to the specification rules.
- c. Submission of RCA and CAPA by the firm.
- d. Product Specific Inspection including verification of RCA and CAPA by panel of inspectors/experts to be nominated by Director QA/LT. During inspection the panel will also confirm the compliance to the specification rules.

5. Letter for Suspension of Registration was issued bearing No. 03-18/2023-QC (326-RB) dated 26-05-2023, and letter No. 03-18/2023-QC (326-RB) dated 08-06-2023 for Product Specific Inspection by inspection panel, was issued.

6. Panel conducted PSI on 16.05.2024 and panel concluded that recommended that suspended registration of Melovetz Injection (Reg. No. 102021) may be resumed and first 2-3 batches of samples may be sent again to CDL for test/analysis before marketing. Also to submit batch validation reports of first three commercial batches with the revised formulation.

7. The Board in its 345th meeting held on 19th - 21st February 2025, after considering the facts of the case, keeping in view recommendations of panel of experts in its report dated 16.05.2024 and after thorough deliberations decided:

- i. *"To resume the production of Melovetz 10 Injection, Registration No. 102021 of M/s. Vetz Pharmaceuticals (Pvt.) Ltd., Kotri, Sindh.*
- ii. *Firm shall inform area FID to take sample from 1st commercial batch for the purpose of test/analysis by CDL Karachi and sale of the product is subject to the standard report by the Central Drugs Laboratory, Karachi and subsequent approval by Director (QA & LT).*
- iii. *Also to submit batch validation reports of first three commercial batches with the revised formulation."*

8. The Federal Inspector of Drugs-II, DRAP, Karachi, during the inspection of M/s. Vetz Pharmaceuticals (Pvt.) Ltd., Plot # Q-1, S.I.T.E Kotri, Sindh dated 28th August, 2025, took samples of Melovetz Injection 50ml 10mg/1ml Reg# (102021) Batch No. 2599063 on Form-3 and sent to the Federal Government Analyst, CDL Karachi for test/analysis on Form-4.

9. Federal Government Analyst, CDL Karachi vide Test Report No KQ-9-25-000125 dated 24th October, 2025, declared Batch No. 2599063 of Melovetz Injection 50ml 10mg/1ml manufactured by M/s. Vetz Pharmaceuticals (Pvt.) Ltd as "Sub-Standard" quality. Details of CDL test report are as under:

Drug Sample	Mfg. Date	Exp. Date	Tests	CDL Report No.	Manufacturer
Melovetz Injection 50ml 10mg/1ml Reg# (102021) Batch No. 2599063	06/2025	05/2027	Sterility Does not comply	KQ-9-25-000125 dated 24 th October 2025 The sample is of sub-standard quality under the Drugs Act 1976.	M/s. Vetz Pharmaceuticals (Pvt.) Ltd., Plot # Q-1, S.I.T.E Kotri, Sindh

10. FID-II, Karachi forwarded copy of the CDL report to the firm with show cause letter vide No.F.5-11/2025-FID-II(K) dated 5th November, 2025. Thereafter, the firm submitted its request for Appellate testing to the office of FID-II, Karachi vide letter No. VTZ 289 dated 21-11-2025.

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

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

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

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

12. In light of the above-mentioned decision of the Board, the division of QA< vide letter F.No.03-67/2025-DDQALT-VI dated 02-01-2026, requested the Federal Government Analyst CDL Karachi and M/s. Vetz Pharmaceuticals (Pvt.) Ltd for the submission of Out of specification (OOS) investigation as directed by the Registration Board.

13. The firm has submitted that total manufactured quantity was 1000 units of which were not marketed as CDL report was awaited as per directions of the Registration Board.

14. Summary of evaluation of Out of specification (OOS) investigation by the division of QA< is given as under:

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

Federal Government Analyst, CDL Karachi has submitted OOS investigation wherein it is informed that the sample is tested in accordance with the BP Vet, 2024 test/analysis method and has ruled out any possibility of error in the method of test/analysis, equipment and/or any operator or analyst related error.

Summary of OOS investigation submitted by M/s. Vetz Pharmaceuticals (Pvt.) Ltd

M/s. Vetz Pharmaceuticals (Pvt.) Ltd in their reply has provided OOS investigation of Melovetz Injection 50ml 10mg/1ml Reg# (102021) Batch No. 2599063 at the laboratory level along with relevant evidences and has claimed to rule out any chance of error in the manufacturing or testing of the product in question.

Technical Evaluation of OOS Investigation:

- i. The product was declared by CDL as sub-standard on the basis of Sterility
- ii. CDL performed Sterility Testing in accordance with BP Vet. 2024 whereas manufacturer referenced USP <71> for Sterility Test in OOS investigation.
- iii. In the initial observation of OOS Investigation, the firm mentioned that the DRAP laboratory reported sterility test failure and that the observation reportedly was based on appearance of turbidity / crystalline particles in sterility test media. However, neither CDL test report nor OOS investigation from CDL, Karachi mentions crystalline particles; rather as per report, the test for visible particulate matter complies with BP vet 2024.
- iv. Furthermore, Confirmatory / Retesting at Manufacturing Site performed by the manufacturer shows that retesting was performed on control/hold samples of the same batch.
strictly as per USP <71> Sterility Test. Results of Retesting showed No microbial growth in either FTM or SCDM after completion of incubation period. However, under the heading

- of Additional Observation, the firm mentioned the presence of **Crystalline material** in sterility test media during incubation which were transparent/white, settled at the bottom, did not cause turbidity, and did not spread or increase over time.
- v. Phase-I Laboratory Investigation conducted by the firm showed that no deficiencies were found in the reviewed Analyst training records, SOP for Sterility test was followed without deviation, Media preparation, sterilization, GPT, and environmental monitoring results reviewed were all within limits, Media Growth Promotion Test was passed, Incubator temperature records were found Within 20–25°C and 30–35°C limits, Sterility test isolator/LAF environmental monitoring also Complied. Therefore, after Phase-I investigation, the firm concluded that no laboratory error or contamination source was identified.
 - vi. Phase II – Full Scale Investigation (Root Cause Analysis) conducted by the firm consisted of Product & Formulation Review which observed that since Meloxicam is a poorly water-soluble drug, therefore, formulation relies on pH adjustment and solubilizing system. Change in pH or temperature can cause drug precipitation/crystallization. Furthermore, the firm noted under interaction with the Sterility test media i.e., FTM/SCDM that they have different pH range, aqueous environment, and incubation at elevated temperatures (30–35°C) which are not representative of product storage conditions and may induce supersaturation and crystallization of Meloxicam. Evaluation of crystals showed no growth on subculture and no proliferation upon incubation; also the microscopic examination of the crystals showed non-cellular crystalline structure. Based on these observations, it was confirmed that the crystals were non-microbial and that drug precipitation/crystal formation was misinterpreted as microbial growth.
 - vii. Based on foregoing, the firm found the Root Cause to be physicochemical precipitation/crystallization of meloxicam in sterility test media due to solubility and pH differences therefore concluding that there was no impact on animal health, or on other batches of the product and the manufacturing process remained validated and Sterility Assurance Level remains maintained.

15. Proceedings and Decision of 356th Meeting of Registration Board

Representative of QA< Division inform the Board that product Melovetz Injection 50ml, 10mg/1ml (Reg# 102021) was declared as of substandard quality. The case was placed before the Boar in its 326th meeting. The product registration was suspended. The panel conducted inspection and submitted PSI. PSI report was presented before the 345th meeting of Registration Board. The Board decided to resume the production of Melovetz Injection, Registration No. 102021 and direct the area FID for fresh sampling from commercial batch before marketing. The area FID take samples of product Melovetz Injection, Registration No. 102021 and send to CDL, Karachi for the purpose of test/analysis. The sample again has been declared substandard. The Board after considering facts of the case, thorough deliberations and considering that the same product i.e., Melovetz Injection 50ml, 10mg/1ml (Reg# 102021) has been declared Substandard by CDL, Karachi for the second time, decided as follows:

- i. “Not to accede to the firm’s request for retesting of sample from Appellate Laboratory under section 22 (5) of the Drugs Act, 1976.*
- ii. Suspension of the Registration of Melovetz Injection 50ml 10mg/1ml (Reg# 102021) manufactured by M/s. Vetz Pharmaceuticals (Pvt.) Ltd., Plot # Q-1, S.I.T.E Kotri, Sindh for a period of six months under section 42 of the Drugs Act, 1976 and rules framed thereunder.*

- iii. *To issue Show Cause Notice to the firm M/s. Vetz Pharmaceuticals (Pvt.) Ltd., Plot # Q-1, S.I.T.E Kotri, Sindh for cancellation of registration of product Melovetz Injection, Registration No. 102021 under Section 42 of the Drugs Act, 1976 and rules framed thereunder.*
- iv. *Destruction of the recalled stock and newly manufactured commercial batch of Melovetz Injection, Registration No. 102021 in the presence of the Area FID”.*

CASE NO.11: MANUFACTURE AND SALE OF SUB-STANDARD GLITRIC TABLET 2.6MG BATCH NO. 25H261, GLITRIC TABLET 6.4MG BATCH NO 25H262 AND BETAHIST TABLET 16MG BATCH NO. 25H249 MANUFACTURED BY M/S. LINTA PHARMACEUTICALS PLOT NO. 3 STREET NO. S-5 NATIONAL INDUSTRIAL ZONE (RCCI) RAWAT, ISLAMABAD DML NO. 000810)

Drug Control Administration of Gilgit Baltistan (GB) issued a medicine recall alert No. CDC/ RA/ 1-1/ 2025 regarding following products declared Substandard by DTL GB:

Serial No	Name of Product	Manufactured by	Reg. No.	Batch No.	DTL, GB Report
1	Glitric Tablet 2.6mg (Each prolong release tablet contains: Glyceryl Trinitrate 2.6mg)	M/s Linta	119607	25H261	Substandard on the basis of Dissolution
2	Glitric Tablet 6.4mg (Each prolong release tablet contains: Glyceryl Trinitrate 6.4mg)	Pharmaceuticals, Plot No. 3, Street No. S-5, National Industrial Zone (RCCI), Rawat, Islamabad	119637	25H262	Substandard on the basis of Dissolution
3	Betahist Tablet 16mg Each tablet contains: Betahistine Dihydrochloride 16mg		091595	25H249	Substandard on the basis of Physical Appearance

2. Upon receiving the above-mentioned recall alert, Director, QA<, DRAP, Islamabad, constituted the following panel to carry out investigative/Product Specific Inspection to determine the Root Cause:

- a. Ms. Tehreem Sara FID-II, DRAP, Islamabad
- b. Mr. Farhad Ullah Deputy Director DRAP, Islamabad.

3. The panel visited M/s Linta Pharmaceutical (Pvt) Ltd Rawat, Islamabad on 21-01-2026 and furnished their inspection report which is being reproduced below:

A. OBSERVATIONS

The Product specific inspection was conducted by the panel to review of pharmaceutical product development procedures with reference to established Critical Process Parameters (CPPs), including mixing time, compression force, granulation parameters, temperature, and humidity, as well as defined Critical Quality Attributes (CQAs), including the physical, chemical, biological, and microbiological characteristics such as assay, dissolution, and content uniformity, which are required to be maintained within specified limits to ensure product quality, safety, and efficacy.

During the inspection, the panel reviewed the product recall status, vendor qualification parameters, and manufacturing records, including the Batch Manufacturing Records (BMRs) of the above-mentioned batches. The inspection further covered a review of testing protocols, method verification and method validation parameters. The availability and control status of reference standards and working standards were also checked.

The following observations were made by the panel during the review of document and then onsite inspection of the general tablet section and Quality Control lab

I. Premises

The firm has got its first layout plan approval in 2015 and later revise the same. The unit is constructed as per approved layout plan with the provision of male and female change room. The panel visited the tablet section and observed that the tablet section contained the areas of mixing, granulation area, drying (tray dryer & fluidized bed dryer) and then two compression rooms. The rooms were hygienically clean.

The panel inquired detailed information on the manufacturing process and control strategy for Glitric Tablets containing **Glyceryl trinitrate**, an active substance with a narrow therapeutic index and highly sensitive. Glyceryl trinitrate is chemically labile and highly susceptible to degradation when exposed to environmental, mechanical, or thermal stress. In view of its low solubility, narrow therapeutic margin, and inherent instability, the manufacturing process needed to be designed with stringent control of formulation composition, excipient compatibility, environmental conditions, and critical process parameters to ensure product quality, dose uniformity, stability, and patient safety.

Ii. Document control and management

Organizational Structure

The organogram is not provided by the firm in the site master file as well as in the documents submitted. However, at the time of inspection Production in-charge, QC in-charge and QA incharge is present. The experience of QA incharge needs to be reevaluated in the light of the DRAP SRO 1460(I)/2019 dated 27-11-2019.

Since the focus of the inspection is to conduct a product specific inspection, hence the panel looked into details related to the products declared as substandard.

The detail of each product is as under;

i)-Glitric tablet

The panel inquired detailed information on the manufacturing process and control strategy for Glitric Tablets containing **Glyceryl trinitrate**, active substance with a narrow therapeutic index. Glyceryl trinitrate is chemically labile and highly susceptible to degradation when exposed to environmental, mechanical, or thermal stress. In view of its low solubility, narrow therapeutic margin, and inherent instability, the manufacturing process needed to be designed with stringent control of formulation composition, excipient compatibility, environmental conditions, and critical process parameters to ensure product quality, dose uniformity, stability, and patient safety.

During inspection and dossier review, **critical deficiencies** were identified in the pharmaceutical development, manufacturing process design, and control strategy for Glitric Tablets containing glyceryl trinitrate. These deficiencies directly impact the product's quality, dose uniformity, stability, and patient safety. The detail review of the product on the basis of the document provided by the firm and evaluated by the panel is as under:

The documents provide by the firm indicted that the product **Glitric 2.6mg** tablet registered vide Reg# 119607 dated 12-02-2024 and **Glitric 6.4mg** tablet vide Reg# 119637 dated 16-02-2024.

ii)-Betahist Tablet 16mg:

It is registered vide registration #091595 dated 31-08-2018 with BP specification. The sample was declared as substandard on the basis of “Physical description “(as the tablet found with softening, cracking, rough orange peel texture, easily break and becomes powder when press with fingers.) indicating poor mechanical strength and/or inadequate protection from moisture. Such defects suggest process control failures in granulation, compression, drying, coating, or packaging. These physical deviations render the product substandard as per BP specifications and pose a risk of dose variability and patient handling difficulties.

The detail of the inspection observations on the basis of the document presented and the onsite inspection conducted by the firm for the individual product is narrated below:

Vendor Qualification:

The management informed them that the vendor qualification is being done on the basis of the testing of the samples and when it qualifies the parameters then the vendor is approved. The SOPs /document vide Document #QA/SOP/020 effective date 20-04-2024, Rev -001 were also reviewed by the panel indicating that the QA department asked for the 3 sample from the purchase department and then these sample were sent to R&D, QC head conduct tests on these samples and qualifies these.

The panel observe that the “reference standards” were not available with the firm, only working standards were present and management of the firm fails to submit the trail record of the standardization of these. So in the absence of such practice, the standardization of the material cannot be achieved. Similar is the case with the Glyceryl trinitrate.

The API is imported from M/s Chin Chem India as **Diluted Glyceryl Trinitrate** which is mixture of glyceryl trinitrate (Nitroglycerine) with lactose, to permit safe handling and to reduce explosion risk. The identification of this material is through Thin Layer Chromatography (TLC) and HPLC but the facility of TLC is not available with the firm. However, the testing is being done with the second method with HPLC, but again in absence of the reference standard or standardized working standard, the methods once again need to be re-validated. In addition to that the firm did not conduct the impurity testing as recorded and it was also observed by the panel that only one vendor is selected by the firm and the qualification studies record of the three batches of the vendor samples has also not been available at the time of inspection

i)-Glitric Tablet 2.6mg (B.No 25H261):

This batch of Glyceryl trinitrate was declared as Substandard on the basis of **Assay & Dissolution** test. The detail of the result is as under

Assay: **144%**

Dissolution:

Time	1st Hour	4th Hour	8th Hour
Release %age	51.6%	108.2%	128.6%
Limit	NMT 50%	35-80%	NLT 70%

The test result shows the results out of the specifications limits and declared substandard by the DTL Gilgit Baltistan

During their visit, the panel also reviewed the BMR of this batch. the findings of the panel is as under:

The subject product is registered with the “innovator specifications” but firms failed to present the innovator testing method and product development data with the panel.

In addition to that the comparative testing with the innovator products and its record was

also not available at the time of inspection with the firm. The firm's technical staff informed the panel that they have conducted the testing on the basis of "Manufacturer specifications." The assay results upto **144%** indicate excessive drug load in the subject prolong release tablet. However, in case of the drugs like Nitroglycerines and vitamins and in certain antibiotics, an addition of $\leq 5-10\%$ is permissible but the finished products must comply with the assay limits. So the assay of 144% may increase the risk of dose dumping, acute overdose and inadequate control of release results which is also evident that the dissolution profile results also indicate the dose dumping.

Observations in BMR:

The document presented before the panel, document title is "Product Analysis Method" and document number is QC/PAM/151, issued date 06-01-2024 and the assay acceptance criteria is 90-120% however it was observed that the in the BMR the assay limit id 90-110% and it has been observed that assay limit varies in document.

Furthermore, the content uniformity which is a critical quality attribute/parameter is not included in part of this document

In addition to that, the **dissolution protocols** are mentioned as below:

Method: USP II (Paddle Method)

Rotation 50rpm

Dissolution medium: distilled water (500ml)

Temperature : $37 \pm 0.5^{\circ}\text{C}$

Sampling intervals :1st hour ,4th hour &8th hour

Limits:

1 st hour	NMT 50%
4 th hour	35-80%
8 th hour	NLT 70%

However, the Dissolution results provided by the DTL, Gilgit Baltistan, demonstrate excessive early and overall drug release, indicating loss of prolonged-release characteristics and potential dose dumping. The batch therefore represents a critical quality defect with significant patient safety risk.

Furthermore, the above reference indicate that the firm has conducted dissolution testing of Glyceryl Trinitrate Prolonged-Release Tablets using **distilled water as the dissolution medium**. This medium is not physiologically relevant and does not comply with regulatory expectations for modified-release dosage forms. Prolonged-release products are required to be evaluated in appropriate buffered media to simulate gastrointestinal environments.

Use of distilled water lacks buffering capacity and pH control, which may lead to misleading dissolution results, failure to detect dose dumping, and inability to assess the true release characteristics of the product.

The dissolution method employed by the firm is therefore scientifically unjustified and regulatory unacceptable. Results generated using this method cannot be considered valid for quality evaluation or batch release purposes.

iii)-Glitric 6.4mq declared as substandard based on assay which is **147%**, so the results of both strengths show excessive drugs load, and this needed to review at the end of the firm. The batch manufacturing records of both the batches shows varies assay limits.

The method validation as well as method verification studies need to be reconsidered.

The firm was already directed by the area FID to recall their products immediately from the market and submit details in the DRAP office.

Practices in Production:

The firm informed the panel that they are manufacturing the nitroglycerine prolong release tablet by **wet granulation method and drying is being done through tray dryer**. The process of pitfalls like mixing time, temperature monitoring etc etc. in these methods has not been kept in mind by the firm. It was also noted by the panel that selection of excipients has not been taken into consideration while formulating the prolong release tablet.

Considering the highly potent and volatile nature and temperature sensitive nature of glyceryl trinitrate, this process presents a high risk of drug migration and content non-uniformity. The observed assay result of 144% as well as 147% and severe dissolution failure indicate inadequate control of granulation and drying processes, leading to excessive drug content and loss of prolonged-release behavior. The explanation provided by the firm is not acceptable from a regulatory point of view and results in opinion by the panel that the method is not validated and the firm should have to reconduct the product development studies. It has also been observed that the firm's management didn't consider the release characteristics of the polymer used in formulation. The rationale between the selection of excipients, selection of production process and validations studies were not available.

iii)-Betahist Tablet 16mg (BP. Specs):

The tablet contains Betahistine Dihydrochloride declared as **substandard** on the basis of "Physical description" "(as the tablet found with softening, cracking, rough orange peel texture, easily break and becomes powder when press with fingers.).

The panel review the document namely "Product Analysis Method" document #QC/PAM/085 issue date 30-12-2023 and revision date is 30-12-2028 (while the product registration date is 31-08-2018). The document indicates that the firm has not made the content uniform as a part of their testing methods. Furthermore, the subject document does not contain any instruction regarding the storage conditions of the products '.

The panel checked the BMR and asked about the nature of the products. Since **Betahistine** is a moisture sensitive product, its production and selection of excipients should be in accordance to the nature of the API which has not been kept on mind.

The panel is of the opinion that the substandard quality on the basis of physical parameter is the result of poor process parameter controls. However, no root cause analysis has been presented before the panel. Although the management informed them that they also observe such changes in their products.

The panel looked into the reason that the in-process parameter has not been properly observed like the parameters of hardness, friability and compression weight. The panel asked the firm regarding the vendor qualification, and it was observed that only one vendor like nitroglycerine has been so far qualified by the firm, but the vendor qualification test and analysis record was not available, and it was observed that the standardized working standard was also not available. Furthermore, the panel observed that in BMR the temperature has been recorded as 22°C and humidity is recorded as 32% but this has not been observed during onsite visit.

Onsite inspection

The panel visited the **raw material store**, tablet section and quality control lab and noted various observations like the firm was advised to place the material according to storage conditions. The alert and action limit is also needed to define on the checklist of the raw material store.

The **tablet section** has also been visited. The dehumidifier is not available at the time of inspection; it was also observed that the cone mixer has been closed with the tape which the

panel advised to replace it and adjust its lid. The firm has two compression rooms, but dust collectors are not provided.

Quality control lab

Furthermore, the firm has recently bought FTIR. The FTIR analysis was performed without the use of a validated reference spectral library. The generated infrared spectra were not compared against authenticated, validated reference spectra so the identification relied solely on visual interpretation or peak presence, without statistical or spectral matching, which does not ensure specificity or identity confirmation.

B. RECALL STATUS: -

- i. The Firm has submitted documents which reveal that the firm has given the advertisement in urdu and English language Newspaper regarding the recall of these products w.r.t DRAP, letter NO. F.2-6/2011-FID-II dated 24th December 2025 and the details of the recall status of the firm is attached (**copy enclosed**). The reconciliation of remaining batch has also been checked by the panel in the recall/rejected store of the firm. The firm is directed to keep these batches in safe custody till the decision by the competent authority.

C. LIST OF DEFICIENCIES:

S.No	Deficiencies/Non-Compliance	Classification of Deficiency Guidance Document No. QALT/GL/CG/002 Effective Date: 30-03-2023
01	Glitric 2.6 mg & 6.4 mg tablets: Assay results 144% & 147%; Dissolution failure with dose dumping.	Critical
02	Use of distilled water as dissolution medium for prolonged-release nitroglycerin tablets.	Critical
03	Absence of reference standards for API and working standards not standardized or validated.	Critical
04	Absence of content uniformity testing for both Glitric and Betahistine tablets.	Critical
05	Wet granulation and tray drying of Glyceryl Trinitrate without validated control of drug migration or thermal stress.	Critical
06	Failure to conduct impurity testing and vendor qualification records incomplete for APIs.	Critical
07	Betahistine tablets: softening, cracking, friability, rough "orange peel" texture.	Critical
08	BMR shows inconsistent assay limits between documents (90–120% vs 90–110%).	Major
09	Manufacturing SOPs not aligned with product-specific requirements (e.g., content uniformity, stability conditions).	Major
10	HPLC and FTIR analysis conducted without validated reference standards or spectral library.	Major
11	Environmental conditions in tablet section (22 °C / 32%	Major

	<i>RH) not consistently monitored; dehumidifier not present.</i>	
12	<i>Cone mixer lid taped; dust collectors missing in compression rooms, could cause cross-contamination and particulate control issues.</i>	Major
13	<i>Stability chambers and QC instruments present but no validated methods for new equipment</i>	Minor
14	<i>Storage conditions for raw materials not clearly defined; alert/action limits not set.</i>	Minor

SUMMARY	
<i>The inspection conducted by the panel identified some critical and systemic deficiencies in the pharmaceutical quality system of the firm, particularly in relation to the manufacturing, quality control, and documentation practices for Glyceryl Trinitrate (Glitric) and Betahistine Dihydrochloride tablet products declared as Substandard by the DTL. Both strengths of Glitric tablets (2.6 mg and 6.4 mg) were found grossly non-compliant with approved specifications, exhibiting excessively high assay values (144% and 147%) and pronounced dissolution failures indicative of uncontrolled drug release and dose dumping. The firm failed to demonstrate compliance with innovator specifications despite registration claims, and no comparative dissolution studies were presented. Critical quality attributes, including content uniformity, were not incorporated into routine testing. Additionally, dissolution testing was conducted using distilled water, which is scientifically unjustified and does not meet regulatory expectations for prolonged-release dosage forms.</i> <i>Betahistine Dihydrochloride tablets were declared substandard on the basis of physical defects, including softening, cracking, friability, and surface irregularities, reflecting inadequate process control, moisture management, and formulation suitability. The inspection further revealed deficiencies in vendor qualification, absence of authenticated reference standards, inconsistent assay limits across quality documents, unvalidated analytical methods, insufficient environmental controls, and non-compliance with established GMP documentation requirements.</i>	
CONCLUSION	
<i>Based on the findings of the inspection, the panel concludes that the firm has not established an effective pharmaceutical quality system capable of ensuring consistent compliance with regulatory, pharmacopoeial, and GMP requirements. The observed deficiencies, particularly those related to excessive drug content, invalid dissolution methodology, lack of content uniformity testing, and inappropriate manufacturing processes for a chemically labile and narrow therapeutic index drug such as glyceryl trinitrate, constitute critical non-compliances with direct implications for patient safety. The physical instability observed in Betahistine Dihydrochloride tablets further demonstrates inadequate control over formulation development, manufacturing parameters, and environmental conditions</i>	
RECOMMENDATION	
<i>In view of the above, the panel recommends that the registrations of Glyceryl Trinitrate (2.6mg & 6.4mg) and Betahistine Dihydrochloride 16mg tablets shall be immediately suspended until full compliance with regulatory requirements is achieved OR the result of the firm request for appellate testing. The panel further recommends that the firm should undertake comprehensive pharmaceutical redevelopment of Glitric tablets, including re-evaluation of formulation design, selection of an appropriate and validated manufacturing process, and establishment of scientifically justified, physiologically relevant dissolution methods, its evaluations and its</i>	

interpretation. All analytical procedures must be revalidated using authenticated reference standards/validated working standards. Similar is the case of Betahistine tablet.

Furthermore, critical quality attributes such as content uniformity must be incorporated into routine quality control testing. Vendor qualification systems should be strengthened; impurity profiling must be conducted in accordance with pharmacopoeial requirements and environmental controls including humidity and temperature, should be implemented and monitored.

Additionally, the firm should update and align all SOPs, batch manufacturing records, and quality documents, ensure that the staff are compliant with regulatory requirements, and show effective implementation of corrective and preventive actions. The CAPA report, in DRAP's prescribed format, shall be submitted to the Drug Regulatory Authority of Pakistan for considerations of the competent authority.

6. In the light of report and recommendations of panel, it was evident that the firm had failed to establish an effective pharmaceutical quality system capable of ensuring consistent compliance with regulatory, pharmacopoeial, and GMP requirements. Thus they had been unable to demonstrate consistent quality, safety and efficacy of the product and were found to have violated section 23(1)(a)(v) of the Drug Act 1976, and the rules made there under read with Schedule-II of the DRAP Act 2012 as well as the conditions of registration which is punishable under section 27 of the Drugs Act, 1976 read with Schedule-III of DRAP Act, 2012. A show cause notice vide letter No.F.03-13/2026-DD(QALT)-VI dated 02-03-2026 was therefore issued to the firm.

7. The firm replied to the said show cause vide letter No. Nil dated 09-03-2026; the statement of the firm is being reproduced below:

"At the outset, we would like to express our sincere commitment to full regulatory compliance and adherence to the Drug Act, 1976 and applicable DRAP Rules & Guidelines. We take the observations communicated in the notice very seriously and have conducted a detailed internal review to identify root causes and implement immediate corrective and preventive actions (CAPA).

All deficiencies highlighted in the notice have been addressed systematically. Updated SOPs, revised records, validation of documents, and other supporting evidence have been prepared and are available for verification. Where structural or operational improvements were required, the same have been executed in line with regulatory expectations.

We respectfully submit that there was no deliberate or intentional non-compliance on our part. Any shortcomings observed were inadvertent and have now been rectified. Our management remains fully committed to maintaining the highest standards of quality, safety, and regulatory compliance.

As we have applied for retesting in Quality Control board, Gilgit Baltistan, we humbly request your good office to kindly wait until the retesting results come out. I would like to request you to grant us an opportunity to appear before the registration board to present our case as well. We assure you of our full cooperation with DRAP at all times."

8. CAPA sheet submitted by the firm is herewith reproduced:

DETAILS:	
NON CONFORMITIES FOUND BY:	Ms. Tehreem Sara (FID-II, DRAP, ISLAMABAD) Mr. Farhad Ullah (Deputy Director DRAP ISLAMABAD)
NON CONFORMITIES IDENTIFIED ON (DATE):	21-01-2026
NON CONFORMANCE INVESTIGATION DATE (In-house):	27-01-2026 - 29-01-2026
NON CONFORMITITES INVESTIGATED BY:	Syeda Javeria Bukhari
CORRECTIVE & PREVENTIVE ACTION TAKEN DATE:	05-02-2026
CORRECTIVE & PREVENTIVE ACTION TAKEN BY:	Syeda Javeria Bukhari (QAM) Muhammad Hashim Baig (PM)
VERIFICATION OF EFFECTIVESS DATE:	09-02-2026
VERIFICATION OF EFFECTIVENESS DONE BY:	Waqar Alam (QCM)

Sr. #	Observation / Deficiency	Root Cause Analysis	Corrective Action	Preventive Action	CAPA STATUS
1	Assay results out of specification & dissolution failure (Citric tablets).	Inadequate process validation.	Batch investigation conducted; No affected batches found other than the recalled ones & they have been segregated.	Full process validation & dissolution method revalidation; in-process controls strengthened.	CAPA OPEN because Process validation is underway.
2	Use of distilled water as dissolution medium.	We were using Distilled water as recommended in this article. Revised-ms_JPRI_95260_v1.pdf and (PDF) Development of sustained release matrix tablet of nitroglycerin containing hydrophilic polymers	Method of analysis has been revised using 6.8 buffer as dissolution medium; as second option given in the same article,	Closely monitor the behavior & results of Dissolution test. Method validation is in process.	CAPA CLOSED (05-02-2026) The medium has been changed.
3	Absence of validated reference standards.	Lack of formal standard qualification procedure.	We were using working standard provided by the manufacturers; Their trail & COAs available for record	We have given demand for the provision of reference standards as well. Quotation	CAPA OPEN (till the sample arrives)

				Attached in Annexure 1	
4	No content uniformity testing.	We were not doing content uniformity before; Incomplete specification compliance.	Content uniformity testing initiated for all relevant products.	BMR & specification updated to include mandatory CU testing.	CAPA CLOSED on 04-03- 2026
5	Un-validated wet granulation/tray drying process.	Lack of process validation study.	Observational batches on direct drying has been carried out & process validation initiated.	Process validation protocol approved & implemented.	CAPA OPEN (till the
6	No impurity testing & incomplete vendor qualification.	We have only one vendor approved for both the APIs instead of three vendors.	Impurity profiling initiated & initiated qualification of two more vendors for both the APIs.	Names of two other vendors whom we have reached out, is attached in Annexure 2	CAPA OPEN (until the vendor qualification process be completed.
7	Physical defects in Betahist tablets.	Humidity control issues.	Defective batch quarantined & examined on the basis of environmental controls.	Specialized Environmental control shall be mentioned on the unit carton from now onwards.	CAPA OPEN UNTILL THE RESULTS FOR OBSERVATIO AL BATCHES ARRIVES.
8	Inconsistent assay limits in BMR.	Clerical errors	Reports attached in the BMR are being corrected and standardized.	Document control system strengthened.	CAPA CLOSED. (05-02-2026)
9	SOPs not aligned with product specific requirements.	Generic SOP usage without customization.	Product-specific SOPs revised.	Annual SOP review mechanism implemented.	CAPA CLOSED. (05-02-2026)
10	HPLC & FTIR without validated standards/library.	Then-Newly purchased FTIR has mechanical errors so we have returned it & got quotations for the new one with library.	Qualification & validation studies shall be carried out when the equipment arrives.	SOP for equipment calibration & verification shall be implemented. Quotation for new FTIR attached in	CAPA CLOSED. (05-02-2026)

				annexure 3.	
11	Environmental monitoring inconsistent; no dehumidifier.	HVAC inadequacy.	Dehumidifier installed; monitoring log initiated.	Environmental monitoring SOP updated; alarm limits defined.	CAPA CLOSED. (05-02-2026)
12	Dust collectors missing; cone mixer lid taped.	Delay in procurement of new equipment	Now the Dust collectors installed & the lid of the mixer has been fixed	Preventive maintenance schedule implemented.	CAPA CLOSED. (05-02-2026)
13	No validated methods for new equipment.	The equipment (FTIR) was then newly purchased & has mechanical errors that's why validation was not performed.	Equipment qualification shall be initiated (IQ/OQ/PQ) when the new equipment arrives.	Validation Master Plan updated.	CAPA CLOSED. (05-02-2026)
14	Storage conditions in the RMS not defined; no alert/action limits.	Incompetent warehouse control system.	Storage conditions defined; temperature/RH monitoring started.	Alert/action limits established; warehouse SOP updated.	CAPA CLOSED.

9. Accordingly, Personal Hearing Notice was issued to the firm vide letter No.F.03-17/2026-QALT(356-RB) dated 01-04-2026.

16. Proceedings and Decision of 356th Meeting of Registration Board

Division of QA & LT presented the case before the Registration Board. The Board, after reviewing the facts, reports of DTL, GB, PSI conducted by the panel, CAPA submitted by the firm, and noting that Glitric Tablet 2.6mg (Reg# 119607) & Glitric Tablet 6.4mg (Reg# 119637) are narrow therapeutic and lifesaving medicines decided to:"

- i. ***"Suspend the Registration of Glitric Tablet 2.6mg (Reg# 119607), Glitric Tablet 6.4mg (Reg# 119637) & Betahist Tablet 16mg (Reg# 091595) manufactured by M/s Linta Pharmaceuticals, Plot No. 3, Street No. S-5, National Industrial Zone (RCCI), Rawat, Islamabad for a period of six months under section 42 of the Drugs Act, 1976 and rules framed thereunder.***
- ii. ***Direct the firm to recall all marketed batches of Glitric Tablet 2.6mg and Glitric Tablet 6.4mg.***
- iii. ***Call the firm M/s Linta Pharmaceuticals, Plot No. 3, Street No. S-5, National Industrial Zone (RCCI), Rawat through its representative in the forthcoming meeting of the Registration Board."***



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



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

Sr. No	Title	Description
1	Case Category	Import (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	(MEQ-WXE-J9YT, 2026-03-10)
	Detail of Fee Submitted	313500, 2025-12-10,
	The proposed proprietary name / brand name	Sunitib 12.5mg Capsules
	Label Claim	Each capsule contains: Sunitinib12.5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	30's-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C.
	For generic drugs (me-too Status)	Sunetic 12.5mg Capsules - Pharmasol Pvt. Ltd
	Pharmacotherapeutic Group of (API)	L01EX01-Antineoplastic agents
	Name, address of Manufacturing site:	Pharmacare Premium Ltd. -HHF003. Hal Far Industrial Estate, Birzebbugia, BBG3000, Malta. -Malta
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Drug Product 3.2.P.2 (PE and CDP) performed against Biobatch
	Name, address of Marketing Authorization Holder:	My Body Healer (Private) Limited , Office No. 104 & 105, 1st Floor, Plot No. 54-C, Al Murtaza Commercial Lane-2, Phase VIII, DHA, Karachi, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	EUDRA GMP MT/007HM/2023 CoPP: Malta Medicines Authority; Certificate No. 2006/007 dated 19-01-2026 (Appostiled)
	Details of Authorization Letter :	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	At long-term and accelerated conditions
	The status in reference regulatory authorities	Sunitinib 12.5 mg hard capsules- EMC UK
	Evaluation Remarks	
	The application fulfils codal formalities.	
	Decision	
	Approved	
	As per policy for inspection abroad.	
2	Case Category	Import (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	(A2Q-BAU-2XL3, 2026-03-10)
Detail of Fee Submitted	313500, 2026-02-13,
The proposed proprietary name / brand name	Pazopan 200mg Tablets
Label Claim	Each film coated tablet contains: Pazopanib hydrochloride equivalent to 200mg of Pazopanib.
Reference to Finished product specifications	European Pharmacopeia
Proposed Pack Size	10's, 20's, 30's and 90's-De-Controlled
Shelf Life (Unit)	3 Year(s)Store below 30°C
For generic drugs (me-too Status)	Votrient 200mg Tablets by Novartis (Pakistan) Ltd.
Pharmacotherapeutic Group of (API)	ATC Code: L01EX03, Antineoplastic agents, protein Kinase Inhibitors
Name, address of Manufacturing site:	Pharmacare Premium Ltd.- HHF003. Hal Far Industrial Estate, Birzebbugia, BBG3000, Malta.-Malta
Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in Module III Section 3.2.P.2
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 No. MT/007HM/2023 CoPP issued by Malta Medicines Agency number 2026/008 dated 19.01.2026
Details of Authorization Letter :	Not applicable for imported product
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	At long-term and accelerated conditions
The status in reference regulatory authorities	Pazopanib 200mg Film Coated Tablets, Zentiva Pharma UK Limited, MHRA, UK.
Evaluation Remarks	
The application fulfills coda formalities.	
Decision	
Approved	
As per policy for inspection abroad.	
3	Case Category
	Import (Abdul Mughees)
	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
	(82S-PBL-RG9P, 2026-03-24)
	Detail of Fee Submitted
	313500, 2025-12-22,
	The proposed proprietary name / brand name
	Sorafen 200mg Tablets
	Label Claim
	Each film coated tablet contains: Sorafenib Tosylate 274mg equivalent to 200mg Sorafenib
	Reference to Finished product specifications
	European Pharmacopeia
	Proposed Pack Size
	1x10's, 2x10's, 1x30's, 1x60's & 1x120's-De-Controlled
	Shelf Life (Unit)
	3 Year(s)Store below 30°C
	For generic drugs (me-too Status)
	Soranib 200mg Tablets by AJM Pharma (Pvt.) Ltd.

	Pharmacotherapeutic Group of (API)	L01EX02 - Antineoplastic agents, protein kinase inhibitors
	Name, address of Manufacturing site:	Pharmacare Premium Ltd.-HHF003. Hal Far Industrial Estate, Birzebbugia, BBG3000, Malta.-Malta
	Pharmaceutical Equivalence and Comparative Dissolution Profile	(PE & CDP).
	Name, address of Marketing Authorization Holder:	My Body Healer (Private) Limited, Office No. 104 & 105, 1 st Floor, Plot No. 54-C, Al Murtaza Commercial Lane-2, Phase VIII, DHA, Karachi. , Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	EUDRA GMP COPP 2026/010 issued by Malta Medicines Authority
	Details of Authorization Letter :	Not applicable for imported product.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	At long-term and accelerated conditions
	The status in reference regulatory authorities	Sorafenib Zentiva 200 mg film-coated tablets by Zentiva Pharma UK Limited - MHRA UK
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
	As per policy for inspection abroad.	
4	Case Category	Import (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	(51P-JGG-R5B3, 2026-03-24)
	Detail of Fee Submitted	313500, 2026-02-13,
	The proposed proprietary name / brand name	Pazopan 400mg Tablets
	Label Claim	Each film coated tablet contains Pazopanib hydrochloride equivalent to 400mg of pazopanib.
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	10's, 20's, 30's and 60's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Votrient 400mg Tablets, Novartis (Pakistan) Ltd.
	Pharmacotherapeutic Group of (API)	ATC Code: L01EX03, Antineoplastic agents, protein Kinase Inhibitors
	Name, address of Manufacturing site:	Pharmacare Premium Ltd.-HHF003. Hal Far Industrial Estate, Birzebbugia, BBG3000, Malta.-Malta
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP
	Name, address of Marketing Authorization Holder:	My Body Healer (Private) Limited, Office No. 104 & 105, 1 st Floor, Plot No. 54-C, Al Murtaza Commercial Lane-2, Phase VIII, DHA, Karachi. , Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	EUDRA GMP certificate CoPP 2026/009 issued by Malta Medicines Authority
	Details of Authorization Letter :	Not applicable for imported product

Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	At long-term and accelerated conditions
The status in reference regulatory authorities	Pazopanib 400mg Film Coated Tablets. Dr. Reddy’s Laboratories UK Limited , MHRA UK.
Evaluation Remarks	
The application fulfills codal formalities.	
Decision	
Approved	
As per policy for inspection abroad.	
Case Category	Import (Abdul Mughees)
Name, address of Applicant.	MSA PHARMA 1st floor, 793-D Block C Faisal Town (05-352-0066-112591D)
Application Form Dy. No / Tracking ID & date of submission	(2Q2-YW7-U96Q, 2026-02-12)
Detail of Fee Submitted	, 313500 , 2026-01-23
The proposed proprietary name / brand name	Niranib capsule 100mg
Label Claim	Each Capsule contains Niraparib Tosylate Monohydrate INN equivalent to Niraparib 100 mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	30's-As per SRO
Shelf Life (Unit)	2 YearDo not store above 30°C.
For generic drugs (me-too Status)	Niraparix 100mg capsule (Niraparib)
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. , Rahman’s Regnum Center (11th Floor) 191/B Tejgaon C/A, Dhaka-1208, Bangladesh , Bangladesh
Details of Certificates (CoPP/FSC/cGMP):	Enclosed
Details of Authorization Letter :	NA
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Enclosed
The status in reference regulatory authorities	Zejula 100 mg hard capsules (Niraparib)
Evaluation Remarks	
In Module 3, applicant claimed that Drug Substance is manufactured by Beijing Sjar Technotogy Development Co., Ltd. China. Accordingly, the working standard COA was attached at page 591 of the dossier in which the country of origin for the same manufacturer was written as India. Clarification was sought from the applicant to which the applicant has attached another document as COA of working standard wherein the dates and results are same as previously submitted COA however country of origin has been changed to China in an entirely different font and format. Furthermore, scanned (unidentifiable) signatures have been pasted. The aforementioned submissions point towards issues in data integrity.	
Decision	
Rejected	
Registration Board rejected the application on account of submission of tempered COA for reference standard	

6	Case Category	Import (Abdul Mughees)
	Name, address of Applicant.	MSA PHARMA 1st floor, 793-D Block C Faisal Town (05-352-0066-112591D)
	Application Form Dy. No / Tracking ID & date of submission	(JBB-LHX-XSD6, 2026-03-16)
	Detail of Fee Submitted	313500, 2025-12-26,
	The proposed proprietary name / brand name	Philanil 200mg Capsule
	Label Claim	Each hard capsule contains.....200 mg Nilotinib (as Hydrochloride Monohydrate).
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	120's-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30°C.
	For generic drugs (me-too Status)	Nilonix 200mg Capsule (Himmel Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	Kaifeng Pharmaceutical (Group) Company Limited, China
	Name, address of Manufacturing site:	Everest Pharmaceuticals Limited.-Rahman's Regnum Centre (11th) Floor) 191/1, Tejgaon C/A, Dhaka-1208,- Bangladesh
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in Relavant section of Module 3.
	Name, address of Marketing Authorization Holder:	Everest Pharmaceuticals Limited., Plot No: B-45, 46 & 33, BSCIC I/A, Kanchpur, Narayanganj, , Bangladesh
	Details of Certificates (CoPP/FSC/cGMP):	01.10.2026 (Valid till)
	Details of Authorization Letter :	Not Applicable for Finished drug Product importer.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	24 Months
	The status in reference regulatory authorities	Tasigna 200mg hard Capsules. (Novartis UK)
Evaluation Remarks		
The applicant submitted Comparative Dissolution Profile which reported upto 100 % release in buffer solutions of 4.5 pH and higher. However, the innovator product as assessed by US FDA shows to be practically insoluble in aforementioned pH. The appciant was asked to prove that submittedComparative Dissolution Profile was actually performed and the values recorded by them for the test and reference product were correct along with the scientific rationale. The applicant has submitted that "The previously submitted document was inadvertently attached. The correct and validComparative Dissolution Profile (CDP) is now attached in the Annexure 5." However, no rationale was given neither data evidence was provided (Protocols, chromatograms, calculation sheets and audit trail) that the CDP was actually performed.		
Decision		
Deferred		
Registration Board deferred the application for submission of Comparative Dissolution Profile protocol and report along with all supporting data including assay results for 12 units for test and reference product across all three mediums, relevant chromatograms, calculation sheets and audit trail.		
7	Case Category	Import (Abdul Mughees)
	Name, address of Applicant.	Karim Traders Cutchi gali no 1, marriott road karachi (616)
	Application Form Dy. No / Tracking ID & date of submission	(ZTQ-HMT-GYLW, 2025-02-13)
	Detail of Fee Submitted	300000.0, 2024-08-27,
	The proposed proprietary name / brand name	Sold with generic name

Label Claim	Each capsule contains Doxycycline Hyclate equivalent to doxycycline 100mg
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	10 Capsule/Blister a-Controlled
Shelf Life (Unit)	3 Year Store in a tight containers protect from light in cool place.
For generic drugs (me-too Status)	Vibramycin Doxycycline Hyclate 100mg Manufactured by; Pfizer Pharmaceutical
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Jinzhou Jiuyang Pharmaceutical Co., Ltd.-No.6, Road three Street jingang Economic & Technological Development Zone, City Jinzhou, province Liaoning, China-China
Pharmaceutical Equivalence and Comparative Dissolution Profile	
Name, address of Marketing Authorization Holder:	Ningbo Sinofin Pharmaceutical Co., Ltd, 9-11 West Zhongshan Road, Ningbo, 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	MHRA Approved

Evaluation Remarks

The sole agency agreement indicates that there are two suppliers i.e. Manufacturer Jinzhou Jiuyang Pharmaceutical Co., Ltd. and its exporter Ningbo Sinofin Pharmaceutical Co., Ltd. Furthermore, the applicant was asked to revise specifications in strict compliance to BP monograph.

Decision

Approved

Approved with revision of specification to British Pharmacopoeia monograph, submission of requisite fee for revision of specifications and as per policy for inspection abroad.

8	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/index.cfm?event=overview.process&ApplNo=202379

Evaluation Remarks

Registration Board in its 355th meeting deferred the case for the following: "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:rn 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 orrn 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. The firm has submitted evidence of approval from the CDSCO, India and US FDA report of inspection for the year 2004. Furthermore, a list of various inspections in various regulatory authorities including US FDA, MHRA and Malaysia has also been submitted.

Decision

Approved

As per policy for inspection abroad.

9

Case Category	Import (Abdul Mughees)
Name, address of Applicant.	NZ Pharmaceutical Suite # 802, 8th Floor, Vital Foakh Tower, Main Shahrah-e-Faisal, Karachi (0848)
Application Form Dy. No / Tracking ID & date of submission	(T7R-V38-DD2V, 2025-10-27)
Detail of Fee Submitted	300000.0, 2025-05-21,
The proposed proprietary name / brand name	Ositiz 80
Label Claim	Each film coated tablet contains Osimertinib mesylate 80mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	30-As per SRO
Shelf Life (Unit)	2 Year(s)30 °C
For generic drugs (me-too Status)	Tagrisso 80mg AstraZeneca Pharmaceuticals Pakistan Private Limit
Pharmacotherapeutic Group of (API)	Anticancer
Name, address of Manufacturing site:	Tizig Pharma Pvt. Ltd.-Maligaun-5, Kathmandu, Nepal. Factory: Tukucha, Nala-1, Banepa, Kavre, Nepal.-Nepal
Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP
Name, address of Marketing Authorization Holder:	Tizig Pharma Pvt. Ltd., Maligaun-5, Kathmandu, Nepal. Factory: Tukucha, Nala-1, Banepa, Kavre, Nepal., Nepal
Details of Certificates (CoPP/FSC/cGMP):	COPP: 081/082 dated 31.03.2026 (un attested) with unknown status under 1.3

	Details of Authorization Letter :	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	24 months
	The status in reference regulatory authorities	TAGRISSO 80 mg film-coated tablets AstraZeneca UK Limited
	Evaluation Remarks	
	The applicant has submitted CoPP that states the status of unknown under 1.3 (if the product is actually in market). The applicant was asked to provide a valid CoPP for which they have stated that: "We guarantee that we will provide a new copp in due course and will be submitted before the issuance of approval letter. Furthermore, the details of market authorization can be checked on https://dams.dda.gov.np/manLogin/publicInfo (website of Ministry of health and papulation Department of Drug Administration) ." Furthermore, the firm was aksed to submit complete stability data for finished product along with relevant chromatograms. It was observed that for B.No.21/0SI-01 _DS4_36M, Bid.Standard Solution, B.No.21/0SM-01 _DS6_36M and others, the vials 33,35,36,38,32 were processed at the same time i.e. 18/09/2024 09:01 :50 1ST with a run time of 10 minutes for each vial, indicating data integrity issues.	
	Decision	
	Rejected	
	Registration Board rejected the application due to submission of tampered chromatograms in the Finished Drug Product Stability data	
10	Case Category	Import (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	(N1U-WZ1-9HRW, 2026-03-31)
	Detail of Fee Submitted	313500, 2026-03-27,
	The proposed proprietary name / brand name	FOSAPRA Injection 150 mg
	Label Claim	Each vial contains: Fosaprepitant Dimeglumine Equivalent to Fosaprepitant 150 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's Vial-As per SRO
	Shelf Life (Unit)	36 Year(s)Store between 2-8 degree centigrade
	For generic drugs (me-too Status)	NA-New Drug Product
	Pharmacotherapeutic Group of (API)	Antiemetic, NK1 receptor antagonists, ATC Code: A04AD12
	Name, address of Manufacturing site:	Qilu Pharmaceutical (Hainan) Co., Ltd.-No.273-A, Nanhai Avenue, National High-Tech Zone, Haikou, Hainan, 570314, China-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence Study performed by Comparison of Innovator's product (EMEND Injection 150mg) with QILU's Applied Product.
	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):	USFDA Approved Manufacturing Site: FEI# 3008250362 CoPP: NQY8-YFWP dated 22 March 2026, issued by US FDA
	Details of Authorization Letter :	Imported product- Not applicable

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies performed on three consecutive commercial batches B# TV8001A, TV8002A and TV8003A on accelerated (6 Months) & Long-term (24 Months). Stability data provided in 3.2.S.7.3
	The status in reference regulatory authorities	EMEND Injection 150mg, NDA# 022023, USFDA Approved
	Evaluation Remarks	
	The application fulfils codal formalities.	
	Decision	
	Approved	
	As per policy for inspection abroad.	
11	Case Category	Import (Abdul Mughees)
	Name, address of Applicant.	Al Qasim Enterprises House No.134-E, Street #01, Sabzazar, Range Road Rawalpindi (01-374-0176-039416D)
	Application Form Dy. No / Tracking ID & date of submission	(43G-G59-ZBLS, 2026-03-25)
	Detail of Fee Submitted	313500, 2026-02-10,
	The proposed proprietary name / brand name	Lenalidomide
	Label Claim	Shall be provided later
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	(1 blister x7 Caps) =7-As per SRO,(2 blister x7 Caps) =14 -As per SRO,(3 blister x7 caps) =21-As per SRO
	Shelf Life (Unit)	3 YearThis medicinal product does not require any special storage conditions.
	For generic drugs (me-too Status)	Yes
	Pharmacotherapeutic Group of (API)	Pharmacotherapeutic group: Immuno suppressants, other immune suppressants. ATC code: L04AX04.
	Name, address of Manufacturing site:	Synthon Chile Ltda. , -El Castano 145, Lampa Santiago Chile -Chile
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attach in Module 3
	Name, address of Marketing Authorization Holder:	Al-Qasim Enterprises , House# 134-E, Street#1, Sabzazar, Range Road, Rawalpindi, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Attached in Module 1
	Details of Authorization Letter :	Attach in Module 3
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached in Module 3.2.S.7
	The status in reference regulatory authorities	Attach in Module 1
	Evaluation Remarks	
	valid License and GMP of the Drug Product Manufacturer	
	Decision	
	Approved	
	Approved subject to submission of valid License and GMP of the Drug Product Manufacturer	
12	Case Category	Import (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	(6DM-1JJ-B2LD, 2026-03-03)
Detail of Fee Submitted	313500, 2025-11-13,
The proposed proprietary name / brand name	Eribulin EVER Pharma 0.44 mg/ml solution for injection
Label Claim	Each 2 ml vial contains Eribulin mesilate equivalent to eribulin.....0.88mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1s(2ml)-As per SRO
Shelf Life (Unit)	2 Year(s)Do not store above 30°C.
For generic drugs (me-too Status)	ERIBULIN AQVIDA
Pharmacotherapeutic Group of (API)	L01XX41 antineoplastic agents
Name, address of Manufacturing site:	EVER Pharma Jena GmbH (Secondary Packaging Site)-Brüsseler Str. 18 07747 Jena, Germany-Germany ,Oncomed manufacturing a.s (Batch Releaser)-Karasek 2229/1b 62100 Brno Czech Republic-Czechia (Czech Republic) ,Oncomed manufacturing a.s.,Karasek 2229/1b 62100 B-Karasek 2229/1b 62100 Brno Czech Republic-Czechia (Czech Republic)
Pharmaceutical Equivalence and Comparative Dissolution Profile	Halaven 1mg/2ml Multiple batches are compared with test product.
Name, address of Marketing Authorization Holder:	EVER Valinject GmbH, Oberburgau 3 4866 Unterach am Attersee, Austria
Details of Certificates (CoPP/FSC/cGMP):	Eudra GMP
Details of Authorization Letter :	Agency agreement is submitted.. COPP is also submitted. COPP is issued in Germany.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	-65C, upto 24 months.
The status in reference regulatory authorities	Eribulin Eisai
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.	
13	Case Category
	Import (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
	(5QE-DYH-YGM8, 2026-03-16)
	Detail of Fee Submitted
	, 313500 , 2026-02-03
	The proposed proprietary name / brand name
	VASEPTA Capsule 1.0gm
	Label Claim
	Each capsule contains: Icosapent ethyl 1.0 gm

Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	120's Bottle Pack-As per SRO
Shelf Life (Unit)	24 Month(s)Store below 30 degree centigrade
For generic drugs (me-too Status)	NA-New Drug Product
Pharmacotherapeutic Group of (API)	Lipid-regulating agent, ATC Code: C10AX06
Name, address of Manufacturing site:	Qilu Pharmaceutical Co., Ltd.-No. 317, Xinluo Road, High-tech Zone, Jinan, Shandong 250101-China
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence study performed by Comparison of Innovator's product (Vascepa capsule 1.0gm) with QILU's Icosapent Ethyl Capsule 1.0gm.
Name, address of Marketing Authorization Holder:	Qilu Pharmaceutical Co., Ltd., No. 317, Xinluo Road, High-tech Zone, Jinan, Shandong 250101, China
Details of Certificates (CoPP/FSC/cGMP):	FDA Establishment Identifier No: 3003802432
Details of Authorization Letter :	COPP and agency agreement is submitted.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies performed on three batches B# 0020170170, 0020170171 & 0020170172, of Icosapent ethyl substance on accelerated (6M) & long-term (36M) conditions. Stability data provided in 3.2.S.7.3
The status in reference regulatory authorities	Icosapent Ethyl Capsule 1.0gm, By Qilu Pharmaceutical Co., Ltd, ANDA#218899, 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.	
14	Case Category
	Import (Adil Saeed)
	Name, address of Applicant.
	Al Qasim Enterprises House No.134-E, Street #01, Sabzazar, Range Road Rawalpindi (01-374-0176-039416D)
	Application Form Dy. No / Tracking ID & date of submission
	(BLP-1QY-YAZY, 2026-03-25)
	Detail of Fee Submitted
	313500, 2026-02-04,
	The proposed proprietary name / brand name
	Tamsulosin 0.4mg Capsule
	Label Claim
	Each capsule contains Tamsulosin hydrochloride (as EC pellets).....0.4mg
	Reference to Finished product specifications
	United States Pharmacopeia
	Proposed Pack Size
	30 (3x10)Capsules-As per SRO
	Shelf Life (Unit)
	2 Year(s)28 C
	For generic drugs (me-too Status)
	Yes
	Pharmacotherapeutic Group of (API)
	Pharmacotherapeutic group: al-adrenoceptor antagonist, ATC Code: G04C A02
	Name, address of Manufacturing site:
	Synthon Hispania S.L- c/ castello, 1, 08830 Sant Boi de Llobregat, Barcelona, Spain-Spain
	Pharmaceutical Equivalence and Comparative Dissolution Profile
	Submitted with multiple batches of Reference product. BA studies are also submitted.
	Name, address of Marketing Authorization Holder:
	Synthon B.V. , Synthon B.V. Microweg 22 6545 CM Nijmegen, The Netherlands

	Details of Certificates (CoPP/FSC/cGMP):	GMP certificate submitted.
	Details of Authorization Letter :	COPP of netherlands and Agency agreement is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Attach in Module 1
	Evaluation Remarks	
	Priority as per decision of 220th meeting. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
	As per policy for inspection abroad.	
15	Case Category	Import (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	(PLW-XS5-3D2Z, 2026-03-26)
	Detail of Fee Submitted	313500, 2025-09-25,
	The proposed proprietary name / brand name	Bio Signora
	Label Claim	Each film coated tablet contains: Cyproterone Acetate2 MG Ethinylestradiol0.035 MG
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1x21's -As per SRO
	Shelf Life (Unit)	36 Year(s)Store in a cool, dry place at a temperature below 30 C
	For generic drugs (me-too Status)	Product Name: Diane 35 Tablet Registration No: 011467 Company Name: Bayer Pakistan Private Limited
	Pharmacotherapeutic Group of (API)	Antiandrogenic drug & Hormonal agents, specifically a synthetic estrogen
	Name, address of Manufacturing site:	West-Coast Pharmaceutical Works Ltd-New Survey No.181, 182,183, 205,206, Old Survey No. 129 144,145,146, NR. Bhagwat Glass Factory Chhartral-Vadaswami Rode, Village: Vadaswami, TAL-KALOL Dist.-Gandhinagar – 382 740 Gujarat State, India-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Diane®35 (Reference product) by Marketing Authorization Holder: Bayer AG, Country: Germany
	Name, address of Marketing Authorization Holder:	West-Coast Pharmaceutical Works Ltd, New Survey No.181, 182,183, 205,206, Old Survey No. 129 144,145,146, NR. Bhagwat Glass Factory Chhartral-Vadaswami Rode, Village: Vadaswami, TAL-KALOL Dist.-Gandhinagar – 382 740 Gujarat State, India, India
	Details of Certificates (CoPP/FSC/cGMP):	Certificate No: 23094523 Dated:15/09/2023 Valid until:14/09/2026
	Details of Authorization Letter :	Cyproterone acetate Batch No: CTA/920017 Qty: 60 gm Mfg. Date: 12/2024 Exp. Date: 11/2029 ETHINYLESTRADIOL BP Batch No : EE/109 Qty.Pur/Mfg. : 100.00 KG Mfg. Date: 12/2024 Exp. Date: 11/2028

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Cyproterone Acetate BP BATCH NO : CTA/920001 CTA/920002 CTA/920003 Ethinylestradiol BP BATCH NO:EE/111 EE/112 EE/113
	The status in reference regulatory authorities	MHRA (UK Approved) Dianette® tablets
	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.	
16	Case Category	Import (Adil 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	(DY5-VRX-JNQ8, 2026-03-16)
	Detail of Fee Submitted	313500, 2026-03-10,
	The proposed proprietary name / brand name	EPILEPKIN 400mg/4ml I.V. Powder and Solvent for Solution for Injection
	Label Claim	Each lyophilized Vial contains Sodium Valproate.... 400 mg of
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	4's-As per SRO
	Shelf Life (Unit)	24 Month(s)Store below 30°C.
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	Anti-epileptic
	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	Epilim Lyophilized powder for Intravenous Injection 400mg B. No. A7777
	Name, address of Marketing Authorization Holder:	VEM İlaç San. ve Tic. ANONİM SİRKETİ, Maslak Mah. AOS 55. Sok. 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	Epilim Intravenous 400mg Powder and Solvent for Solution for Injection or Infusion (Sanofi Aventis Ireland)
	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.	
17	Case Category	Import (Adil Saeed)

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	(TEA-W3W-R82Q, 2026-02-12)
Detail of Fee Submitted	, ,
The proposed proprietary name / brand name	Ventoxen Tablets 100mg
Label Claim	Each film coated tablet contains Venetoclax 100 mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	60s-As per SRO
Shelf Life (Unit)	2 Year(s)Store below 30°C
For generic drugs (me-too Status)	Ventonix 100mg Tablet
Pharmacotherapeutic Group of (API)	Antineoplastic agents
Name, address of Manufacturing site:	Everest Pharmaceuticals Limited. -Plot No.: B-45, 46 & 33, BSCIC I/A, Kanchpur, Narayanganj, -Bangladesh
Pharmaceutical Equivalence and Comparative Dissolution Profile	Venclexta 100 Tablet Abbvie Ireland NL B.V B. No. 1235108
Name, address of Marketing Authorization Holder:	Everest Pharmaceuticals Limited. , Rahman’s Regnum Center (11 th Floor) 191/B Bir Uttam Mir Shawkat Sarak Tejgaon C/A, Dhaka-1208, Bangladesh, Bangladesh
Details of Certificates (CoPP/FSC/cGMP):	Sumbitted
Details of Authorization Letter :	COPP and agency agreement is submitted.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached in Relavant section of Module 3.
The status in reference regulatory authorities	Venclyxto® 100 mg film-coated tablets
Evaluation Remarks	
Priority as per decision of 220th meeting of RB. Application fulfills codal formalities. Recommended for consideration of board.	
Decision	
Approved	
As per policy for inspection abroad.	
Case Category	Import (Adil Saeed)
Name, address of Applicant.	Contraceptives Pakistan (Pvt.) Ltd. Office No. 4A, Street No. 1, 116 Apartments Shah Jamal, Lahore (05-352-0063-120175D)
Application Form Dy. No / Tracking ID & date of submission	(7E2-L13-YW12, 2025-03-12)
Detail of Fee Submitted	75000.0, 225000.0 2024-12-23, 2025-03-10
The proposed proprietary name / brand name	Medogen 104mg/0.65ml Injection
Label Claim	Each 0.65ml Uniject Injector contains: Medroxyprogesterone Acetate BP.....104mg
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	1) One single-dose c-As per SRO
Shelf Life (Unit)	2 Year(s)Not exceeding 30 Centigrade
For generic drugs (me-too Status)	-----
Pharmacotherapeutic Group of (API)	G03AC06 Progestogens

Name, address of Manufacturing site:	Incepta Pharmaceuticals Ltd.-Krishnapura Sahabelishor, Dhamrai, Dhaka, Bangladesh-Bangladesh
Name & address of API manufacturer	NA
Detail of stability batches of drug product	upto 36 months, Zone IVb.
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	Sayana PRes B. No. FJ6772
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted.
The status in reference regulatory authorities	Sayana Press 104mg/0.65ml Injection
GMP status of the firm	GMP certificate valid till 04.04.2026 is submitted.
Evidence of approval of manufacturing facility	Certificate of renewal of license is submitted.

Evaluation Remarks

Priority as per decision of 220th meeting of Authority. Applied product is WHO PQ. WHO Reference No. RH106
Application fulfills codal formalities. Recommended for consideration of board.

Decision

Approved

As per policy for inspection abroad.

19	Case Category	Import (Adil Saeed)
	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	(UUG-HBN-7ZM6, 2026-03-30)
	Detail of Fee Submitted	313500, 2025-11-21,
	The proposed proprietary name / brand name	ZYLOTIDE 40mg Capsule
	Label Claim	Each Soft Capsule contains: Enzalutamide ... 40mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2 x 14's-As per SRO
	Shelf Life (Unit)	24 Month(s)20~25°C
	For generic drugs (me-too Status)	Xylutide 40mg Capsules
	Pharmacotherapeutic Group of (API)	Anti-androgens L02BB04
	Name, address of Manufacturing site:	Jiangsu Hansoh Pharmaceutical Group Co., Ltd.- Address: No. 5 Dongjin Road, Economic and Technical Development Zone, Lianyungang, Jiangsu 222069, China-China
	Name & address of API manufacturer	Jiangsu Hansoh Pharmaceutical Group Co., Ltd.
	Detail of stability batches of drug product	As per zone IVb
	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	USFDA RLD B. No. 2052928
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted.
	The status in reference regulatory authorities	XTANDI capsules, 40mg.
	GMP status of the firm	EUDRA GMP enclosed

	Evidence of approval of manufacturing facility	Attached
	Evaluation Remarks	
	Priority as per decision of 220th meeting of RB. Application fulfills codal formalities. recommended for consideration of board.	
	Decision	
	Approved	
	As per policy for inspection abroad.	
20	Case Category	Import (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	(MY5-BXZ-HENU, 2026-03-16)
	Detail of Fee Submitted	313500, 2025-10-03,
	The proposed proprietary name / brand name	Testosterone Undecanoate EVER Pharma 1000 mg/4 ml, solution for injection
	Label Claim	Each vial of 4 ml contains 1000 mg testosterone undecanoate
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 x 4 ml. -As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Nebido 1000/4ml
	Pharmacotherapeutic Group of (API)	Androgens, 3-oxoandrostene (4) derivatives
	Name, address of Manufacturing site:	EVER Pharma Jena GmbH- Brüsseler Strasse 18 07747 Jena Germany -Germany
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in Relevant section of Module 3.
	Name, address of Marketing Authorization Holder:	EVER Valinject GmbH, Oberburgau 3, 4866 Unterach am Attersee, Austria, Austria
	Details of Certificates (CoPP/FSC/cGMP):	Valid
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached in Relevant section of Module 3.
	The status in reference regulatory authorities	Nebido 1000/4ml
	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.	
21	Case Category	Import (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	Each 20ml ampoule contains; Propofol (emulsion).....200mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	20ml x 5's-As per SRO
Shelf Life (Unit)	3 Year(s)Store 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, FEROFZ 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 stadies 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 of 355th meeting: 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.

Response of firm: Firm has stated that they had discussed this with their manufacturer and they have told that they had by mistake mentioned the Long Term Stability Data condition as ZONE II, instead of ZONE-IVa, while Data containing according to ZONE-IVa. Firm has submitted copy of email correspondence with drug product manufacturer dated 17.03.2026 wherein same is stated by GM of M/s Ningbo Voice Biochemic Co Ltd.

Evaluation: Mistake or typo error can happen on one or two pages. Its not justifiable to say that manufacturer has mentioned Zone-II Stability conditions in whole P parts of Module 2 and 3. It indicates more towards issue of data integrity rather than a typographic error.

Decision

Rejected

The board deliberated on the matter and rejected the case due to concerns regarding the integrity of the submitted data. These concerns arose from inconsistencies identified during comparisons of the product stability data presented in Module 2 and Module 3, as well as the revised data submitted in Module 3 in response to the evaluator's observations.

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Case Category	Import (Adil Saeed)
Name, address of Applicant.	RG Pharmaceutica Pvt Ltd BF1-01 First Floor, Gate No.1 Bahria Orchard Main Raiwind Road, Lahore, Pakistan (05-352-0066-059010D-E)
Application Form Dy. No / Tracking ID & date of submission	(UVP-ZAG-4XM2, 2026-03-16)
Detail of Fee Submitted	,
The proposed proprietary name / brand name	CERVIGEST 400MG
Label Claim	Each suppository contains: : Progesterone..... 400mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	15's-De-Controlled
Shelf Life (Unit)	3 Year(s)30 C
For generic drugs (me-too Status)	CYCLOGEST 400mg
Pharmacotherapeutic Group of (API)	hormones and modulators of the genital system; Progestogens; Pregnen-(4) derivatives
Name, address of Manufacturing site:	HA NOI CPC1 PHARMACEUTICAL JOINT STOCK COMPANY-Ha Binh Phuong Industrial Zone, Van Binh Commune, Thuong Tin District Ha Noi City, Vietnam-Vietnam
Pharmaceutical Equivalence and Comparative Dissolution Profile	Cyclogest 400mg Zuellig Pharma singapore

	Name, address of Marketing Authorization Holder:	HA NOI CPC1 PHARMACEUTICAL JOINT STOCK COMPANY, Ha Binh Phuong Industrial Zone, Van Binh Commune, Thuong Tin District Ha Noi City, Vietnam, Vietnam
	Details of Certificates (CoPP/FSC/cGMP):	GMP of abroad finished product manufacturer Attached in Module-1
	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	Therapeutic Goods Administration (TGA)
	Evaluation Remarks	
	Priority as per decision of 220th meeting. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
	As per policy for inspection abroad.	
23	Case Category	Import (Adil Saeed)
	Name, address of Applicant.	RG Pharmaceutica Pvt Ltd BF1-01 First Floor, Gate No.1 Bahria Orchard Main Raiwind Road, Lahore, Pakistan (05-352-0066-059010D-E)
	Application Form Dy. No / Tracking ID & date of submission	(WJ6-WGB-MT35, 2026-03-16)
	Detail of Fee Submitted	,
	The proposed proprietary name / brand name	CERVIGEST 200MG
	Label Claim	Each suppository contains: Progesterone ...200mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	15's-De-Controlled
	Shelf Life (Unit)	3 Year(s)30 C
	For generic drugs (me-too Status)	Cyclogest 200mg
	Pharmacotherapeutic Group of (API)	ex hormones and modulators of the genital system; Progestogens; Pregnen-(4) derivatives
	Name, address of Manufacturing site:	HA NOI CPC1 PHARMACEUTICAL JOINT STOCK COMPANY-Ha Binh Phuong Industrial Zone, Van Binh Commune, Thuong Tin District Ha Noi City Vietnam-Vietnam
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Cyclogest 200mg marketed in Singapore.
	Name, address of Marketing Authorization Holder:	HA NOI CPC1 PHARMACEUTICAL JOINT STOCK COMPANY, Ha Binh Phuong Industrial Zone, Van Binh Commune, Thuong Tin District Ha Noi City Vietnam, Vietnam
	Details of Certificates (CoPP/FSC/cGMP):	GMP of abroad finished product manufacturer Attached in Module-1
	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	Therapeutic Goods Administration (TGA)
	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	Import (Adil Saeed)
	Name, address of Applicant.	Atco Pharma International (Pvt) Ltd B-18, S.I.T.E., Karachi (046)
	Application Form Dy. No / Tracking ID & date of submission	(EBB-25S-9PDD, 2025-09-29)
	Detail of Fee Submitted	300000.0, 2025-07-18,
	The proposed proprietary name / brand name	AGGRASTAT 50 mcg/ml, 250ml solution for infusion
	Label Claim	Each ml of solution for infusion contains: Tirofiban hydrochloride monohydrate equivalent to tirofiban.....50 mcg.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	250ml bag-De-Controlled
	Shelf Life (Unit)	36 Year(s)Store between 15°C to 30°C in the foil overpouch to protect it from light. Do not freeze
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Tirofiban Hydrochloride belongs to a class of antiplatelet named glycoprotein IIb/IIIa inhibitors.
	Name, address of Manufacturing site:	Fresenius Kabi France-6 rue du Rempart 27400 Louviers France-France
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The equivalency of Aggrastat Solution for Infusion manufactured at Baxter and FKF is supported by batch data presented
	Name, address of Marketing Authorization Holder:	Focus Pharmaceuticals Limited, Dashwood House, 69 Old Broad Street, London, EC2M 1QS, United Kingdom., United Kingdom
	Details of Certificates (CoPP/FSC/cGMP):	Eudra GMP certificate attached
	Details of Authorization Letter :	COPP and agency agreement is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data on long term and accelerated condition enclosed
	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.	
25	Case Category	Import (Adil Saeed)
	Name, address of Applicant.	Bristol Mayer Biotech Pakistan 73 B Guldast Town Zarrar Shaheed Lahore (05-352-0068-109282D)
	Application Form Dy. No / Tracking ID & date of submission	(JXP-GHN-NXRZ, 2026-03-26)

Detail of Fee Submitted	313500, 2025-09-25,
The proposed proprietary name / brand name	Histone 10mg Tablet
Label Claim	Each film coated tablet contains: Dydrogesterone BP.....10 mg
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	30's-As per SRO
Shelf Life (Unit)	36 Year(s)Store in a dry place below 30°C
For generic drugs (me-too Status)	Duphaston 10mg Tablets by Abbott Laboratories (Pakistan) Limited
Pharmacotherapeutic Group of (API)	Pregnadien derivative progestogens
Name, address of Manufacturing site:	WEST-COAST PHARMACEUTICAL WORKS LTD- New Survey No.181,182,183,205,206 Old Survey No. 129,144,145,146, NR. Bhagwati glass factory, Chhatral – Vadaswami road, Village: Vadaswami, Tal. – Kalol, Dist. – Gandhinagar-382740-India
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence is provided with reference drug DUPHASTONE® 10 mg (Reference product) by MYLAN IRE HEALTHCARE LIMITED
Name, address of Marketing Authorization Holder:	WEST-COAST PHARMACEUTICAL WORKS LTD, New Survey No.181,182,183,205,206 Old Survey No. 129,144,145,146, NR. Bhagwati glass factory, Chhatral – Vadaswami road, Village: Vadaswami, Tal. – Kalol, Dist. – Gandhinagar-382740, India
Details of Certificates (CoPP/FSC/cGMP):	Certificate No: 23094523 Dated:15/09/2023 Valid until:14/09/2026
Details of Authorization Letter :	Batch No. DYD/N/23/001 , Batch Qty.15Kgs Date of manufacture. Jan-2023
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies of three batches of Dydrogesterone manufactured at Cropel Lifescience pvt ltd. are performed as mentioned below. DYD/N/21/001, DYD/N/21/002 & DYD/N/21/003 40 ± 2° / 75 ± 5% RH (in accelerated condition) for six months and 30 ± 2° / 75 ± 5% RH (in real time condition) for 60 months.
The status in reference regulatory authorities	HPRA (Ireland Approved) Duphaston 10 mg film coated tablets by Theramex Ireland Limited
Evaluation Remarks	
Priority as per decision of 220th meeting. Application fulfills codal formalities. Recommended for consideration of board.	
Decision	
Approved	
As per policy for inspection abroad.	
Case Category	Import (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	(Q9M-WM5-6R35, 2026-03-16)
Detail of Fee Submitted	313500, 2025-11-12,
The proposed proprietary name / brand name	Dino 2mg Tablet

Label Claim	Each Film Coated contains; Dienogest..... 2 mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's (28 Tablets)-As per SRO
Shelf Life (Unit)	24 Month(s)Store in a dry place at a temperature below 30°C.
For generic drugs (me-too Status)	Visanne Dienogest 2Mg Tablets by Bayer.
Pharmacotherapeutic Group of (API)	Progestogens; ATC code: G03DB08
Name, address of Manufacturing site:	West-Coast Pharmaceutical Works Ltd-New Survey No.181,182,183,205,206, Old Survey No.129 144,145,146, NR. Bhagwat Glass Factory Chhartral-Vadaswami Road, Village: Vadaswami, TAL-KALOL Dist.- Gandhinagar -382 740 Gujarat State, India.-India
Pharmaceutical Equivalence and Comparative Dissolution Profile	Dissolution Profile is provided against the reference product Dimetrum by Besins Healthcare UK.
Name, address of Marketing Authorization Holder:	West-Coast Pharmaceutical Works Ltd, New Survey No.181,182,183,205,206, Old Survey No.129 144,145,146, NR. Bhagwat Glass Factory Chhartral-Vadaswami Road, Village: Vadaswami, TAL-KALOL Dist.- Gandhinagar -382 740 Gujarat State, India., India
Details of Certificates (CoPP/FSC/cGMP):	Certificate No. S-GMP & GLP/ 25055742 Valid Until Date: 05/05/2027
Details of Authorization Letter :	COPP and letter of authorization is submitted.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies of three batches of Dienogest manufactured at M/s Swati Spentose Private Limited, are performed as mentioned below. DNG/919001, DNG/919002 & DNG/919003 $40 \pm 2^\circ / 75 \pm 5\%$ RH (in accelerated condition for six months), $25 \pm 2^\circ\text{C}$, RH $60 \pm 5\%$ and $30 \pm 2^\circ / 75 \pm 5\%$ RH (in real time condition) for 24 months and further studies are going on.
The status in reference regulatory authorities	MHRA approved (Dimetrum 2 mg Tablets by Besins Healthcare (UK) 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.

27	Case Category	Import (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	(EMD-GLQ-XEYZ, 2026-03-06)
	Detail of Fee Submitted	313500, 2025-11-17,
	The proposed proprietary name / brand name	Estra-D 2mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Estradiol Valerate USP2 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	36 Year(s)Store in dry place at a temperature below 30°C.

For generic drugs (me-too Status)	Progynova 2mg Tablets by Bayer
Pharmacotherapeutic Group of (API)	Progestagens and oestrogens, fixed combinations; ATC code: G03CA03.
Name, address of Manufacturing site:	West-Coast Pharmaceutical Works Ltd-New Survey No. 181,182,183,205,206 Old Survey No. 129,144,145,146, NR. Bhagwati Glass factory, chhatral - vadaswami road, village : vadaswami, tal.- kalol, dist.- Gandhinagar - 382 740-India
Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative dissolution profile is provided.
Name, address of Marketing Authorization Holder:	West-Coast Pharmaceutical Works Ltd, New Survey No. 181,182,183,205,206 Old Survey No. 129,144,145,146, NR. Bhagwati Glass factory, chhatral - vadaswami road, village : vadaswami, tal.- kalol, dist.- Gandhinagar - 382 740, India
Details of Certificates (CoPP/FSC/cGMP):	Certificate No. S-GMP & GLP/ 25055742 Valid Until Date: 05/05/2027
Details of Authorization Letter :	Batch No.: EDVFP25011, Mfg. Date: 06/2025, Exp. Date: 05/2029
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies of three batches of Estradiol Valerate manufactured at M/s ANDROST BIOTECH INDIA PVT. LTD, are performed as mentioned below. EDV20001, EDV20002 & EDV20003 $40 \pm 2^\circ / 75 \pm 5\%$ RH (in accelerated condition for 6 months), $30 \pm 2^\circ / 65 \pm 5\%$ RH (in real time condition) for 36 months.
The status in reference regulatory authorities	MHRA approved (Progynova 2mg Tablets)
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
	Import (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
	(RAY-MLP-ABXV, 2026-03-06)
	Detail of Fee Submitted
	313500, 2025-11-17,
	The proposed proprietary name / brand name
	Sugest Gel 8% w/w
	Label Claim
	Contains; Progesterone8%W/W
	Reference to Finished product specifications
	As per Innovators Specification
	Proposed Pack Size
	1's-As per SRO
	Shelf Life (Unit)
	24 Month(s)Store in dry place at a temperature below 30°C.
	For generic drugs (me-too Status)
	N/A
	Pharmacotherapeutic Group of (API)
	Progesterone gel progestins family; ATC code: G03DA04
	Name, address of Manufacturing site:
	West-Coast Pharmaceutical Works Ltd-New Survey No. 181,182,183,205,206 Old Survey No. 129,144,145,146, nr. Bhagwati Glass factory, chhatral - vadaswami road,

	village : vadaswami, tal.- kalol, dist.- Gandhinagar - 382 740-India
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
Name, address of Marketing Authorization Holder:	West-Coast Pharmaceutical Works Ltd, New Survey No. 181,182,183,205,206 Old Survey No. 129,144,145,146, nr. Bhagwati Glass factory, chhatral - vadaswami road, village : vadaswami, tal.- kalol, dist.- Gandhinagar - 382 740, India
Details of Certificates (CoPP/FSC/cGMP):	Certificate No. S-GMP & GLP/ 25055742 Valid Until Date: 05/05/2027
Details of Authorization Letter :	COPP and LOA is submitted
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies of three batches of Estradiol Valerate manufactured at M/s CROPEL LIFESCIENCES PVT LTD, are performed as mentioned below. PGN/N/21/001, PGN/N/21/002 & PGN/N/21/003 at 40° C ± 2°???? & 75 % ±5% RH (in accelerated condition for 6 months), 30° C ± 2°???? & 75 % ±5% RH (in real time condition) for 24 months.
The status in reference regulatory authorities	MHRA approved (CRINONE Progesterone Gel 8 %)
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
	Import (Adil Saeed)
	Name, address of Applicant.
	Bristol Mayer Biotech Pakistan 73 B Guldast Town Zarrar Shaheed Lahore (05-352-0068-109282D)
	Application Form Dy. No / Tracking ID & date of submission
	(T9N-RAG-GQXT, 2026-03-06)
	Detail of Fee Submitted
	313500, 2025-11-25,
	The proposed proprietary name / brand name
	Lyno 0.5 mg
	Label Claim
	Each Uncoated Tablet Contains: Lynestrenol0.5 mg
	Reference to Finished product specifications
	As per Innovators Specification
	Proposed Pack Size
	1's-As per SRO
	Shelf Life (Unit)
	36 Year(s)Store in a dry place at a temperature below 30°C.
	For generic drugs (me-too Status)
	Minipyl 500mcg Tablet (Zafa Pharmaceutical Laboratories (Pvt) Ltd)
	Pharmacotherapeutic Group of (API)
	Synthetic progesterone derivatives ATC code: G03AD01
	Name, address of Manufacturing site:
	West-Coast Pharmaceutical Works Ltd-New Survey No. 181,182,183,205,206 Old Survey No. 129,144,145,146, NR. Bhagwati Glass factory, chhatral - vadaswami road, village : vadaswami, tal.- kalol, dist.- Gandhinagar - 382 740-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile
	Comparative Dissolution Profile at Buffer pH 1.2, Buffer pH 4.5 and Buffer pH 6.8 is provided. EXLUTON 500

	MCG TABLET DR-XY18077
Name, address of Marketing Authorization Holder:	West-Coast Pharmaceutical Works Ltd, New Survey No. 181,182,183,205,206 Old Survey No. 129,144,145,146, NR. Bhagwati Glass factory, chhatral - vadaswami road, village : vadaswami, tal.- kalol, dist.- Gandhinagar - 382 740, India
Details of Certificates (CoPP/FSC/cGMP):	Certificate No. S-GMP & GLP/ 25055742 Valid Until Date: 05/05/2027
Details of Authorization Letter :	Batch No.SSPL/LNZ/250091, Mfg.Date : 06/2025, Exp.Date : 05/2030
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies of three batches of Lynestrenol Tab 0.5 mg manufactured at M/s Swati Spentose Private Limited, are performed as mentioned below. SSPL/LNZ/110001, SSPL/LNZ/110002 & SSPL/LNZ/110003 at 40°C ± 2°C / 75% RH ± 5% and 25°C ± 2°C / 60% RH ± 5% (in accelerated condition for 6 months and 60 months respectively), Temperature 30°C ± 2°C / 75% RH ± 5% (in real time condition for 60 months).
The status in reference regulatory authorities	CBG MEB Netherlands (EXLUTON Tabs 0.5 mg)
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.	
Case Category	Import (Adil Saeed)
Name, address of Applicant.	Hakimsons (Pvt)., Ltd. A-58/B , SITE Karachi (055)
Application Form Dy. No / Tracking ID & date of submission	(HSW-L42-UGA4, 2025-08-06)
Detail of Fee Submitted	300000.0, 2025-05-02,
The proposed proprietary name / brand name	PLERISTEM 20 mg/mL Solution for Injection
Label Claim	Each 1ml vial contains : Plerixafor20 mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	1's or As per Market-De-Controlled
Shelf Life (Unit)	24 Month(s)store below 30C
For generic drugs (me-too Status)	Not Available
Pharmacotherapeutic Group of (API)	ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS L03AX16 Other immunostimulant
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	MOZOBIL® Plerixafor 20 mg/mL solution for Injection B. No. 8HV0582 Genzyme Limited (United Kingdom)
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):	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	MOZOBIL® approved by USFDA
	Evaluation Remarks	
	The COPP submitted mentions that product is actually present on market in country of origin, when FSc submitted mentions that product is for export only. The Form 28 clearly mentions that applied product (1ml single dose vial) is registered for export purpose only. Firm was asked on 31.03.2026 to submit their clarification regarding this matter, but they have not submitted any response.	
	Decision	
	Rejected	
	The board rejected the case due to the reason that firm has not submitted sufficient evidence to establish free sale status of applied product in the country of origin.	
31	Case Category	Import (Adil Saeed)
	Name, address of Applicant.	Graton Pharma Suite # 501 & 502, 5th Floor, Plot # 42C/2, Lane 8,, Bukhari Commercial, DHA Phase VI, (208)
	Application Form Dy. No / Tracking ID & date of submission	(QMA-NMQ-REMD, 2026-02-19)
	Detail of Fee Submitted	,
	The proposed proprietary name / brand name	Qaistabin
	Label Claim	Each lyophilized vial contains; Gemcitabine hydrochloride eq. to Gemcitabine 1g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1,s -As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30 degrees
	For generic drugs (me-too Status)	GEMZAR Injection 1gm/vial
	Pharmacotherapeutic Group of (API)	Antineoplastic Agent
	Name, address of Manufacturing site:	Jodas Expoim Pvt Ltd-Plot No.55, Biotech Park, Phase III, Karkapatla (V), Markook (M), Siddipet (D), Telangana State Pin – 502 279, India-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	-----
	Name, address of Marketing Authorization Holder:	Graton Pharma, 42c/2,501,502 5th floor Phase 6 lane 8 Bukhari commercial DHA clifton, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	GMP certificate is submitted.
	Details of Authorization Letter :	COPP and letter of authorization is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Attached
	Evaluation Remarks	
	The COPP mentions that product is present in market of country of origin but FSC submitted mentions that its for export purpose only. Firm was asked to submit clarification and Registration letter of product India, but they have not responded yet. Observation was communicated on 20.03.2026. Further Pharmaceutical equivalence(3.2.P.2.2) is also not submitted.	
	Decision	
	Rejected	

The board rejected the case due to the fact that firm has not submitted sufficient evidence to establish free sale status of applied product in country of origin.

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Case Category	Import (Farooq Aslam)
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	(56Z-3UD-E8XW, 2026-03-10)
Detail of Fee Submitted	313500, 2026-02-12,
The proposed proprietary name / brand name	Bortmex
Label Claim	Each vial contains: bortezomib 3.5 mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1 vial in unit carton-Controlled
Shelf Life (Unit)	24 Month(s)30 degree
For generic drugs (me-too Status)	Bortezomib Pharmidea 3.5 mg Injection by Himmel Pharma
Pharmacotherapeutic Group of (API)	Anti neoplastic agent
Name, address of Manufacturing site:	Laboratorio Kemex S.A.-Nazarre 3446/54 Ciudad Autónoma de Buenos Aires - República Argentina-Argentina
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the reference product i.e. Velcade by M/s Jansen Pharmaceutical NV.
Name, address of Marketing Authorization Holder:	Laboratorio Kemex S.A., Nazarre 3446/54 Ciudad Autónoma de Buenos Aires - República Argentina, Argentina
Details of Certificates (CoPP/FSC/cGMP):	GMP certificate valid till 04-12-2026 is submitted with scope of manufacturing of lyophilized injectables.
Details of Authorization Letter :	CoPP: Legaized CoPP No. CE-2024-137957539-APN-INAME#ANMAT dated 20-12-2024 is submitted. (Valid for 12 months). The applied product is available in free sale in the exporting country and, the facilities and operations fonform to WHO-GMP. LOA: LOA dated 16-12-2024 is submitted. DSL: DSL valid till 21-03-2026 is submitted.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted.
The status in reference regulatory authorities	EMA, USFDA

Evaluation Remarks

The application has been processed in compliance to the decision of DRAP Authority (220th meeting). The application is deficient for: 1. DSL is valid till 21-03-2026, please submit receipt for renewal f DSL. 2. valid and legalized/apostille CoPP since the submitted CoPP is expired. 3. Applicable fee for correction of specifications for finished product from USP to innovator's.

Decision

Approved

as per policy of import for inspection of manufacturer abroad.

The firm shall submit following documents:

1. Valid copy of drug sale license.

	2. Valid and Legalized/apostille CoPP.	
	3. Applicable fee for correction of specifications of finished product from USP to innovator's.	
33	Case Category	Import (Farooq Aslam)
	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	(5HN-NNL-R7GW, 2026-03-05)
	Detail of Fee Submitted	300000, 13500 2025-03-20, 2025-11-03
	The proposed proprietary name / brand name	Anazole 1mg Tablets
	Label Claim	Each film coated tablet contains: Anastrozole 1mg
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	1x10's & 3x10's, 2x10's & 28's-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Arimisol 1mg Tablets by Swiss Pharmaceuticals (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Aromatase Inhibitors
	Name, address of Manufacturing site:	Pharmacare Premium Ltd.- HHF003. Hal Far Industrial Estate, Birzebbugia, BBG3000, Malta.-Malta
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e Arimidex 1mg FC tablet by Astrazeneca.
	Name, address of Marketing Authorization Holder:	Pharmacare Premium Ltd., HHF003. Hal Far Industrial Estate, Birzebbugia, BBG3000, Malta. , Malta
	Details of Certificates (CoPP/FSC/cGMP):	GMP certificate (Eudra GMP) issued on the basis of inspection conducted on 19-12-2022 is submitted.
	Details of Authorization Letter :	CoPP: Copy of Apostille CoPP No. 2025/284 dated 19-08-2025 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 issued by Medicines Authority Malta. DSL: DSL valid till 20-01-2030. LOA: Apostille LOA dated 05-06-2025 is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	(Batch No. AL0020907, AL0030907, AL0040907) 06 months accelerated and 60 months real time (25°C ± 2oC / 60 % ± 5 %RH) stability data is submitted.
	The status in reference regulatory authorities	Arimidex 1mg Film Coated Tablets by AstraZeneca UK Limited - MHRA
Evaluation Remarks		
The application has been processed in compliance to the decision of DRAP Authority (220th meeting).		
Decision		
Approved		
as per policy of import for inspection of manufacturer abroad.		
34	Case Category	Import (Farooq Aslam)
	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	(Q2G-2X1-Y9S2, 2026-03-04)

Detail of Fee Submitted	313500, 2026-02-27,
The proposed proprietary name / brand name	Caspogin 50mg Injection
Label Claim	Each vial contains: Caspofungin (as acetate)....50mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's-Controlled
Shelf Life (Unit)	24 Month(s)2°C - 8°C
For generic drugs (me-too Status)	Caspogin 50mg Injection - M/s. AJM Pharma Pvt Ltd
Pharmacotherapeutic Group of (API)	Antifungal agents
Name, address of Manufacturing site:	Hainan Hailing Chemipharma Corporation Limited -No. 281, Nanhai Avenue, Haikou City, China -China
Pharmaceutical Equivalence and Comparative Dissolution Profile	the Pharmaceutical Equivalence was conducted on multiple batches of the RLD " Cancidas" with applied drug product.
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):	DML NO. Qiong20160065 valid till 13-08-2030 with scope of manufacturing of lyophilized powder injection.
Details of Authorization Letter :	CoPP: Copy of CoPP No. Hainan20250227 vali till 14-12-2027 is submitted. LOA: letter of authorization dated 12-01-2026 for the applied product is submitted. DSL: DSL valid till 21-12-2027 is submitted.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Data Accelerated stability study: the data of 6 months (-20 °C ± 5 °C) were provided. Long term stability study below -70 °C): the data of 36 months provided. Batch No. : DKB-180810, DKB-180811 and DKB-180812
The status in reference regulatory authorities	Active Ingredient Caspofungin Acetate Proprietary Name: Caspofungin Acetate Dosage Form: Injection Route of Administration: Intravenous infusion Strength: 50mg/vial Application Number: A200833 Approval Date: Jun 28, 2018 Applicant Holder Full Name: JIANGSU HENGRUI PHARMACEUTICALS CO LTD

Evaluation Remarks

The application has been processed in compliance to the decision of DRAP Authority (220th meeting). The firm has submitted copy of CoPP which is verifiable from the official website of NMPA.

[https://www.nmpa.gov.cn/datasearch/en/other-info.html?](https://www.nmpa.gov.cn/datasearch/en/other-info.html?nmpa=dXJsPTgyODA4MDgxODg5YTBiNTYwMTg4OWEyNTFIMzMwMDVjL2RldGFpbC5odG1sJmlkPWE0Z)

nmpa=dXJsPTgyODA4MDgxODg5YTBiNTYwMTg4OWEyNTFIMzMwMDVjL2RldGFpbC5odG1sJmlkPWE0Z

Decision

Approved

as per policy of import for inspection of manufacturer abroad.

35	Case Category	Import (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 copt 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 product was deferred in 355th meeting for submission analytical method verification studies for drug substance. Reply: The firm has submitted AMV study report for drug substance.	
Decision	
Approved	
as per policy of import for inspection of manufacturer abroad.	
36	Case Category
	Import (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
	(RWB-X6X-ESXR, 2026-03-16)
	Detail of Fee Submitted
	, 313500 , 2026-02-03
	The proposed proprietary name / brand name
	MYCAGEN Injection 50 mg
	Label Claim
	Each Vial Contains: Micafungin as sodium..... 50mg

Reference to Finished product specifications	United States Pharmacopeia
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)	NA- New Drug Product
Pharmacotherapeutic Group of (API)	Antifungal, ATC Code: J02AX05
Name, address of Manufacturing site:	Qilu Pharmaceutical (Hainan) Co., Ltd.-No.273-A, Nanhai Avenue, National High-Tech Zone, Haikou, Hainan, 570314, China-China
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence study performed by Comparison of Innovator's product (MYCAMINE Injection 50mg).
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):	GMP certificate valid till 31-01-2026 is submitted with the scope of manufacturing of sterile products (Lyophilisates)
Details of Authorization Letter :	CoPP: Copy of CoPP No. Hainan20250208 valid till 04-11-2027 is submitted. The applied product is available in free sale in exporting country and The facilities and operations conform to WHO-GMP. DSL: DSL valid till 21-05-2027 is submitted. LOA: Authorization letter dated 17-12-2025 is submitted.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies performed on three batches B# TMC-221101T, TMC-221202T, TMC-221203T of Micafungin sodium substance on accelerated (6M) (5 °C±3 °C) & long-term (24M) (-20 °C±5 °C) conditions.
The status in reference regulatory authorities	Micafungin sodium, EQ 50mg base (Micafungin)/vial Injection, ANDA: 219273, USFDA Approved

Evaluation Remarks

The application has been processed in compliance to the decision of DRAP Authority (220th meeting). The firm shall submit valid GMP certificate/drug manufacturing license of finished product manufacturer.

Decision

Approved

as per policy of import for inspection of manufacturer abroad. The firm shall submit valid GMP certificate/drug manufacturing license of finished product manufacturer.

37	Case Category	Import (Farooq Aslam)
	Name, address of Applicant.	Amson Vaccines & Pharma (Pvt.) Ltd Plot # 115, Industrial Triangle Kahuta Road (017/DSL(D)/PS&DC-ICT/2025)
	Application Form Dy. No / Tracking ID & date of submission	(TA9-AAH-AV17, 2025-09-29)
	Detail of Fee Submitted	300000.0, 2025-07-18,
	The proposed proprietary name / brand name	Urocare 3g sachet
	Label Claim	Each sachet contains: Fosfomycin as trometamol..... 3 g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 sachet /box-As per SRO

Shelf Life (Unit)	24 Month(s)Below 25°C
For generic drugs (me-too Status)	Focin Ultra Sachet Manufacturer: TABROS PHARMA (PVT). LTD.. Registraion No: 061315
Pharmacotherapeutic Group of (API)	Antibacterials used systemically (Other antibacterials)
Name, address of Manufacturing site:	Drogsan İlaçları San. ve Tic. A.Ş.-Esenboğa Merkez Mah. Çubuk Cad. No:31 Çubuk-Ankara -Turkey
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the reference product i.e. Monurol Sachet by M.s Zambon Italy.
Name, address of Marketing Authorization Holder:	Drogsan İlaçları San. ve Tic. A.Ş., Esenboga Merkez Mah. Cubuk Cad. No:31 Cubuk-Ankara/Turkiye, Turkiye
Details of Certificates (CoPP/FSC/cGMP):	GMP certificate issued on the basis of inspection conducted on 19-23-09-2022 is submitted.
Details of Authorization Letter :	CoPP: Apostille CoPP No. 2025/1730 dated 11-06-2025 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. LOA: Sole agency agreement dated 28-04-2023 is submitted for the applied product. DSL: Distributor license valid till 30-11-2027.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 24 months real time stability data according to zone IV-B.
The status in reference regulatory authorities	(01) US-FDA Approved MONUROL Sachet 3g Zambon Switzerland Ltd. (Division of Zambon Group, SpA) Link: https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/041651Orig1s01.pdf (02) MHRA: MONURIL 3g granules Zambon S.p.A Italy. https://mhraproducts4853.blob.core.windows.net/docs/76d...

Evaluation Remarks	
The application has been processed in compliance to the decision of DRAP Authroity (220th meeting).	
Decision	
Approved	
The firm shall submit valid GMP certificate/drug manufacturing license of finished product manufacturer.	
Case Category	Import (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	(WAV-16Q-NBXW, 2025-10-01)
Detail of Fee Submitted	300000.0, 2025-07-12,
The proposed proprietary name / brand name	Diclofenac (generic name)
Label Claim	Each 3ML ampoule contains: Diclofenac sodium.....75 MG
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	5× 3ml ampoules-As per SRO
Shelf Life (Unit)	3 Year(s)Room temperature
For generic drugs (me-too Status)	Dicloran (Sami)
Pharmacotherapeutic Group of (API)	NSAID
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	PE studies have been performed against the comparator's product i.e. Diclofenaco Sodico by M/s Huazhing Pharmaceutical Co. Ltd.
Name, address of Marketing Authorization Holder:	Inaya traders, Flat No. 1, first floor, plot No. A-152, block 8, KAECHS, , Karachi-Pakistan
Details of Certificates (CoPP/FSC/cGMP):	DML No. Yu20150048 valid till 31-12-2030 is submitted.
Details of Authorization Letter :	CoPP: Apostille CoPP No. 230131005 valid till 30-01-2028 is submitted. The applied product is available in free sale in the exporting country and, the facilities and operations conform to WHO-GMP. 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 stability data of 03 batches according to zone IV-A.
The status in reference regulatory authorities	Available MHRA UK
Evaluation Remarks	
The application has been processed in compliance to the decision of DRAP Authority (220th meeting). The firm shall submit notarized letter of authroiation.	
Decision	
Approved	
as per policy of import for inspection of manufacturer abroad. The firm shall submit notarized letter of authoriztaion.	
Case Category	Import (Farooq Aslam)
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	(ZLH-AV7-XEAZ, 2025-10-03)
Detail of Fee Submitted	300000.0, 2025-07-11,
The proposed proprietary name / brand name	GADOTERM
Label Claim	Each ml contains: Gadopentetate Dimeglumine 469mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	1's (20ml)-As per SRO
Shelf Life (Unit)	24 Month(s)Store between 15-30° C (59- 86° F) and protected from light.
For generic drugs (me-too Status)	Magnevist Injection (011539) of M/s Bayer Pakistan (Pvt) Limited.
Pharmacotherapeutic Group of (API)	Paramagnetic contrast agent
Name, address of Manufacturing site:	Shandong New Time Pharmaceutical-No. 1, North Outer Ring Road, Feixian County, Shandong, -China
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE stduies have been performed against reference product i.e. Magnevist by M/s Bayer AG.
Name, address of Marketing Authorization Holder:	Shandong New Time Pharmaceutical, No. 243, Yin Queshan Road, Linyi, Shandong Province, China. , China
Details of Certificates (CoPP/FSC/cGMP):	GMP certificate No. GMP2025016 dated 24-01-2025 with scope of manufacturing of small volume injections is submitted.

Details of Authorization Letter :	COPP: Copy of CoPP No. Shandong2025070 valid till 02-12-2025 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. LOA: Copy of LOA dated 16-06-2025 is submitted. DSL: DSL valid till 15-08-2029 is submitted.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated stability data from three primary batches (0704GDDM0001, 0704GDDM0002, and 0704GDDM0003) have been submitted for a 6-month study period. Long-term stability data according to zone II for the same three batches have been submitted for a 60-month period.
The status in reference regulatory authorities	MAGNEVIST® (gadopentetate dimeglumine) 469.01MG/ML IV Injection of Bayer HealthCare, approved in TGA Therapeutic Good Administration), Australia

Evaluation Remarks

The application has been processed in compliance to the decision of DRAP Authority (220th meeting). The firm shall submit apostille/legalized CoPP and notarized LOA.

Decision

Approved

as per policy of import for inspection of manufacturer abroad. The firm shall submit apostille/legalized CoPP and notarized letter of authorization.

40	Case Category	Import (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	(NJ1-X8U-R1HH, 2025-08-01)
	Detail of Fee Submitted	300000.0, 2025-01-16,
	The proposed proprietary name / brand name	Calcium gluconate injection (generic name)
	Label Claim	Each mL contains: Calcium gluconate monohydrate.....100 mg (eq. to 94mg of calcium gluconate and 4.5mg of Calcium Secharate tetrahydrate)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50 ampoules-As per SRO
	Shelf Life (Unit)	3 Year(s)Room temperature
	For generic drugs (me-too Status)	Calcium gluconate injection (United international)
	Pharmacotherapeutic Group of (API)	Mineral supplement
	Name, address of Manufacturing site:	Shandong Qidu Pharmaceutical Co., Ltd. -No.17, Hongda Road, Linzi District, Zibo City, Shandong Province, China -China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against Calcium Gluconate Injection by M/s Sinopharm Ronshyn Pharmaceutical Co. Ltd., China.
	Name, address of Marketing Authorization Holder:	Shandong Qidu Pharmaceutical Co., Ltd. , No.17, Hongda Road, Linzi District, Zibo City, Shandong Province, China , China
	Details of Certificates (CoPP/FSC/cGMP):	DML No. Lu20160064 valid till 23-11-2025 is submitted which includes the scope of manufacturing of injectables.

Details of Authorization Letter :		CoPP: Apostille CoPP No. Shandong20243051 valid till 25-03-2026 is submitted. The product is available in free sale in exporting country and, the facilities nad operations conform to WHO-GMP. DSL: DSL valid till 21-06-2029 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		Available MHRA UK
Evaluation Remarks		
The application has been processed on priority in compliance to the decision of DRPA Authority (220th meeting). The firm shall submit: 1. Notarized letter of authorization. 2. Apostille and valid CoPP since the submitted CoPP is expired on 25-03-2026. 3. Applicable fee for correction of drug product's specifications from BP to USP and label claim as per the reference product.		
Decision		
Approved		
The firm shall submit:		
1. apostille/legalized CoPP and notarized letter of authorization.		
2. Applicable fee for correction of drug product's specifications and revision of label claim as per innovator's product.		
41	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 firm has submitted a GMP certificate and an FSC attested only by MEA India not by High Commission of Pakistan in India. However, MEA has clarified on GMP certificate that it does not take responsibility for the content of the document. Furthermore, the FSC does not confirm the free sale status of the product in the domestic market.		
Decision		
Rejected		
Registration Board decided to reject the product based on following:		
1. Submitted FSC fails to adequately confirm the free sale status of the product in the domestic markets of country of origin.		
2. Ministry of External Affairs has explicitly stated on the GMP certificate that it does not assume responsibility for the contents of the document, thereby limiting its validity for regulatory purposes		
42	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	(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		
The firm has submitted a GMP certificate and an FSC attested by MEA India. However, MEA has clarified that it does not take responsibility for the content of the document. Furthermore, the FSC does not confirm the free sale status of the product in the domestic market.		
Decision		
Rejected		
Registration Board decided to reject the product based on following:		
1. Submitted FSC fails to adequately confirm the free sale status of the product in the domestic markets of country of origin.		
2. Ministry of External Affairs has explicitly stated on the GMP certificate that it does not assume responsibility for the contents of the document, thereby limiting its validity for regulatory purposes		
43	Case Category	Import (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Mustafa Brothers 186-D, Peoples Colony No. 1, Faisalabad (06-331-0168-031770D)
	Application Form Dy. No / Tracking ID & date of submission	(GZJ-HPH-GUJY, 2025-03-12)
	Detail of Fee Submitted	300000.0, 2025-03-12,
	The proposed proprietary name / brand name	Medimectin
	Label Claim	Each ml Contains: Ivermectin 10mg
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	3 YearStore at room temprature
	For generic drugs (me-too Status)	Bovimec LA, (Pak Reg. No. 053951, Mfg. By Laboratorio Hofarm for Agrovot Market , Lima, Peru, Imported by Mustafa Brother
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Ave & Vetmedic doo-Bregalnička32, Vršac-Serbia
	Name, address of Marketing Authorization Holder:	Ave & Vetmedic doo, Belgrade, Serbia
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
	Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy	
44	Case Category	Import (Muhammad Sarfraz Nawaz)

Name, address of Applicant.	MS Enterprises P42/2, Opp Municipal Degree College, Jaranwala Road Fasialabad (063310168118843D)
Application Form Dy. No / Tracking ID & date of submission	(7Y8-3L6-HB6Y, 2025-06-25)
Detail of Fee Submitted	300000.0, 2025-06-23,
The proposed proprietary name / brand name	Alcofan 6%
Label Claim	Each 1 ml contains: Ketoprofen60mg
Reference to Finished product specifications	European Pharmacopeia
Proposed Pack Size	50ml Vial-De-Controlled
Shelf Life (Unit)	2 YearStore at Temperature not exceeding 30°C used after opening for 28 days when stored at temperature not exceeding 30°C
For generic drugs (me-too Status)	Not Available
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Eva Pharma for Pharmaceuticals and Medical Applian-176 El Sadat st. from Elmansouriya Canal - Kafr El Gabal -El Giza.-Egypt
Name, address of Marketing Authorization Holder:	Eva Pharma for Pharmaceuticals and Medical Applian, 176 El Sadat st. from Elmansouriya Canal - Kafr El Gabal -El Giza., Egypt
Details of Certificates (CoPP/FSC/cGMP):	
Details of Authorization Letter :	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	

Evaluation Remarks

the application is complete as per codal formalities for consideration by the Registration Board

Decision

Deferred

Deferred for further deliberation.

45	Case Category	Import (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	MS Enterprises P42/2, Opp Municipal Degree College, Jaranwala Road Fasialabad (063310168118843D)
	Application Form Dy. No / Tracking ID & date of submission	(UAV-ELR-YBXQ, 2025-06-25)
	Detail of Fee Submitted	300000.0, 2025-06-23,
	The proposed proprietary name / brand name	EVABACT
	Label Claim	Each 100 gm: Lincomycin HCL40g (Eq to Lincomycin Base 35.3g)
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	150 gm-De-Controlled
	Shelf Life (Unit)	2 YearStore at Temperature not exceeding 30°C
	For generic drugs (me-too Status)	Product General Detail Product Name:: Lincosol 40% Oral Powder Registration No: 081301 Company Name: UNICARE ENTERPRISES
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Eva Pharma for Pharmaceuticals and Medical Applian-176 El Sadat st. from Elmansouriya Canal - Kafr El

		Gabal -El Giza. -Egypt
	Name, address of Marketing Authorization Holder:	Eva Pharma for Pharmaceuticals and Medical Applian, 176 El Sadat st. from Elmansouriya Canal - Kafr El Gabal -El Giza. , Egypt
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
	Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy	
46	Case Category	Import (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Mustafa Brothers 186-D, Peoples Colony No. 1, Faisalabad (06-331-0168-031770D)
	Application Form Dy. No / Tracking ID & date of submission	(ESN-7EE-S8TS, 2025-07-28)
	Detail of Fee Submitted	300000.0, 2025-07-28,
	The proposed proprietary name / brand name	PGF VEYX FORTE
	Label Claim	1ml contains: Cloprostenol 250 micrograms (equivalent to 263 micrograms Cloprostenol sodium)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10ml-De-Controlled
	Shelf Life (Unit)	24 MonthStore below 25°C Temperature, Protect from sunlight,
	For generic drugs (me-too Status)	PGF VEYX® FORTE” Solution For Injection vide registration No. 118478 (50ml Packaging), Manufactured by Veyx Pharma GmbH, Germany, Imported by Mustafa Brothers,Faisalabad, Pakistan
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Veyx Pharma B.V-Forellenweg 16, NL-4941 SJ Raamsdonksveer, -Netherlands
	Name, address of Marketing Authorization Holder:	Veyx-Pharma GmbH , Sohreweg 6, 34639, Schwarzenborn, Germany
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
	Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy	

47	Case Category	Import (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	AL ASAR ENTERPRISES GULSHAN E GULAB COLONY BEHIND ABDULLAH HEART CARE HOSPITAL, NEAR PULWASAL SURAJ MIANI ROAD MULTAN (04-361-0159-96972D)
	Application Form Dy. No / Tracking ID & date of submission	(2MA-GW9-X8JA, 2025-07-13)
	Detail of Fee Submitted	300000.0, 2025-07-09,
	The proposed proprietary name / brand name	NEOCEP
	Label Claim	Each syringe of 30 mL contains: Cephalexin monohydrate600 mg Neomycin sulfate1.02 g Cloxacillin benzathine 1.50 g Vitamin A30 000 IU Exp. qs 30 mL
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	30 ml -De-Controlled
	Shelf Life (Unit)	2 Year15-30 C
	For generic drugs (me-too Status)	NEFA-MAC IMM by NAWAN LABORATORIES
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	VEMEDIM ANIMAL HEALTH-SONG HAU INDUSTRIAL ZONE DONG PHU COMMUNE CHAU THANH DISTRICT HAU GIANG PROVINCE - Vietnam
	Name, address of Marketing Authorization Holder:	VEMEDIM ANIMAL HEALTH, SONG HAU INDUSTRIAL ZONE DONG PHU COMMUNE CHAU THANH DISTRICT HAU GIANG PROVINCE , Vietnam
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
48	Evaluation Remarks	
	Applied prouct in 30ml while generic reference in 10ml	
	Decision	
	Deferred	
	Deferred for clarification of on availability of pack size of 30ml.	
48	Case Category	Import (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Karim Traders Cutchi gali no 1, marriott road karachi (616)
	Application Form Dy. No / Tracking ID & date of submission	(4Y5-NLZ-NTYW, 2024-10-08)
	Detail of Fee Submitted	300000.0, 2024-07-25,
	The proposed proprietary name / brand name	Sold with generic name
	Label Claim	Lincomycin Hydrochloride Injection 600mg/2ml Each 2ml of solution contains Lincomycin Hydrochloride equivalent to Lincomycin 600mg.

Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	5 ampoules/Box , 20b-Controlled
Shelf Life (Unit)	3 YearStore in airtight containers, protect from light, store at dry and cool places. KEEP ALL MEDICINES AWAY FROM CHILDREN.
For generic drugs (me-too Status)	LINCOCIN Lincomycin Hydrochloride Injection 600mg/2ml from Manufacturer: Pfizer
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Huazhong Pharmaceutical Co., Ltd.-No.118 Xian Shan Road., Xiang Yang City, Hubei, China-China
Pharmaceutical Equivalence and Comparative Dissolution Profile	
Name, address of Marketing Authorization Holder:	Ningbo Sinofin Pharmaceutical Co., Ltd, 9-11 West Zhongshan Road, Ningbo, 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	TGA 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.	
Case Category	Import (Muhammad Sarfraz Nawaz)
Name, address of Applicant.	Karim Traders Cutchi gali no 1, marriott road karachi (616)
Application Form Dy. No / Tracking ID & date of submission	(77W-HTY-WU11, 2024-12-20)
Detail of Fee Submitted	300000.0, 2024-10-04,
The proposed proprietary name / brand name	Sold with generic name
Label Claim	Each 10ml of solution contains Calcium Gluconate 1gm.
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	50ampoules/box-Controlled
Shelf Life (Unit)	3 YearControlled room temperature: 15°C to 30°C (59F to 86F). Protect from light, heat and moisture.
For generic drugs (me-too Status)	Calcium Gluconate 10% Injection Manufactured by wuhan Grand Pharmaceutical Co Ltd.
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Huazhong Pharmaceutical Co., Ltd.-No.118 Xian Shan Road., Xiang Yang City, Hubei, China-China
Pharmaceutical Equivalence and Comparative Dissolution Profile	
Name, address of Marketing Authorization Holder:	Ningbo Sinofin Pharmaceutical Co., Ltd, 9-11 West Zhongshan Road, Ningbo, 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	MHRA 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.	
50	Case Category	Import (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Karim Traders Cutchi gali no 1, marriott road karachi (616)
	Application Form Dy. No / Tracking ID & date of submission	(G5D-R5V-VRV8, 2024-08-29)
	Detail of Fee Submitted	300000.0, 2024-07-12,
	The proposed proprietary name / brand name	Sold with generic name
	Label Claim	Diclofenac Sodium Injection 75mg/3ml Each 3ml ampoule contains 75mg diclofenac sodium.
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	5 ampoules/box , 20b-Controlled
	Shelf Life (Unit)	3 YearKeep container in the outer carton. Do not freeze. Store below 25° C. Any unused portion should be discarded immediately after use
	For generic drugs (me-too Status)	VOLTRAL Diclofenac Sodium Injection 75mg/3ml, Manufactured By Novartis
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Huazhong Pharmaceutical Co., Ltd.-No.118 Xian Shan Road., Xiang Yang City, Hubei, China-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	Ningbo Sinofin Pharmaceutical Co., Ltd, 9-11 West Zhongshan Road, Ningbo, 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	MHRA 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.	
51	Case Category	Import (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Karim Traders Cutchi gali no 1, marriott road karachi (616)

Application Form Dy. No / Tracking ID & date of submission	(QML-J9W-JSUY, 2024-08-28)
Detail of Fee Submitted	300000.0, 2024-07-25,
The proposed proprietary name / brand name	Sold with generic name
Label Claim	Gentamicin Sulphate Injection B.P. 80mg/2ml
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	10Ampoules/Tray 10Tr-Controlled
Shelf Life (Unit)	3 YearStore in airtight containers, protect from light, store at dry and cool places. KEEP ALL MEDICINES AWAY FROM CHILDREN.
For generic drugs (me-too Status)	Gentic 80mg/2ml from bosch Pharmaceutical
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Huazhong Pharmaceutical Co., Ltd.-No.118 Xian Shan Road., Xiang Yang City, Hubei, China-China
Pharmaceutical Equivalence and Comparative Dissolution Profile	
Name, address of Marketing Authorization Holder:	Ningbo Sinofin Pharmaceutical Co., Ltd, 9-11 West Zhongshan Road, Ningbo, 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	MHRA 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.	
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	(8EV-JY2-82MH, 2024-07-03)
Detail of Fee Submitted	300000.0, 2024-05-24,
The proposed proprietary name / brand name	Lincomycin injection (generic name)
Label Claim	Each 2ml contains: Lincomycin (as HCL) USP.....600 mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	5× 2ml ampoules-As per SRO
Shelf Life (Unit)	3 YearRoom temperature
For generic drugs (me-too Status)	Olinec 600mg 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 TGA Australia
	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.	
53	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	(MH2-A8R-1VM8, 2024-10-25)
	Detail of Fee Submitted	300000.0, 2024-09-04,
	The proposed proprietary name / brand name	Doxycycline capsule(generic name)
	Label Claim	Each capsule contains: Doxycycline (as hyclate).....100 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10×10's-As per SRO
	Shelf Life (Unit)	3 YearRoom temperature
	For generic drugs (me-too Status)	Doxycycline capsule(Avensis pharmaceuticals)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Liaoning Huarui Union Pharmaceutical Co., Ltd-Yuanqu Road No.1, Tongyuanpu Economic, Development Zone, Dandong City, Liaoning-China
	Name & address of API manufacturer	Hebei Dongfeng Pharmaceutical Co., Ltd Address: No. 365, Guanyuan West Street, Yongnian District, Handan City, Hebei
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Available TGA Australia
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

the application is complete as per codal formalities for consideration by the Registration Board		
Decision		
Approved		
Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy.		
54	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	(XAN-93S-6A7J, 2024-09-30)
	Detail of Fee Submitted	300000.0, 2024-09-05,
	The proposed proprietary name / brand name	Oxytetracycline capsule (generic name)
	Label Claim	Each capsule contains: Oxytetracycline (as hydrochloride).....250mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10×10's-As per SRO
	Shelf Life (Unit)	3 YearRoom temperature
	For generic drugs (me-too Status)	Epoxylin capsule(epoch pharma)
	Pharmacotheapeutic Group of (API)	
	Name, address of Manufacturing site:	Liaoning Huarui Union Pharmaceutical Co., Ltd-Yuanqu Road No.1, Tongyuanpu Economic, Development Zone, Dandong City, Liaoning-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	Liaoning Huarui Union Pharmaceutical Co., Ltd, Yuanqu Road No.1, Tongyuanpu Economic, Development Zone, Dandong City, Liaoning, 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.	
55	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	(M7U-AB2-DGA7, 2024-11-21)
	Detail of Fee Submitted	300000.0, 2024-10-30,
	The proposed proprietary name / brand name	Oxytetracycline capsule (generic name)

Label Claim	Each capsule contains: Oxytetracycline Hcl equivalent to Oxytetracycline B.P250MG
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	10×10's-As per SRO
Shelf Life (Unit)	3 YearRoom temperature
For generic drugs (me-too Status)	Epoxylin capsule(epoch pharma)
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	JIANGXI XIER KANGTAI PHARMACEUTICAL CO., LTD-North Zone, High-New Technology Industrial Zone, Pingxiang, Jiangxi-China
Pharmaceutical Equivalence and Comparative Dissolution Profile	
Name, address of Marketing Authorization Holder:	JIANGXI XIER KANGTAI PHARMACEUTICAL CO., LTD, North Zone, High-New Technology Industrial Zone, Pingxiang, Jiangxi, 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	
Subject to submission of CoPP from relevant regulatory body.	
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.	Inaya International Plot # 08 Kahyaban e Rizwan Phase 7 DHA Karachi (331)
Application Form Dy. No / Tracking ID & date of submission	(W72-E62-95U4, 2024-11-11)
Detail of Fee Submitted	300000.0, 2024-08-29,
The proposed proprietary name / brand name	Indomethacin(generic name)
Label Claim	Each capsule contains: Indomethacin.....25MG
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	10×10's-As per SRO
Shelf Life (Unit)	3 YearRoom temperature
For generic drugs (me-too Status)	Indobid(adamjee pharmaceuticals)
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Liaoning Huarui Union Pharmaceutical Co., Ltd-Yuanqu Road No.1, Tongyuanpu Economic, Development Zone, Dandong City, Liaoning-China
Pharmaceutical Equivalence and Comparative Dissolution Profile	
Name, address of Marketing Authorization Holder:	Liaoning Huarui Union Pharmaceutical Co., Ltd, Yuanqu Road No.1, Tongyuanpu Economic, Development Zone, Dandong City, Liaoning, 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 TGA Australia
	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.	
57	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	(ZA7-UN6-VHH8, 2024-11-19)
	Detail of Fee Submitted	300000.0, 2024-10-30,
	The proposed proprietary name / brand name	Doxycycline capsule(generic name)
	Label Claim	Each capsule contains: Doxycycline hyclate equivalent to doxycycline BP.....100 MG
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10×10's-As per SRO
	Shelf Life (Unit)	3 YearRoom temperature
	For generic drugs (me-too Status)	Doxycycline capsule(Avensis pharmaceuticals)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	JIANGXI XIER KANGTAI PHARMACEUTICAL CO., LTD-North Zone, High-New Technology Industrial Zone, Pingxiang, Jiangxi-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	JIANGXI XIER KANGTAI PHARMACEUTICAL CO., LTD, North Zone, High-New Technology Industrial Zone, Pingxiang , Jiangxi, 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	
	Subject to submission of valid legalized CoPP from relevant regulatory body.	
	Decision	
	Approved	
	Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy.	
58	Case Category	Import (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	HIGHNOON LABORATORIES LIMITED 17.5 KM, MULTAN ROAD, LAHORE (05-352-0066-027583D)

Application Form Dy. No / Tracking ID & date of submission	(L2X-RPS-W97H, 2024-10-13)
Detail of Fee Submitted	300000.0, 2024-10-09,
The proposed proprietary name / brand name	Dynase Nasal Spray
Label Claim	Each g of suspension contains Azelastine hydrochloride.....1000 mcg fluticasone propionate.....365 mcg Each metered dose contains: Azelastine hydrochloride 137mcg eq.to azelastine.....125mcg Fluticasone propionate.....50 mcg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's (120 MD)-As per SRO
Shelf Life (Unit)	2 YearDo not Store above 30°C
For generic drugs (me-too Status)	Not Available
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Beximco Pharmaceuticals Ltd.-19 Dhanmondi R/A, Road No. 7, Dhaka 1205, Bangladesh.-Bangladesh
Pharmaceutical Equivalence and Comparative Dissolution Profile	
Name, address of Marketing Authorization Holder:	Beximco Pharmaceuticals Ltd., 126 Kathaldia, Auchpara, Tongi, Gazipur, Bangladesh., Bangladesh
Details of Certificates (CoPP/FSC/cGMP):	
Details of Authorization Letter :	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
The status in reference regulatory authorities	Dymista Nasal Spray
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.	
59	Case Category
	Import (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.
	HIGHNOON LABORATORIES LIMITED 17.5 KM, MULTAN ROAD, LAHORE (05-352-0066-027583D)
	Application Form Dy. No / Tracking ID & date of submission
	(R6B-1WA-8NPY, 2024-10-11)
	Detail of Fee Submitted
	300000.0, 2024-10-09,
	The proposed proprietary name / brand name
	Nasomet Nasal spray
	Label Claim
	Each spray contains: Mometasone Furoate (as monohydrate)50µg
	Reference to Finished product specifications
	British Pharmacopeia
	Proposed Pack Size
	140MD-As per SRO
	Shelf Life (Unit)
	2 YearDo not Store above 30°C
	For generic drugs (me-too Status)
	Nasomet Aqueous Nasal Spray (086852)
	Pharmacotherapeutic Group of (API)

Name, address of Manufacturing site:	Beximco Pharmaceuticals Ltd.-126 Kathaldia, Auchpara, Tongi, Gazipur, Bangladesh.-Bangladesh
Pharmaceutical Equivalence and Comparative Dissolution Profile	
Name, address of Marketing Authorization Holder:	Beximco Pharmaceuticals Ltd., 19 Dhanmondi R/A, Road No. 7, Dhaka 1205, Bangladesh., Bangladesh
Details of Certificates (CoPP/FSC/cGMP):	
Details of Authorization Letter :	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
The status in reference regulatory authorities	Mometasone Furoate 50 micrograms/actuation Nasal Spray
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.	
Case Category	Import (Muhammad Sarfraz Nawaz)
Name, address of Applicant.	Fizon Pharma 103-K Block-2, PECHS Shahrah-e-Quaideen (0319)
Application Form Dy. No / Tracking ID & date of submission	(NQB-4SP-9MUV, 2024-10-22)
Detail of Fee Submitted	300000.0, 2024-09-04,
The proposed proprietary name / brand name	EMAGEL
Label Claim	Each 100 ml contains: Polygeline Polypeptides of degraded gelatin, cross-linked via urea bridges.....3.5 g (equivalent to 0.63g of nitrogen) Sodium Chloride....0.85g Potassium Chloride....0.038g Calcium Chloride....0.070g Water for Injection...q.s.
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's (500ml)-As per SRO
Shelf Life (Unit)	24 MonthsBelow 30°C
For generic drugs (me-too Status)	Haemaccel
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	PIRAMAL PHARMA LIMITED-Village Bhatauli Khurd, Baddi – 173205, Dist Solan (H.P)-India
Pharmaceutical Equivalence and Comparative Dissolution Profile	
Name, address of Marketing Authorization Holder:	PIRAMAL PHARMA LIMITED, Village Bhatauli Khurd, Baddi – 173205, Dist Solan (H.P), 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	UK-MHRA
Evaluation Remarks	
Drug manufacturer license was granted on loan basis	

	Decision	
	Deferred	
	Deferred till decision of the Appellate Board on appeals filed against decision of the Registration Board on loan license cases.	
61	Case Category	Import (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Fizon Pharma 103-K Block-2, PECHS Shahrah-e-Quaideen (0319)
	Application Form Dy. No / Tracking ID & date of submission	(NG7-34V-T736, 2024-09-19)
	Detail of Fee Submitted	300000.0, 2024-08-22,
	The proposed proprietary name / brand name	Sojourn
	Label Claim	Each Glass Bottle Contains: Sevoflurane 100% v/v.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's (250ml)-As per SRO
	Shelf Life (Unit)	60 MonthDo not store above 25°C
	For generic drugs (me-too Status)	VISEVO
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	PIRAMAL PHARMA LIMITED-Sy. Nos 7-70, 70/1 & 70/2 Digwal village, Kohir Mandal, Sangareddy Dist. 502 321 Telangana, State India-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	PIRAMAL PHARMA LIMITED, Sy. Nos 7-70, 70/1 & 70/2 Digwal village, Kohir Mandal, Sangareddy Dist. 502 321 Telangana, State India, India
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	USFDA
	Evaluation Remarks	
	The same brand name, Sojourn Inhalational Liquid (Reg. 088891), has already been issued to M/s Piramal Critical Care, Inc., Bethlehem, PA 18017, United States of America, in the name of M/s Allied Distributors, Karachi Firm reply: We acknowledge that the same brand name Sojourn Inhalational Liquid (Reg. No. 088891) has already been registered in the name M/s Allied Distributors, Karachi.In this regard, we respectfully submit that: • In view of the resemblance with the registered brand name, we propose to submit alternative brand names separately for your kind consideration upon receipt from the manufacturer.	
	Decision	
	Approved	
	Approved with change in brand name and subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy.	
62	Case Category	Import (Najia Saleem)
	Name, address of Applicant.	punjad pharma PVT LTD 35-km shamy bhattian multan road lahore (053520066059717D)
	Application Form Dy. No / Tracking ID & date of submission	(3NB-X6N-Q9NV, 2025-04-21)

Detail of Fee Submitted	300000.0, 2025-04-16,
The proposed proprietary name / brand name	Ceftisin injectable suspension
Label Claim	Each ml contains: Ceftiofur HCl eq. to Ceftiofur.....50mg
Reference to Finished product specifications	European Pharmacopeia
Proposed Pack Size	100ml -De-Controlled
Shelf Life (Unit)	3 Year(s)Store below 25 °C. Protect from light
For generic drugs (me-too Status)	Cefur-RTU Injection 100ml (049605)
Pharmacotherapeutic Group of (API)	Cephalosporin
Name, address of Manufacturing site:	Teknovet İlaç San. ve Tic. A.Ş.-Ç.O.S.B. Gazi Osman Paşa Mahallesi 18. Sokak No: 3 59500 Çerkezköy / Tekirdağ/ TÜRKİYE-Turkey
Name, address of Marketing Authorization Holder:	TEKNOVET İlaç San. ve Tic. A.Ş, I.O.S.B. Mah. Marmara San. Sitesi Marmara M Blok Sokak No: 16 Küçükçekmece/ İstanbul/ TÜRKİYE, Türkiye
Details of Certificates (CoPP/FSC/cGMP):	Submitted GMP Certificate No: 151/022/GMP valid till 11-05-2025
Details of Authorization Letter :	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
Evaluation Remarks	
The firm has submitted scanned copies of apostille certified FSC, GMP and notarized LOA; hence, shall submit original legalized FSC, GMP and LOA before issuance of registration letter.	
Decision	
Approved	
subject to compliance of current Import Policy for finished drugs along with submission of following documents before issuance of registration letter:	
i. original legalized FSC, GMP and LOA	
ii. fee for revision of FPP specifications since the official monograph of Ceftiofur injectable suspension is not available in the latest edition of European pharmacopoeia.	
63	Case Category
	Import (Najia Saleem)
	Name, address of Applicant.
	AA PHARMA DISTRIBUTOR FLAT NO 16,17 FIRST FLOOR KALA KHAN SHOPING CENTRE, SHAMAS ABAD MURREE ROAD RAWALPINDI (01-374-0177-113628D)
	Application Form Dy. No / Tracking ID & date of submission
	(NNU-9SZ-HA45, 2024-10-20)
	Detail of Fee Submitted
	300000.0, 2024-09-26,
	The proposed proprietary name / brand name
	FQ Grow Feed Premix
	Label Claim
	Each 1kg Contains: Metabolize Energy (ME) 3.015 Kcal Amylase 187.500mg Crude Protein 220.000mg Calcium 3.307mg Crude fat 91.820mg Protease 25.000IU Tryptophan 900mg Lysine 15.080mg Cystine 1.040mg Cellulase 10.000IU Threonine 304mg Choline 10.000mg Minerals 17.000mg Lipase 7.500IU Vitamin E 500mg Methionine 5.160mg Phosphorous 4.073mg Pectinase 5.000IU

	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 KG SACHETS-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in a cool and dry place and keep away from direct sunlight.
	For generic drugs (me-too Status)	SAN GROW FEED PREMEX (could not be confirmed)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Shijiazhuang Fengqiang Animal Pharmaceutical Co., - No. 16 Zhenzhu Road, Xinzhaidian Industrial Park, Zhaoxian County, Shijiazhuang City, China-China
	Name, address of Marketing Authorization Holder:	AA Pharma Distributors, Office no. 16 & 17, First Floor Kala Khan Shopping Centre, Shamsabad Murree Road, Rawalpindi, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Scanned copy submitted
	Details of Authorization Letter :	Scanned copy of supplement of agency agreement submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	The PLH vide letter No. 2511080/H46323 dated 23-09-2025 has informed that FQ grow feed premix is not on China market, it is produced by Pakistan company. Viet Anh Joint Venture Investment Joint Stock Company and distributed in Pakistan. Moreover, the evidence of approval of applied product in RRAs/ as me-too product could not be confirmed.	
	Decision	
	Rejected	
	since the applied product is not on free sale in exporting country and its approval status in RRAs as well as availability of me-too product could not be confirmed.	
64	Case Category	Import (Najia Saleem)
	Name, address of Applicant.	MB Marketing Gulshan e gulab colony behind al basit medical center near pull wasal chowk suraj miani road multan cant Bosan Town (04-361-0159-061335D)
	Application Form Dy. No / Tracking ID & date of submission	(ZRB-3JQ-ZQ8N, 2024-06-25)
	Detail of Fee Submitted	300000.0, 2024-06-13,
	The proposed proprietary name / brand name	Nameillin-50% w/w
	Label Claim	Each G contains: Amoxicillin Trihydrate 575mg eq. to Amoxicillin.....500mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1kg-De-Controlled
	Shelf Life (Unit)	3 Year(s)Cool and dry place
	For generic drugs (me-too Status)	125971 Poul Mox-50 WSP of M/s. Poulvet Pharmaceutical (Pvt) Ltd, Multan.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	NAM PHARMA SDN. BHD.-5,LEBUH PERUSAHAAN KLEBANG 11 TAMAN PERINDUSTRIAN ANTARABANGSA IGB 31200 CHEMOR,PERAK, MALAYSIA-Malaysia
	Name, address of Marketing Authorization Holder:	NAM PHARMA SDN. BHD., 5,LEBUH PERUSAHAAN KLEBANG 11 TAMAN

		PERINDUSTRIAN ANTARABANGSA IGB 31200 CHEMOR,PERAK, MALAYSIA, Malaysia
	Details of Certificates (CoPP/FSC/cGMP):	Scanned copies of FSC and GMP submitted
	Details of Authorization Letter :	Scanned copy of exclusive/ sole distributor agent agreement dated 01-04-2024 submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	The manufacturer confirms Cephalosporin & Penicillin are produced in same facility under PIC/S guidelines. The firm shall submit original legalized FSC, GMP and LOA before issuance of registration letter.	
	Decision	
	Deferred	
	for further deliberation and till implementation of PIC/s GMP guidelines for local manufacturers in Pakistan.	
65	Case Category	Import (Najia Saleem)
	Name, address of Applicant.	u.m.enterprises plot no.12 sector 15 korangi industrial area-74900 (313)
	Application Form Dy. No / Tracking ID & date of submission	(VZ3-RU1-V86X, 2025-04-30)
	Detail of Fee Submitted	300000.0, 2025-04-21,
	The proposed proprietary name / brand name	Cefa-Dry Intramammary Infusion
	Label Claim	Each intramammary syringe with 3 g suspension contains 250 mg Cefalonium (as cefalonium dihydrate)
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	3gm-De-Controlled
	Shelf Life (Unit)	36 Month(s)Store in a well-closed container and below 30°C. Don't freeze.
	For generic drugs (me-too Status)	116977 CEPRAMAST INTRAMAMMARY SUSPENSION of M/S. SELMORE PHARMACEUTICALS (PVT) LIMITED, LAHORE.
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Name, address of Manufacturing site:	M/S, QILU ANIMAL HEALTH PRODUCTS CO., LTD- No. 10688, Wenliang Road, Dongjia Town, Licheng District, Jinan, Shandong, China Zip code: 250100-China
	Name, address of Marketing Authorization Holder:	U.M. Enterprises, Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900 (Pakistan, Pakistan)
	Details of Certificates (CoPP/FSC/cGMP):	Scanned copy of COPP confirms GMP status of the manufacturer along with free sale status of the applied product
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	The manufacturer has informed that they have dedicated manufacturing area for Cephalosporin product and don't produce penicillin product at those sites. The firm has submitted scanned copies of LOA and COPP hence, shall submit original legalized COPP and LOA before issuance of registration letter.	
	Decision	
	Approved	

subject to compliance of current Import Policy for finished drugs along with submission of following documents before issuance of registration letter:

i. original legalized COPP and LOA

ii. confirmation of dedicated facility for Cephalosporin containing products during inspection.

66	Case Category	Import (Najia Saleem)
	Name, address of Applicant.	tab INTERNATIONAL Office No. 77-K, Phase-I, Defence, Commercial Market, Lahore, Nishter Town (05-352-0065-107628D)
	Application Form Dy. No / Tracking ID & date of submission	(MDQ-S9A-UMYJ, 2024-10-10)
	Detail of Fee Submitted	300000.0, 2024-10-07,
	The proposed proprietary name / brand name	Leva-Cloza Sav
	Label Claim	Each ml contains: Levamisole Hydrochloride.....30mg Oxyclozanide.....60mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1000ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at Room Temperature
	For generic drugs (me-too Status)	128548 Levozan Suspension of Ms Remedix Peshawar
	Pharmacotherapeutic Group of (API)	Anthelmintics
	Name, address of Manufacturing site:	Saudi Pharmaceutical Industries-Street No.248, Second Industrial City, Riyadh, Kingdom of Saudi Arabia-Saudi Arabia
	Name, address of Marketing Authorization Holder:	Saudi Pharmaceutical Industries, Street No.248, Second Industrial City, Riyadh, Kingdom of Saudi Arabia, Saudi Arabia
	Details of Certificates (CoPP/FSC/cGMP):	Scanned copy of COPP confirms GMP as well as free sale status of the applied product
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
67	Evaluation Remarks	
	The firm shall submit the following before issuance of registration letter: i. original legalized COPP (along with appendix) and LOA ii. fee for pre-approval correction/revision of FPP specifications.	
	Decision	
	Approved	
	subject to compliance of current Import Policy for finished drugs along with submission of following documents before issuance of registration letter:	
67	i. original legalized COPP (along with appendix) and LOA	
	ii. fee for pre-approval correction/revision of FPP specifications.	
	Case Category	Import (Najia Saleem)
	Name, address of Applicant.	punjnad pharma PVT LTD 35-km shamy bhattian multan road lahore (053520066059717D)
	Application Form Dy. No / Tracking ID & date of submission	(YRX-EJJ-8WRU, 2024-04-22)
67	Detail of Fee Submitted	300000.0, 2024-04-19,

The proposed proprietary name / brand name	Bupartek Injectable Solution
Label Claim	Each ml contains: Buparvaquone.....50 mg
Reference to Finished product specifications	Manufacturer Specification
Proposed Pack Size	50 ml-De-Controlled
Shelf Life (Unit)	3 Year(s)storage at below 25 degree centigrade.. do not freeze. Protect from Light
For generic drugs (me-too Status)	Bupaquone Solution for Injection Reg#087824, imported by Ghazi Brothers
Pharmacotherapeutic Group of (API)	Antiprotozoal
Name, address of Manufacturing site:	Teknovet İlaç San. ve Tic. A.Ş.-Ç.O.S.B. Gazi Osman Paşa Mahallesi 18. Sokak No: 3 59500 Çerkezköy / Tekirdağ -Turkey
Name, address of Marketing Authorization Holder:	Punjad Pharma (Pvt) Ltd, 35-Km, Multan Road, Shamkey Bhattian Lahore,, Pakistan
Details of Certificates (CoPP/FSC/cGMP):	Apostille attestedscanned copy of FSC is submitted. Copy of GMP certificate No. 151/2022/GMP dated 11-07-2022 verified from EUDRA GMP
Details of Authorization Letter :	Scanned copy of LOA dated 17-06-2025 notarized from exporting country
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	data submitted as per zone II conditions, commitment to submit data as per zone IV-A when completed.
Evaluation Remarks	
The firm has submitted fee Rs 9400/- vide challan No. 65104350463 for pre-approval revision of FPP specifications and shall submit original legalized FSC, GMP and LOA before issuance of registration letter.	
Decision	
Approved subject to compliance of current Import Policy for finished drugs along with submission of original legalized FSC, GMP and LOA before issuance of registration letter.	
68	Case Category
	Import (Najia Saleem)
	Name, address of Applicant.
	u.m.enterprises plot no.12 sector 15 korangi industrial area-74900 (313)
	Application Form Dy. No / Tracking ID & date of submission
	(5PY-GBP-P322, 2025-04-30)
	Detail of Fee Submitted
	300000.0, 2025-04-21,
	The proposed proprietary name / brand name
	Umec
	Label Claim
	Each ml contains: 10mg of doramectin
	Reference to Finished product specifications
	Any Other
	Proposed Pack Size
	100 ml-De-Controlled
	Shelf Life (Unit)
	24 Month(s)Sore at room temperature
	For generic drugs (me-too Status)
	13942 122207 "MECTIN-D INJECTION " "EACH ML CONTAINS:- DORAMECTIN.....10MG (AS PER INNOVATOR'S SPECIFICATIONS)*" LOCALLY MANUFACTURED "M/S. A & K PHARMACEUTICAL, 94-A PUNJAB SMALL INDUSTRIAL ESTAT
	Pharmacotherapeutic Group of (API)
	Antiparasitic
	Name, address of Manufacturing site:
	QILU ANIMAL HEALTH PRODUCTS CO., LTD.- No.23999, Gongye North Road, Licheng District, Jinan, Shandong, China -China

	Name, address of Marketing Authorization Holder:	QILU ANIMAL HEALTH PRODUCTS CO., LTD., No.23999, Gongye North Road, Licheng District, Jinan, Shandong, China Zip code: 250100, China
	Details of Certificates (CoPP/FSC/cGMP):	Scanned COPP confirms free sale status and GMP status
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	The firm shall submit original legalized COPP and LOA before issuance of registration letter.	
	Decision	
	Approved	
	subject to compliance of current Import Policy for finished drugs along with submission of original legalized COPP and LOA before issuance of registration letter.	
69	Case Category	Import (Najia Saleem)
	Name, address of Applicant.	tab INTERNATIONAL Office No. 77-K, Phase-I, Defence, Commercial Market, Lahore, Nishter Town (05-352-0065-107628D)
	Application Form Dy. No / Tracking ID & date of submission	(YW9-9ZZ-AM7J, 2024-08-19)
	Detail of Fee Submitted	300000.0, 2024-08-16,
	The proposed proprietary name / brand name	Ketovet
	Label Claim	Ketovet Solution for Injection: Each ml contains Ketoprofen..... 100mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at Room Temperature
	For generic drugs (me-too Status)	Ketoject Selmore, Annex-G (Page N0: 27-28)
	Pharmacotherapeutic Group of (API)	NSAID
	Name, address of Manufacturing site:	Saudi Pharmaceutical Industries-Street No.248, Second Industrial City, Riyadh, Kingdom of Saudi Arabia.-Saudi
	Name, address of Marketing Authorization Holder:	Saudi Pharmaceutical Industries, Street No.248, Second Industrial City, Riyadh, Kingdom of Saudi Arabia., Saudi
	Details of Certificates (CoPP/FSC/cGMP):	Scanned copy of legalized FSC (expired now but valid upon submission) and valid GMP certificate submitted
	Details of Authorization Letter :	Scanned copy of legalized LOA valid till 15-05-2027 submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	The firm shall submit original legalized FSC/GMP/COPP and LOA before issuance of registration letter.	
	Decision	
	Approved	
	subject to compliance of current Import Policy for finished drugs along with submission of following documents before issuance of registration letter:	
	i. original legalized FSC, GMP and LOA	

ii. fee for pre-approval correction/revision of FPP specifications.

70	Case Category	Import (Najia Saleem)
	Name, address of Applicant.	tab INTERNATIONAL Office No. 77-K, Phase-I, Defence, Commercial Market, Lahore, Nishter Town (05-352-0065-107628D)
	Application Form Dy. No / Tracking ID & date of submission	(5ED-S1H-2A8M, 2024-09-11)
	Detail of Fee Submitted	300000.0, 2024-09-11,
	The proposed proprietary name / brand name	Dexasone Sav
	Label Claim	Each ml contains: Dexamethasone (as Dexamethasone Sodium Phosphate..... 2mg)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at Room Temperature
	For generic drugs (me-too Status)	Dexavet (Star Lab), Dexamethasone (Venus Pharma), Dexafar (Farvert)
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Name, address of Manufacturing site:	Saudi Pharmaceutical Industries-Street No.248, Second Industrial City, Riyadh, Kingdom of Saudi Arabia.-Saudi Arabia
	Name, address of Marketing Authorization Holder:	Saudi Pharmaceutical Industries, Street No.248, Second Industrial City, Riyadh, Kingdom of Saudi Arabia., Saudi Arabia
	Details of Certificates (CoPP/FSC/cGMP):	Scanned copy of COPP submitted
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	The firm shall submit original legalized COPP and LOA before issuance of registration letter.	
	Decision	
	Approved	
	subject to compliance of current Import Policy for finished drugs along with submission of original legalized COPP and LOA before issuance of registration letter.	
71	Case Category	Import (Najia Saleem)
	Name, address of Applicant.	tab INTERNATIONAL Office No. 77-K, Phase-I, Defence, Commercial Market, Lahore, Nishter Town (05-352-0065-107628D)
	Application Form Dy. No / Tracking ID & date of submission	(V4W-HDL-8M9L, 2024-10-04)
	Detail of Fee Submitted	300000.0, 2024-09-19,
	The proposed proprietary name / brand name	Enro Sav 10% Solution
	Label Claim	Enro Sav 10% Solution contains: Enrofloxacin..... 100mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	100ml-De-Controlled,50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at Room Temperature
	For generic drugs (me-too Status)	Encure-10 (Nawan Lab), Enro 20% (Ghazi Brothers)
	Pharmacotherapeutic Group of (API)	antibacterial

Name, address of Manufacturing site:	Street No.248, Second Industrial City, Riyadh, Kin-Street No.248, Second Industrial City, Riyadh, Kingdom of Saudi Arabia-Saudi Arabia
Name, address of Marketing Authorization Holder:	Saudi Pharmaceutical Industries, Street No.248, Second Industrial City, Riyadh, Kingdom of Saudi Arabia, Saudi Arabia
Details of Certificates (CoPP/FSC/cGMP):	scanned copies of FSC (valid upon submission but expired now) and valid GMP certificate submitted
Details of Authorization Letter :	Scanned copy submitted
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	24 months real time and 06 months accelerated stability data as per zone IV-A conditions
Evaluation Remarks	
The firm shall submit original legalized FSC, GMP and LOA.	
Decision	
Approved	
subject to compliance of current Import Policy for finished drugs along with submission of following documents before issuance of registration letter:	
i. original legalized FSC, GMP and LOA	
ii. fee for pre-approval correction/revision of FPP specifications.	
72	Case Category
	Import (Najia Saleem)
Name, address of Applicant.	AL ASAR ENTERPRISES GULSHAN E GULAB COLONY BEHIND ABDULLAH HEART CARE HOSPITAL, NEAR PULWASAL SURAJ MIANI ROAD MULTAN (04-361-0159-96972D)
Application Form Dy. No / Tracking ID & date of submission	(M18-LWR-2SRE, 2024-08-12)
Detail of Fee Submitted	300000.0, 2024-07-29,
The proposed proprietary name / brand name	CEPTIFI 4P
Label Claim	one powder vial contains: Ceftiofur (as sodium ceftiofur)..... 4 g Dissolve the 4 g sterile powder in 80 ml of Water for Injection. Each ml of reconstituted solution contains 50 mg ceftiofur
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	100ml vial -De-Controlled
Shelf Life (Unit)	2 Year(s)unreconstituted product in a dry place not exceeding 30oC. Protect from light and moisture
For generic drugs (me-too Status)	125635 CEFTOFUR-S 4GM INJECTION of M/S. LUCKY CORE INDUSTRIES LIMITED, LAHORE.
Pharmacotherapeutic Group of (API)	cephalosporin
Name, address of Manufacturing site:	vemedim animal health -Song Hau Industrial Zone, Dong Phu Commune, Chau Thanh District, Hau Giang Province, Viet Nam -Vietnam
Name, address of Marketing Authorization Holder:	vemedim animal health , Song Hau Industrial Zone, Dong Phu Commune, Chau Thanh District, Hau Giang Province, Viet Nam , Vietnam
Details of Certificates (CoPP/FSC/cGMP):	scanned copies of FSC (expired now but valid upon submission) stating the applied product CAN BE freely

		sold in Vietnam and overseas market and valid GMP certificate submitted
	Details of Authorization Letter :	scanned copy submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	The MAH abroad confirms the following: i. The product is available in two pack sizes: 4g and 100ml. • The applied product is a combo pack, consisting of: a. One vial of dry powder for injection (containing Cefotiofur as sodium); and b. One vial of solvent (diluent) for reconstitution ii. Cephalosporin and Penicillin products are manufactured in the same section of our facility. The Free sale status of applied product in country of origin cannot be confirmed.	
	Decision	
	Deferred	
	for submission of following:	
	i. confirmation of free availability of applied product in country of origin.	
	ii. Summary of in-use studies along with proposed in-use storage statement and in-use shelf-life.	
	iii. further deliberation and till implementation of PIC/s for local manufacturers in Pakistan.	
73	Case Category	Import (Najia Saleem)
	Name, address of Applicant.	u.m.enterprises plot no.12 sector 15 korangi industrial area-74900 (313)
	Application Form Dy. No / Tracking ID & date of submission	(6R4-GR4-PMYR, 2024-04-16)
	Detail of Fee Submitted	150000.0, 9000.0 2023-12-14, 2025-07-16
	The proposed proprietary name / brand name	Fertigon
	Label Claim	Each ml contains; Gonadorelin...50mcg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	5 Vials per Box -De-Controlled
	Shelf Life (Unit)	24 Month(s) Store at a cool and dark place
	For generic drugs (me-too Status)	118477 "GONAVET VEYX SOLUTION FOR INJECTION " "EACH ML CONTAINS:- GONADORELIN ACETATE...52.4 µG EQ. TO GONADORELIN50µG (AS PER INNOVATOR'S SPECIFICATION)* " BULK MANUFACTURER:- M/S. VEYX PHA
	Pharmacotherapeutic Group of (API)	Synthetic Gonadotrophin releasing hormone.
	Name, address of Manufacturing site:	M/s Ningbo Sansheng Biological Technology Co., Ltd- No.159, Buzheng East Road, Haishu District, Ningbo, Zhejiang, China Country: China-China
	Name, address of Marketing Authorization Holder:	M/s Ningbo Sansheng Biological Technology Co., Ltd, No.159, Buzheng East Road, Haishu District, Ningbo, Zhejiang Province, China, China
	Details of Certificates (CoPP/FSC/cGMP):	Scanned copy of valid Legalized FSC & GMP certificate has been submitted.
	Details of Authorization Letter :	scanned copy of legalized Distribution agreement with MAH has been submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	

Evaluation Remarks	
Decision of M-347 meeting: Since the Board was apprised by the Division of Biological evaluation & Research (BE&R) that the active substance in the product is synthetic in nature, the Board deferred the case and directed the Division of BE&R to forward the application to Division of PE&R for further evaluation and processing.	
Decision	
Approved	
with as per innovator's specifications, subject to compliance of current Import Policy for finished drugs along with submission of following documents before issuance of registration letter:	
i. original legalized FSC, GMP and LOA	
ii. adjusted fee challan for registration of imported drug	
Case Category	Import (Najia Saleem)
Name, address of Applicant.	u.m.enterprises plot no.12 sector 15 korangi industrial area-74900 (313)
Application Form Dy. No / Tracking ID & date of submission	(P3S-YSP-LHY4, 1970-01-01)
Detail of Fee Submitted	300000.0, 9000.0 2024-02-29, 2025-07-16
The proposed proprietary name / brand name	SIDA
Label Claim	Each device contains: 1.38g of progesterone
Reference to Finished product specifications	Manufacturer Specification
Proposed Pack Size	1.38g of progesteron-De-Controlled
Shelf Life (Unit)	24 Month(s)Store at a cool and dark place
For generic drugs (me-too Status)	112228 EAZI-BREED CIDR CATTLE INSERT of M/S. GHAZI BROTHERS, KARACHI.
Pharmacotherapeutic Group of (API)	Veterinary Hormone
Name, address of Manufacturing site:	M/s Ningbo Sansheng Biological Technology Co., Ltd-No.159, Buzheng East Road, Haishu District, Ningbo, Zhejiang, China Country: China-China
GMP status of the firm	Valid legalized CoPP & GMP has been submitted.
Evidence of approval of manufacturing facility	
Evaluation Remarks	
Decision of M-347 meeting: Since the Board was apprised by the Division of Biological evaluation & Research (BE&R) that the active substance in the product is synthetic in nature, the Board deferred the case and directed the Division of BE&R to forward the application to Division of PE&R for further evaluation and processing.	
Decision	
Approved	
subject to compliance of current Import Policy for finished drugs along with submission of following documents before issuance of registration letter:	
i. original legalized FSC, GMP and LOA	
ii. adjusted fee challan for registration of imported drug	
Case Category	Import (Najia Saleem)
Name, address of Applicant.	Brand Station 69 Wocland Villas Lahore Near Raiwind Road (05-352-0065-042264D)

Application Form Dy. No / Tracking ID & date of submission	(38D-ADQ-Y88L, 2024-05-13)
Detail of Fee Submitted	300000.0, 9000.0 2024-04-30, 2025-07-06
The proposed proprietary name / brand name	Lincospect BS (Water Soluble Powder)
Label Claim	Each gram contains: Amoxicillin trihydrate200mg Lincomycin hydrochloride88mg Vitamin E acetate30mg Spectinomycin hydrochloride88mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	- Aluminum coated PE-De-Controlled
Shelf Life (Unit)	36 Month(s)Store in dry, cool place. Stay away from direct sunlight. FOR VETERINARY USE ONLY.
For generic drugs (me-too Status)	093832 "LINCAMOX-S WATER SOLUBLE POWDER of Ms ICI
Pharmacotherapeutic Group of (API)	Antibiotics
Name, address of Manufacturing site:	M/s THIENQUAN JOINT STOCK COMPANY-Plot 17F-2-F8, road, Tra Noc 1 Industrial Zone, Tra Noc ward, Binh Thuy district, Can Tho city, Vietnam-Vietnam
Name, address of Marketing Authorization Holder:	M/s Brand Station , 69 Wocland villas Lahore, near Raiwind road Lahore , Pakistan
Details of Certificates (CoPP/FSC/cGMP):	Scanned copy of FSC issued by Department of animal Health, Ministry of Agriculture and Rural Development, Vietnam stating the applied product CAN BE freely sold in Viet Nam and overseas market. Validity: 2 years Copy of legalized GMP certificate No. 17/
Details of Authorization Letter :	Scanned copy of letter of distribution agreement dated 06- 01-2024 between the supplier and PLH
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
Evaluation Remarks	
Free sale status in country of origin cannot be confirmed.	
Decision	
Deferred	
for confirmation of free availability of applied product in country of origin.	
76	
Case Category	Import (Najia Saleem)
Name, address of Applicant.	HIPRA PAKISTAN PVT LTD. House no 86-88, J-1 Sunflower Society, M.A Johar Town, Lahore (05-352- 0058-050528D)
Application Form Dy. No / Tracking ID & date of submission	(VQD-SJN-9GZJ, 2025-04-09)
Detail of Fee Submitted	300000.0, 2025-04-08,
The proposed proprietary name / brand name	Eficur
Label Claim	Each ml contains: Ceftiofur as HCl.....50mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	250 ml-De-Controlled
Shelf Life (Unit)	24 Year(s)store below 25 degree C
For generic drugs (me-too Status)	Eficur 100 ml (080159)

Pharmacotherapeutic Group of (API)	Cephalosporin antibacterial
Name, address of Manufacturing site:	Laboratorios Hipra-Laboratorios Hipra, S.A.,Avda. la Selva, 1,17170 Amer (Girona), Spain-Spain
Name, address of Marketing Authorization Holder:	Laboratorios Hipra, Laboratorios Hipra, S.A., Avda.la Selva,135,17170 Amer (Girona), Spain, Spain
Details of Certificates (CoPP/FSC/cGMP):	submitted, could be verified online
Details of Authorization Letter :	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
Evaluation Remarks	
The cephalosporin/penicillin are manufactured in the building named VIF1 (Manufacture of Inactivated Vaccines and Pharmacological Products for animal use). Inside this building other activities are carried out as:Manufacture of viral, bacterial and combined inactivated vaccines Manufacture of solvents for vaccines. Manufacture of β -lactam injectable suspensions Manufacture of Pharmacological Products Aseptic filling lines However, cephalosporin/penicillin are considered substance with special requirements. Therefore, penicillanic antibiotics are handled in dedicated rooms using dedicated equipment and operated by dedicated personnel to avoid any contamination. The firm has submitted scanned copies of LOA, GMP, FSCDecision of M-353: Deferred for further deliberation.Updated status: The firm has submitted that the applied product is already registered in 100ml pack size vide Reg. No. 080159	
Decision	
Deferred	
for further deliberation and till implementation of PIC/s for local manufacturers in Pakistan.	
77	Case Category
	Import (Saima Hussain)
	Name, address of Applicant.
	Amson Vaccines & Pharma (Pvt.) Ltd Plot # 115, Industrial Triangle Kahuta Road (017/DSL(D)/PS&DC-ICT/2025)
	Application Form Dy. No / Tracking ID & date of submission
	(8T8-H7J-3R5Z, 2025-10-16)
	Detail of Fee Submitted
	313500.0, 2025-08-22,
	The proposed proprietary name / brand name
	Pulmor 30mg / 5ml Syrup
	Label Claim
	Each 5 ml contains: Ambroxol Hydrochloride 30 mg (European Pharmacopoeia)
	Reference to Finished product specifications
	European Pharmacopeia
	Proposed Pack Size
	1's x 150ml-As per SRO
	Shelf Life (Unit)
	36 MonthBelow 25°C
	For generic drugs (me-too Status)
	Product Name:: Mucosolvan 30mg Registration No: 008577 Company Name: Martin Dow Marker Limited Label Claim: Mucosolvan 30 mg Each 5 ml contain: Ambroxol Hydrochloride BP 30 mg (As per Innovator'
	Pharmacotherapeutic Group of (API)
	Mucolytic, expectorant
	Name, address of Manufacturing site:
	Drogsan İlaçları San. ve Tic. A.S.-Esenboğa Merkez Mah. Çubuk Cad. No:31 Çubuk-Ankara -Turkey
	Pharmaceutical Equivalence and Comparative Dissolution Profile
	Provided
	Name, address of Marketing Authorization Holder:
	M/s. Amson Vaccines & Pharma Pvt. Ltd., 115, Industrial Triangle ,Kahuta Rd Islamabad, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):
	GMP certificate (No. TR/GMP/2024/154) is provided
	Details of Authorization Letter :
	Not Applicable

Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Given in Module 3
The status in reference regulatory authorities	Reference Authority: France ANSM Brand Name: Surbronc expectorant Manufacturer and marketing authorisation holder: Boehringer ingelheim france 14, rue jean antoine de baïf 75013 paris Link: https://agence-prd.anism.sante.fr/php/ecodex/rcp/R0286947.htm
Evaluation Remarks	
Firm submitted CoPP of certificate no.2025/1725 dated 11/06/2025 valid for 2 years, issuing authority Turkish Medicine and Medical Devices Agency. Sole Agency Agreement dated 28/04/2023, in which Drogsan İlaçları San. ve Tic A.Ş., with its registered office in Oğuzlar Mah. 1370. Sok. No : 7/3Balgat, Ankara, established and reputable manufacturers of the below mentioned product having factory at Esenboğa Merkez Mah. Çubuk Cad. No:31 06760 Çubuk - Ankara do hereby confirm that they have appointed Amson Vaccine & Pharma (Pvt) LTD, 115, Industrial Triangle as their sole agent and exclusive distributor in Pakistan for registration, import, promotion and marketing of the applied product.	
Decision	
Approved	
Approved as per policy for inspection abroad	
78	Case Category
	Priority As Per 257-M of RB (Saima Hussain)
	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
	(JU7-E57-Y2ZA, 2025-10-08)
	Detail of Fee Submitted
	313500, 2025-10-03,
	The proposed proprietary name / brand name
	Olanib 150mg Tablet
	Label Claim
	Each film-coated tablet contains....Olaparib 150mg
	Reference to Finished product specifications
	As per Innovators Specification
	Proposed Pack Size
	120's (1x120)-As per SRO
	Shelf Life (Unit)
	2 Year(s)Store below 30°C.
	For generic drugs (me-too Status)
	Olaparix 150mg Tablet. (Himmel Pharmaceuticals)
	Pharmacotherapeutic Group of (API)
	Kaifeng Pharmaceutical (Group) Company Limited, China
	Name, address of Manufacturing site:
	Everest Pharmaceuticals Limited.-Rahman's Regnum Centre (11th) Floor) 191/1, Tejgaon C/A, Dhaka-1208,- Bangladesh
	Pharmaceutical Equivalence and Comparative Dissolution Profile
	Attached in Relavant section of Module 3.
	Name, address of Marketing Authorization Holder:
	Everest Pharmaceuticals Limited., Plot No.: B-45, 46 & 33, BSCIC I/A, Kanchpur, Narayanganj, , Bangladesh
	Details of Certificates (CoPP/FSC/cGMP):
	Firm submitted the GMP certificate dated 01-10-2024 certificate no. DGDA/6-227/2018/17218 valid for two years.
	Details of Authorization Letter :
	Not Applicable for Finished drug Product importer.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)
	24 Months
	The status in reference regulatory authorities
	Lynparna 150mg Film-coated Tablets. (AstraZeneca, Sweden)
Evaluation Remarks	

Firm submitted the CoPP certificate no. DGDA/6-227/2018/19585 dated 10/Nov/2024 issued by the Directorate General of Drug Administration, Dhaka, Bangladesh. Letter of Authorization dated 12th January, 2025 of the instant product is submitted by the firm. If the innovator brand revealed the dissolution condition and acceptance limit, then it is recommended to use the same method or otherwise complete scientific justifications shall be provided along with the results of the scientific experiment supporting their argument. Firm in their reply submitted the following commitment: The product dossier development and the associated testing activities were conducted in 2019, prior to the issuance and implementation of updated regulatory guidance, including the U.S. Food and Drug Administration's guidance on Comparative Dissolution Profiles (CDP), which was finalized in February 2024. It is important to note that the updated guidance does not have any impact on the validity or integrity of the results previously generated. However, if required, we are fully prepared to perform additional studies and provide comparative dissolution data in accordance with the current FDA guidance to ensure compliance with the latest regulatory expectations after product registration. However, the product Approved and document available date mentioned on the official website of USFDA is August 17, 2017, in which the USFDA-approved dissolution method as well as the acceptance criteria that were agreed is as follows: Apparatus USP I, Medium 50 mM pH 6.8 phosphate buffer, volume: 900 mL, speed: 100 rpm, temp: 37 °C Acceptance limit: for 150 mg: NLT % in 30 min, NLT (Q) in 60 min. While the dissolution method and acceptance limit by the applicant is as follows: Dissolution Medium: 1.0% SLS 10.0 gm sodium lauryl sulfate dissolved in 1000 mL of purified water and mix well. Speed: 100 RPM, acceptance limit: Not less than 75%(Q) of the labeled amount of Olaparib is dissolved in 60 minutes.

Decision

Deferred

Deferred to provide scientific justification for the selection of dissolution conditions and acceptance criteria that differ from those specified in the innovator literature, that was available since 2017 on the official website of USFDA. The dissolution method provided in the response continues to deviate from that of the reference (innovator) product. In cases where the proposed dissolution conditions differ from those of the reference product, submit bioequivalence study data conducted against the reference/innovator product.

79	Case Category	Import (Saima Hussain)
	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	(AAE-SDW-9TTE, 2025-06-19)
	Detail of Fee Submitted	300000.0, 2025-05-20,
	The proposed proprietary name / brand name	Elopag 25 Tablet
	Label Claim	Each Film Coated Tablet Contains Eltrombopag Olamine INN Equivalent to 25 mg Eltrombopag.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	28's-As per SRO
	Shelf Life (Unit)	24 Year(s) Store below 30°C.
	For generic drugs (me-too Status)	Elbonix 25mg Tablet (Himmel Pharmaceuticals, Lahore)
	Pharmacotherapeutic Group of (API)	MSN Laboratories Private Limited, India
	Name, address of Manufacturing site:	Everest Pharmaceuticals Limited.-Plot No: B-45, 46 & 33, BSCIC I/A, Kanchpur, Narayanganj, -Bangladesh
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP has performed against the innovator product Revolade Tablet
	Name, address of Marketing Authorization Holder:	Everest Pharmaceuticals Limited., Factory: Plot No: B-45, 46 & 33, BSCIC I/A, Kanchpur, Narayanganj, Bangladesh. Head office Address: Rahman's Regnum Centre (11th Floor) 191/1, Tejgaon C/A, Dhaka-1208, Bangladesh, Bangladesh
	Details of Certificates (CoPP/FSC/cGMP):	19.07.2023 to 19.07.2025 (For Manufacturing Facility)

Details of Authorization Letter :		Not Applicable for Finished drug Product Importer.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		Firm submitted the stability data of drug substance till 72 months
The status in reference regulatory authorities		Revolade 25 mg film-coated tablets, (Glaxo Operations UK Ltd)
Evaluation Remarks		
Applicant submitted the CoPP Certificate no. DGDA/6-227/2018/ 21965 dated 29,12.2024 issued by Directorate General of Drug Administration Mohakhali, Dhaka-1212, Bangladesh, valid for 2 years. Letter of Authorization dated 12 January, 2025 is submitted by the applicant.		
Sr.no.	Observation	Response of the firm
1.	Submit the specification along with the detailed analytical procedures for the drug substance by the drug product manufacturer.	Firm submitted the specification along with the detailed analytical procedures for the drug substance by the drug product manufacturer.
2.	Provide the analytical method validation report of drug substance performed by the drug product manufacturer.	Firm submitted the analytical validation report
3.	Submit the batch analysis report of the drug substance performed by the drug product manufacturer. Additionally, considering that Eltrombopag olamine is practically insoluble within the pH range of 1.2 to 6.8, and particle size distribution is a critical quality attribute, provide a scientific justification for not performing the particle size distribution test during drug substance analysis.	Firm submitted the batch analysis report of drug substance performed by drug product manufacturer. Further, in their reply firm stated that Particle size distribution (PSD) is a critical quality attribute (CQA) for poorly soluble drug substances due to its potential impact on dissolution rate. However, for Eltrombopag Olamine drug substance, the omission of routine PSD testing is scientifically justified based on the following considerations: 1. Consistent Dissolution Performance of the Drug Product We have reviewed the dissolution data form 26 commercial batches manufactured during the period 2023-2024. The results of dissolution are reproducible under validated analytical conditions. No significant batch-to-batch variability has been observed across the evaluated batches. These findings indicate that any potential variability in the PSD of the drug substance does not have a meaningful impact on the in vitro performance of the finished drug product. Therefore, PSD is not considered a critical determinant of drug product quality for this product.
4.	Provide a scientific justification for adding 2% overage of the active pharmaceutical ingredient in the proposed formulation.	Firm replied that "As per ICH Q8 (R2) Pharmaceutical Development, the overage in the final formulated product should be justified. We, Everest Pharmaceuticals Ltd., hereby declare that 2% overage of Eltrombopag Olamine API was used in the formulated product to mitigate the process loss and ensure that the product meets its potency specifications throughout its shelf life. Stability data is given in as supporting data.
5.	Provide a scientific justification for not adopting the dissolution medium recommended in the USFDA dissolution database.	Firm in their reply claimed that they had adopted the dissolution medium recommended in the USFDA dissolution database. However, the dissolution medium adopted by the applicant is different from the innovator product, comparison of both mediums is as under: Dissolution condition by the applicant: Apparatus USP: Type II (Paddle system) Dissolution

medium: Purified water with 1% tween 80 Volume: 900 mL Revolution: 100 rpm Temperature: 37 °C ± 0.5 °C Dissolution condition recommended in the USFDA Dissolution database: Apparatus USP: Type II (Paddle) Dissolution medium: 0.5% Polysorbate 80 in Phosphate Buffer, pH 6.8 Volume: 900 mL Revolution: 50 rpm

Decision

Deferred

Deferred for the submission of following shortcomings:

- Submit a scientifically justified rationale for the adding 2% overage of the active pharmaceutical ingredient (API) in the proposed formulation. The justification provided including process loss and maintenance of potency throughout shelf life is not acceptable in the absence of supporting evidence from reference literature and comprehensive pharmaceutical development data. This should include documented evidence demonstrating the degradative nature of the API and details of any specialized manufacturing processes that may result in API loss during production.
- Provide a scientific justification for the selection of a dissolution medium that differs from that specified in the USFDA dissolution database. In cases where the dissolution conditions deviate from those of the reference (innovator) product, submit bioequivalence study data conducted against the reference/innovator product to support the proposed conditions.

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Case Category	Import (Saima Hussain)
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	(USQ-B7N-T7X5, 2025-06-19)
Detail of Fee Submitted	300000.0, 2025-06-02,
The proposed proprietary name / brand name	Elopag 50 Tablet
Label Claim	Each Film Coated Tablet Contains..... Eltrombopag Olamine INN Equivalent to 50 mg Eltrombopag.
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	28's-As per SRO
Shelf Life (Unit)	24 Year(s)Store below 30°C.
For generic drugs (me-too Status)	Elbonix 50mg Tablet (Himmel Pharmaceuticals, Lahore)
Pharmacotherapeutic Group of (API)	MSN Laboratories Private Limited, India
Name, address of Manufacturing site:	Everest Pharmaceuticals Limited.-Plot No: B-45, 46 & 33, BSCIC I/A, Kanchpur, Narayanganj, -Bangladesh
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP has performed against the innovator product Revolade Tablet
Name, address of Marketing Authorization Holder:	Everest Pharmaceuticals Limited., Factory: Plot No: B-45, 46 & 33, BSCIC I/A, Kanchpur, Narayanganj, Bangladesh. Head office Address: Rahman's Regnum Centre (11th Floor) 191/1, Tejgaon C/A, Dhaka-1208, Bangladesh, Bangladesh
Details of Certificates (CoPP/FSC/cGMP):	19.07.2023 to 19.07.2025 (For Manufacturing Facility)
Details of Authorization Letter :	Not Applicable for Finished drug Product importer.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm submitted the stability data of drug substance till 72 months

The status in reference regulatory authorities	Revolade 50 mg film-coated tablets, (Glaxo Operations UK Ltd)
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Evaluation Remarks

Applicant submitted CoPP certificate no. DGDA/6-227/2018/ 21 966 dated 29-12-2024 issued by the Directorate General of Drug Administration Mohakhali, Dhaka-1212, Bangladesh Letter of Authorization dated 12-01-2025 is submitted by the applicant.

Sr.no.	Observation	Response of the firm
1.	Submit the specification along with the detailed analytical procedures for the drug substance by the drug product manufacturer.	Firm submitted the specification along with the detailed analytical procedures for the drug substance by the drug product manufacturer.
2.	Provide the analytical method validation report of drug substance performed by the drug product manufacturer.	Firm submitted the analytical validation report
3.	Submit the batch analysis report of the drug substance performed by the drug product manufacturer. Additionally, considering that Eltrombopag olamine is practically insoluble within the pH range of 1.2 to 6.8, and particle size distribution is a critical quality attribute, provide a scientific justification for not performing the particle size distribution test during drug substance analysis.	Firm submitted the batch analysis report of drug substance performed by drug product manufacturer. Further, in their reply firm stated that Particle size distribution (PSD) is a critical quality attribute (CQA) for poorly soluble drug substances due to its potential impact on dissolution rate. However, for Eltrombopag Olamine drug substance, the omission of routine PSD testing is scientifically justified based on the following considerations: 1. Consistent Dissolution Performance of the Drug Product We have reviewed the dissolution data form 26 commercial batches manufactured during the period 2023-2024. The results of dissolution are reproducible under validated analytical conditions. No significant batch-to-batch variability has been observed across the evaluated batches. These findings indicate that any potential variability in the PSD of the drug substance does not have a meaningful impact on the in vitro performance of the finished drug product. Therefore, PSD is not considered a critical determinant of drug product quality for this product.
4.	Provide a scientific justification for adding 2% overage of the active pharmaceutical ingredient in the proposed formulation.	Firm replied that "As per ICH Q8 (R2) Pharmaceutical Development, the overage in the final formulated product should be justified. We, Everest Pharmaceuticals Ltd., hereby declare that 2% overage of Eltrombopag Olamine API was used in the formulated product to mitigate the process loss and ensure that the product meets its potency specifications throughout its shelf life. Stability data is given in as supporting data.
5.	Provide a scientific justification for not adopting the dissolution medium recommended in the USFDA dissolution database.	Firm in their reply claimed that they had adopted the dissolution medium recommended in the USFDA dissolution database. However, the dissolution medium adopted by the applicant is different from the innovator product, comparison of both mediums is as under: Dissolution condition by the applicant: Apparatus USP: Type II (Paddle system) Dissolution medium: Purified water with 1% tween 80 Volume: 900 mL Revolution: 100 rpm Temperature: 37 °C ± 0.5 °C Dissolution condition recommended in the USFDA Dissolution database: Apparatus USP: Type

II (Paddle) Dissolution medium: 0.5% Polysorbate 80 in Phosphate Buffer, pH 6.8 Volume: 900 mL
Revolution: 50 rpm

Decision

Deferred

Deferred for the submission of following shortcomings:

- Submit a scientifically justified rationale for the adding 2% overage of the active pharmaceutical ingredient (API) in the proposed formulation. The justification provided including process loss and maintenance of potency throughout shelf life is not acceptable in the absence of supporting evidence from reference literature and comprehensive pharmaceutical development data. This should include documented evidence demonstrating the degradative nature of the API and details of any specialized manufacturing processes that may result in API loss during production.
- Provide a scientific justification for the selection of a dissolution medium that differs from that specified in the USFDA dissolution database. In cases where the dissolution conditions deviate from those of the reference (innovator) product, submit bioequivalence study data conducted against the reference/innovator product to support the proposed conditions.

81	Case Category	Import (Saima Hussain)
	Name, address of Applicant.	RG Pharmaceutica Pvt Ltd BF1-01 First Floor, Gate No.1 Bahria Orchard Main Raiwind Road, Lahore, Pakistan (05-352-0066-059010D-E)
	Application Form Dy. No / Tracking ID & date of submission	(YAA-VPA-DUDT, 2026-03-31)
	Detail of Fee Submitted	313500, 2026-03-04,
	The proposed proprietary name / brand name	Utifib 10 mg Tablet
	Label Claim	Each film-coated tablet contains 10 mg dydrogesterone.
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	10-De-Controlled,20-De-Controlled,28-De-Controlled
	Shelf Life (Unit)	4 Year30 C
	For generic drugs (me-too Status)	Duphaston 10mg Tablets
	Pharmacotherapeutic Group of (API)	Sex Hormones and Modulators of Genital System, Pregnatriene derivatives, ATC Code: G03DB01
	Name, address of Manufacturing site:	CYNDEA PHARMA, S.L.-Polígono Industrial Emiliano Revilla Sanz. Avenida de Ágreda, 31, Ólvega 42110 Soria, Spain-Spain
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in Module 3 . Drug Product Part
	Name, address of Marketing Authorization Holder:	Gedeon Richter Plc , Gyomroi ut 19-21 Budapest HU 1103, Hungary , Hungary
	Details of Certificates (CoPP/FSC/cGMP):	GMP of abroad finished product manufacturer Attached in Module-1
	Details of Authorization Letter :	Not Applicable in case of finished drug import
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached in Module 3 Drug Substance Part
	The status in reference regulatory authorities	MHRA UK

Evaluation Remarks

Applicant submitted CoPP Certificate Number: PP10198040 dated 10th February,2026 mentioned Exporting Country: United Kingdom, Importing: Pakistan, The name and address of the Product License/Marketing Authorisation holder are: Name: GEDEON RICHTER PLC Address: GYOMROI UTCA 19-21, BUDAPEST, HU-107
Minutes of 356th Meeting of Registration Board (07th April, 2026)

1103, HUNGARY , Name of Manufacturer: Name: CYNDEA PHARMA SL Address: POLIGONO INDUSTRIAL EMILIANO REVILLA SANZ, AVENIDA DE AGREDA 31, OLVEGA (SORIA), E-42110, SPAIN. Letter of Authorization: We, CYNDEA PHARMA S.L., located at Polígono Industrial Emiliano Revilla Sanz Avenida Agreda 31, 42110, Ólvega (Soria), Spain, as drug product manufacturer of the product Product name Dydrogesterone, 10 mg film-coated tablets, hereby authorizes RG Pharmaceutica (Pvt). Ltd, located at Plot 247, Sundar Industrial Estate, Lahore, to distribute/market the UTIFIB Tablet in the territory of Pakistan. Product Name: UTIFIB Tablet Composition: Dydrogesterone, 10 mg LICENCE AND SUPPLY AGREEMENT by and between RG Pharmaceutica (Pvt.) Ltd., a company established under the laws of Pakistan, having its registered offices at BF1-01 First Floor, Gate No.1 Bahria Orchard Main Raiwind Road, Lahore and SECP registered office address at 247-Sunder Estate, Raiwind Road – Lahore, Pakistan, represented by duly authorized representatives, as undersigned below hereinafter referred to as RG Pharmaceutica and Welding GmbH & Co. KG, a company established under the laws of Germany, having its registered offices at Esplanade 39, 20354 Hamburg, Germany, represented by duly authorized representatives, as undersigned below: "RG Pharmaceutica has carried out an assessment of Welding's Registration Dossier and is satisfied with its contents; therefore, RG Pharmaceutica wishes to acquire certain rights to the Registration Dossier, to obtain one (1) Marketing Authorisation in each country of the Territory and to purchase all of its requirements of the Product from Welding for sale in the Territory". In light of the above submission, clarification is required from the applicant. A query has already been communicated; however, no response has been received to date. Clarify the submission of the CoPP indicating the exporting country as the United Kingdom, while the product license holder is M/s. Gedeon Richter Plc., located at Gyömrői utca 19–21, Budapest, Hungary (HU-1103), and the manufacturer is Cyndea Pharma S.L., located at Polígono Industrial Emiliano Revilla Sanz, Avenida Ágreda 31, 42110 Ólvega (Soria), Spain. Further, the Letter of Authorization has been issued by the manufacturer, Cyndea Pharma S.L., whereas it should be issued by the product license holder/Marketing Authorization holder. Furthermore, this is inconsistent with the License and Supply Agreement submitted in Module-I, which states that M/s. Welding GmbH & Co. KG owns certain rights to the Registration Dossier and grants RG Pharmaceutica the exclusive right to use the Registration Dossier and Marketing Authorization to market the product in the territory. In this regard, please submit duly legalized documents clearly establishing the relationship between the product license holder, the manufacturer, and M/s. Welding GmbH & Co. KG. The documents should also clarify which entity holds the authority to grant sole agency rights to RG Pharmaceutica, and specify the country from which the finished product will be exported to Pakistan following registration approval.

Decision

Deferred

Deferred for the submission of following shortcomings:

1. Clarify the submission of the CoPP indicating the exporting country as the United Kingdom, while the product license holder is M/s. Gedeon Richter Plc., located at Gyömrői utca 19–21, Budapest, Hungary (HU-1103), and the manufacturer is Cyndea Pharma S.L., located at Polígono Industrial Emiliano Revilla Sanz, Avenida Ágreda 31, 42110 Ólvega (Soria), Spain.
2. The Letter of Authorization has been issued by the manufacturer, Cyndea Pharma S.L., whereas it should be issued by the product license holder/Marketing Authorization holder. Furthermore, this is inconsistent with the License and Supply Agreement submitted in Module-I, which states that M/s. Welding GmbH & Co. KG owns certain rights to the Registration Dossier and grants RG Pharmaceutica the exclusive right to use the Registration Dossier and Marketing Authorization to market the product in the territory. In this regard, please submit duly legalized documents clearly establishing the relationship between the product license holder, the manufacturer, and M/s. Welding GmbH & Co. KG. The documents should also clarify which entity holds the authority to grant sole agency rights to RG Pharmaceutica and specify the country from which the finished product will be exported to Pakistan following registration approval.

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Case Category	Import (Saima Hussain)
Name, address of Applicant.	Bristol Mayer Biotech Pakistan 73 B Guldasht Town Zarrar Shaheed Lahore (05-352-0068-109282D)
Application Form Dy. No / Tracking ID & date of submission	(J9H-QJ1-8Z79, 2025-02-07)

Detail of Fee Submitted	300000.0, 2025-01-08,
The proposed proprietary name / brand name	Cetrorelix acetate 0.25mg/vial
Label Claim	Each Vial Contains: Cetrorelix acetate equivalent to Cetrorelix (base)...0.25 mg As per Innovator's Specification Each 1ml ampoule contains..... sterile water for injection BP
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's (Combi pack with-As per SRO
Shelf Life (Unit)	24 MonthStore in a refrigerator (2°C – 8°C)
For generic drugs (me-too Status)	Cetrotide 0.25mg Injection (Reg.No 059031) by Martin Dow Specialities (Private) Limited,Karachi
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Kaliberr Bioscience Pvt. Ltd.-GUT No.444/1, Ground, First, Second Floor Khadki, Koshimba Road, Lakhmapur, Nashik-422202-India
Pharmaceutical Equivalence and Comparative Dissolution Profile	
Name, address of Marketing Authorization Holder:	Kaliberr Bioscience Pvt. Ltd., GUT No.444/1, Ground, First, Second Floor Khadki, Koshimba Road, Lakhmapur, Nashik-422202, 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	MHRA Approved Cetrotide® by Merck KGaA, Darmstadt, Germany

Evaluation Remarks

Sr.no.	Observations	Response of the firm
1.	Submit the Product Permission Certificate of applied product issued by the regulatory agency/authority of country of origin.	Firm in their reply submitted Form 28(A), according to which SANZYME (P) LTD (709484 - Private Limited) of INJECTABLE UNIT, FIRST FLOOR, BESIDE OF CONFERENCE HALL, PLOT NO.8, SY. NO. 542,, KOLTUR, VILLAGE SHAMIRPET MANDAL, MEDCHAL ±MALKAJIGIRI (DISTRICT), TELENGANA - 500101,Taluka: OutState Taluka, District: OutState Districtis hereby granted a loan licence to manufacture on the premises situated at GUT NO. 444/1, GROUND,FIRST,SECOND FLOOR,,KHADKI, KOSHIMBA ROAD, LAKHMAPUR,,NASHIK -422202 C/o KALIBERR BIOSCIENCE PRIVATE LIMITED (707747). Further, License has been granted with the product : Manufacturer: L-KALIBERR BIOSCIENCE PRIVATE LIMITED (NZ3-NASHIK)1. Cetrorelix Acetate for Injection 0.25mg/vial (Export) Each vial contains: - Cetrorelix Acetate equivalent to Cetrorelix (0.25 mg)
2.	Submit valid and legalized CoPP/Free sale certificate issued by the regulatory authority of country of origin.	Applicant in their reply submitted the CoPP issued for Bahrain as an Exporting Country.

3.	Submit valid and legalized Letter of Authorization of applied product.	Firm submitted Letter of Authorization dated Date: 24th March'2026.

Decision

Deferred

Deferred for decision by Appellate Board for similar cases.

83	Case Category	Import (Saima Hussain)
	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	(ALS-N1R-A9X1, 2025-06-04)
	Detail of Fee Submitted	300000.0, 2025-03-19,
	The proposed proprietary name / brand name	DYDROBOON 10mg Tablet
	Label Claim	Each film-coated tablet contains: Dydrogesterone Ph. Eur. 10 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1 × 10's-As per SRO, 1 × 20's-As per SRO
	Shelf Life (Unit)	24 Year(s) Do not store above 30°C. Protect from light.
	For generic drugs (me-too Status)	Duphaston 10mg Tablet // Reg No. 006654
	Pharmacotherapeutic Group of (API)	Genito Urinary system and sex hormones
	Name, address of Manufacturing site:	Mankind Pharma Limited-Plot No SP1-3, RIICO Industrial Area, Village- Kaladwas (Extn.) Tehsil-Girwa, Dist. Udaipur- 313003 (Rajasthan) India.-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP has performed against reference product [Product Name: Duphaston®, Marketing Authorization Holder Abbott healthcare]
	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 certificate dated 09-07-2024 : No. DC/Mfg/WHO-GMP/E-01451/2024/ 4105 of M/s. M/s Mankind Pharma Ltd., Plot No SP1-3, RIICO Industrial Area, Village - Kaladwas (Extn.) Tehsil-Girwa, Distt. Udaipur-313003 (Rajasthan) validity up to 03 years is submitted
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of drug substance is submitted
	The status in reference regulatory authorities	GYNOREST 10mg Tablet/ US FDA

Evaluation Remarks

Applicant submitted CoPP dated 07-01-2025, certifying authority FOOD SAFETY AND DRUGS CONTROL Commissionerate (Drug Control Wing) SWASTHYA BHAWAN, TILAK MARG Udaipur Rajasthan, valid till 08.07.2027. Letter of Authorization dated 07-03-2025 stated that, Mankind Pharma Ltd, do hereby authorized A.J.Mirza Pharma (Pvt) Ltd, a company incorporated under the laws of Pakistan having its registered office address at, 1st floor, Shafi Court, Merewether Road, Civil Lines, Karachi-75520, Pakistan to apply for registration of Dydrogesterone Tablets BP 10 mg products manufactured by Mankind Pharma Ltd, facility located at Plot No SP1-3, RIICO Industrial Area, Village - Kaladwas (Extn) Tehsil- Girwa, Dist Udaipur313003 (Rajasthan), India for importation and distribution in the Territory of Pakistan.

	Decision	
	Approved	
	Approved as per policy for inspection abroad	
84	Case Category	Import (Saima Hussain)
	Name, address of Applicant.	Lucky Core Industries Limited 5 West Wharf Road Karachi (013)
	Application Form Dy. No / Tracking ID & date of submission	(N4N-PL7-5H8A, 2026-02-10)
	Detail of Fee Submitted	,
	The proposed proprietary name / brand name	Dasanib-100
	Label Claim	Each film coated tablet contains: Dasitanib.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	20's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Anti-cancer
	Name, address of Manufacturing site:	DRUG INTERNATIONAL LIMITED -13A & 14A, Tongi I/A, Squibb Road Tongi, Gazipur, Bangladesh.- Bangladesh
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
	Name, address of Marketing Authorization Holder:	DRUG INTERNATIONAL LIMITED , 13A & 14A, Tongi I/A, Squibb Road Tongi, Gazipur, Bangladesh., Bangladesh
	Details of Certificates (CoPP/FSC/cGMP):	CoPP attached
	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/index.cfm?event=overview.process&ApplNo=202103

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 replied that Tablet Dasinib (Dasatinib INN 100 mg/Tablet), manufacturing is performed in a dedicated oncology containment facility due to the highly potent nature of Dasatinib. All manufacturing activities are carried out using a fully contained and online transfer system to ensure maximum protection for personnel, product, and environment.
2.	Provide a scientifically justified rationale for the use of isopropyl alcohol and methylene chloride in the coating solution of the proposed formulation. The justification should be supported by references from stringent regulatory authorities and must demonstrate compliance with ICH Q3C residual solvent limits, Minutes of 356th Meeting of Registration Board (07th April, 2026)	Firm in their reply informed that Isopropyl alcohol and methylene chloride are used as volatile organic solvents to prepare the coating solution. Further, this system is suitable for moisture-sensitive drugs such as Dasatinib. Firm mentioned the safety limits of both

	including control strategy and residual solvent specifications in the finished product.	solvent from, but residual solvent test has not performed during the quality analysis of finished product to meet the requirements for control of residual solvents.
3.	In the comparative dissolution report, Pregabalin has been mentioned at various places. Clarify this discrepancy.	Firm has not provided any clarification regarding this matter.
4.	Justify the rationale for not adopting the dissolution medium and acceptance criteria as recommended by the innovator product. Dissolution method and acceptance criteria by the applicant: Apparatus: Paddle (USP apparatus 2) Medium: 0.3% w/v SLS (Sodium Lauryl sulfate) Volume: 500 mL Speed: 100 rpm Time: (a) For routine analysis: 45 minutes. Dissolution method and acceptance criteria by the innovator: Apparatus: Rotation Speed: Medium: Volume: Analytical: USP Apparatus II (Paddle Method) 60 rpm pH 4.0 acetate buffer with 1% Triton X-100 Volume: 1000 mL Acceptance limit: Q=at 30 minutes	Firm replied that, the dissolution medium and acceptance criteria of the innovator product were not adopted because the proposed formulation, although containing the same active ingredient Dasatinib, differs in excipient composition and manufacturing process, which can influence drug release behaviour. A dissolution method was independently developed to provide appropriate sink conditions and to be discriminatory for the proposed product. The method was validated in accordance with ICH Q2(R1) and found to be precise, accurate, and robust.
5.	In Module 3 (Drug Substance section), the API manufacturer is stated as M/s. Anhui Haikang Pharmaceutical Co., Ltd., whereas the drug product stability data refer to M/s Shandong Boyuan Pharmaceutical Co., Ltd. Clarify this inconsistency and confirm the actual API manufacturer used for the batches submitted for stability and registration, supported by appropriate documentary evidence	The firm, in its reply, submitted amended stability data in which only the name of the API manufacturer was changed from M/s. Shandong Boyuan Pharmaceutical Co., Ltd. to M/s. Anhui Haikang Pharmaceutical Co., Ltd., while the remaining stability data remained the same as previously submitted under the name of M/s. Shandong Boyuan Pharmaceutical Co., Ltd.

Decision

Rejected

The Registration Board has decided to reject the instant application due to the following deficiencies:

The firm initially submitted stability data of the drug product specifying the API manufacturer as M/s Shandong Boyuan Pharmaceutical Co., Ltd, while the drug substance manufacturer mentioned in the drug substance part of module-III is M/s Anhui Haikang Pharmaceutical Co., Ltd. However, in response to a query requesting clarification of the actual API manufacturer, the firm resubmitted the same stability data only changing the name of API manufacturer to M/s Anhui Haikang Pharmaceutical Co., Ltd.

The firm adopted dissolution conditions and acceptance criteria that deviate from those of the innovator product, without providing adequate scientific justification or supporting data.

The firm failed to provide a scientific rationale for the use of methylene chloride as a solvent in the manufacturing process of the drug product. Additionally, no references from stringent regulatory authorities were submitted, nor was a suitable control strategy or residual solvent test included the finished product specification.

The firm did not address the discrepancy identified in the comparative dissolution report, specifically the inconsistent and incorrect mention of “pregabalin” at various points in the document.

85	Case Category	Import (Saima Hussain)
	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	(A4V-8W3-WTRD, 2025-06-19)
Detail of Fee Submitted	300000.0, 2025-04-23,
The proposed proprietary name / brand name	Gesnat 25 mg
Label Claim	Each film coated tablet contains: Eltrombopag (as eltrombopag olamine 31.9 mg) 25 mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	30 tablets-De-Controlled
Shelf Life (Unit)	24 Month30 degree
For generic drugs (me-too Status)	Revolade 25 mg
Pharmacotherapeutic Group of (API)	active thrombopoietin receptor agonist
Name, address of Manufacturing site:	Laboratorio ELEA PHOENIX S.A.-Gral. Juan Gregorio Lemos 2809 (B1613AUE). Los Polvorines, Buenos Aires, República Argentina.-Argentina
Pharmaceutical Equivalence and Comparative Dissolution Profile	Both are Attached
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):	GMP attached
Details of Authorization Letter :	NA
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached, studies conducted at 25C / 60 % RH
The status in reference regulatory authorities	EMA, USFDA
Evaluation Remarks	
Applicant submitted the CoPP certificate no.CE-2024-82321156-APN-INAME#ANMAT dated Monday, August 5, 2024 as per the Additional Signature Sheet Certificate, Name and address of Certifying Authority: INAME - Instituto Nacional de MedicamentosNational Institute of Drugs Avenida Caseros 2161 Ciudad Autónoma de Buenos Aires- República Argentina.- validity for twelve months. Letter of Appointment as distributor ,this is to certify that We, LABORATORIO ELEA PHOENIX S.A., a legal entity registered under the laws of Republic of Argentina, having our Legal address: Av. del Libertador N° 6550, floor 3°, zip code C1428ARV, CABA, Republic of Argentina, hereby appoint Amgomed, having its head office at Office No.4, First Floor, Ghausia Plaza, Jinnah Avenue, Blue Area, Islamabad, 44000, Pakistan, as our authorized distributors in Pakistan for the following products (In terms of Section 23 (1) (i) and Section 32 of the Drugs Act, 1976 for supply of the following products in Pakistan. M/s Amgomed will be legally entitled to issue the warranty on Form-2A to the purchasers on our behalf.Active Ingredient and StrengthEltrombopag 25 mg (as Eltrombopag olamine 31.9 mg)Eltrombopag 50 mg (as Eltrombopag olamine 63.8 mg).Brand NameGESNAT, coated tabletGESNAT, coated tabletThis Letter of Authorization is effective from the issuance date (11/11/2024) through & valid for 5 years from the date mentioned.	
Decision	
Approved	
Approved as per policy for inspection abroad	
86	Case Category
	Import (Saima Hussain)
	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
	(UZW-8X4-Z9AW, 2025-06-19)
	Detail of Fee Submitted
	300000.0, 2025-04-23,

The proposed proprietary name / brand name	Gesnat 50 mg
Label Claim	Each film-coated tablet contains: Eltrombopag (as eltrombopag olamine 63.8 mg) 50 mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	30 tablets-De-Controlled
Shelf Life (Unit)	24 Month30 degree
For generic drugs (me-too Status)	Revolade 50 mg
Pharmacotherapeutic Group of (API)	active thrombopoietin receptor agonist
Name, address of Manufacturing site:	Laboratorio ELEA PHOENIX S.A.-Gral. Juan Gregorio Lemos 2809 (B1613AUE). Los Polvorines, Buenos Aires, República Argentina.-Argentina
Pharmaceutical Equivalence and Comparative Dissolution Profile	Both are Attached
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):	GMP attached
Details of Authorization Letter :	NA
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached, studies conducted at 25C / 60 % RH
The status in reference regulatory authorities	EMA, USFDA

Evaluation Remarks

Applicant submitted the CoPP certificate no.CE-2024-82321156-APN-ENAME#ANMAT dated Monday, August 5, 2024 as per the Additional Signature Sheet Certificate, Name and address of Certifying Authority: INAME - Instituto Nacional de MedicamentosNational Institute of Drugs Avenida Caseros 2161 Ciudad Autónoma de Buenos Aires- República Argentina.- validity for twelve months. Letter of Appointment as distributor ,this is to certify that We, LABORATORIO ELEA PHOENIX S.A., a legal entity registered under the laws of Republic of Argentina, having our Legal address: Av. del Libertador N° 6550, floor 3°, zip code C1428ARV, CABA, Republic of Argentina, hereby appoint Amgomed, having its head office at Office No.4, First Floor, Ghausia Plaza, Jinnah Avenue, Blue Area, Islamabad, 44000, Pakistan, as our authorized distributors in Pakistan for the following products (In terms of Section 23 (1) (i) and Section 32 of the Drugs Act, 1976 for supply of the following products in Pakistan. M/s Amgomed will be legally entitled to issue the warranty on Form-2A to the purchasers on our behalf.Active Ingredient and StrengthEltrombopag 25 mg (as Eltrombopag olamine 31.9 mg)Eltrombopag 50 mg (as Eltrombopag olamine 63.8 mg).Brand NameGESNAT, coated tabletGESNAT, coated tabletThis Letter of Authorization is effective from the issuance date (11/11/2024) through & valid for 5 years from the date mentioned.

Decision

Approved

Approved as per policy for inspection abroad

87	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Huzafa International commercial area, aziz bhatti town, Sargodha (08-384-0120-022405D)
	Application Form Dy. No / Tracking ID & date of submission	(MM2-LGV-6X75, 2025-10-28)
	Detail of Fee Submitted	313500, 2025-08-06,
	The proposed proprietary name / brand name	Tylocom LA 20% Injection
	Label Claim	Each 100 ml contains: Tylosin Tartrate (Tylosin base)20 g (Eu. Ph. Specifications) For veterinary use only
	Reference to Finished product specifications	European Pharmacopeia

Proposed Pack Size	100 ml-De-Controlled
Shelf Life (Unit)	24 Year(s)30 °C
For generic drugs (me-too Status)	Reg. No. 113562 , Brand name: Tylox-20 Injection (100ml) : Manufactured by: M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK
Pharmacotherapeutic Group of (API)	Antibiotics
Name, address of Manufacturing site:	Shandong Soocom Animal Remedy Co., Ltd-Xundakang Road No.666 of Agricultural High & New Technology Development Zone of Jinan, China-China
Name, address of Marketing Authorization Holder:	Shandong Soocom Animal Remedy Co. Ltd., Xundakang Road No.666 of Agricultural High & New Technology Development Zone of Jinan, China, China
Details of Certificates (CoPP/FSC/cGMP):	
Details of Authorization Letter :	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	

Evaluation Remarks

Address of manufacturer on GMP certificate is different from that mentioned on other documents. Firm submitted Statement bearing stamp of Shandong Provincial Animal Husbandry & Veterinary Bureau, it states as "It is hereby certify that: The 1st address shown on GMP certificate of Shandong Soocom Animal Remedy Co. Ltd. China is "AGRICULTURAL HIGH & NEW TECHNOLOGY DEVELOPMENT ZONE OF CHANGQING DISTRICT JINAN CITY." is same as "Xundakang Road No.666 of Agricultural High & New Technology Development Zone of Jinan China." both are the same address for the veterinary medicine production site of SHANDONG SOOCOM ANIMAL REMEDY CO.,LTD. China. The GMP declaration of 1st address will be rectified in next term issuance of GMP certificate after expiration of current validity period, (according to veterinary pharmaceutical regulations of China)."

Decision

Approved

88	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Mian Traders Railways Road, Morre Eminabad (09-341-0135-118497D)
	Application Form Dy. No / Tracking ID & date of submission	(1BJ-RTX-MAW1, 2025-11-14)
	Detail of Fee Submitted	313500, 2025-11-11,
	The proposed proprietary name / brand name	DOXY 500
	Label Claim	Each 1 g contains: Doxycycline Hyclate500 mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	- Pack 1 aluminum bag of 1 kg. - Pack 20 aluminum bag of 1 kg in an ou-De-Controlled
	Shelf Life (Unit)	-36 Year(s)Store in shade and dry place, temperature below 30oC.
	For generic drugs (me-too Status)	DOX PLUS 50% Water Soluble Powder by M/s Bio Labs
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	Asia Animal Pharmaceutical Co., Ltd-Address: 130, 1A National Road, Ba Lang Ward, Cai Rang District, Can Tho City, Vietnam.-Vietnam
	Name, address of Marketing Authorization Holder:	MIAN TRADERS, Railways Road , Morre Eminabad , Gujranwala , Pakistan , Pakistan

	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	Firm submitted copy of FSC certificate issued by Department of Animal Health & Production, Viet Nam wherein it is stated that Product CAN BE freely sold in Vietnam & oversea market.	
	Decision	
	Deferred	
	Deferred for confirmation of Free Sale status in country of origin.	
89	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Mian Traders Railways Road, Morre Eminabad (09-341-0135-118497D)
	Application Form Dy. No / Tracking ID & date of submission	(1DB-8AQ-HXGV, 2025-11-02)
	Detail of Fee Submitted	313500, 2025-10-27,
	The proposed proprietary name / brand name	AMOX 500 Water Soluble Powder
	Label Claim	Each 1 g contains: Amoxicillin trihydrate 500 mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	Pack 1 aluminum bag of 1 kg-De-Controlled
	Shelf Life (Unit)	36 Year(s)Store in shade and dry place, temperature below 30oC.
	For generic drugs (me-too Status)	Amoxicilina 500 Karizoo M/s Unicare Enterprises, Faisalabad (Reg. # 081302)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	Asia Animal Pharmaceutical Co., Ltd-Address: 130, 1A National Road, Ba Lang Ward, Cai Rang District, Can Tho City, Vietnam. Phone: (+84) (0292) 3913347. Fax: (+84) (0292) 3913349-Vietnam
	Name, address of Marketing Authorization Holder:	DR ALI RAZA CH, GUJRANWALA, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	Firm submitted copy of FSC certificate issued by Department of Animal Health & Production, Viet Nam wherein it is stated that Product CAN BE freely sold in Vietnam & oversea market.	
	Decision	
	Deferred	
	Deferred for confirmation of free sale status in country of origin.	
90	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Mian Traders Railways Road, Morre Eminabad (09-341-0135-118497D)
	Application Form Dy. No / Tracking ID & date of submission	(G39-5SP-Y8B4, 2025-12-20)
	Detail of Fee Submitted	313500, 2025-12-17,

The proposed proprietary name / brand name	TILCO 250 ORAL SOLUTION
Label Claim	Each ml contains: Tilmicosin phosphate 250 mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	- Pack 20 cans of 1 liter or 500 ml - Pack 1 can of 5 liters or 10 lit-De-Controlled
Shelf Life (Unit)	36 Year(s)Store in shade and dry place, temperature below 30oC. Protected from light.
For generic drugs (me-too Status)	Tilmicobak Oral Liquid Reg no 075706 by M/s Attabak pharmaceuticals,
Pharmacotherapeutic Group of (API)	Antibiotic
Name, address of Manufacturing site:	ASIA ANIMAL PHARMACEUTICAL CO., LTD- Address: 130, 1A National Road, Ba Lang Ward, Cai Rang District, Can Tho City, Vietnam. Phone: (+84) (0292) 3913347. Fax: (+84) (0292) 3913349-Vietnam
Name, address of Marketing Authorization Holder:	MIAN TRADERS, GUJRANWALA, Pakistan
Details of Certificates (CoPP/FSC/cGMP):	
Details of Authorization Letter :	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
Evaluation Remarks	
Firm submitted copy of FSC certificate issued by Department of Animal Health & Production, Viet Nam wherein it is stated that Product CAN BE freely sold in Vietnam & oversea market.	
Decision	
Deferred	
Deferred for confirmation of Free Sale status in country of origin.	
91	Case Category
	Routine (Sara Mehreen)
	Name, address of Applicant.
	Mian Traders Railways Road, Morre Eminabad (09-341-0135-118497D)
	Application Form Dy. No / Tracking ID & date of submission
	(P71-YRW-LYJV, 2025-12-20)
	Detail of Fee Submitted
	313500, 2025-12-17,
	The proposed proprietary name / brand name
	FLOR-ORAL ORAL SOLUTION
	Label Claim
	Each ml contains: Florfenicol..... 200mg
	Reference to Finished product specifications
	Manufacturer Specification
	Proposed Pack Size
	- Pack 5 cans of 500 ml or 1 liter - Pack 1 can of 5 liters or 10 lite-De-Controlled
	Shelf Life (Unit)
	36 Year(s)Store in shade and dry place, temperature below 30oC. Protected from light.
	For generic drugs (me-too Status)
	Florfenic 20% Oral Solution , Registration No: 101479 ,STAR LABORATORIES PVT. LTD. Pakistan
	Pharmacotherapeutic Group of (API)
	Antibiotic
	Name, address of Manufacturing site:
	Asia Animal Pharmaceutical Co., Ltd-Address: 130, 1A National Road, Ba Lang Ward, Cai Rang District, Can Tho City, Vietnam. Phone: (+84) (0292) 3913347. Fax: (+84) (0292) 3913349-Vietnam
	Name, address of Marketing Authorization Holder:
	MIAN TRADERS, GUJRANWALA, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):

	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	Firm submitted copy of FSC certificate issued by Department of Animal Health & Production, Viet Nam wherein it is stated that Product CAN BE freely sold in Vietnam & oversea market.	
	Decision	
	Deferred	
	Deferred for confirmation of Free Sale status in country of origin.	
92	Case Category	Import (Sara Mehreen)
	Name, address of Applicant.	Minaa Medicos MR 127- 128, SHOP NO. 15, KATCHI GALI NO.2, MARRIOT ROAD, Karachi South Lyari Town (0152)
	Application Form Dy. No / Tracking ID & date of submission	(TZL-SRT-W2ND, 2025-11-07)
	Detail of Fee Submitted	313500, 2025-11-05,
	The proposed proprietary name / brand name	AMOXYHOPE LA
	Label Claim	Each ml contains: Amoxicillin Trihydrate 150mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	3 Year(s)Do not store above 25°C. Protect from light.
	For generic drugs (me-too Status)	REGISTRATION NO. 125652 AMOXI 15% INJECTION
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	M/s.Hebei Hope Harmony Pharmaceutical Co.,ltd- Industry Development Area Yuanshi County,Shijiazhuang City,Hebei Province,People's Republic of China-China
	Name, address of Marketing Authorization Holder:	M/s.Hebei Hope Harmony Pharmaceutical Co.,ltd, Industry Development Area Yuanshi County,Shijiazhuang City,Hebei Province,People's Republic of China, China
	Details of Certificates (CoPP/FSC/cGMP):	Firm submitted copy of apostilled GMP certificate issued by Deptt. of Agriculture & Rural Affairs of Hebei Province, China.
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	Firm was asked to provide evidence of dedicated manufacturing facility for penicillin, and they provided layout of manufacturing plant and stated as "Hereby Hebei Hope Harmony Pharmaceutical Co., Ltd. informs that our company have dedicated β -lactam workshop and specialized production line for penicillin products. Workshop 204 has been designated as a production workshop for β -lactam products. It occupies a separate building with its own water treatment system, industrial gas system, and HVAC system, along with specialized isolation and waste disposal methods. This workshop includes an injection production line, which is suitable for penicillin injection products, including Amoxyhope (Amoxicillin injection 15%). Please refer to Builing #3, Workshop 204 in the attached site lay out". However, In reply to another application of Ceftiofur firm mentioned same workshop details	

as being used for Cephalosporin. Workshop as described by firm is being used for manufacturing of both Penicillin and Cephalosporin. Submitted for consideration of the Board please.

Decision

Deferred

For verification of dedicated manufacturing facility for Penicillin Products

93	Case Category	Import (Sara Mehreen)
	Name, address of Applicant.	Minaa Medicos MR 127- 128, SHOP NO. 15, KATCHI GALI NO.2, MARRIOT ROAD, Karachi South Lyari Town (0152)
	Application Form Dy. No / Tracking ID & date of submission	(6JU-8SE-STD2, 2025-11-07)
	Detail of Fee Submitted	313500, 2025-11-05,
	The proposed proprietary name / brand name	1gm Ceftiofur injection”
	Label Claim	Each vial contains.....1 gram ceftiofur (as sodium)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1-De-Controlled
	Shelf Life (Unit)	3 Year(s)Store in a refrigerator (2 °C - 8°C). Protect from light.
	For generic drugs (me-too Status)	Ceftisel Dry Powder Injection 1gm pak reg# 114794
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	M/s.Hebei Hope Harmony Pharmaceutical Co.,ltd- Industry Development Area Yuanshi County,Shijiazhuang City,Hebei Province,People's Republic of China-China
	Name, address of Marketing Authorization Holder:	M/s.Hebei Hope Harmony Pharmaceutical Co.,ltd, Industry Development Area Yuanshi County,Shijiazhuang City,Hebei Province,People's Republic of China, China
	Details of Certificates (CoPP/FSC/cGMP):	Firm submitted copy of apostilled GMP certificate issued by Deptt. of Agriculture & Rural Affairs of Hebei Province, China.
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	

Evaluation Remarks

Firm was asked to provide evidence of dedicated manufacturing facility for penicillin, and they provided layout of manufacturing plant and stated as "Hereby Hebei Hope Harmony Pharmaceutical Co., Ltd. informs that our company have dedicated β -lactam workshop and specialized production line for penicillin products. Workshop 204 has been designated as a production workshop for β -lactam products. It occupies a separate building with its own water treatment system, industrial gas system, and HVAC system, along with specialized isolation and waste disposal methods. This workshop includes a powder for injection production line, which is suitable for cephalosporin powder for injection products, including 1gm Ceftiofur Injection (Ceftiofur sodium powder for injection 1g). Please refer to Builing #3, Workshop 204 in the in the attached site lay out". However, In reply to another application of Amoxicillin firm mentioned same workshop details as being used for Cephalosporin. Workshop as described by firm is being used for manufacturing of both Penicillin and Cephalosporin. Submitted for consideration of the Board please.

Decision

Deferred

	For verification of dedicated manufacturing facility for Cephalosporin Products	
94	Case Category	Import (Sara Mehreen)
	Name, address of Applicant.	Mustafa Brothers 186-D, Peoples Colony No. 1, Faisalabad (06-331-0168-031770D)
	Application Form Dy. No / Tracking ID & date of submission	(ZRP-15P-GY1P, 2025-11-03)
	Detail of Fee Submitted	313500, 2025-10-27,
	The proposed proprietary name / brand name	CEFTIVET L.A
	Label Claim	Each ml contains: Ceftiofur hydrochloride 50 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at not more than 30 C
	For generic drugs (me-too Status)	Clinexin, Pakistan Registration No is 085728, Manufactured by Centrovvet LTDA, Chile and imported is by Mustafa Brothers Faisalabad
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	VIETVET PHARMACEUTICAL JOINT STOCK COMPANY -Lot B103, Road No. 4, Thai Hoa Industrial Park, Duc Lap Ha Commune, Duc Hoa District, Long An Province. -Vietnam
	Name, address of Marketing Authorization Holder:	VIETVET PHARMACEUTICAL JOINT STOCK COMPANY , Lot B103, Road No. 4, Thai Hoa Industrial Park, Duc Lap Ha Commune, Duc Hoa District, Long An Province. , Vietnam
	Details of Certificates (CoPP/FSC/cGMP):	Firm submitted copy of GMP certificate.
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
95	Evaluation Remarks	
	Firm submitted copy of FSC certificate issued by Department of Animal Health Viet Nam wherein it is stated that Product CAN BE freely sold in Vietnam & oversea market.	
	Decision	
	Deferred	
	Deferred for confirmation of Free Sale status in country of origin.	
95	Case Category	Import (Shahrukh Ali)
	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	(64G-JVQ-JDJE, 2025-03-19)
	Detail of Fee Submitted	300000.0, 2024-12-09,
	The proposed proprietary name / brand name	Amoxicillin capsule (generic name)
	Label Claim	Each capsule contains: Amoxicillin (as Amoxicillin trihydrate)..... 500mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10×10's-As per SRO

Shelf Life (Unit)	3 Year(s)Room temperature
For generic drugs (me-too Status)	Amoxil 500mg capsule (GSK)
Pharmacotherapeutic Group of (API)	penicillin
Name, address of Manufacturing site:	ZhongShan Lean&Leap Pharmaceutical Co., Ltd-No.28 Huaye Road, Yongning District, Xiaolan Town, Zhongshan City, Guangdong-China
Pharmaceutical Equivalence and Comparative Dissolution Profile	Amoxil Glaxo Welcome Production
Name, address of Marketing Authorization Holder:	ZhongShan Lean&Leap Pharmaceutical Co., Ltd, No.28 Huaye Road, Yongning District, Xiaolan Town, Zhongshan City, Guangdong, China
Details of Certificates (CoPP/FSC/cGMP):	copp valid till 20.10.25
Details of Authorization Letter :	-
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Iv
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	
subject to the policy for inspection abroad.	
Case Category	Import (Shahrukh Ali)
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	(SR3-UZT-4668, 2025-01-23)
Detail of Fee Submitted	300000.0, 2024-12-19,
The proposed proprietary name / brand name	CLOMICENT-50
Label Claim	Each Uncoated Tablet contains: Clomiphene Citrate USP 50 mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	1's (10 tablets)-As per SRO
Shelf Life (Unit)	36 MonthStore at a temperature not exceeding 30°C
For generic drugs (me-too Status)	Clomid Tablet 50mg (Pacific Pharmaceutical Ltd)
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), 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	MHRA Approved (Clomid 50mg Tablet)

	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
	subject to the policy for inspection abroad.	
97	Case Category	Import (Shahrukh Ali)
	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	(G34-LBR-UPN4, 2025-03-17)
	Detail of Fee Submitted	300000.0, 2024-12-09,
	The proposed proprietary name / brand name	Indomethacin(generic name)
	Label Claim	Each capsule contains: Indomethacin BP.....25 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10×10's-As per SRO
	Shelf Life (Unit)	3 Year(s)Room temperature
	For generic drugs (me-too Status)	Indobid(adamjee pharmaceuticals)
	Pharmacotherapeutic Group of (API)	Cyclo-oxygenase inhibitor; analgesic; anti-inflammatory.
	Name, address of Manufacturing site:	JIANGXI XIER KANGTAI PHARMACEUTICAL CO., LTD-North Zone, High-New Technology Industrial Zone, Pingxiang, Jiangxi-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Aspen Pharma Trading Ltd. Indocid
	Name, address of Marketing Authorization Holder:	JIANGXI XIER KANGTAI PHARMACEUTICAL CO., LTD, North Zone, High-New Technology Industrial Zone, Pingxiang, Jiangxi, China
	Details of Certificates (CoPP/FSC/cGMP):	COPP VALID TILL 3.11.27
	Details of Authorization Letter :	-
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	iv-A
	The status in reference regulatory authorities	Available TGA Australia
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
	subject to the policy for inspection abroad.	
98	Case Category	Import (Shahrukh Ali)
	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	(7EY-HP1-TNR5, 2025-02-21)
	Detail of Fee Submitted	300000.0, 2024-12-03,
	The proposed proprietary name / brand name	Optivue Injection

Label Claim	each injection contains Iopamidol Injection 370mgI/ml in 100ml.
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	1 vial per box.-As per SRO
Shelf Life (Unit)	36 Year(s)Store below 30 degrees celsius and protect from light.
For generic drugs (me-too Status)	-
Pharmacotherapeutic Group of (API)	Examination. Arthrography. Fistulography. WHO ATC code of Iopamidol: V08AB04
Name, address of Manufacturing site:	Beijing Beilu Pharmaceutical Co., Ltd.-No. 3, Shuiyuan West Road, Miyun District, Beijing, China.-China
Pharmaceutical Equivalence and Comparative Dissolution Profile	Iopamiro M/s Bracco imaging italia
Name, address of Marketing Authorization Holder:	Beijing Beilu Pharmaceutical , No. 3, Shuiyuan West Road, Miyun District, Beijing, China., China
Details of Certificates (CoPP/FSC/cGMP):	COPP valid till 13.01.25
Details of Authorization Letter :	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
The status in reference regulatory authorities	USA, Japan, Italy.
Evaluation Remarks	
"The application is complete as per codal formalities for consideration by the Registration Board"	
Decision	
Approved	
subject to the policy for inspection abroad.	



Drug Regulatory Authority of Pakistan

(Biological Evaluation & Research Division)



Item No. IV Division of Biological Evaluation & Research

Sr. No	Title	Description
1	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	AGP Limited B-23-C, S.I.T.E., Karachi (001)
	Application Form Dy. No / Tracking ID & date of submission	(B56-VB3-YAP1, 2025-08-19)
	Detail of Fee Submitted	300000.0, 2025-07-25,
	The proposed proprietary name / brand name	OstioGen Injection
	Label Claim	One pre-filled pen of 2.4 mL contains 600 mcg of Teriparatide (corresponding to 250 mcg/mL).
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's vial (Cartridge for pen)-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C. Do not Freeze
	For generic drugs (me-too Status)	Forsteo (Pre-Filled Pen) 250mcg/ml by M/s Eli Lilly Pakistan (Pvt.) Ltd
	Pharmacotherapeutic Group of (API)	Recombinant human parathyroid hormone WHO ATC Code: H05AA02
	Name, address of Manufacturing site:	M/s Shanghai United Cell Biotechnology Co., Ltd.-1150 Guigiao Road, China (Shanghai) Pilot Free Trade Zone, 201206, P.R. China-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Name, address of Marketing Authorization Holder:	M/s Shanghai United Cell Biotechnology Co.,Ltd., 1150 Guigiao Road, China (Shanghai) Pilot Free Trade Zone, 201206, P.R. China, China
	Details of Certificates (CoPP/FSC/cGMP):	Apostile COPP No.Shanghai20250049 dated 23-01-2025 issued by : SHANGHAI MEDICAL PRODUCTS ADMINISTRATION, 28 Yishan Road, Shanghai, China, Validity: 22-01-2027
	Details of Authorization Letter :	Letter of authorization dated 09-01-2025
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	The accelerated stability studies was conducted until the drug substance was unstable under the condition of 2 ~ 8°C or 25 °C and 60%±5%RH respectively. And the longterm stability studies was conducted until the drug substance was unstable at 24 months under the condition of -40 ~ -20°C, covering shelf life 18 months.
	The status in reference regulatory authorities	FORSTEO INJECTION (250mcg/mL) by Eli Lilly, Netherland, 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.

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Case Category	Routine (Anam Saeed)
Name, address of Applicant.	M & M Pharma Javaid Plaza, Gurumangat Road, Gulberg II, Lahore (05-352-0065-035822D)
Application Form Dy. No / Tracking ID & date of submission	(2QY-GWH-XJXQ, 2026-03-12)
Detail of Fee Submitted	300000.0, 2025-07-23,
The proposed proprietary name / brand name	BCG Vaccine (Freeze Dried)
Label Claim	Each vial contains 1 mg of Mycobacterium bovis BCG, Danish Strain 1331, Live attenuated.
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	20 vials-Controlled
Shelf Life (Unit)	2 Year(s)Store at +2°C to +8°C in dark place
For generic drugs (me-too Status)	BCG VACCINE B.P. (FREEZE-DRIED) 053816
Pharmacotherapeutic Group of (API)	Vaccine
Name, address of Manufacturing site:	Green Signal Biopharma Pvt. Ltd-No. 49, Pappankuppam Village, Gummidipoondi, Chennai 601201-India
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
Name, address of Marketing Authorization Holder:	Green Signal Biopharma Pvt. Ltd, No. 49, Pappankuppam Village, Gummidipoondi, Chennai 601201, India
Details of Certificates (CoPP/FSC/cGMP):	COPP No. L.DIS NO 1159 DI 14 2025 dated 10-02-2025 with one-year validity is submitted by the firm. COPP is not legalized.
Details of Authorization Letter :	LOA dated 14-03-2025 is attached.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Not provided.
The status in reference regulatory authorities	MHRA UK

Evaluation Remarks

Background of the case: The product, BCG vaccine BP (Freeze Dried), was approved in 268th meeting of Registration Board on the basis of WHO PQ status and registration letter was issued on 10th May, 2017. On 1 November 2019, WHO removed the product from its list of prequalified vaccines because company was operating at unacceptable levels of compliance with WHO guidelines on good manufacturing practices, potentially endangering the performance of the vaccine and posing a high risk to recipients. The case was again considered in 296th meeting of Registration Board and the Board decided as under; Decision of 296th meeting: "Registration Board deliberated that the product was registered and exempted from inspection of manufacturer abroad on the basis of then WHO Prequalification. Now, WHO has removed the vaccine from WHO list of prequalified products, therefore, Registration Board decided to issue show cause notice to M/s M&M Pharma, Lahore under section 42 of the Drugs Act, 1976 read with rule 24 (17) of the Drugs (Licensing, Registering, Advertising) Rules, 1976 regarding the delisting of their product BCG Vaccine BP (Reg. No. 084608) from the list of WHO Pre-qualified vaccines." However, no further proceedings were carried out in the case. Now the firm has again applied for registration of BCG vaccine BP (Freeze Dried) which has got WHO Prequalification on 03-12-2024. The firm informed that they did not apply for renewal of their registered product, so now they are applying for the new registration of the same product with complete CTD dossier. Remarks: The case was evaluated and following were the observations which were asked from the applicant; The applied product BCG vaccine BP (Freeze Dried) is registered in India for export purpose only. COPP not legalized. Stability data of 3 batches is submitted at real time conditions till 12 months. Complete stability data till 2 years is required. Stability of drug substance is not provided.

SmPC of applied product as per DRAP SmPC guidelines is required. Submit updated status of previously registered BCG vaccine BP (Freeze Dried) after show cause issued by DRAP as per 296th meeting of Registration Board. The applicant has not submitted a reply yet but the product is WHO PQ.

Decision

Approved

Registration Board approved the product subject to compliance of current import policy for Finished products and submission of requisite documents as per deficiencies highlighted by the BE&R Division.

3	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Immunonet Pharma Pvt Ltd 12-F1, Johar Town, Lahore, Pakistan. (05-352-0066-034495D)
	Application Form Dy. No / Tracking ID & date of submission	(3NE-XM3-Z276, 2025-07-04)
	Detail of Fee Submitted	300000.0, 2025-01-15,
	The proposed proprietary name / brand name	Enoxaparin Sodium 4000IU PS
	Label Claim	Each 0.4ml PFS contains: Enoxaparin Sodium.....4000IU
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	2's-As per SRO
	Shelf Life (Unit)	36 Year(s)25C
	For generic drugs (me-too Status)	Clexane 0.4ml
	Pharmacotherapeutic Group of (API)	Low Molecular Weight Heparins
	Name, address of Manufacturing site:	Suzhou Erye Pharmaceutical Co.,LTD- No.2, Dongqiao, Anmin Road, Xiangcheng District, Suzhou, Jiangsu, China.-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Data in light of 281st meeting provided.
	Name, address of Marketing Authorization Holder:	Suzhou Erye Pharmaceutical Co.,LTD, No. 2 Dongqiao, Anmin Road, Huangdai Town, Xiangcheng District, Suzhou, China
	Details of Certificates (CoPP/FSC/cGMP):	Scanned copy of CoPP No. 20240360 dated 06-08-2024
	Details of Authorization Letter :	Scanned Copy of distribution Agreement dated 15-05-2024.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches 0200301, 0200302, 0200402 Accelerated at 40 & 75RH for 06 months Realtime at 30 & 75RH for 36 months
	The status in reference regulatory authorities	Clexane 0.4ml Sanofi

Evaluation Remarks

Registration Board in its 352nd meeting deferred the case for submission of following by the firm: 1. Characterization studies with Reference product. 2. The study performed to compare Anti Factor Xa and Anti Factor IIa activity of applied product with reference product is single center study with only 23 subjects. The firm in response submitted references of two products registered in EMA i.e. Inhixa and Thorinane wherein the PK/PD study indicate number of subjects as 20. Moreover, for characterization with Reference product, the firm submitted that the already submitted characterization was performed in comparison with Innovator Product and while in the report it is mentioned as reference standard.

Decision

Approved

Keeping in view CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import policy for finished drugs.

4	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Immunonet Pharma Pvt Ltd 12-F1, Johar Town, Lahore, Pakistan. (05-352-0066-034495D)
	Application Form Dy. No / Tracking ID & date of submission	(V3S-WSX-XT87, 2025-07-04)
	Detail of Fee Submitted	300000.0, 2025-01-15,
	The proposed proprietary name / brand name	Enoxaparin Sodium 6000IU PFS
	Label Claim	Each 0.6ml PFS contains: Enoxaparin Sodium.....6000IU
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	2's-As per SRO
	Shelf Life (Unit)	36 Year(s)25C
	For generic drugs (me-too Status)	Clexane 0.6ml
	Pharmacotherapeutic Group of (API)	Low Molecular Weight Heparins
	Name, address of Manufacturing site:	Suzhou Erye Pharmaceutical Co.,LTD-No.2, Dongqiao, Anmin Road, Xiangcheng District, Suzhou, Jiangsu, China.-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Data in light of 281st meeting provided.
	Name, address of Marketing Authorization Holder:	Suzhou Erye Pharmaceutical Co.,LTD, No. 2 Dongqiao, Anmin Road, Huangdai Town, Xiangcheng District, Suzhou, China
	Details of Certificates (CoPP/FSC/cGMP):	Scanned copy of CoPP No. 20240361 dated 06-08-2024
	Details of Authorization Letter :	Scanned Copy of distribution Agreement dated 15-05-2024.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches 0200301, 0200302, 0200402 Accelerated at 40 & 75RH for 06 months Realtime at 30 & 75RH for 36 months
	The status in reference regulatory authorities	Clexane 0.6ml Sanofi
	Evaluation Remarks	
	Registration Board in its 352nd meeting deferred the case for submission of following by the firm: 1. Characterization studies with Reference product. 2. The study performed to compare Anti Factor Xa and Anti Factor IIa activity of applied product with reference product is single center study with only 23 subjects. The firm in response submitted references of two products registered in EMA i.e. Inhixa and Thorinane wherein the PK/PD study indicate number of subjects as 20. Moreover, for characterization with Reference product, the firm submitted that the already submitted characterization was performed in comparison with Innovator Product and while in the report it is mentioned as reference standard.	
5	Decision	
	Approved	
	Keeping in view CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import policy for finished drugs.	
	Case Category	Routine (M. Zubair Masood)
5	Name, address of Applicant.	Orion Group 97 Commercaile Area, Usman Block, Muslim Town No.1, (06-331-0167-038556D)
	Application Form Dy. No / Tracking ID & date of submission	(DMW-ELG-GHL9, 2026-01-11)

Detail of Fee Submitted	75000, 2025-11-05,
The proposed proprietary name / brand name	IMMUDOLL-CG
Label Claim	Each ml contains: Inactivated Cutibacterium granulosum.....20mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	50 ml-De-Controlled
Shelf Life (Unit)	24 Year(s)+2 to +8 C
For generic drugs (me-too Status)	Vet Eqstim, Neogen USA
Pharmacotherapeutic Group of (API)	Veterinary Vaccine
Name, address of Manufacturing site:	DOLLVET BIYOTEKNOLOJI A.S-Kocoren OSB Mahallesi, 106 Cad No. 6 EYYUBIYE / SANLIURFA / TURKEY-Turkey
Name, address of Marketing Authorization Holder:	DOLLVET BIYOTEKNOLOJI A.S, Konaklar Mah. Akasyalı Sk. No:10 Beşiktaş / İSTANBUL / TÜRKİYE, Turkey
Details of Certificates (CoPP/FSC/cGMP):	Scanned legalized CoPP without any number and date.
Details of Authorization Letter :	Scanned legalized POA dated 21-07-2025.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A

Evaluation Remarks

Following are the observations in the application: 1. The submitted CoPP is neither numbered nor dated. 2. The submitted GMP certificate is expired. 3. As per submitted stability data of three batches, results of every batch are same throughout the studies, moreover, at 27 month time point, result of efficacy is mentioned as "Harmless" while its limit is ≥ 2.5 and Description is mentioned as "2.5" while its specification is "Whitish". The case is placed before Registration Board as firm has submitted a letter from Sindh Institute of Animal Health, Livestock & Fisheries Department, Government of Sindh stating the following: "It is submitted that the Sindh Institute of Animal Health, Karachi working under Livestock & Fisheries Department Government of Sindh has entered into an agreement and MOU with Dollvet Turkey for the transfer of the technology and research in various vaccines and biologics, among which Immunostimulant is one of them. This immunostimulant product has proven a results against certain diseases by raising the titers of the vaccines remarkably resulting in creating long term immunity in the animals against these diseases i.e. Mastitis of cattle and PPR of sheep and goat. Both of these diseases Mastitis and PPR are very much prevalent in Pakistan and are even hampering the process of export of livestock products, so therefore it's of a national importance to have a quality immunostimulant product as well. As the Sindh Institute of Animal Health has collaborated with Dollvet Turkey to import high quality and cost efficient products. M/s Orion Group will coordinate and facilitate to import these products from Dollvet Turkey. We at Sindh Government through M/s Orion Group has already procured various vaccines i.e. PPR Vaccine and some other vaccines from the above mentioned Turkish manufacturer and are satisfied with the quality of their vaccines which are also already registered with DRAP. Therefore, it is requested to your kind authority to please register the said Immunostimulant biological product (Immudoll-CG) to M/s Orion Group for smooth availability of this product in the country in the best interest of the farmers of the country and nation at large."

Decision

Deferred

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

1. The submitted CoPP is neither numbered nor dated.
2. Valid legalized GMP Certificate.
3. As per submitted stability data of three batches, results of every batch are same throughout the studies, moreover, at 27 month time point, result of efficacy is mentioned as "Harmless" while its limit is ≥ 2.5 and Description is mentioned as "2.5" while its specification is "Whitish".

6	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Orion Group 97 Commercaile Area, Usman Block, Muslim Town No.1, (06-331-0167-038556D)
	Application Form Dy. No / Tracking ID & date of submission	(X9R-1TQ-DQS3, 2026-01-20)
	Detail of Fee Submitted	313500, 2026-01-06,
	The proposed proprietary name / brand name	PASTEDOLL Suspension for Injection
	Label Claim	Each dose contains: Inactivated Pasteurella multocida antigen.....≥1/40 ELISA seropositive Inactivated Mannheimia haemolytica A1 antigen and leucotoxin.....≥1/40 ELISA seropositive Inactivated Mannheimia haemolytica A2 antigen and leucotoxin.....≥1/40 ELISA seropositive *Antibody titer by ELISA of rabbit serum vaccinated with 1 sheep dose (2 ml)
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	20 ml -De-Controlled
	Shelf Life (Unit)	24 Year(s)+2 to +8 C
	For generic drugs (me-too Status)	PULMOVAC, DRAP Registration No. 115109, imported by Mustafa Brothers
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	DOLLVET BIYOTEKNOLOJİ A.S-Kocoren OSB Mahallesi, 106 Cad No. 6 EYYUBİYE / SANLIURFA / TURKEY-Turkey
	Name, address of Marketing Authorization Holder:	DOLLVET BIYOTEKNOLOJİ A.S, Konaklar Mah. Akasyalı Sk. No:10 Beşiktaş / İSTANBUL / TÜRKİYE, Turkey
	Details of Certificates (CoPP/FSC/cGMP):	Scanned legalized CoPP without any number and date.
	Details of Authorization Letter :	Scanned legalized POA dated 21-07-2025.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A

Evaluation Remarks

Following are the observations in the application: 1. The submitted CoPP is neither numbered nor dated. 2. The submitted GMP certificate is expired. 3. As per submitted stability data of three batches, results of every batch are same throughout the studies. 4. Batch size is different for all the three batches i.e. 2500, 5000 & 7500 packs. The case is placed before Registration Board as firm has submitted a letter from Sindh Institute of Animal Health, Livestock & Fisheries Department, Government of Sindh stating the following: "It is submitted that the Sindh Institute of Animal Health, Karachi working under Livestock & Fisheries Department Government of Sindh has entered into an agreement and MOU with Dollvet Turkey for the transfer of the technology and research in various vaccines and biologics, among which PASTEDOLL (Inactivated Bacterial Vaccine against Pasteurella Multocida and Mannheimia Haemolytica Infections) is one of them. The disease is very much prevalent in Pakistan and hampering the process of export of livestock products, so therefore it's of a national importance to have a quality vaccine against this disease as well. As the Sindh Institute of Animal Health has collaborated with Dollvet Turkey to import high quality and cost efficient products. M/s Orion Group will coordinate and facilitate to import these products from Dollvet Turkey. We at Sindh Government through M/s Orion Group has already procured various vaccines i.e. PPR Vaccine, FMD Vaccine and some other vaccines from the above mentioned Turkish manufacturer and are satisfied with the quality of their vaccines which are also already registered with DRAP. Therefore, it is requested to your kind authority to please register the said biological (Vaccine) product (Pastedoll) to M/s Orion

Group for smooth availability of this product in the country in the best interest of the farmers of the country and nation at large."

Decision

Deferred

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

1. The submitted CoPP is neither numbered nor dated.
2. Valid legalized GMP Certificate.
3. As per submitted stability data of three batches, results of every batch are same throughout the studies.
4. Batch size is different for all the three batches i.e. 2500, 5000 & 7500 packs.

7	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Orion Group 97 Commercaile Area, Usman Block, Muslim Town No.1, (06-331-0167-038556D)
	Application Form Dy. No / Tracking ID & date of submission	(M5W-4E7-N849, 2026-01-15)
	Detail of Fee Submitted	225000, 2025-09-05,
	The proposed proprietary name / brand name	PEST & POXDOLL Lyophilisate for suspension for injection and solvent
	Label Claim	Lyophilisate: Each dose (1ml) contains: Attenuated SPV (Bk) LK ₆₃10 ^{2.5} TCID ₅₀ Attenuated PPRV Nigeria 75/1 Strain.....10 ^{2.5} TCID ₅₀
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 Doses with Diluent-De-Controlled
	Shelf Life (Unit)	24 Year(s)+2 to +8 C
	For generic drugs (me-too Status)	PESTDOLL-S, ORION GROUP and POXVAC, HUZAIFA INTERNATIONAL
	Pharmacotherapeutic Group of (API)	Vetrinary Vaccine
	Name, address of Manufacturing site:	DOLLVET BIYOTEKNOLOJI A.S-Kocoren OSB Mahallesi, 106 Cad No. 6 EYYUBIYE / SANLIURFA / TURKEY-Turkey
	Name, address of Marketing Authorization Holder:	DOLLVET BIYOTEKNOLOJI A.S, Konaklar Mah. Akasyalı Sk. No:10 Beşiktaş / İSTANBUL / TÜRKİYE, Turkey
	Details of Certificates (CoPP/FSC/cGMP):	Scanned Legalized FSC No. 17705 Scanned legalized GMP No. 21269 dated 08-03-2023 valid till 20-01-2026.
	Details of Authorization Letter :	Scanned legalized POA dated 21-07-2025.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A

Evaluation Remarks

The submitted GMP certificate is expired. The case is placed before Registration Board as firm has submitted a letter from Sindh Institute of Animal Health, Livestock & Fisheries Department, Government of Sindh stating the following: "It is submitted that the Sindh Institute of Animal Health. Karachi working under Livestock & Fisheries Department Government of Sindh has entered into an agreement and MOU with Dollvet Turkey for the transfer of the technology and research in various vaccines and biologics, among which PEST&POXDOLL (Live, attenuated

vaccine, it is used for protection of sheep and goats against PPR and sheep-goat pox) is one of them. Both of these diseases are very much prevalent in Pakistan and hampering the process of export of livestock products as mortality ratio in sheep and goats is very high when under attack from these diseases. Furthermore there isn't any of the vaccine available in the country yet, preventing from both of these viral diseases at the same time, so therefore it's of a national importance to have a quality vaccine against this disease as well. As the Sindh Institute of Animal Health has collaborated with Dollvet Turkey to import high quality and cost efficient products. M/s Orion Group will coordinate and facilitate to import these products from Dollvet Turkey. We at Sindh Government through M/s Orion Group has already procured various vaccines i.e. PPR Vaccine, FMD Vaccine and some other vaccines from the above mentioned Turkish manufacturer and are satisfied with the quality of their vaccines which are also already registered with DRAP. Therefore, it is requested to your kind authority to please register the said biological (Vaccine) product (PEST&POXDOLL) to M/s Orion Group for smooth availability of this product in the country in the best interest of the farmers of the country and the nation at large."

Decision

Approved

Keeping in view the FSC indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs and submission of valid legalized GMP certificate.

8	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	ROSACEAE PHARMA (PRIVATE) LIMITED ALTIMI House, Plot No. 21-C, Suite # 301, Khalid Commercial Street # 4, Phase 7 (Ext), D.H.A., Karachi-755350 (0377)
	Application Form Dy. No / Tracking ID & date of submission	(NVP-Q6Z-MHXY, 2025-07-08)
	Detail of Fee Submitted	300000.0, 2025-05-08,
	The proposed proprietary name / brand name	L'OSEM-3 (3mg) Tablet
	Label Claim	Each box of L'OSEM-3 Tablets consist up of 30 tablets. 3 blisters of 10 tablets each. And each tablet consist of 3 mg Semaglutide.
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	30's (Box packing), -As per SRO
	Shelf Life (Unit)	24 MonthsProtect from sunlight, sealed and stored at 20°C to 25°C. Keep out of reach of children
	For generic drugs (me-too Status)	RYBELSUS 3 mg (Semaglutide) Tablet of Novo Nordisk registered by DRAP (Reg. No. 115139)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Laos Alliance Pharmaceutical Group Co. Ltd.-Nano Village, Saysettha Development Zone, Saysettha District, Vientiane Capital, Lao PDR-Laos
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	MAH (Abroad): Laos Alliance Pharmaceutical Group C, Nano Village, Saysettha Development Zone, Saysettha District, Vientiane Capital, Lao PDR, Laos
	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	RYBELSUS 3 mg (Semaglutide) Tablet of Novo Nordisk approved by US-FDA

Evaluation Remarks

Following are still shortcomings after 3 rounds of communications: 1. Complete Chromatograms of HPLC Peptide Mapping in Biosimilarity studies are not provided. 3. Following tests in biosimilarity are not performed for Innovator product: i. High-resolution mass spectrometry molecular weight ii. ¹H NMR spectrum. iii. Carbon-13 NMR spectrum iv. Elemental analysis 4. Assessment Report of Regulatory Authority of country of origin for this product. 5. Details of other pharmaceutical tablets manufactured in this Section. 6. There was difference in Molecular Weight Distribution Spectra of Reference product and applied product. The firm submitted that they had only performed Molecular Weight Distribution Spectra of Reference product and not of their product. 8. Comparative dissolution profile with Innovator product as per guidance document is required. 9. Excipient compatibility study as one of the excipient is not as per Innovator? 10. Realtime stability data provided is of 12 months with commitment while proposed shelf life is 24 months.

Decision**Deferred**

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

1. Complete Chromatograms of HPLC Peptide Mapping in Biosimilarity studies are not provided.
3. Following tests in biosimilarity are not performed for Innovator product:
 - i. High-resolution mass spectrometry molecular weight
 - ii. ¹H NMR spectrum.
 - iii. Carbon-13 NMR spectrum
 - iv. Elemental analysis
4. Assessment Report of Regulatory Authority of country of origin for this product.
5. Details of other pharmaceutical tablets manufactured in this Section.
6. There was difference in Molecular Weight Distribution Spectra of Reference product and applied product. The firm submitted that they had only performed Molecular Weight Distribution Spectra of Reference product and not of their product.
8. Comparative dissolution profile with Innovator product as per guidance document is required.
9. Excipient compatibility study as one of the excipient is not as per Innovator?
10. Realtime stability data provided is of 12 months with commitment while proposed shelf life is 24 months.

9

Case Category	Routine (M. Zubair Masood)
Name, address of Applicant.	ROSACEAE PHARMA (PRIVATE) LIMITED ALTIMI House, Plot No. 21-C, Suite # 301, Khalid Commercial Street # 4, Phase 7 (Ext), D.H.A., Karachi-755350 (0377)
Application Form Dy. No / Tracking ID & date of submission	(HYE-X6X-SNYU, 2025-07-08)
Detail of Fee Submitted	300000.0, 2025-05-08,
The proposed proprietary name / brand name	L'OSEM-14 (14 mg) Tablet
Label Claim	Each box of L'OSEM-14 contains 30's tablets. Each box has 3 blisters (each of 10's tablets). Each L'OSEM-14 tablet contains 14 mg of Semaglutide.
Reference to Finished product specifications	Manufacturers Specification

Proposed Pack Size	30's (Box), 10's (Bl-As per SRO)
Shelf Life (Unit)	24 MonthsProtect from sunlight, sealed and stored at 20°C to 25°C. Keep out of reach of children
For generic drugs (me-too Status)	RYBELSUS 14 mg (Semaglutide) Tablet of Novo Nordisk registered by DRAP (Reg. No. 115141)
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Laos Alliance Pharmaceutical Group Co. Ltd. -Nano Village, Saysettha Development Zone, Saysettha District, Vientiane Capital, Lao PDR-Laos
Pharmaceutical Equivalence and Comparative Dissolution Profile	
Name, address of Marketing Authorization Holder:	MAH Abroad: Laos Alliance Pharmaceutical Group Co., Nano Village, Saysettha Development Zone, Saysettha District, Vientiane Capital, Lao PDR, Laos
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	RYBELSUS 14 mg (Semaglutide) Tablet of Novo Nordisk approved by US-FDA

Evaluation Remarks

Following are still shortcomings after 3 rounds of communications: 1. Complete Chromatograms of HPLC Peptide Mapping in Biosimilarity studies are not provided. 3. Following tests in biosimilarity are not performed for Innovator product: i. High-resolution mass spectrometry molecular weight ii. ¹H NMR spectrum. iii. Carbon-13 NMR spectrum iv. Elemental analysis 4. Assessment Report of Regulatory Authority of country of origin for this product. 5. Details of other pharmaceutical tablets manufactured in this Section. 6. There was difference in Molecular Weight Distribution Spectra of Reference product and applied product. The firm submitted that they had only performed Molecular Weight Distribution Spectra of Reference product and not of their product. 8. Comparative dissolution profile with Innovator product as per guidance document is required. The provided summary is of pH 6.8 and of one lot which is submitted in all the strengths. 9. Excipient compatibility study as one of the excipient is not as per Innovator? 10. Realtime stability data provided is of 12 months with commitment while proposed shelf life is 24 months.

Decision

Deferred

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

1. Complete Chromatograms of HPLC Peptide Mapping in Biosimilarity studies are not provided.
2. Following tests in biosimilarity are not performed for Innovator product:
 - i. High-resolution mass spectrometry molecular weight
 - ii. ¹H NMR spectrum.
 - iii. Carbon-13 NMR spectrum
 - iv. Elemental analysis
3. Assessment Report of Regulatory Authority of country of origin for this product.
4. Details of other pharmaceutical tablets manufactured in this Section.

5. There was difference in Molecular Weight Distribution Spectra of Reference product and applied product. The firm submitted that they had only performed Molecular Weight Distribution Spectra of Reference product and not of their product.
6. Comparative dissolution profile with Innovator product as per guidance document is required.
7. Excipient compatibility study as one of the excipient is not as per Innovator?
8. Realtime stability data provided is of 12 months with commitment while proposed shelf life is 24 months.

10	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	ROSACEAE PHARMA (PRIVATE) LIMITED ALTIMI House, Plot No. 21-C, Suite # 301, Khalid Commercial Street # 4, Phase 7 (Ext), D.H.A., Karachi-755350 (0377)
	Application Form Dy. No / Tracking ID & date of submission	(DLW-GA1-J1J2, 2025-07-08)
	Detail of Fee Submitted	300000.0, 2025-05-08,
	The proposed proprietary name / brand name	L'OSEM-7 (7mg) Tablet
	Label Claim	Each box of L'OSEM-7 contains 30's tablets. Each box has 3 blisters (each of 10's tablets). Each L'OSEM-7 tablet contains 7 mg of Semaglutide.
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	30's (Box packing), -As per SRO
	Shelf Life (Unit)	24 MonthsProtect from sunlight, sealed and stored at 20°C to 25°C. Keep out of reach of children
	For generic drugs (me-too Status)	RYBELSUS 7 mg (Semaglutide) Tablet of Novo Nordisk registered by DRAP (Reg. No. 115140)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Laos Alliance Pharmaceutical Group Co. Ltd.-Nano Village, Saysettha Development Zone, Saysettha District, Vientiane Capital, Lao PDR-Laos
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	MAH Abroad: Laos Alliance Pharmaceutical Group Co., Nano Village, Saysettha Development Zone, Saysettha District, Vientiane Capital, Lao PDR, Laos
	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	RYBELSUS 7 mg (Semaglutide) Tablet of Novo Nordisk approved by US-FDA

Evaluation Remarks

Following are still shortcomings after 3 rounds of communications: 1. Complete Chromatograms of HPLC Peptide Mapping in Biosimilarity studies are not provided. 3. Following tests in biosimilarity are not performed for Innovator product: i. High-resolution mass spectrometry molecular weight ii. ¹H NMR spectrum. iii. Carbon-13 NMR spectrum iv. Elemental analysis 4. Assessment Report of Regulatory Authority of country of origin for this product. 5. Details of other pharmaceutical tablets manufactured in this Section. 6. There was difference in Molecular Weight Distribution Spectra of Reference product and applied product. The firm submitted that they had only performed Molecular Weight Distribution Spectra of Reference product and not of their product. 8. Comparative dissolution profile with Innovator product as per guidance document is required. The provided summary is of pH 6.8 and of one lot which is submitted in all the strengths. 9. Excipient compatibility study as one

of the excipient is not as per Innovator? 10. Realtime stability data provided is of 12 months with commitment while proposed shelf life is 24 months.

Decision

Deferred

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

1. Complete Chromatograms of HPLC Peptide Mapping in Biosimilarity studies are not provided.
3. Following tests in biosimilarity are not performed for Innovator product:
 - i. High-resolution mass spectrometry molecular weight
 - ii. ¹H NMR spectrum.
 - iii. Carbon-13 NMR spectrum
 - iv. Elemental analysis
4. Assessment Report of Regulatory Authority of country of origin for this product.
5. Details of other pharmaceutical tablets manufactured in this Section.
6. There was difference in Molecular Weight Distribution Spectra of Reference product and applied product. The firm submitted that they had only performed Molecular Weight Distribution Spectra of Reference product and not of their product.
8. Comparative dissolution profile with Innovator product as per guidance document is required.
9. Excipient compatibility study as one of the excipient is not as per Innovator?
10. Realtime stability data provided is of 12 months with commitment while proposed shelf life is 24 months.

11	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Hakimsons (Impex) (Pvt.) Ltd. Hakimsons Building, 19 West Wharf Road, Karachi 74000, Pakistan. (030)
	Application Form Dy. No / Tracking ID & date of submission	(32X-P4B-HGQZ, 2024-12-24)
	Detail of Fee Submitted	300000.0, 2024-11-12,
	The proposed proprietary name / brand name	STPASE Injection
	Label Claim	Each Vial contains..... Streptokinase concentrate 1500000 IU
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's-Controlled
	Shelf Life (Unit)	24 Month(s)Store between 2-8 °C. Protect from Light
	For generic drugs (me-too Status)	Diclair-ST Gene Tech Laboratories BBT Biotech , Germany Registration No. 059023
	Pharmacotherapeutic Group of (API)	Thrombolytic protein ATC Code: B01AD01
	Name, address of Manufacturing site:	Cadila Pharmaceuticals Limited-1389,Trasad Road, Dholka – 382 225, District: Ahmedabad Gujarat State, INDIA-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A

Name, address of Marketing Authorization Holder:	Cadila Pharmaceuticals Limited, 1389,Trasad Road, Dholka – 382 225, District: Ahmedabad Gujarat State, INDIA, India
Details of Certificates (CoPP/FSC/cGMP):	COPP: Firm has submitted the legalized COPP and Product is available freely in the country of Export [Certificate No. MFG/WHO/GMP COPP/2024/4550243710 Issuance Date: 15-02-2024 Validity: 16.11-2025 Name and address of Issuing Regulatory Authority: Foo
Details of Authorization Letter :	Firm has submitted Legalized letter of distribution certificate from Cadila Pharmaceuticals Limited. The letter species that the manufacturer appoints M/s Hakimsons (Impex) (Pvt.) Ltd. to register their products in Pakistan issued on 03-05-2024.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted the 3 batches data 14019, 14020, 14021 Accelerated 2-8°C (6Months) & Long Term (Real Time) Studies - 20° C ± 2° C (12Months)
The status in reference regulatory authorities	Streptokinase Karma 1,500,000 IU (MHRA approved)

Evaluation Remarks

Registration Board in its 352nd meeting decided as follows: The Registration Board, after detailed deliberation and in view of the importance and need of the product, decided to refer the case to the Authority for a decision regarding the manufacturing of Streptokinase in the general section with a dedicated filling line. The Board further advised the applicant to submit the approved layout plan issued by the regulatory authority of the country of origin, clearly indicating the dedicated line for Streptokinase, and to provide the Site Master File (SMF) of the manufacturer that was submitted to the PIC/S member country (Malaysia) for GMP inspection. DRAP Authority in its 219th meeting decided as follows: "The Authority, after thorough deliberation, concluded that the primary mandate for assessing the adequacy of manufacturing facilities based on product risk lies with the Registration Board. Therefore, the Authority referred the agenda to Registration Board for decision." Moreover, the firm has not yet submitted any response of above decision.

Decision

Rejected

The Registration Board rejected the application as applied product is being manufactured in non-biological facility.

12	Case Category	Priority As Per 257-M of RB (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. The case was again included in 355th meeting of Registration Board wherein the Board deferred for following data/ clarifications: Number of doses manufactured since registration. AEFIs reported to NRA/ Uppsala Monitoring Centre of WHO. Status of

application for WHO prequalification (if any). The firm submitted response in this regard which is as under: Recombinant Human Papillomavirus 9-valent Vaccine (Cecolin® 9) was approved for marketing in China in May 2025. Since approval, a total of 83 million doses (10 batches) have been released by the National Institute for Food and Drug Control (NIFDC), China. Batch-wise lot release certificates are attached as supporting evidence. As of 01 March 2026, a total of 65 AEFI cases have been reported, comprising: a. 63 non-serious cases b. 2 serious cases. These AEFIs have been monitored and documented by the manufacturer in accordance with pharmacovigilance requirements. As the product was recently approved (May 2025), the Periodic Safety Update Report (PSUR) is not yet due. The first PSUR, including detailed AEFI analysis, is expected to be finalized by October 2026. Currently, no application for WHO Prequalification has been submitted. However, the manufacturer is planning to apply for WHO Prequalification, with an expected timeline around 2027. The product is also under registration in multiple countries, including Indonesia, Thailand, India, Turkey, and Pakistan. Additionally, it is highlighted that the bivalent HPV vaccine (Cecolin®) from the same manufacturer has been WHO prequalified in 2021 and is approved in multiple countries and national immunization programs.

Decision

Approved

Keeping in view the recommendations of Federal Directorate of Immunization and CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. The registration letter shall be issued with the condition that M/s Lab Diagnostic Systems (SMC) Pvt. Ltd., Taxila shall be responsible for monitoring and reporting of Adverse Drug Reactions (ADRs) and also to submit Risk Management Plan (RMP) before issuance of registration letter.

13	Case Category	Routine (Muneeb Ahmed Cheema)
	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	(1VL-4Y6-LUUV, 2026-04-06)
	Detail of Fee Submitted	313500, 2026-01-06,
	The proposed proprietary name / brand name	Ovinox Solution for Injection 4000 anti-Xa IU/0.4ml
	Label Claim	Each pre-filled syringe Ovinox 4000 anti-Xa IU contains: Enoxaparin Sodium.....40mg Water for Injections..... up to 0.4ml
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2 pre-filled syringes packed in a box, (1 ml of Each Syringe).-Controlled
	Shelf Life (Unit)	36 Month Do not store and transport above 25 degree centigrade.
	For generic drugs (me-too Status)	Clexane Injection Imported by Hoechst Pakistan Limited, Plot 23, Sector 22, Korangi Industrial Area, Karachi, Pakistan.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Suzhou Erye Pharmaceutical Co., Ltd.-Factory: No. 2, Anmin Road, Dongqiao, Huangdai Town, Xiangcheng District. Suzhou, Jiangsu 215152, China-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	Suzhou Ronnsi Pharma Co., Ltd. , 108 Yuxin Road, Suite 1001, building A Suzhou, Jiangsu 215123, 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	Clexane Injection Manufactured by Sanofi: 46 Avenue de la Grande Armée, 75017 Paris, France
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Evaluation Remarks

Following queries were raised during evaluation: a. Please submit CoPP issued by Regulatory Authority of Country of Origin. b. Long term stability data of drug substance and finished product as per Zone IV-A. The response of applicant is as below: a. As per submitted Chinese CoPP, the product is not registered in country of origin, However the applicant submitted that the product is registered in Indonesia and Bangladesh. b. The response regarding stability is as under: Product Classification (Biological, not Chemical): Enoxaparin sodium is a biological medicinal product (heterogeneous oligosaccharide mixture), not a small-molecule drug. Its stability is measured via functional activity (anti-Xa/IIa), not just chemical degradation. Therefore, biological product guidelines (ICH Q5C) apply, not chemical stability frameworks (ICH Q1A). Applicable Guideline – ICH Q5C: This guideline does not use climatic zones (I–IV) and does not require testing at 30°C/65% RH. Stability programs for biologicals must be case-by-case and based on real-time data under intended storage conditions, not exaggerated conditions. Labeled Storage Condition: The product is labeled for storage below 25°C (do not freeze). Zone IV-A conditions (30°C) exceed the labeled range and are not relevant for shelf-life determination. Degradation Science: Enoxaparin degrades via temperature-sensitive pathways (depolymerization, desulfation, loss of anti-Xa potency). Testing at 30°C accelerates unrealistic degradation, does not predict real-world stability, and adds no meaningful value. Supporting Data Provided: The submission includes available long-term and accelerated stability data for both drug substance and finished product. Zone IVA long-term stability studies are not required for this ovine-derived enoxaparin injection and is not aligned with ICH Q5C, WHO TRS 1010, or the biological nature of the product.

Decision

Deferred

Registration Board deferred the case for following:

1. Confirmation of registration status of product in Indonesia.
2. Post Marketing Surveillance data of applied product from Indonesia.
3. Confirmation of equivalence of results of PK/PD studies of applied product of ovine source with Innovator product.

14	Case Category	Routine (Muneeb Ahmed Cheema)
	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	(7L6-V1B-ZM4G, 2026-04-06)
	Detail of Fee Submitted	313500, 2026-01-06,
	The proposed proprietary name / brand name	Ovinox Solution for Injection 10000 anti- Xa IU/1ml
	Label Claim	Each pre-filled syringe Ovinox 10000 anti-Xa IU contains: Enoxaparin Sodium.....100mg Water for Injections..... up to 1ml
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2 pre-filled syringes packed in a box, (1 ml of Each Syringe).-Controlled
	Shelf Life (Unit)	36 Month Do not store and transport above 25 degree centigrade.
	For generic drugs (me-too Status)	Not Available.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Suzhou Erye Pharmaceutical Co., Ltd.-Factory: No. 2, Anmin Road, Dongqiao, Huangdai Town, Xiangcheng District. Suzhou, Jiangsu 215152, China-China

Pharmaceutical Equivalence and Comparative Dissolution Profile	
Name, address of Marketing Authorization Holder:	Suzhou Ronnsi Pharma Co., Ltd. , 108 Yuxin Road, Suite 1001, building A Suzhou, Jiangsu 215123, 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	Clexane Injection Manufactured by Sanofi: 46 Avenue de la Grande Armée, 75017 Paris, France
Evaluation Remarks	
Following queries were raised during evaluation: a. Please submit CoPP issued by Regulatory Authority of Country of Origin. b. Long term stability data of drug substance and finished product as per Zone IV-A. The firm has submitted CoPP issued by Jiangsu Medical Product Administration China. As per submitted Chinese CoPP, the product is not registered in country of origin, However the applicant submitted that the product is registered in Indonesia and Bangladesh. b. The response of applicant regarding stability is as under: Product Classification (Biological, not Chemical):Enoxaparin sodium is a biological medicinal product (heterogeneous oligosaccharide mixture), not a small-molecule drug. Its stability is measured via functional activity (anti-Xa/IIa), not just chemical degradation. Therefore, biological product guidelines (ICH Q5C) apply, not chemical stability frameworks (ICH Q1A). Applicable Guideline – ICH Q5C:This guideline does not use climatic zones (I–IV) and does not require testing at 30°C/65% RH. Stability programs for biologicals must be case-by-case and based on real-time data under intended storage conditions, not exaggerated conditions. Labeled Storage Condition:The product is labeled for storage below 25°C (do not freeze). Zone IV-A conditions (30°C) exceed the labeled range and are not relevant for shelf-life determination. Degradation Science:Enoxaparin degrades via temperature-sensitive pathways (depolymerization, desulfation, loss of anti-Xa potency). Testing at 30°C accelerates unrealistic degradation, does not predict real-world stability, and adds no meaningful value. Supporting Data Provided:The submission includes available long-term and accelerated stability data for both drug substance and finished product. Zone IVA long-term stability studies are not required for this ovine-derived enoxaparin injection and is not aligned with ICH Q5C, WHO TRS 1010, or the biological nature of the product.	
Decision	
Deferred	
Registration Board deferred the case for following:	
1. Confirmation of registration status of product in Indonesia.	
2. Post Marketing Surveillance data of applied product from Indonesia.	
3. Confirmation of equivalence of results of PK/PD studies of applied product of ovine source with Innovator product.	
Case Category	Routine (Muneeb Ahmed Cheema)
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	(8NB-TT2-NHJE, 2026-04-06)
Detail of Fee Submitted	313500, 2026-01-06,
The proposed proprietary name / brand name	Ovinox Solution for Injection 6000 anti-Xa IU/0.6ml
Label Claim	Each pre-filled syringe Ovinox 6000 anti-Xa IU contains: Enoxaparin Sodium.....60mg Water for Injections..... up to 0.6ml
Reference to Finished product specifications	United States Pharmacopeia

Proposed Pack Size	2 pre-filled syringes packed in a box, (1 ml of Each Syringe).-Controlled
Shelf Life (Unit)	36 MonthDo not store and transport above 25 degree centigrade.
For generic drugs (me-too Status)	Clexane Injection Imported by Hoechst Pakistan Limited, Plot 23, Sector 22, Korangi Industrial Area, Karachi, Pakistan.
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Suzhou Erye Pharmaceutical Co., Ltd.-Factory: No. 2, Anmin Road, Dongqiao, Huangdai Town, Xiangcheng District. Suzhou, Jiangsu 215152, China-China
Pharmaceutical Equivalence and Comparative Dissolution Profile	
Name, address of Marketing Authorization Holder:	Suzhou Ronnsi Pharma Co., Ltd. , 108 Yuxin Road, Suite 1001, building A Suzhou, Jiangsu 215123, 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	Clexane Injection Manufactured by Sanofi: 46 Avenue de la Grande Armée, 75017 Paris, France
Evaluation Remarks	
Following queries were raised during evaluation: a. Please submit CoPP issued by Regulatory Authority of Country of Origin. b. Long term stability data of drug substance and finished product as per Zone IV-A. The firm has submitted CoPP issued by Jiangsu Medical Product Administration China. As per submitted Chinese CoPP, the product is not registered in country of origin, However the applicant submitted that the product is registered in Indonesia and Bangladesh. b. The response of applicant regarding stability is as under: Product Classification (Biological, not Chemical):Enoxaparin sodium is a biological medicinal product (heterogeneous oligosaccharide mixture), not a small-molecule drug. Its stability is measured via functional activity (anti-Xa/IIa), not just chemical degradation. Therefore, biological product guidelines (ICH Q5C) apply, not chemical stability frameworks (ICH Q1A). Applicable Guideline – ICH Q5C:This guideline does not use climatic zones (I–IV) and does not require testing at 30°C/65% RH. Stability programs for biologicals must be case-by-case and based on real-time data under intended storage conditions, not exaggerated conditions. Labeled Storage Condition:The product is labeled for storage below 25°C (do not freeze). Zone IV-A conditions (30°C) exceed the labeled range and are not relevant for shelf-life determination. Degradation Science:Enoxaparin degrades via temperature-sensitive pathways (depolymerization, desulfation, loss of anti-Xa potency). Testing at 30°C accelerates unrealistic degradation, does not predict real-world stability, and adds no meaningful value. Supporting Data Provided:The submission includes available long-term and accelerated stability data for both drug substance and finished product. Zone IVA long-term stability studies are not required for this ovine-derived enoxaparin injection and is not aligned with ICH Q5C, WHO TRS 1010, or the biological nature of the product.	
Decision	
Deferred	
Registration Board deferred the case for following: 1. Confirmation of registration status of product in Indonesia. 2. Post Marketing Surveillance data of applied product from Indonesia. 3. Confirmation of equivalence of results of PK/PD studies of applied product of ovine source with Innovator product.	
16	Case Category Routine (Muneeb Ahmed Cheema)

Name, address of Applicant.	Searle IV Solutions (Pvt) Ltd. 1.5 KM Manga Raiwind Road, Manga Mandi, District Lahore. (000586)
Application Form Dy. No / Tracking ID & date of submission	(4G8-UTU-Q6PV, 2026-04-06)
Detail of Fee Submitted	97200, 2025-09-18,
The proposed proprietary name / brand name	Trimesa 1mg/0.75 ml pre-filled Syringe
Label Claim	Each 0.75 ml contains: Semaglutide1mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's PFS-As per SRO
Shelf Life (Unit)	2 YearStore in a refrigerator (2 °C-8 °C)
For generic drugs (me-too Status)	Sematide Prefilled Syringe 1mg/0.75mL Manufactured by M/s BF Biosciences Ltd (Reg.No 120530)
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	M/s. Nextar Pharma (Pvt) Ltd-Plot No. E-58, North Western Industrial Zone, Port Qasim, Karachi, Pakistan.-
The status in reference regulatory authorities	OZEMPIC (semaglutide) solution for injection 2 mg/1.5 ml (USFDA APPROVED)
Detail of previous approval	SEMAVI-PFS 1mg/0.75ml, Minutes of 350th Meeting of Registration Board

Evaluation Remarks

Decision

Approved

Keeping in view the already approved data in its 350th meeting; Registration Board approved the product with following conditions:

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.
2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the

Registration Board, if desired so:

- a. Peptide mapping.
 - b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA & LT.
3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.
 4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

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

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

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Case Category	Routine (Muneeb Ahmed Cheema)
Name, address of Applicant.	Searle IV Solutions (Pvt) Ltd. 1.5 KM Manga Raiwind Road, Manga Mandi, District Lahore. (000586)
Application Form Dy. No / Tracking ID & date of submission	(A8G-5DH-UBD7, 2026-04-06)
Detail of Fee Submitted	97200, 2025-09-18,
The proposed proprietary name / brand name	Trimesa 0. 5mg/0.375 ml pre-filled Syringe
Label Claim	Each 0.375ml contains: Semaglutide0.5mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's PFS-As per SRO
Shelf Life (Unit)	2 YearStore in a refrigerator (2 °C-8 °C)
For generic drugs (me-too Status)	Sematide Prefilled Syringe 0.5mg/0.375mL Manufactured by M/s BF Biosciences Ltd (Reg.No 120529)
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	M/s. Nextar Pharma (Pvt) Ltd-Plot No. E-58, North Western Industrial Zone, Port Qasim, Karachi, Pakistan.-
The status in reference regulatory authorities	OZEMPIC (semaglutide) solution for injection 2 mg/1.5 ml (USFDA APPROVED)
Detail of previous approval	SEMAVI-PFS 0.5mg/0.375ml, Minutes of 350th Meeting of Registration Board

Evaluation Remarks**Decision****Approved**

Keeping in view the already approved data in its 350th meeting; Registration Board approved the product with following conditions:

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

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

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

18	Case Category	Routine (Muneeb Ahmed Cheema)
	Name, address of Applicant.	Searle IV Solutions (Pvt) Ltd. 1.5 KM Manga Raiwind Road, Manga Mandi, District Lahore. (000586)
	Application Form Dy. No / Tracking ID & date of submission	(P2E-96B-662R, 2026-04-06)
	Detail of Fee Submitted	97200, 2025-09-18,
	The proposed proprietary name / brand name	Trimesa 0. 25mg/0.188ml pre-filled Syringe
	Label Claim	Each 0.188ml contains: Semaglutide0.25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's PFS-As per SRO
	Shelf Life (Unit)	2 YearStore in a refrigerator (2 °C-8 °C)
	For generic drugs (me-too Status)	Sematide Prefilled Syringe 0.25mg/0.188mL Manufactured by M/s BF Biosciences Ltd (Reg.No 120528)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s. Nextar Pharma (Pvt) Ltd-Plot No. E-58, North Western Industrial Zone, Port Qasim, Karachi, Pakistan.-
	The status in reference regulatory authorities	OZEMPIC (semaglutide) solution for injection 2 mg/1.5 ml (USFDA APPROVED)
Detail of previous approval		SEMAVI-PFS 0.25mg/0.188ml, Minutes of 350th Meeting of Registration Board
Evaluation Remarks		
Decision		
Approved		
Keeping in view the already approved data in its 350th meeting; Registration Board approved the product with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA & LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.		

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| <p>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.</p> <p>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.</p> <p>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.</p> |
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Case No. 1: Imported Veterinary Biological applied by M/s Lucky Core Industries Limited, Karachi.

Following product of M/s Lucky Core Industries Limited, Karachi was approved in 353rd meeting of Registration Board as per following details:

Sr. No.	Name of Importer & Manufacturer	Brand Name & Composition	Pack Size, Shelf Life & Storage Conditions	Recommendations of EWG in its 8th Meeting	Decision of 353 rd meeting
1.	Applicant: Name: M/s Lucky Core Industries Limited, 5 West Wharf, Karachi Manufacturer: M/s Intervet International B.V. Wim de Korverstraat 35, 5831 AN Boxmeer, the Netherlands.	Bovilis Lumpyvax-E Lyophilisate and Solvent for Suspension for Injection for Cattle Each 1ml dose of reconstituted vaccine contains; Live attenuated lumpy skin disease virus (Neethling)... $\geq 1 \times 10^4$ and $\leq 5.0 \times 10^5$ TCID ₅₀ Solvent: Disodium phosphate dihydrate....1.4mg Potassium dihydrogen phosphate...0.2mg Sodium chloride.....8mg Potassium chloride....0.2mg Water for Injection.....Upto 1m	20 doses 100 doses 24 months	The Committee recommended the product for grant of registration.	Keeping in view the recommendations of EWG; Registration Board approved the product subject to compliance of current Import Policy for finished drugs and submission of following by the firm: i. Valid GMP certificate of manufacturer abroad. ii. Proposed pack size along with its stability study data for 3 commercial scale batches. iii. Revised label specimen with name of importer.

In this context, it is submitted that it has been mentioned in the CoPP that the product is not licensed to be placed on the market of country of origin since the disease has never occurred. However, while presenting the agenda this point was inadvertently missed as the same point was previously discussed in 8th meeting of Expert Working Group and vaccine was recommended by the EWG as the strain in vaccine is the same as circulating in Pakistan.

However, while processing the case for issuance of registration letter, Chairman Registration Board observed this point and advised to again place the case in registration Board.

Decision:

Keeping in view the recommendations of Expert Working group on veterinary drugs regarding the strain relevance for Pakistan; Registration Board endorsed its decision of 353rd meeting for the product.

Case No. 2: Imported Human Biological applied by M/s Medipak pvt. Limited, 132/1, Industrial Estate, Kot Lakhpat, Lahore deferred in 320th meeting of Registration Board.

Following product of M/s Medipak Pvt. Limited, 132/1, Industrial Estate, Kot Lakhpat, Lahore was deferred in 320th meeting as per following details:

Name, address of Applicant / Importer	M/s Medipak Pvt. Limited,132/1, Industrial Estate, Kot Lakhpat, Lahore, 54770, Pakistan
Details of Drug Sale License of importer	License No: 05-352-0070-079516D Validity: 06 th October, 2023
Name and address of marketing authorization holder (abroad)	Laboratories Pablo Cassara S.R.L. Carhue 1096 (C1408GBV) La Rosa W/Nº, between Av. Gral. Paz and Saladillo (C1439BVJ) Autonomous City of Buenos Aires, Republic of Argentina.
Name, address of manufacturer(s)	As above
Name of exporting country	Republic of Argentina
Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	Firm has submitted Legalized CoPP issued by The National Institute of Drugs, (ANMAT), Republic of Argentina. The COPP specifies that the product is licensed for sale in country of origin. The COPP also specifies the GMP status of manufacturer.
Details of letter of authorization / sole agency agreement	Firm has submitted Pakistan notarized copy of distribution certificate from M/s Laboratories Pablo Cassara; According to the letter, the firm M/s Laboratories Pablo Cassara., authorizes “M/s Medipak Limited. for the purpose of registration, distribution and marketing of the product. The letter was issued on 14th May, 2021.
Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
Dy. No. and date of submission	Form -5F Dy. No.21015 dated: 26 th July, 2022,
Details of fee submitted	Rs: 150,000/- dated: 14 th June, 2022
The proposed proprietary name / brand name	Synteparin Injection 5000IU
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each dose contains: Sodium Heparin....5000 IU
Dosage form of applied drug	Injection
Pharmacotherapeutic Group of (API)	Anticoagulants

Reference to Finished product specifications	USP
Proposed Pack size	1's x 5ml 10's x 5ml
Proposed unit price	As per SRO
Shelf Life	24 months
Storage Conditions	Store at 20°C -- 30°C
The status in reference regulatory authorities	Heparin Sodium Injection, USP FDA Approved
For generic drugs (me-too status)	Brand Name: Heparin Injection 5000 IU/ ml, 1's Pack Importer Name: M/s Leo/ Zam Zam Pharma
Module-II (Quality Overall Summary	Firm has submitted QOS as per WHO. Firm has summarized information related to nomenclature, structure, general properties, manufacturers, description of manufacturing process and controls, Characterization (Elucidation of Structure and Other Characteristics), impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
Name, address of drug substance manufacturer	Laboratories Pablo Cassara Carhue 1096 (C1408GBV) Autonomous City of Buenos Aires 54770, Republic of Argentina
Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis an justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches at long term conditions. The real time stability data is conducted at 25 °C RH 60%±10% for 48months and at 40°C ± 2 °C /60% ± 5%RH for 06 months for accelerated conditions.
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Analytical method validation/verification of product	Firm has submitted the details of analytical method validation.
Container closure system of the drug product	Type-I glass ampoule vial (5mL), injection-type opening, colorless. Bromobutyl stopper for injection-type vial, gray color with seal composed of an aluminum capsule with an aluminum cap that allows opening of its central section.

Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data: 3 pilot scale batches (1500 units each) at 25± 2C & 60 ±5% RH (real time conditions) for 24 months. One production scale batch (109.45 Lt) at 25± 2C & 60 ±5% RH (real time conditions) for 12 months. (ongoing) One production scale batch (109.45 Lt) at 30± 2C & 60 ±5% RH (real time conditions) for 12 months. (ongoing) One production scale batch (109.45 Lt) at 40± 2C & 75 ±5% RH (accelerated conditions) for 06 months.
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Decision of RB in its 320th Meeting:

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

- Clarification regarding difference in pack size mentioned in dossier and proposed packing.*
- Real time stability data of 03 commercial batches up to the demanded shelf life.*
- Accelerated stability data of 03 commercial batches up to 06 months.*
- Evidence of availability of demanded pack size in country of origin.*

Response:

The firm has submitted the following documents:

- The proposed pack is 100's x 5ml.
- Real time stability data of 03 commercial batches up to the demanded shelf life.
- Accelerated stability data of 03 commercial batches up to 06 months.

The firm has submitted following weblink to provide evidence of availability of demanded pack size in country of origin:

<http://anmatvademecum.servicios.pami.org.ar/>

However, the link is not accessible.

Decision:

Registration Board deliberated that it has already been decided in previous meetings that for Heparin Injection, if the availability of a strength in country of origin is confirmed from submitted CoPP/ FSC; then any pack size as approved in RRAs for Heparin Injection will be considered for approval. Hence, Registration Board approved the product subject to compliance of current Import Policy for finished drugs.

Case No. 3: APPLICATION FOR THE APPROVAL OF MANUFACTURER'S SPECIFICATIONS FOR SOLVENT FOR HERCEPTIN 440 MG VIAL (Reg. No. 032131).

M/s Roche Pakistan Limited, Karachi has submitted a request for grant of manufacturer specifications for their registered drug, Solvent for Herceptin (Reg No. 032131) which is Bacteriostatic Water for Injection.

It is submitted that aforesaid solvent's monograph is included in the USP Pharmacopeia and however not available in BP and European Pharmacopeia. The firm has submitted the comparison of the their specs with USP monograph wherein all other specs defined in USP are stringent/ equivalent except pH. Comparison is as under:

Specifications	USP	Roche
pH	pH <791> USP Sample: To 100 mL of Bacteriostatic Water for Injection add 0.3 mL of saturated potassium chloride solution. Acceptance criteria: 4.5–7.0	Same method applied. Acceptance criteria set to 4.5 – 9.0 pH measurement performed in accordance to USP and Ph. Eur. 2.2.3

The applicant was asked to submit justification regarding the wide range of pH limits as compared to the USP Pharmacopeia and they responded as under:

Herceptin 440 mg is formulated in a L-Histidine buffer system. The side chain (imidazole) of histidine has a pKa of approximately 6.0–6.5, making it capable of acting as a buffer to maintain a drug product and reconstituted solution pH to ensure stability. As demonstrated by the calculations, a 5 mM Histidine buffer provides excess capacity to buffer any diluent variability within the specified range for BWFI (pH 4.5–9.0). The Bacteriostatic Water for Injection (BWFI) provided is not intended for independent sale; it is marketed exclusively as a co-packaged combination with Herceptin 440 mg for reconstitution of the drug product. The variability of the BWFI is therefore to be assessed in the context of the reconstituted dose solution. As calculated above, the buffer capacity of the Herceptin formulation is sufficient to buffer the ionic load from BWFI within its specified pH range. The L-Histidine buffer system ensures that the pH remains within a range of 5.9–6.4 upon reconstitution which was furthermore demonstrated in the study. This ensures stability of Trastuzumab in the dose solution.

Decision:

Registration Board deferred the case due to relaxed pH specifications of applied Bacteriostatic Injection as compared to United States Pharmacopoeia.

Case No. 5 REGISTRATION BOARD INSTRUCTIONS FOR REGISTRATION HOLDERS OF SEMAGLUTIDE AND TIRZEPATIDE

Registration Board, in its 351st meeting held on September 23–24, 2025, after detailed deliberations regarding the registrations granted to local manufacturers for Semaglutide and Tirzepatide, issued the following instructions:

- i) Submit data, including LC/MS peptide mapping of previously marketed batches, in accordance with the registration conditions set by the Registration Board.
- ii) Until the procurement of their own LC/MS equipment, conduct LC/MS peptide mapping of registered products through any government-approved Drug Testing Laboratory or DRAP-licensed laboratory, and submit the corresponding testing data to the relevant field office before marketing or sale of each batch.
- iii) Provide an updated status on the initiation of Bioequivalence/PK/PD studies and keep the Board informed accordingly.

2. In view of the above decision of the Registration Board, all registration holders of Semaglutide and Tirzepatide were directed to submit a compliance report within seven working days vide DRAP letter No. 1-18/2025-DD(BIO) dated 04th November 2025. No reply has been received so far.

Decision:

Registration Board deferred the case to the decision of the Appellate Board on the appeals filed by M/s. Eli Lilly against registrations of semaglutide containing formulations.



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



Item No. V Additional/Supplementary Minutes:

Pharmaceutical Evaluation Cell (PEC)

Sr. No	Title	Description
1	Case Category	Import (Adil Saeed)
	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	(L24-ESM-XSPB, 2025-09-30)
	Detail of Fee Submitted	300000.0, 2025-07-12,
	The proposed proprietary name / brand name	Vitamin B-12 IM injection
	Label Claim	Each 2ML ampoule contains: Cyanocobalamin.....1000mcg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	25 ampoules-As per SRO
	Shelf Life (Unit)	2 Year(s)Room temperature
	For generic drugs (me-too Status)	Vitamin B12 1MG/2ML (Avensis pharma)
	Pharmacotherapeutic Group of (API)	Vitamin B12
	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	With similar product of another Chinese manufacture i.e TianJin KingYork Group Hubei Tianyao Pharmaceutical Co.,Ltd B. No. 240930
	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):	DML 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	Bfram Germany Approved.
	Evaluation Remarks	
	Priority as per decision of 220th meeting of authority. Application fulfills codal formalities. Recommended for consideration of Board.	
2	Decision	
	Approved	
	As per policy for inspection abroad.	
	Case Category	Import (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	(5B8-AUV-6GBS, 2025-09-16)

Detail of Fee Submitted	313500.0, 2025-08-07,
The proposed proprietary name / brand name	OLATAB 100mg Tablet
Label Claim	Each film coated tablet contains: Olaparib 100mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	3×10's-De-Controlled
Shelf Life (Unit)	2 Year(s)Not Store and Transport above 30 degree centigrade.
For generic drugs (me-too Status)	Not Available
Pharmacotherapeutic Group of (API)	ANTINEOPLASTIC AGENTS
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 are Attached and performed against the Lynparza ®100 Film Coat ed Tablet , AstraZeneca AB, Sweden
Name, address of Marketing Authorization Holder:	Atco Life Sciences (Private) Limited., B-18 S.I.T.E., Karachi-75700., Pakistan
Details of Certificates (CoPP/FSC/cGMP):	Firm submitted CoPP ,Certificate no. DGDA/6- 214/15317 dated 28-08-2024 issued by Directorate General of Drug Administration, Bangladesh. Product specific Letter of Authorization dated May 31,2025 is submitted by the applicant.
Details of Authorization Letter :	NA
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 Months Data of Accelerated Stability and 12 Months Data of Long-Term Stability is attached in Module 3.
The status in reference regulatory authorities	Lynparza 100 mg film-coated tablets manufactured by AstraZeneca UK Limited, 1 Francis Crick Avenue, Cambridge, CB2 0AA, U.K.

Evaluation Remarks

Registration Board in its 354th meeting decided to defer the case for submission of complete stability data of three commercial batches of the drug product performed as per zone-IV conditions. All batch-related manufacturing documents for these stability batches should be maintained and available. The stability data should be submitted along with the corresponding Batch Manufacturing Records (BMRs). Firm in their reply stated that, " With reference to the query regarding Executed BMR, We have communicated with our principle, they have started manufacturing fresh batches and within 12-15 days they will provide us BMRs. Then we will upload it as soon as we get it from the principal".

Decision

Approved

Firm shall submit Batch Manufacturing Record of three stability batches along with the complete stability data till the claimed shelf life before the issuance of Registration Letter.

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

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